

Corporate Responsibility Report 2012

Responsibility

*Our contribution
to sustainable development*



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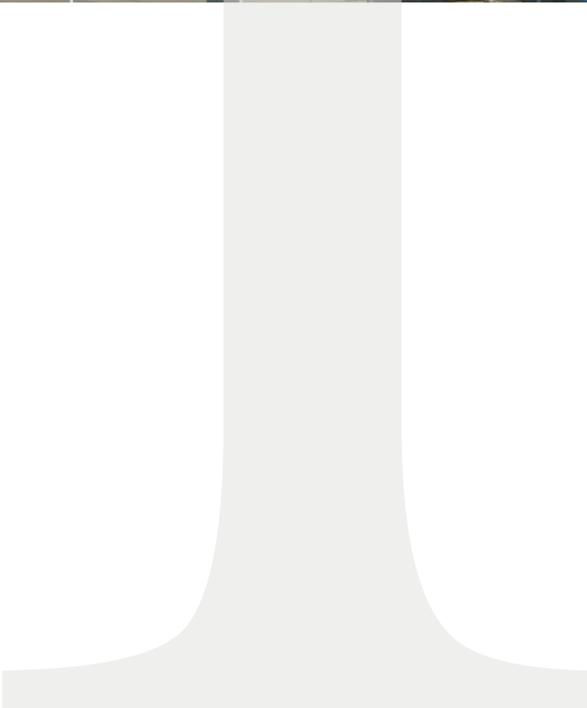
Corporate Responsibility Report 2012

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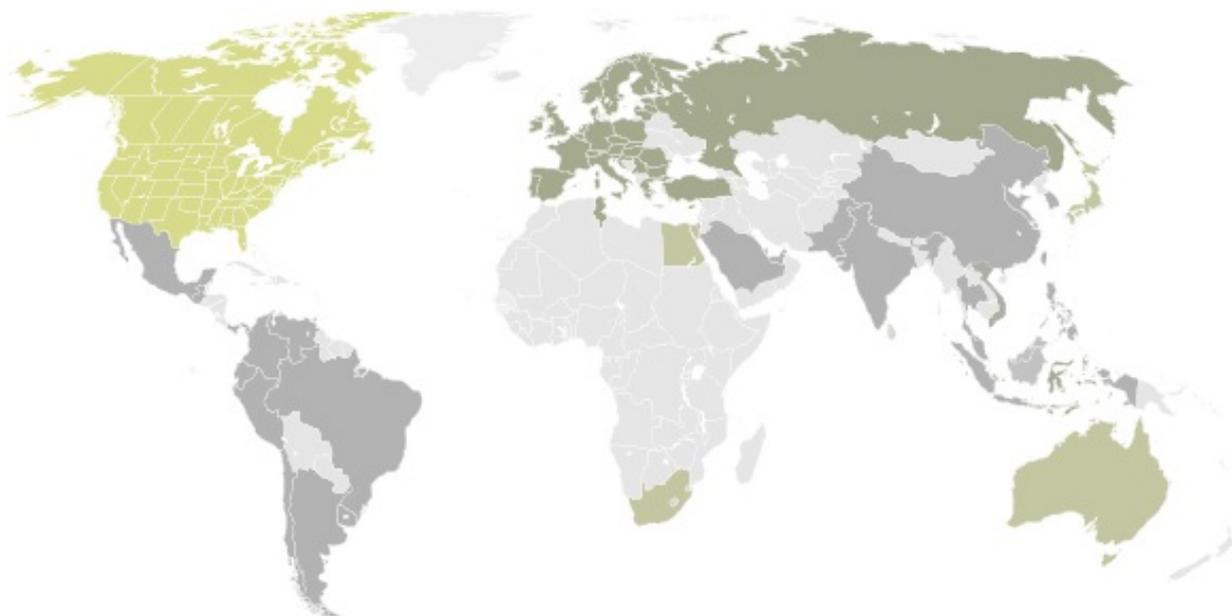
We aim to save paper and have therefore only published the complete CR Report 2012 in a digital format. This PDF was automatically created from the content of an online version, which offers additional interactive features. → <http://reports.emdgroup.com/2012/cr-report>

A printed brochure highlighting the key developments can be ordered via e-mail.
→ comms@emdgroup.com

Company profile



Company profile



- Region: Europe**
 Sales: 3,943 € million (37%), Employees: 20,777 (54%)
- Region: North America**
 Sales: 2,128 € million (20%), Employees: 4,848 (12%)
- Region: Emerging markets**
 Sales: 3,712 € million (34%), Employees: 11,642 (30%)
- Region: Rest of world**
 Sales: 958 € million (9%), Employees: 1,580 (4%)

Merck KGaA, Darmstadt, Germany is a global pharmaceutical, chemical and life science company with total revenues of nearly € 11 billion in 2012 and a history that began in 1668. Around 39,000 employees at 203 companies in 66 countries contribute to shaping our future. 65 production sites are located in 22 countries.

Sales by region 2012



1 Europe	37%
2 North America	20%
3 Emerging markets	34%
4 Rest of world	9%

→ Company profile

Employees by region 2012



1 Europe	54%
2 North America	12%
3 Emerging markets	30%
4 Rest of world	4%

Corporate structure – four divisions

Merck KGaA, Darmstadt, Germany is a global company whose wide-ranging business activities include innovative pharmaceuticals and biopharmaceutical products, life science tools, and specialty chemicals. Merck KGaA, Darmstadt, Germany is organized into four divisions.

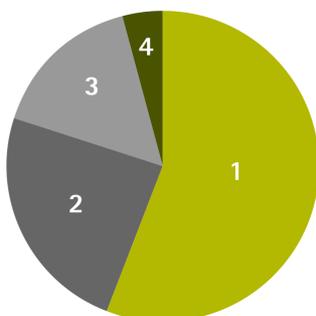
Prescription medicines is Merck KGaA, Darmstadt, Germany's largest division. It markets innovative prescription drugs to treat cancer, multiple sclerosis, infertility, and growth disorders, as well as certain cardiovascular and metabolic diseases. Prescription medicines division's products are primarily prescribed by specialists and largely manufactured using biotechnology. The product portfolio of this division includes leading prescription drugs such as Erbitux® for patients with cancer and Rebif® for patients with multiple sclerosis.

Our **Consumer Health** division offers over-the-counter pharmaceuticals. We focus on eight strategic brands that specialize in health themes such as mobility, everyday health protection, women's health, cough and cold, and allergies. Our scientifically backed product portfolio meets the needs of consumers worldwide.

Performance Materials provides a wide range of high-tech performance chemicals for customers in sectors such as consumer electronics, lighting, coatings, printing, plastics, and cosmetics. With a market share ranging between 50% and 60%, Merck KGaA, Darmstadt, Germany has been the market leader in liquid crystal mixtures for many years.

Our **Life science tools** division is the world's third-largest supplier of products and services for the life science industry, which are used by customers working in research and analytical laboratories as well as in pharmaceutical manufacturing. Life science tools division's portfolio features more than 60,000 products.

Sales by division 2012



1 Prescription medicines	56%
2 Life science tools	24%
3 Performance Materials	16%
4 Consumer Health	4%

→ Company profile

Management of the company

Merck KGaA, Darmstadt, Germany is managed in the legal form of a Kommanditgesellschaft auf Aktien (KGaA, corporation with general partners), with headquarters in Darmstadt (Germany). Shareholders hold around 30% of the total capital of Merck KGaA, Darmstadt, Germany, and the Merck KGaA, Darmstadt, Germany family owns an interest of around 70% via the general partner, E. Merck KG [\[7\]](#), Darmstadt, Germany. Merck KGaA, Darmstadt, Germany shares have been included in the DAX® 30, the blue chip index of the Deutsche Börse, since 2007. In September 2008, Merck KGaA, Darmstadt, Germany was added to the FTSE4Good Index, a sustainability index that evaluates the social, ecological and ethical behavior of companies.

› More information about our corporate strategy can be found in our Annual Report 2012 [\[7\]](#)

Merck KGaA, Darmstadt, Germany's goal is to participate successfully in the pharmacy, life science tools and specialty chemicals sectors with leading positions in attractive segments of these markets. Building upon its leading branded products in all four divisions, Merck KGaA, Darmstadt, Germany aims to generate income that is largely independent of the prevailing economic cycle as we presently understand it. Moreover, Merck KGaA, Darmstadt, Germany holds a good position in emerging markets, which now contribute to more than one-third of sales. Current and future investments are being targeted to benefit from future volume growth in emerging markets.

Strategy and management



Corporate responsibility has always been an integral part of our corporate culture. It is reflected in both our Mission Statement and our Values. Our corporate responsibility strategy allows us to systematically address the key issues impacting our business and stakeholders, with whom we maintain a close dialogue at all times. We have specified our requirements for the responsible conduct of all employees in numerous guidelines. With the help of management systems, we set and steer goals, actions and responsibilities in key action areas.

→ Letter from Karl-Ludwig Kley

Letter from Karl-Ludwig Kley

Ladies and gentlemen,

The term "responsibility" originates from the Latin word "responder", which means to respond or reply. Today, companies are required more than ever to respond to certain questions: How are they contributing to society and the environment? How do they treat the people who work for and with them?

"Taking responsibility means responding to questions."

We are deeply engaged in these questions. To us, they have always been part of our entrepreneurial approach. Responsibility is one of our six Values that guide our actions each and every day. We have thus been supporting the United Nations Global Compact and its principles since 2005, which cover human rights, labor standards, the environment, and anti-corruption.

In 2011, we refined our corporate responsibility strategy, which comprises three spheres of activity: people, products and the environment. Here are some select examples of our engagement:

1. With our innovative **products**, we are helping to resolve global challenges such as climate change and a energy scarcity. For instance, the innovative liquid crystals from Merck KGaA, Darmstadt, Germany enable computer displays and televisions to consume significantly less electricity. In addition to this, we are bolstering the health care systems in developing countries and emerging markets through a multitude of activities. As an example, we have developed a mini-laboratory to detect counterfeit medicines, thus facilitating access to health.
2. Our engagement in climate protection represents one expression of our responsibility for the **environment**. We aim to reduce our direct and indirect **greenhouse gas emissions** by 20% by 2020, measured against the 2006 baseline. In order to reach this goal, we are instituting Group-wide measures through our EDISON program, such as the construction of a biomass power plant at our Goa, India site. Through the EDISON projects, we aim to prevent 64,000 metric tons of CO₂ emissions per year.
3. One way in which we take on responsibility for people is as an employer. One of our primary focuses over the last several years has been to continually improve occupational safety through targeted programs. We promote workforce diversity and are aiming for a 25%-30% increase in the percentage of management positions held by women by 2016. We also demonstrate our social engagement through **our fight against the neglected tropical disease schistosomiasis** in Africa, which we are combating in collaboration with the World Health Organization (WHO). Since starting our Praziquantel Donation Program in 2007, we have donated over 100 million praziquantel tablets to treat more than 28 million children. In 2012, we decided to increase the number of tablets donated tenfold in the medium term.

Merck KGaA, Darmstadt, Germany has been listed in the FTSE4Good sustainability index since 2008. In the 2012 Access to Medicine Index, we went up nine places to eighth place. As in the previous years, we have received various awards for both our innovative products as well as for our performance as an employer.

Corporate responsibility is part of our daily conduct and thus a fundamental prerequisite for our business success. Only a healthy company that operates sustainably can contribute as an employer, taxpayer and corporate citizen to a functioning society. Through our "Fit for 2018" efficiency and growth program, which we announced at the end of 2011, we are ensuring that we can continue to do so also in the future.

In 2018, we want to be a company that is synonymous with innovation, quality and sustainability. A company that continues to be recognized for performance, efficiency and the career opportunities that it offers around the world. A company that is respected for its values, its culture, and for its constantly responsible conduct.



→ Company values and external initiatives

Since the company was founded nearly 350 years ago, Merck KGaA, Darmstadt, Germany has had a solid tradition of taking responsibility in the long term and supporting sustainability. We will carry this tradition on and continue to respond to questions of responsibility in the future as well.

Sincerely,



Karl-Ludwig Kley
Chairman of the Executive Board

Company values and external initiatives

Our corporate culture has always been characterized by responsible behavior – whether with respect to our products, our employees, the environment, or society. Our approach and our conduct have evolved from a history dating back nearly 350 years; they are derived from our Mission Statement and our Values, and shaped by the external initiatives that we support.

Our aim is to operate as a global company that creates added value for consumers, our market partners and the community and that helps them lead better lives. We strive to achieve positive recognition for our company in the community and are committed to operating safely and respecting the environment.

Our conduct is founded on our **Values** : courage, achievement, responsibility, respect, integrity, and transparency. They underpin our daily work and our interactions with our customers and business partners. We view open, honest communication internally and externally as an essential trust-building element.



Furthermore, Merck KGaA, Darmstadt, Germany supports relevant initiatives by other organizations concerning for responsible corporate governance:

- Merck KGaA, Darmstadt, Germany has been participating in the United Nations Global Compact since 2005 and has expressed its commitment to comply with the compact's ten principles regarding human rights, labor standards, environmental protection, and anti-corruption. In our annual Global Compact Communication on Progress, we explain how we incorporate the ten principles into our business processes.
- In 2006, Merck KGaA, Darmstadt, Germany signed the Responsible Care Global Charter adopted by the International Council of Chemical Associations (ICCA). Within the scope of this voluntary initiative and of the resulting guidelines of the German **Responsible Care® program** , we have committed ourselves to defining standards in the areas of product responsibility, environmental protection, health, plant safety, and security that go beyond legal obligations. In particular, Merck KGaA, Darmstadt, Germany is currently focusing on product safety, environmental protection and occupational safety.
- Merck KGaA, Darmstadt, Germany signed the **Code of Responsible Conduct for Business**  in 2010. This code is the result of an initiative of German companies with the aim of firmly establishing measurable standards with respect to fair competition, social partnership, merit and sustainability at the involved companies.

→ Human rights

In 2012, we contributed to the policy paper "Das Nachhaltigkeitsverständnis der deutschen Chemie-Branche" ("The Understanding of Sustainability within the German Chemical Industry"), in which three partners formulated their common understanding of sustainability: the German Chemical Industry Association (VCI), the German Employers' Federation of the Chemical Industry (BAVC) and the German Mining, Chemical and Energy Industrial Union (IBBCE). The aim of this special sustainability initiative is to:

1. Expand the position of the chemical industry as a key industry of the German economy for sustainable development
2. Continue to create attractive working conditions in the chemical industry
3. Create a climate of transparency and trust through active, open dialogue with government, business and society

Our corporate Mission Statement, our Values and these external initiatives result in requirements for responsible corporate governance that we incorporate into both our Corporate Responsibility strategy and our Group-wide guidelines. These guidelines include the Merck KGaA, Darmstadt, Germany **Social Charter** and the **Code of Conduct**  as well as other topic-specific corporate principles, policies and standards. In this way, we provide our employees with the support they need to implement the above-stated requirements in their daily work and thus put them to practice within the company.

Human rights

Merck KGaA, Darmstadt, Germany's corporate culture has always been characterized by responsible behavior – whether with respect to products, employees, the environment, or society. Consequently, Merck KGaA, Darmstadt, Germany is committed to upholding human rights within its sphere of influence and welcomes the **Guiding Principles for Business and Human Rights**  adopted by the UN Human Rights Council in 2011. This set of principles created a global framework for countries to protect human rights, and for companies to respect these rights, by setting forth key principles in their business practices.

Countries are obliged to establish a regulatory framework for protecting human rights. For global companies, it is important that this be implemented in the various countries in order to create uniform competitive conditions for all companies.

The duty of companies is to uphold and respect human rights; they must not violate any human rights in the course of their activities. Furthermore, companies must fulfill their responsibility by acting with the necessary due diligence, which includes identifying and managing risks.

Human rights risk assessment

In exercising this due diligence, we conducted a human rights risk assessment in 2012 with the support of external specialists. The goal was to identify the risks to human rights resulting from our activities as a global pharmaceutical, chemical and life science company. In the process, we identified a number of areas where Merck KGaA, Darmstadt, Germany has made significant progress with regard to respecting and complying with human rights (for example, in the prevention of product misuse as well as the associated health hazards). On the other hand, we also determined areas where we can further improve the existing regulations and processes with regard to human rights. As a result, we defined three high-priority action areas:

1. Merck KGaA, Darmstadt, Germany places high demands on its suppliers with regard to compliance with social and ecological standards. We refine and enhance our supplier management process in order to adhere more closely to environmental, compliance and social standards in our supply chain worldwide and to prevent violations. This is particularly a challenge beyond the first supplier.
2. Merck KGaA, Darmstadt, Germany always abides by the highest legal, ethical and scientific standards in all clinical trials, whether in industrialized or developing countries, whether multinational or multicentric. However, we held a discussion with independent experts on our Bioethics Advisory Board concerning the topic of clinical trials in resource-poor countries. This revealed that, regardless of our high standards, additional aspects must be addressed in developing countries. For example, one aspect is an effective risk analysis conducted with due diligence of the contract parties participating in the trials.
3. Merck KGaA, Darmstadt, Germany would like to make further progress in the area of access to health. For example, we are expanding our research program within the scope of our Praziquantel Donation Program, a partnership with the World Health Organization (WHO) to combat the worm disease schistosomiasis. We are now working to develop a pediatric tablet formulation for preschool children, a previously untreated age group. Furthermore, we plan to establish an overall management process for access to health.

→ Responsible care

The Corporate Responsibility Committee has decided to develop a comprehensive human rights policy. The aim is to increase awareness of the topic within Merck KGaA, Darmstadt, Germany and to identify company-specific risks more accurately.

Merck KGaA, Darmstadt, Germany is a member of the Human Rights Peer Learning Group within the German Global Compact Network. The purpose of this working group is the mutual exchange of experiences and best practices related to the topic of business and human rights.

Responsible care

The Responsible Care® principles of the chemical industry constitute an important external guideline for our sector of industry. The Responsible Care Global Charter was adopted by the International Council of Chemical Associations (ICCA) in 2006 and was used as a basis for the principles of the German Responsible Care program. The charter and the Responsible Care program both aim to continually improve performance by the chemical industry with regard to product safety, environmental protection, health, plant safety, and security. Responsible Care® focuses on voluntary cooperation with government bodies and other stakeholders that goes far beyond complying with statutory regulations.



All of our Responsible Care® activities are founded on internal guidelines such as the "Corporate EHS Policy" and our EHS, Security and Quality Manual. In implementing the Responsible Care Global Charter, we are currently focusing in particular on the topics of product safety, environmental protection and occupational safety.

Our activities in the area of product safety cover a range of measures, including the implementation of regulatory requirements such as REACH and GHS, voluntary initiatives such as our [Global Product Strategy](#), and sustainable product development. One example of this is the Green³ concept for liquid crystal products.

Within the scope of our broad-based company environmental protection activities, we are currently focusing on climate protection. We want to reduce our greenhouse gas emissions by 20% by 2020, measured against the 2006 baseline. Other core topics are water and wastewater, material consumption and recycling as well as biodiversity. Process safety has traditionally had high priority at Merck KGaA, Darmstadt, Germany – both in economic and ecological terms as well as to protect our employees. It comprises the planning, construction, normal operation, modification, and shutdown of production facilities and warehouses.

Integrated occupational safety encompasses the prevention of workplace accidents, workplace-related illnesses and workplace-related health hazards. Our goal, redefined in 2010, is to reduce the Lost Time Injury Rate (LTIR – the number of workplace accidents resulting in lost time per one million working hours) to 2.5 by 2015.

Corporate Security is an integral element of our daily work that serves to protect intellectual and material assets as well as our reputation with respect to external threats. In addition to handling security-related incidents, Corporate Security also works to establish preventive mechanisms in relevant units. The "Merck KGaA, Darmstadt, Germany Corporate Security Policy" defines the responsibilities and objectives of Corporate Security for the company. Corporate Security audits our legal entities regularly in order to identify optimization potential. Corporate Security focuses on areas such as product-related crime, cyber crime, and intellectual property protection.

Corporate responsibility strategy and organization



Mankind is confronted with major global issues, such as climate change, the increasing demand for affordable, renewable energy, and a growing need for access to health – especially in emerging and developing countries – and the prevention of greenhouse gas emissions. We are aware that our business operations impact our environment and the people around us. However, we also believe that responsible company management makes a contribution toward resolving global challenges, helps ensure viability and increases our acceptance in society.

But what does responsible company management mean for us? What topics are especially relevant to us locally and globally? What impact do our business operations have on people and the environment? What solutions to social challenges do our stakeholders expect? What risks do these solutions entail – and what opportunities? What goals should we achieve in the coming months and years?

To answer these questions, in 2011 we revised our Corporate Responsibility (CR) strategy based on our corporate strategy. Our CR strategy covers the three action areas products, the environment, and people. Important main topics are innovations and global trends, energy and climate, ethics (e.g. human rights and animal welfare) and our social engagement. The diagram above provides an overview of the strategic approaches and relevant topics, which are explained in detail in other sections of this report.

CR organization

Implementation and review of the CR strategy are steered by the Group-wide CR Committee, which consists of representatives from divisions as well as from relevant Group functions, such as Environment Health Safety Security Quality, Human Resources, and Procurement. Karl-Ludwig Kley, Chairman of the Executive Board, is a member of the CR Committee, which was established in 2011. Prior to that, the Executive Board regularly handled topics related to corporate responsibility. Kley became chairman of the CR Committee in March 2013.

The committee's tasks include setting and regularly reviewing the goals and measures that pertain to our CR strategy. In addition, the committee ensures that initiatives of the Group functions, divisions and legal entities are in line with the Group-wide CR strategy. It is also responsible for developing suggestions for better aligning CR goals and actions with the corporate strategy. Measures adopted by the Committee are embedded in the operative business by experts in the specific topic and by interdisciplinary project teams.

→ Compliance

The CR Committee normally meets two to three times per year. The main focus in 2011 and 2012 was on the topics of access to health, animal welfare, human rights, and environmental and social standards in the supply chain.

The CR Committee reviews the CR strategy with regard to coverage of the topics relevant to Merck KGaA, Darmstadt, Germany and the need for action. We aim to identify challenges early on in order to minimize risks, but also to seize the opportunities that arise for our business from societal changes. In this context, a mega trend analysis and a human rights risk assessment were conducted during the 2011–2012 period. We also use the results from the materiality analyses conducted regularly during the preparation of our CR reports in order to ensure that all the relevant topics are addressed.

Goals: CR strategy and management

Strategic goal	Action	By?	Status in 2011 and 2012	Status
Improve management of CR topics	Establish a CR Committee	End of 2011	The CR Committee was founded in 2011. It convened four times in 2011 and 2012.	■

Legend: ■ Achieved ■ In progress ■ Not achieved + New goal

Compliance

First and foremost, responsible entrepreneurial conduct means legally compliant conduct. All activities of Merck KGaA, Darmstadt, Germany must comply with statutory rules and regulations worldwide. Violations might not only entail legal prosecution, but could also seriously harm our corporate reputation, meaning its standing as a business partner or employer. Therefore, compliance with statutory rules and regulations has top priority for us. Compliance for us also means acting in accordance with the ethical principles defined in our Values. Merck KGaA, Darmstadt, Germany wants to do "good" business, that is, operate profitably, but at the same time also meet high ethical standards.



Globally binding rules of conduct

Our **Code of Conduct** is a compulsory set of rules for all employees. It explains the principles for interacting with business associates, general partners, colleagues, and employees, as well as with the communities in which we operate. Thus, it supports all employees in acting ethically – not only in their interactions with one another, but also outside the company.

Our **Social Charter** supplements the Code of Conduct with globally valid principles regarding human rights as well as the core labor standards of the International Labour Organization (ILO). The managing directors of our legal entities are responsible for ensuring that these principles are adhered to. We also expect our business partners worldwide to follow these principles.

Compliance organization

We support compliance with statutory and company-internal rules and regulations through our compliance organization. The central Group function Compliance, with the Group Compliance Officer (GCO) and other specialists, is responsible for maintaining and further developing the compliance program.

In the legal entities abroad, local compliance officers are responsible for implementing the compliance measures. They are advised by the Merck KGaA, Darmstadt, Germany Group function and provided with training documentation, among other forms of support. The approximately 80 local compliance officers at this time report to the GCO at regular intervals. The GCO in turn reports at least once a year to the Executive Board, with a focus on the status of compliance activities, compliance risks, and serious compliance violations. The Executive Board informs the supervisory bodies at least once a year about the key compliance issues.

→ Compliance

Central SpeakUp Line

All employees are called upon to report compliance violations to their supervisor, Legal, HR or other relevant departments. Employees can report violations by telephone or via a web-based application in their respective national language, free of charge and anonymously, via the SpeakUp Line, a central reporting system.

The received reports are reviewed by the GCO and submitted to the Compliance committee for coordinating the necessary investigation of the facts. The Compliance committee consists of senior representatives of the Internal Auditing, Compliance, Group Security and Human Resources departments. It monitors the processing of reported incidents and initiates, if necessary, corresponding corrective measures. Disciplinary actions are also taken, where needed, against the employee who has violated a compliance rule. These actions may range from a simple warning up to dismissal of the employee, depending on the severity of the violation.

Altogether 29 compliance-related reports were received via the SpeakUp Line in 2011, and 20 in 2012. In five cases each in 2011 and 2012, the alleged violation of our rules of conduct was confirmed. Most cases were undisclosed conflicts of interest between employees and third parties; this led to disciplinary actions. In two cases, the behavior of our business partners did not meet our expectations with respect to compliant and responsible business conduct. For this reason, we terminated the business relationship in both cases.

Compliance audits

The Group Compliance function conducts audits in cooperation with Internal Auditing. The audits focus on the existence and quality of compliance guidelines, processes and structures. In addition, our sites are reviewed for violations of our Code of Conduct and Social Charter. The topic of corruption and the requirements of the Social Charter are an integral part of our standard audit program and are audited within the scope of general audits at our sites. Altogether 28 audits were conducted to check for corruption in 2011, and 40 in 2012. In addition, a total of 26 sites in 26 countries were audited on Social Charter topics in 2011, and 40 sites in 35 countries were audited in 2012. During the audits, violations of working hour regulations were found in one case. Management at the site took measures to prevent such violations in the future.

Compliance training courses

Our regular compliance training provided as classroom and online courses has a high priority. Employees at all levels of the hierarchy are trained in topics related to the Code of Conduct, such as corruption, competition law and handling conflicts of interest. Employees are sensitized to the consequences of compliance violations and are shown ways to avoid them. The training plan is regularly updated and adapted in response to new developments. For example, a corresponding course was added in 2011 as a result of the UK Bribery Act. Depending on the course content, some courses on specific topics are offered only to employees above a certain global grade.

Altogether 29,597 employees participated in 82,597 online courses on various compliance topics in 2012, and 19,263 employees participated in 34,433 courses in 2011. In addition, numerous classroom courses on compliance topics were held worldwide in order to provide employees with effective training on local topics in particular.

Many of the online courses dealt with anti-corruption: We trained 22,890 employees on anti-corruption in 2012, and 13,399 employees in 2011. This included 10,164 employees with management responsibility in 2012, and 7,540 employees with management responsibility in 2011.

Guidelines and management systems

We use a structured guideline system to translate our Values and Mission Statements into concrete terms. The purpose is to ensure that all employees know the relevant rules and can apply them in the workplace. Proven management systems ensure that the processes relevant to our CR strategy are steered and monitored systematically.

Group-wide guideline system

The Group-wide guideline system contains all company guidelines and explains which guidelines apply to which parts of the company. They range from the charters and principles valid for the entire company to specific standards and procedures for divisions and legal entities of the Merck KGaA, Darmstadt, Germany, or for individual sites.

The charters and principles include, for example, our [Code of Conduct](#), our [Social Charter](#) and the [Access to Health Charter](#).

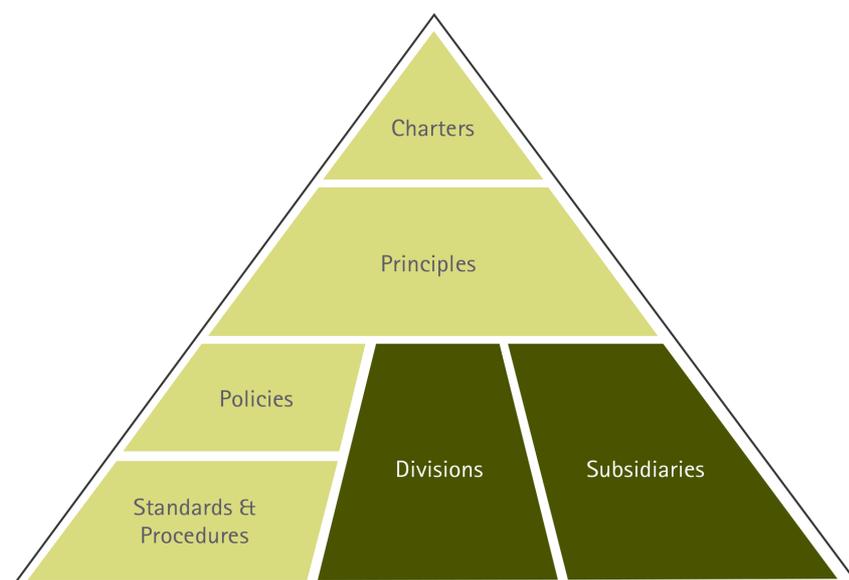
Examples of policies in the company are the "Corporate EHS Policy" valid throughout the Group, which establishes the framework for principles, strategies and organizational structures for environment, health and safety at Merck KGaA, Darmstadt, Germany; our Animal Welfare Policy, which describes the treatment of laboratory animals throughout the company; and our guidelines for stem cell and fertility research, which define the ethical framework for our research and development departments.

In addition, we have numerous other division-specific policies, such as the Safety Policy for chemical products, with which we have established global processes for defining, steering and implementing product safety as well as the corresponding management structures.

Our standards specify in concrete terms the provisions from charters, principles and policies for the persons responsible for the operational processes. In the area of company environmental protection, for example, we have standards for protecting water, managing waste, and ensuring warehouse and transport safety. For pharmaceutical marketing, for instance, a standard exists that defines the Group-wide specifications for product advertising and sponsoring.

The rules are kept up-to-date by the relevant departments and are available on the intranet. Managers are responsible for implementation in their respective areas of responsibility. Our employees receive information and training regarding rules that apply to them. In this way, we ensure that they are familiar with both the overarching rules from the charters and principles as well as the concrete specifications that affect their individual range of activities.

Group-wide guideline system



→ Stakeholder dialogue

CR management systems

The guideline system that we use to implement corporate responsibility in the Merck KGaA, Darmstadt, Germany is integrated into our management systems. With the help of these systems, we set and steer goals, actions and responsibilities in key action areas. Our management systems are based on standards such as the internationally recognized ISO 9001 and 13458 standards (for quality management, the latter specifically for medical devices), GxP (guidelines for "good working practices in the pharmaceutical industry") and ISO 14001 (environmental management). The ISO 14001 environmental management system and the ISO 9001 quality management systems are certified at regular intervals by an independent auditing firm. Merck KGaA, Darmstadt, Germany holds group certificates for the quality and environmental management systems.

Other management systems also exist, such as the Group-wide occupational health and safety management system as well as local systems at the sites. Examples of local management systems include wastewater, waste and energy management.

Program for continuous process improvement

Operational Excellence is the Group-wide program Merck KGaA, Darmstadt, Germany introduced in 2006 to continuously improve entrepreneurial processes. The purpose of Operational Excellence is to achieve the most economic and efficient level of operation in all our production facilities. Operational Excellence calls for a working culture that enables continuous improvement and performance enhancement. For this purpose, we leverage the expertise and knowledge of our employees.

Operational Excellence is a continuous process, a program that consists of an annual cycle of four stages: self-assessment and analysis, goal-setting, best practice sharing and implementation of improvement measures.

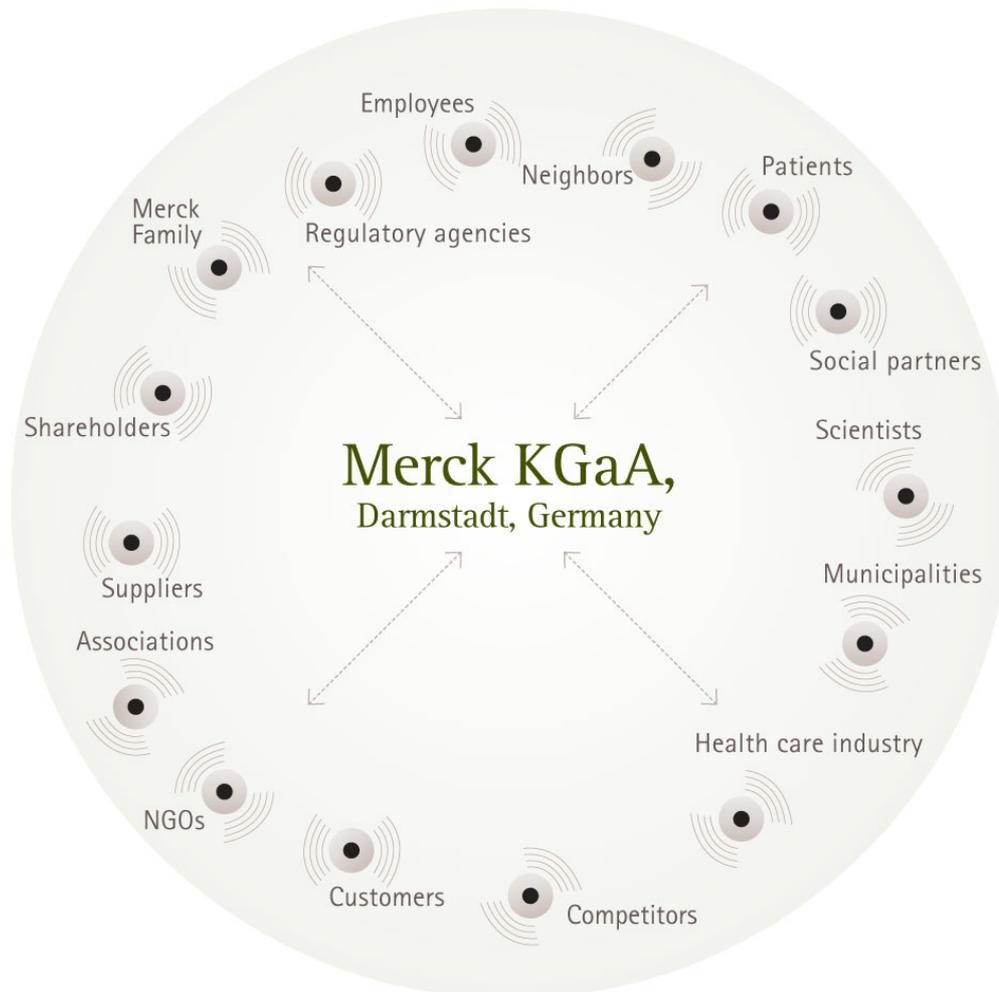
The program is divided into six management fields: goals, change management, production, logistics, innovation/technology, and employees. These fields in turn contain different bricks, including our Values, employee development, safety culture and EHS, that can be supplemented as needed. Each year, top management defines Group-wide priorities for implementing the bricks. In recent years, the program has focused primarily on the globalization of structures and processes and efficiency improvements. For instance, during the 2011-2012 period, the topic of utility management (with emphasis on energy management) became mandatory to support achievement of our climate protection target. Our individual sites can additionally define their own priorities.

Stakeholder dialogue

Our business operations intersect the interests of many people. The dialogue with relevant stakeholder groups is therefore of fundamental importance to us. These stakeholders include our employees, our business partners, the owner family, investors, regulatory agencies, associations, neighbors in the vicinity of our sites, and non-governmental organizations (NGOs). This continuous exchange enables us to demonstrate how we live our Values and to show the CR strategy we have chosen to pursue. This dialogue should also convey our esteem for our stakeholders. We strive to sustain and build trust and – wherever possible – harmonize divergent interests. Our primary goal is for Merck KGaA, Darmstadt, Germany to ensure public acceptance.



Our stakeholders



Topic-specific dialogues

We have contact with many groups in society through our daily work. The dialogues are mostly organized and held directly by the specialist departments at Merck KGaA, Darmstadt, Germany. Merck KGaA, Darmstadt, Germany also becomes involved by collaborating in industry-specific networks and participating in relevant specialist conventions.

During the 2011–2012 period, dialogues were held especially on the topics of access to health in developing health care systems and bioethics; the latter subject was primarily discussed by our Bioethics Advisory Panel (MBAP), which was founded in 2011. Moreover, we also initiated exchange with the relevant players in the public and private sectors. For example, in 2011 and 2012, Merck KGaA, Darmstadt, Germany invited internationally renowned experts from science and NGOs to debate on the global challenges facing access to health. The dialogues focused on initiatives of the legal entities of the Merck KGaA, Darmstadt, Germany that aim to improve access to health in developing health care systems; the dialogues also addressed the role of pricing in access to health in developing health care systems, the increasingly stricter requirements of government and society on pharmaceutical companies, and possible alliances and partnerships.

Discussion and information forums

We have set up discussion and information forums for local residents at our large sites. For example, with the public planning forum that we have held annually at our company headquarters in Darmstadt since 1994, we aim to provide residents with the opportunity to obtain information and discuss our development at the site. The “Fit for 2018” efficiency program was the focus of the discussions in 2011 and 2012. In addition, we discussed the dismantling, construction and renovation of buildings, participation in a city anniversary, sponsoring in the neighborhood, and vocational training at Merck KGaA, Darmstadt, Germany.

→ Stakeholder dialogue

In the context of expanding our biotech production facilities in Corsier-sur-Vevey, Switzerland, discussions were started with NGOs and the local authorities to ensure the greatest possible transparency during the entire planning, construction and completion stages. For construction, Merck KGaA, Darmstadt, Germany committed to implementing high environmental and safety standards going beyond the statutory requirements. The annual forum was also continued after the construction project was completed. It provides an opportunity for regular discussions and reviews of the implementation of agreed measures and is scheduled to be held again in 2013. Because Merck KGaA, Darmstadt, Germany presents the plans transparently and implements the agreed measures on schedule, trust was established, and the discussions were therefore positive. In 2012, we completed the agreed landscape design, which an independent expert rated as positive.

Stakeholder surveys

We survey our employees, customers and other relevant stakeholder groups regularly on how they view our performance with regard to corporate responsibility, and what expectations they have for systematic dialogue on the CR topics in focus. In total, 85 stakeholders participated in our online survey in summer 2012. In addition, 14 select experts were surveyed by phone. Besides our performance in terms of CR, the current relevance of CR topics and our last CR report were evaluated. The feedback was highly positive. The respondents gave Merck KGaA, Darmstadt, Germany a rating of good or very good for CR performance in the area of product responsibility. The main areas of focus for this CR report were also derived from the survey results.

At our life science tools division, questions on the strategic direction of the division with regard to sustainability are also discussed with customers and representatives from NGOs and from science in the Sustainability Stakeholder Advisory Group (SSAG).

Lobbying and working with associations

Part of our stakeholder dialogue is also to participate actively in the political process, where we become involved and present our positions and viewpoints – either in direct dialogue with politicians or via our work with associations. Examples of important national and international industry associations in which we hold positions include:

- The German Chemical Industry Association (Verband der Chemischen Industrie – VCI)
- The European Chemical Industry Council (Conseil Européen des Fédérations de l'Industrie Chimique – [CEPIC](#))
- The German Association of Research-based Pharmaceutical Manufacturers (Verband Forschender Arzneimittelhersteller – [VFA](#))
- The European Federation of Pharmaceutical Industries and Associations ([EFPIA](#))
- The International Federation of Pharmaceutical Manufacturers Et Associations ([IFPMA](#))

Examples of [positions](#) accepted by members of our Executive Board:

- In October 2012, Karl-Ludwig Kley, Chairman of the Executive Board, was elected as President of the VCI. He is also the Vice President of the Federation of German Industry (Bundesverband der Deutschen Industrie e.V. – [BDI](#)).
- Stefan Oschmann, Executive Board Member responsible for the prescription medicines and Consumer Health divisions, is Vice President of the IFPMA and a Board Member of the VFA.
- Bernd Reckmann, Executive Board Member responsible for the Performance Materials and life science tools divisions, is Chairman of the Hessian Chapter of the VCI.

Furthermore, Merck KGaA, Darmstadt, Germany is active in numerous charitable organizations, such as the Goethe Institute, the Remembrance, Responsibility and Future Foundation, and the World Environment Center (WEC). In addition, we participate in initiatives and projects whose other participants share our standards of entrepreneurial conduct. For instance, we support the Code of Responsible Conduct for Business. During the 2011–2012 period, intensely discussed topics in the scope of our work with associations included in particular the Responsible Care® initiative, the new chemicals legislation [REACH](#), and counterfeit medicines.

Products



Our success and our future are founded on innovative products that benefit people and help improve quality of life. Our products are highly trusted worldwide – whether our innovative medicines of chemical or biological origin, our over-the-counter products, our liquid crystals for LC displays, our pigments for the coatings, plastics and printing industries, products for the cosmetics industry, or customer-oriented lab solutions for the life science industry.

Responsibility for our products will always be at the core of our corporate responsibility. Here, we are driven by our ethical standards as well as our high expectations for our products in terms of safety and environmental compatibility.

→ Sustainable products

Sustainable products

Responsibility for our products is at the core of our corporate responsibility. We therefore strive to minimize the impact our products have on people and the environment during their development, manufacture, and distribution, as well as during and after their use. This includes providing comprehensive information on responsible, safe and proper use of those products. It is, however, also crucial to conserve resources and minimize the generation of emissions and waste.

Through our products, we are helping to overcome global challenges such as climate change and energy scarcity. Our specialty chemicals help our customers save energy. **Liquid crystals** (LCs) provide computer monitors and televisions with high picture quality while also consuming little energy. Our materials for PS-VA (polymer-stabilized vertical alignment) technology help significantly reduce the amount of background lighting needed, which is the largest power consumer in these devices. New potential applications for LCs are smart windows: They let more solar heat inside in winter, less in summer. Organic light-emitting diodes (OLEDs) make it possible to produce energy-efficient displays with brilliant colors and sharp picture quality. In October 2012, Merck KGaA, Darmstadt, Germany strengthened its partnership with Epson, a Japanese printer manufacturer. Our common goal is the mass production of large-surface OLED displays. Modern **light sources** such as light-emitting diodes (LEDs) and organic light-emitting diodes (OLEDs) are key technologies that will make it possible to decrease the energy consumption of lighting. Our printable structuring materials are enabling the **photovoltaics** industry to manufacture solar cells in a more environmentally sound way while improving their efficiency.



We strive to continuously enhance the sustainability footprint of our products, developing suitable product and process innovations in order to do so. And we are working to offer our customers products that enable them to reduce the impact of their own activities as well as achieve their own sustainability goals. One example is the **Green³** program of the Performance Materials division, with which we help customers develop energy-efficient LCDs, OLEDs and LEDs. The concept has been extended to include our portfolio of cosmetic pigments and cosmetic actives; it covers various areas such as the sustainable procurement and production of cosmetic ingredients as well as the optimization of the related production processes.

In dialogue with our customers from the cosmetics industry, we also develop proposals for cosmetic formulations that meet strict sustainability criteria and are in line with the current trend toward more natural cosmetics. Several of our products have recently been certified by ECOCERT, an independent organization that represents high international standards for environmentally sustainable products.

Analysis as a prerequisite for improvement

In order to reduce the unwanted effects of our products, we must understand our products across their life cycle, which is why we perform corresponding analyses.

In some cases, we investigate the complete life cycle ("cradle to grave"); in other cases, we focus on parts of the cycle through the "cradle-to-gate" approach, meaning that we analyze the R&D phase of a product up to the point of delivery to the customer. Sometimes we concentrate on particular aspects, such as greenhouse gas emissions, water consumption, or packaging. The results of the analyses show us where we have potential for improvement. Our experts from R&D, Product Management, Quality, Procurement, and other units can use these data as a basis to develop specific measures and initiatives across the entire product life cycle; they furthermore engage in an exchange of relevant best practices and ideas. We share the results of our analyses with our customers as well.

We have calculated the product carbon footprint for pearl-luster pigments and liquid crystal mixtures as well as the product water footprint for liquid crystal mixtures using the "cradle-to-gate" approach. Our customers utilize these data to calculate footprints for their products. Since our performance materials are only present in the end product in minute amounts, our contribution to the end product's footprint is generally very minor.

20%

Displays use 20% less energy* thanks to innovative liquid crystals from Merck KGaA, Darmstadt, Germany for PS-VA technology (*in comparison to VA technology).

→ Access to health: Our approach

In the 2011–2012 period, our life science tools division conducted a life cycle assessment that was reviewed by experts; it also developed a methodology for evaluating various waste disposal solutions and calculated more than 20 carbon footprints for individual products.

Sustainability even at the product development stage

We lay the cornerstone for our products' sustainability during the product development phase. We have implemented various guidelines in order to reduce potentially negative effects, such as our Group-wide "Product Safety Chemicals" Policy. In our Performance Materials division, we adhere to the "Halogen-free Policy" of our customers and have implemented the "Green Product Policy". Among other things, this forbids the use of acutely toxic, mutagenic, or otherwise severely hazardous substances that remain present in the end product. We furthermore ensure that our products adhere to national and international regulations such as REACH and RoHS, as well as fulfill other industry- and customer-specific requirements.

In addition to this, we have developed systems within the Merck KGaA, Darmstadt, Germany that incorporate sustainability criteria into the product development process. In our Performance Materials division, we have introduced a structured analysis of the ecological impact of the products from the business unit Advanced Materials; called the Innosessment, this analysis is conducted during the development stage. In 2011 and 2012, we analyzed more than 100 products with regard to toxicity, the substitution of critical reagents and other aspects.

As part of the Design for Sustainability program, the life science tools division has developed a number of tools to drive sustainability across the product development process. One example is a scorecard which identifies key health and environmental impacts in certain life cycle stages as well as opportunities for improvement. This program is especially aimed at reducing our customers' own environmental impact, including their carbon footprint and water use.

In order to improve resource efficiency, we examine different materials for our product packaging to determine which ones are best suited to the task.

We help our customers avoid generating waste and offer take-back and recycling programs.

Conscientious production processes

Efficient processes make economic sense and are good for the environment. In our operational processes, mandatory standards apply Group-wide to ensure resource conservation and avoid negative environmental impact. In order to reduce greenhouse emissions during the manufacture of our products, we have set a Group-wide climate protection goal and are making good progress toward achieving this goal.

Access to health: Our approach

We want to improve the access to health care for underserved populations. As a pharmaceutical, chemical and life science company, we provide innovative products and services to improve the quality of human life. We are committed to the safe and appropriate use of and access to Merck KGaA, Darmstadt, Germany medicines and health solutions.

We acknowledge that not only medicines are lacking in the poorest countries of the world; there is also a great need for doctors and medical personnel to administer them. There is often no refrigerated storage or suitable infrastructure for the transport and distribution of medicines. Furthermore, clean drinking water and basic sanitation are often unavailable or difficult to access.

Improving access to health care therefore poses a complex challenge. It involves factors such as development and health policy, health system infrastructure and distribution systems, trained health workers, pricing, and appropriate use of medicines, as well as adequate, sustainable funding.



→ Access to health: Our approach

In order to achieve universal access to high-quality, safe medicines and sustainable solutions for patients in developing health care systems, all the relevant stakeholders – both governmental and non-governmental – must pool their efforts, share their knowledge and expertise, and work together to develop creative ideas.

Since we consider it important to have a wide-ranging, holistic perspective, our programs refer to “access to health”, not merely “access to medicines”. Working at the interface of medicines, diagnostics, nutritional supplements and chemicals, we utilize our expertise and core competencies in order to promote access to health.

In doing so, we set ourselves high ethical standards, in accordance with the charters, guidelines and principles of our company. All legal entities and employees are part of our Group-wide commitment to increasing access to health. Through our programs and charter on Access to Medicines in Developing Countries, we strive to lead and form partnerships to improve global access to medicine, thereby improving the lives of patients.

The Charter covers the following topics: pharmaceutical donations and philanthropy, research and development for neglected tropical diseases (NTDs), product pricing, intellectual property, and anti-counterfeiting measures.

Governance

Merck KGaA, Darmstadt, Germany is working on a long-term strategy for access to health solutions, including medicines, devices (e.g. RebiSmart™, easypod™), nutritional supplements (e.g. probiotics), diagnostics (Minilab, Guava, Muse™), as well as capacity building. In doing so, we are working in partnership with key stakeholders, from both public and private sectors, to improve access to health care.

The strategy is defined by a multidisciplinary steering committee that is chaired by Stefan Oschmann, the Executive Board Member responsible for the prescription medicines and Consumer Health divisions. Decisions made by the committee are implemented by an ad-hoc Access to Health Task Force that was founded in 2011. This task force also defines objectives and develops indicators in order to gauge and assess the progress of the strategy. The Executive Board at Merck KGaA, Darmstadt, Germany maintains the overall responsibility for our access to health charters and initiatives.

Access to Medicine Index

Every two years, the **Access to Medicine Index**  rates pharmaceutical companies in terms of their contributions to improving access to medicines in developing health care systems. This index aims to increase transparency as well as to sustainably improve access to health. Merck KGaA, Darmstadt, Germany ranked eighth in 2012, nine places higher than in 2010.

2012

8th place

Merck KGaA, Darmstadt, Germany ranked 8th in the Access to Medicine Index 2012 (2010: 17th out of a total of 20 companies).

Stakeholder dialogue

In order to make informed decisions, Merck KGaA, Darmstadt, Germany interacts with stakeholders such as patient groups, government representatives, employees, non-governmental organizations (NGOs), practicing doctors, private donors, and experts on topics that are relevant to access to health. We believe that all those involved must work together in order to achieve sustainable improvements in this area.

Furthermore, the continuous dialogue provides us with valuable feedback on our activities and programs.

The following events represent prime examples of constructive discussions and engagement in 2012:

1. At the United to Combat Neglected Tropical Diseases event hosted in London by the Bill & Melinda Gates Foundation in January 2012, Merck KGaA, Darmstadt, Germany jointly signed the London Declaration along with twelve other leading pharmaceutical companies, the World Health Organization (WHO) and key global health stakeholders. On this occasion, Merck KGaA, Darmstadt, Germany announced a tenfold increase in the amount of praziquantel donated annually and to continue the donation program until schistosomiasis has been eliminated.
2. At the end of September 2012, experts from WHO, the Bill & Melinda Gates Foundation, and the British parliament, as well as representatives from the pharmaceutical industry, convened in Berlin to discuss the progress and challenges in the fight against neglected tropical diseases. Merck KGaA, Darmstadt, Germany informed health experts on our Praziquantel Donation Program.

→ Access to health: Philanthropy and product donations

3. In collaboration with EFPIA, our prescription medicines division supported numerous access to health activities and educational seminars at the European Parliament in Brussels, covering topics such as "Breaking the vicious cycle of poverty and disease: Research on neglected tropical diseases" and "Technology transfer in the Third World: A win-win situation".
4. In March 2012, Merck KGaA, Darmstadt, Germany became the pharmaceutical industry's representative on the European Commission's Tajani Initiative, which in particular aims to improve access to medicines in Africa.
5. In July 2012, Merck KGaA, Darmstadt, Germany hosted the Partnership for Disease Control Initiatives (PDCI) meeting. This meeting enabled an exchange of best practices among pharmaceutical companies that are pursuing a common goal through their own donation programs: to eliminate neglected tropical diseases.
6. At the Geneva Health Forum in April 2012, Merck KGaA, Darmstadt, Germany organized a panel session on "Schistosomiasis – New Perspectives for Elimination and Control of a Chronic Disease".
7. In September 2012, Merck KGaA, Darmstadt, Germany sponsored a symposium on the diagnosis of schistosomiasis at the International Conference on Schistosomiasis in Belo Horizonte, Brazil.
8. Merck KGaA, Darmstadt, Germany contributed to the global conference on neglected tropical diseases held jointly by the World Bank and the Bill & Melinda Gates Foundation in November 2012 in Washington D.C. The event aimed, following the London Declaration, to strengthen collaboration among all key players and stakeholders in the global health sector in the fight against neglected tropical diseases.
9. In partnership with EFPIA, Merck KGaA, Darmstadt, Germany is actively engaged in the preparation of the strategic research agenda for EDCTP-II (European and Developing Countries Clinical Trials Partnership), in order to include NTDs in addition to TB, malaria and HIV/AIDS.
10. In 2011, a Merck KGaA, Darmstadt, Germany representative was the key note speaker at the Global Health Progress Meeting that took place in Geneva on the eve of the 65th World Health Assembly. This meeting between African health authorities and the private sector aimed to discuss innovative public-private partnerships to improve children's health in Africa.
11. Our regional head for North and West Africa discusses access to health with local stakeholders, such as pharmacovigilance organizations, local WHO representatives, health authorities, and education representatives.

Access to health: Philanthropy and product donations

Product donations and philanthropic activities are not stand-alone initiatives. To us, they are part of a broader, holistic approach. We support awareness and education programs as well as capacity and infrastructure building in developing countries in order to ensure sustainable access to medicines as well as improved distribution and use of them.

Medicine donations

Our Praziquantel Donation Program (MPDP) is Merck KGaA, Darmstadt, Germany's largest such philanthropic initiative. In 2007, in collaboration with WHO, Merck KGaA, Darmstadt, Germany launched this program to combat the parasitic worm disease schistosomiasis, the second most common tropical disease in Africa after malaria. Our program was originally limited to 2017. However, at the end of 2011, we decided to continue its engagement indefinitely. The goal formulated jointly with WHO is to eliminate the worm disease in Africa. For this purpose, we will increase the number of tablets donated in the medium term, raising the total to 250 million tablets annually. Around 100 million children can thus be treated each year.

Medicine donations are not intended to undermine the operational health care systems in the recipient countries and often are not a long-term solution to providing access to medicines. We therefore only donate medicines in response to specific requests if these are endorsed by host governments. We consult with our partners regarding decisions on our medicine donations; these are based on an assessment of the need for the product, as well as its potential benefit for patients and its potential to improve health outcomes.

In general, we conduct our medicine donation activities within developing health care systems. However, in response to emergencies or specific one-time requests, medicines may also be donated to industrialized countries, such as during the earthquake in Japan.

→ Access to health: Philanthropy and product donations

We collaborate with both private and public sector partners on donation campaigns that provide access to health solutions in developing countries. We direct the majority of our medicine donations through global institutions such as WHO and non-governmental organizations (NGOs). Only a small portion of our donations are handled locally by our legal entities in response to emergencies or specific requests from ministries of health and charitable organizations.

All medicine donations by Merck KGaA, Darmstadt, Germany are in alignment with the WHO [Guidelines for Medicine Donations](#), our company's Policy and Procedure for Approval and Notifications of Donations and Support, as well as our Code of Conduct and relevant local regulations. Where Merck KGaA, Darmstadt, Germany distributes its products directly, our local management is responsible for ensuring that the products are distributed and used before the labeled expiration dates, and that they are delivered to the intended beneficiaries. Local management must furthermore document the intended delivery as well as the safe disposal of expired products, in compliance with local regulations. When an external partner manages the distribution, we monitor the donation process to ensure compliance with the WHO Guidelines for Medicine Donations.

In China, Merck KGaA, Darmstadt, Germany established the Erbitux® China Patients Aid Program, which was primarily targeted at low-income patients with advanced-stage colorectal cancer. In collaboration with the Beijing Red Cross Foundation, the program succeeded in providing this medicine free-of-charge, reaching 510 patients in 97 hospitals across 35 cities in China by the end of 2012.

Improving health infrastructure and awareness

We are committed to supporting health awareness and education programs in developing countries that raise awareness among patients, health care professionals and governments and explain the benefits and proper administration of treatment.

Building capacities and infrastructure in developing countries is also a priority for Merck KGaA, Darmstadt, Germany. In this way, we strive to ensure sustainable access to medicines and/or improved distribution and use of them.

Examples include a hospital that we run in Karachi, Pakistan, our support for the Mother and Child Health Program (MCH) run by Terre des Hommes in Sri Lanka, and our support for the largest health education program to date on thyroid diseases in China. As part of our Praziquantel Donation Program, educational material is produced and distributed in order to further promote the prevention of schistosomiasis.

In Kenya, we are supporting the work of a patient organization that is conducting a diabetes awareness campaign. The campaign started in Kenya and will expand into other countries in Africa. It addresses the communities and works in partnership with local stakeholders such as diabetes foundations, health ministries, local hospitals, medical students, and local community partners such as supermarkets. It is part of our three-year Capacity Advancement Program (CAP) in Africa.

The objective of the campaign is to create the awareness required to:

- prevent or stop the spread of diabetes
- improve the early diagnosis of diabetes
- improve the quality of life and reduce complications of the disease.

The campaign has reached 1,000 Kenyans, providing information, free screening and medical check-ups. Patients who have been diagnosed with diabetes have been advised and treated. Mobile messages (SMS) of diabetes health tips will be sent to them. As part of the campaign, shopping guide leaflets for people with diabetes have been distributed in the country's largest supermarket chains.

Helping people help themselves

In Africa, we are currently setting up the Capacity Advancement Program (CAP). In collaboration with local stakeholders, we are aiming to help build medical skills and capacities locally. The initiative's goal is to improve education for the key players in the health care sector as well as promote the development of health care systems. This involves obtaining a university education and building research skills in both applied as well as clinical research, including clinical trials.

The program is to be rolled out first in Kenya and Namibia and will primarily address the topics of research and development, clinical research, integrity along the supply chain, pharmacovigilance, and scientific education.

In addition to this, via Tomorrow's Trust, we are funding three scholarships in South Africa for underprivileged students planning a career in medicine or pharmacy.

→ Access to health: Pricing, production and distribution

Access to health: Pricing, production and distribution

Our pharmaceutical pricing approach helps us recover research, development, manufacturing, regulatory, distribution, and other costs incurred by the company in bringing its products to market, in order to ensure a sustainable supply of products for future generations of patients. This process enables us to continue investing in the discovery and development of new medicines. Recognizing the importance of affordable access to medicines in developing countries, we adapt pricing through flexible, differentiated pricing and product donations.

Pricing

Merck KGaA, Darmstadt, Germany reviews its pricing on a regular basis to ensure that our products are competitive and also accessible. In addition, Merck KGaA, Darmstadt, Germany supports a zero import duty approach, as advocated by WHO, as import duties constitute a large portion of the price of medicines in many countries.

Merck KGaA, Darmstadt, Germany regularly bids in government tender processes in developing countries in order to provide medicines at affordable prices. We offer products to governments at reduced rates in Africa, Latin America, and Southeast Asia. Such products include metformin (active ingredient to treat diabetes) via state-funded pharmacies (Farmácia Popular) in Brazil as well as the social health insurance system in Mexico and in Guatemala; Euthyrox® (to treat thyroid diseases) via the social health insurance fund in Costa Rica and the national health system in Cuba; cefixime (an antibiotic) via the health authorities in South Africa; Concor®, Concor Cor®, Glucophage®, Glucophage XR®, Glucovance® (for diabetes), Thyrosol®, and Levothyrox® (for thyroid diseases) in government hospital tenders through the official local distributor in Vietnam; and Concor, Euthyrox, and Glucovance via the Ministry of Health in Malaysia.

Merck KGaA, Darmstadt, Germany's portfolio has more than 80 products that are on the WHO Essential Medicines List [↗](#). They are currently distributed in 65 developing countries including 34 countries in Africa, 19 in Asia and 8 in Latin America. These products are available in around half of the least developed countries (LDCs) such as Afghanistan, Benin, Burkina Faso, Ethiopia, Haiti, Mali, Senegal, and Sudan. The prices are determined by our legal entities, taking local purchasing power into consideration.

In order to improve access to high-quality, affordable diabetes treatment for low-income segments of the population, Merck KGaA, Darmstadt, Germany is developing a dual pricing strategy for Glucophage (active ingredient: metformin) in West Africa.

Local manufacturing

Merck KGaA, Darmstadt, Germany believes that local manufacturing in developing health care systems is appropriate for particular products. Local manufacturing and the transfer of technology, skills and intellectual property are contingent on compliance with our quality and safety standards. All our products, whether for developed or developing markets, are produced in manufacturing plants that meet Good Manufacturing Practices (GMPs [↗](#)).

A number of treatments for chronic diseases are manufactured at production plants located in countries such as India, Pakistan and Indonesia. The medicines are marketed in the country of manufacture and exported to developing countries such as Afghanistan, Maldives, Sri Lanka, Nepal and Kenya. We export products manufactured in Pakistan and India to a number of African countries through our legal entities in South Africa and Tunisia. Our production plant in Indonesia supplies developing health care systems across Southeast Asia.

Through our qualification program for our contract manufacturers, we support them in developing their own quality system by offering coaching or consultation services, as needed. We are currently working with a partner in Algeria that handles the packaging of Glucophage for local distribution. Merck KGaA, Darmstadt, Germany intends to further develop this local partner so that they can perform other steps along the value chain on our behalf.

→ Access to health: Research and development

Product approval and distribution

When deciding which products to submit for approval in which countries, we take our patients' needs for our products into consideration.

Merck KGaA, Darmstadt, Germany continuously works to guarantee product availability for its customers. Our requirements for the quality and effectiveness of the distribution process are uniform worldwide. We are committed to performing rigorous and frequent checks on our distribution network to ensure that partners are adhering to our quality and safety requirements and to ensure full compliance with global Good Distribution Practices (GDPs).

Global Drug Safety is responsible for continuously, systematically monitoring the safety of our drugs (pharmacovigilance). Pharmacovigilance information is compiled from doctors and patients in all countries in which our products are marketed. Medical specialists and pharmacovigilance teams ensure that information on adverse affects is correctly compiled, tracked, and communicated. The data for all of our drugs are evaluated centrally by Global Drug Safety, and risk-benefit evaluations are adapted where necessary. In line with regulatory requirements, changes to the risk-benefit evaluation and potential safety risks are reported to the responsible authorities, as well as to doctors and patients.

In 2011 and 2012, Merck KGaA, Darmstadt, Germany worked with local key players to develop and implement good pharmacovigilance practices in northwestern Africa. We collaborated with pharmaceutical regulatory authorities (the National Centre of Pharmacovigilance in Tunis) to align their national regulations with the EU pharmacovigilance directives.

Product safety and anti-counterfeit measures

To protect patients, Merck KGaA, Darmstadt, Germany supports initiatives to fight counterfeit products. In this regard, we are involved in organizations (VFA, EFPIA, and IFPMA), support industry-wide initiatives, and collaborate closely with the responsible authorities at a national, regional and international level. A special focus is on our collaboration with the **Pharmaceutical Security Institute**  (PSI), an organization dedicated to protecting public health, improving the exchange of information on counterfeit medicines, and initiating enforcement actions against product counterfeiters.

Our Anti-Counterfeiting Operational Network (MACON) consists of experts from various parts of the company such as Legal/Trademarks, Product Security, Export Control, Supply Chain, and Quality Assurance. Managed by Corporate Security, this network is responsible for monitoring and implementing anti-counterfeiting measures for all products worldwide.

We utilize innovative solutions to help our customers and patients determine the identity and authenticity of a pharmaceutical product themselves. One example is the Mobile Anti-counterfeiting System (MAS) in Nigeria, an identification system operated via mobile phone. After texting the scratched bar code encrypted on the package, patients receive a text message regarding the authenticity of the drug. In addition to this, we support the non-profit Global Pharma Health Fund, which offers the GPHF Minilab. This is a portable, compact quality analysis kit enabling the detection of substandard and counterfeit medicines.

Access to health: Research and development

More than 1.4 billion people are exposed to the dangers of neglected tropical diseases (NTDs). This group of diseases is classed as "neglected" because, despite the significant number of people impacted by them, they have historically received less attention and research funding than other diseases. Neglected tropical diseases occur particularly in developing countries. We are committed to pursuing our R&D efforts in order to improve the lives of the millions of people who suffer from NTDs in developing countries. Currently, we are conducting NTD research and development for schistosomiasis and malaria.

We believe that the most effective way to achieve progress and develop new approaches to fighting NTDs is to work through robust public-private partnerships, innovative alliances and interdisciplinary approaches in health and development. Besides our existing partnerships, we are open to engaging in new multilateral partnerships.

Within the framework of our Praziquantel Donation Program (MPDP), we are working to optimize the formulation of the drug. In particular, this involves a tablet coating that will make it easier for school-age children to swallow the tablets and will better protect the drug against external influences. Furthermore, a hint of fruit flavor has been added to make the tablets

→ Access to health: Intellectual property

more palatable for children. Within the scope of a public-private partnership (PPP), we are also researching a new formulation of praziquantel for pre-school children. Praziquantel tablets in their current form are suitable for adults and children over the age of six; for children younger than six, it is currently not possible to properly treat the disease. A pediatric formulation of praziquantel will significantly contribute to achieving the goal of eliminating schistosomiasis in Africa. The partners of this PPP, which was founded in July 2012, include Merck KGaA, Darmstadt, Germany, TI Pharma, Astellas Pharma Inc., and the Swiss Tropical and Public Health Institute (Swiss TPH) in Basel.

In a partnership with the Tropical Disease Research (TDR) program of the World Health Organization (WHO), we are involved in the discovery and development of new treatments for malaria. A lead compound to treat malaria was identified in 2010. We are currently running a lead optimization program internally that has resulted in the preclinical testing of several candidate compounds.

In 2012, Merck KGaA, Darmstadt, Germany sponsored a position for a post-doctoral scientist in Geneva to conduct research on malaria compounds. Merck KGaA, Darmstadt, Germany furthermore provided supervision, all drug discovery infrastructure (including labs, lab supply, access to assays at all research sites, and access to compound collections), and access to advanced testing capabilities.

In addition, Merck KGaA, Darmstadt, Germany is involved in other R&D collaborations on neglected tropical diseases. These include a research project on schistosomiasis and malaria with the Swiss TPH and a collaboration with the London School of Hygiene and Tropical Medicine (LSHTM [\[3\]](#)). Via the WHO parasite testing network, Merck KGaA, Darmstadt, Germany has entered into a collaboration with the Theodor Bilharz Research Institute in Egypt. Merck KGaA, Darmstadt, Germany is also participating in stakeholder dialogues and discussions with the African Network for Drugs and Diagnostics Innovation (ANDI [\[4\]](#)). Using ANDI as the interface, we are actively exploring new research activities and knowledge transfer to develop new treatments for diseases in developing countries.

Furthermore, we are currently conducting adaptive R&D for our Guava system for HIV diagnostics. In the dialogue with national research institutes and universities in Africa, we are discussing potential types of collaboration in order to better address local needs as well as build scientific expertise.

Access to health: Intellectual property

Merck KGaA, Darmstadt, Germany invests in innovation to provide patients with new medicines and to improve current therapies. A prudent approach is needed when evaluating intellectual property.

In the context of this approach, Merck KGaA, Darmstadt, Germany supports the principles of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), including the Doha declaration and Article 31f, and refrains from filing any patent applications relating to pharmaceuticals in least developed countries.

We believe that patent pools can be a suitable method to develop and market products for NTDs. Therefore, Merck KGaA, Darmstadt, Germany has no general objections to joining patent pools in appropriate circumstances, in particular for the development of drugs for neglected diseases.

Also, we believe that voluntary licensing can be an appropriate tool for improving access to medicines. Merck KGaA, Darmstadt, Germany will consider opportunities for non-exclusive voluntary licensing providing fair and reasonable compensation for all interested parties, particularly to increase access and affordability of products in least developed countries.

→ Access to health: Diagnostics

Access to health: Diagnostics

More than 30 million people are infected with HIV worldwide. In the course of an HIV infection, CD4 cells indicate the state of the immune system and act as markers for T cell lymphocytes. Patients with a low count of these cells in their blood are at increased risk of opportunistic infections. Merck KGaA, Darmstadt, Germany's Guava Auto CD4/CD4% Flow Cytometry System is being used to identify and quantify both absolute CD4 T cell counts as well as CD4% values in blood samples.

In Zambia, more than one in every seven adults is infected with HIV, and life expectancy at birth has therefore already fallen to under 39 years. Organizations such as the Catholic Relief Services and the Elizabeth Glaser Pediatric AIDS Foundation have been purchasing the Guava instruments over the past five years for use by the Centre for Infectious Diseases Research in Zambia (CIDRZ). By deploying these devices in provincial CIDRZ labs, the status of patients' immune systems can be monitored using the CD4 test, as soon as HIV is diagnosed. Based on the experiences of these agencies, Zambia's Ministry of Health has adopted the Guava CD4/CD4% system as one of their approved CD4 testing platforms.

Guava systems are ideal for small clinics because the involved costs as well as the needed materials and manpower are low. The system is easy to use and produces results in 45 minutes.

Currently, there are more than 300 Guava systems in use in Sub-Saharan Africa, 35 of which are in Zambia.

Access to health: Clinical trials in developing health care systems

As regards clinical trials, we are committed to complying with all applicable national regulations and requirements, the ICH Note for Guidance on Good Clinical Practice, and the principles of the Declaration of Helsinki. Our clinical trials are performed according to the same high ethical and scientific standards in all countries worldwide.

› Read more in the chapter "Clinical trials".

Access to health: Responsible marketing

In order to ensure professional and transparent conduct in our pharmaceutical marketing activities, we comply not only with numerous statutory regulations, but have also defined our own code of practice, namely our Pharmaceutical Marketing Best Practices.

Merck KGaA, Darmstadt, Germany requires even distributors to comply with its marketing standards. Since 2011, pharmaceutical distributors have had to guarantee their compliance in writing.

› Read more in the chapter "Responsible marketing".

→ Product safety

Product safety

Our products have to be safe – as long as used properly they should not pose a danger to patients, customers or the environment. We therefore examine product safety across the entire life cycle and continuously take steps to make improvements. We make our products safer to use by providing patients and customers with extensive informational material that partly goes beyond the statutory requirements.

- › [Read more about the safety of our drugs.](#)
- › [Read more about the safety of our chemical products.](#)



Product safety: Safety of our drugs

In everything we do, our number one priority is our patients' safety. Before an active pharmaceutical ingredient (API) is used in humans, we conduct extensive pre-clinical trials that test for aspects such as efficacy and toxicity. After this, the API is tested in humans within the scope of clinical trials that extensively investigate the API's efficacy and adverse effects. The trial results are then used to assess the drug's risk-benefit ratio, weighing the benefits of the treatment against its risks. In the case of severe or even life-threatening diseases that have no other treatment option, a higher risk of adverse effects can be more acceptable than for less severe conditions.

Information from clinical trials provides the basis for a drug to be approved by the regulatory authorities. Even after receiving marketing approval, however, we continue to conduct further risk-benefit evaluations on the drug since the number of patients using it increases exponentially – to thousands or millions worldwide. We thus gain a deeper understanding of the safety profile of our drugs and continue performing risk-benefit evaluations.

At our prescription medicines division, Global Drug Safety is responsible for continuously, systematically monitoring the safety of our drugs (pharmacovigilance). Global Drug Safety processes safety information from various sources such as clinical trials, adverse reaction reports and scientific literature in order to provide patients with immediate safety information during the entire life cycle of our drugs.

Pharmacovigilance information is compiled from doctors and patients in all countries in which our products are marketed. Medical specialists and pharmacovigilance teams ensure that information on adverse affects is correctly compiled, tracked, and communicated. The data for all of our drugs are evaluated centrally by Global Drug Safety, and risk-benefit evaluations are modified accordingly, as necessary. In line with regulatory requirements, changes to the risk-benefit evaluation and potential safety risks are reported to the responsible authorities, as well as to doctors and patients.

Global Drug Safety and the drug safety units within our legal entities in all countries where our products are used continuously review changes in the pharmacovigilance regulations worldwide – for products in both the development and the marketing phase. New regulations are continuously integrated into our group-wide processes, thus allowing us to ensure that regulatory requirements and statutory regulations are adhered to.

Health authorities regularly conduct inspections to review adherence to regulatory requirements as well as to our own internal drug safety standards.

The Medical Safety and Ethics Board (MSEB), chaired by the Head of Drug Development and Medical as well as by the Chief Medical Officer, bears ultimate responsibility for drug safety at our prescription medicines division; it convenes once a month, or as required. In addition to the chairpersons, the MSEB consists of experienced drug safety and product experts from our prescription medicines division, and its tasks include assessing risk-benefit evaluations during drug development and marketing, reviewing risk management, and dealing with safety-related communication. Furthermore, it reviews proposals for first-in-man (FIM) dosages as well as for updates to the safety warnings on package inserts.

→ Product safety: Safety of our chemical products

In collaboration with other companies as well as organizations from the public sector, Merck KGaA, Darmstadt, Germany is engaged in the global research project **PROTECT** of the Innovative Medicines Initiative (IMI), which was launched during the 2011-2012 period. This project aims to further develop and optimize instruments and methods for the risk-benefit evaluation of drugs.

Our Quality Training Management standard applies to all employees whose work impacts the quality and safety of a drug or clinical trial data. This standard describes how to conduct training workshops and seminars at both the Group level as well as locally within the legal entities. Compliance with these requirements is regularly reviewed during the audits of the safety quality system.

GMP production

In producing pharmaceuticals, quality assurance is a key topic because deviations can impact patients' health. In order to ensure that pharmaceuticals meet the standards set for identity, purity, potency and safety, they must be manufactured according to cGMP (current **Good Manufacturing Practice**). Consequently, as a manufacturer we must have appropriately trained employees as well as suitable facilities, processes and procedures. Compliance with cGMP guidelines is required and monitored by the health authorities.

On December 15, 2011, Merck KGaA, Darmstadt, Germany received a warning letter from the U.S. Food and Drug Administration related to inspections of production facilities in Tiburtina in Italy, and Aubonne and Vevey in Switzerland. Rebif® and other products for distribution in the United States are manufactured at these sites. The letter primarily addressed several processes related to the manufacture of Rebif, which the FDA concluded were not in full compliance with good manufacturing practice standards. Merck KGaA, Darmstadt, Germany is working closely with the FDA to address its observations. The agency has completed its initial evaluation of our responses. In its own response, the FDA agreed that the proposed corrective actions, if properly implemented, would adequately address the violations in question. Since this initial evaluation, all actions stipulated by the plan submitted to the FDA have been implemented in a timely fashion. In September 2012, Merck KGaA, Darmstadt, Germany sent a final report to the FDA, and the FDA has already conducted another round of inspections.

Labeling of packaging

All our pharmaceutical packaging comes with the required package insert that informs patients how to correctly use the product. The package inserts furthermore inform patients of the risks and adverse effects associated with taking the drug. They are regularly reviewed and updated to ensure that they are state-of-the-art, particularly in terms of safety-relevant information. The Labeling Oversight Group coordinates this process and regularly reports these updates to the Medical Safety and Ethics Board (MSEB).

Product safety: Safety of our chemical products

Compliance with regulatory requirements

When it comes to chemicals, some of which are also classed as hazardous substances, proper use is a prerequisite for the safety of people and the environment. This is why we provide our customers with extensive information about the safe use of our products.

Numerous regulations are intended to ensure that chemicals pose no danger to humans or the environment. Compliance with these regulatory requirements is an important part of our work. They pertain to the production, handling, import, marketing, recycling, and disposal of chemicals.

With our Group-wide "Product Safety Chemicals" policy, we have established global processes for defining, steering and implementing product safety, as well as the corresponding management structures. This policy covers all relevant national and international chemical regulations, including the Globally Harmonised System of Classification and Labeling of Chemicals (GHS) and its implementation in regional legislation (such as the CLP regulation in the EU and HazCom in the United States), the EU chemicals regulation REACH, the U.S. Toxic Substances Control Act (TSCA), and the German federal law on protection from hazardous substances (ChemG). The policy also incorporates legal standards that relate to the

→ Product safety: Safety of our chemical products

transport of hazardous substances, biocides, cosmetics, chemicals used in food and animal feed, etc. It is regularly updated with regard to new regulatory requirements – the last update was made in September 2012. The Group Product Safety Committee (GPSC) is responsible for continuously monitoring the relevant regulatory requirements; the Executive Board Member responsible for product safety is a member of this committee. Corporate Regulatory Affairs, a department within the Group function Environment Health Safety Security Quality (EQ), and local units are responsible for compliance with the relevant regulatory requirements for product safety.

Safety analysis during product development

We have developed various instruments in order to ensure that the development process yields products that are as safe to use as possible. This includes conducting analyses that show us how we can enhance product safety. At our life science tools division, we subject all product innovations to a formal EHS analysis that covers aspects such as environmental impact and the identification of harmful chemical substances. During the 2011–2012 period, a procedure called Innosessment was developed in the Advanced Materials business unit of the Performance Materials division; this process aims to help examine product innovations in terms of health-related and environmental effects such as toxicity. As a result of these analyses, for instance, critical constituents such as certain solvents are being replaced.

Transparent information for safer use

In order to increase user safety, we only deliver our chemicals to our customers with safety data sheets. These correspond to current relevant national regulatory requirements such as REACH and are available in more than 35 languages. We also provide our customers with declarations and analytical reports with which they can in turn fulfill their obligation to implement the EU directive RoHS.

We are committed to advanced product safety and especially transparency, going beyond the legal requirements. We support the goals of the Global Product Strategy, an international initiative of the chemical industry. In this context, we provide our customers with product safety summaries that are available on the website of the International Council of Chemical Associations (ICCA [↗](#)).

All information on using our products is also accessible on our website. There, we furthermore provide a program called SciDeEx® [↗](#) that enables users to check whether, based on the information in our safety data sheet, a chemical can be safely used even for a slightly modified use. This program helps significantly in making our chemicals safe for users. It is based on ECETOC TRA2, a program that is recognized by the European Chemicals Agency (ECHA). In 2012, we produced a film [↗](#) on the safe use of life science tools division products in the lab, which is accessible on our website.

Goals: Product safety

Strategic goal	Action	By?	Status in 2011 and 2012	Status
Establish a globally uniform hazard and risk communication system for all relevant Merck KGaA, Darmstadt, Germany chemicals in the supply chain, incorporating the principles of prevention	Implementation of REACH:	End of 2011	The program SciDeEx® ↗ has been published on Merck KGaA, Darmstadt, Germany's website.	
	Publish the SciDeEx® calculation program on the Merck KGaA, Darmstadt, Germany Chemicals portal			
	Provide all mixtures with new safety data sheets in accordance with REACH Annex II	End of 2012	All safety data sheets were converted to the new format by the deadline.	
	Register substances produced in quantities ranging from 100-1,000 metric tons per year (phase 2 of REACH implementation) and register non-phase-in substances	Mid-2013	For more than 75 substances, and thus a majority of the relevant substances, the work has already been done. Merck KGaA, Darmstadt, Germany is on schedule in terms of reaching its goal.	

→ Nanotechnology

Goals: Product safety

Strategic goal	Action	By?	Status in 2011 and 2012	Status
	Register substances produced in quantities ranging from 1-100 metric tons per year (phase 3 of REACH implementation) and register non-phase-in substances	Mid-2018	We have started the process of registering substances for phase 3.	■
	Implementation of GHS/CLP: Classify mixtures and sets according to the CLP regulation	Mid-2015	We have started the process of classifying mixtures.	■
	Implementation of the Global Product Strategy (GPS): Within the scope of GPS, provide product safety summaries for all hazardous substances registered under REACH	End of 2020	The first product safety summaries are available on the website of the International Council of Chemical Associations (ICCA ¹). In parallel to the registration of substances for REACH, Merck KGaA, Darmstadt, Germany will produce further product safety summaries in order to achieve the goal for all substances.	■
	Projects for hazard communication: Update safety data sheets for non-hazardous materials	End of 2020	We have started updating the safety data sheets.	■
	Increase the number of safety data sheets prepared to a globally uniform standard	End of 2020	A Group-wide standard is currently being developed.	■

Legend: ■ Achieved ■ In progress ■ Not achieved + New goal

Nanotechnology

Nanotechnology is a highly innovative field of development that researches and uses structures that are 50,000 times thinner than a human hair. Nanotechnology makes it possible to produce materials with completely new properties, benefits and functions for a wide variety of applications.

Nanotechnology offers many opportunities for us. In our Chemicals business, we can use nanoscale materials to develop products with new functions and properties – thus increasing, for example, efficiency in terms of resource and energy use. In our Pharmaceuticals business, we work with external partners to explore the use of nanomaterials to improve therapeutic options. Within the scope of joint European research projects, we are currently also investigating the suitability of nanoparticles as vehicles for active pharmaceutical ingredients.



However, the special structure of nanoparticles can also involve risks. We utilize the new technology only with the greatest care. We take into account Group-wide requirements for safety as well as environmental and health protection, employing our existing processes and systems for product safety. We abide by the precautionary principle and take nanomaterial safety issues seriously.

→ Use of genetic engineering

At the end of 2008, we instituted our Group-wide "Use and Handling of Nanomaterials" policy; this document governs the handling of nanomaterials, whether used in pharmaceutical and chemical laboratories, production plants, filling plants, or warehouses.

We also provide our customers with information on the proper handling of nanomaterials, for example during transport, processing, storage, and disposal.

In manufacturing and processing products, we pay strict attention to compliance with all statutory regulations and other applicable standards, such as the [guidelines](#) of the German Federal Institute for Occupational Safety and Health (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin – BAuA) as well as the German Chemical Industry Association (Verband der Chemischen Industrie – VCI).

Both internally and externally, we are constantly engaged in an exchange regarding the opportunities and risks of nanotechnology. In the 2011–2012 period, Merck KGaA, Darmstadt, Germany established an internal nano-coordination group consisting of analysts, researchers, toxicologists, safety experts, and experts from other relevant areas of the company. We also maintain a continuous dialogue with other companies, associations and regulatory agencies, such as in the nano-coordination group of the Technology and Environment (Technik und Umwelt) committee of the VCI, and in the Responsible Production and Use of Nanomaterials group, a technology working group of [DECHEMA](#) (Society for Chemical Engineering and Biotechnology) and the VCI.

Use of genetic engineering

Merck KGaA, Darmstadt, Germany utilizes genetically modified organisms in research and development. Since the 1980s, Merck KGaA, Darmstadt, Germany has been manufacturing biotech products that are produced using genetically modified organisms (GMOs). Without this technology, the major medical advances of the last several years would not have been possible.

Our major research centers for medical biotechnology are located in Darmstadt (Germany), Boston (United States), Beijing (China), and Tokyo (Japan). Important production sites for this are Aubonne and Corsier-sur-Vevey in Switzerland. In 2012, we completed the expansion of our site in Corsier-sur-Vevey. Now one of the most state-of-the-art biotech production facilities in Europe, it has enabled us to bolster our market-leading position in this field.



All biotechnological activities at Merck KGaA, Darmstadt, Germany are subject to strict legal regulations worldwide; compliance with these regulations is monitored by biological safety officers. Merck KGaA, Darmstadt, Germany continually tracks regulatory changes pertaining to biotech products and adapts its processes accordingly, thus ensuring compliance with all statutory requirements.

Product-related crime

Across the globe, the pharmaceutical and chemical industry is confronted with product-related crime.

Counterfeit medicines in particular pose a major challenge, while also representing a serious threat to public health. According to the World Health Organization, a considerable proportion of the medicines for sale in developing health care systems is counterfeit or substandard. Interpol estimates this at up to 30%. This issue is aggravated by the lack of adequate protection, security and drug approval systems. Due to the sale of products through unlicensed internet pharmacies and online underground business-to-business platforms, the percentage of substandard and/or counterfeit medicines is growing rapidly in industrialized nations as well.



→ Use of genetic engineering

› Info box: Product-related crime

Key aspects of product-related crime

Counterfeiting (including illegal production):

- Counterfeit products and/or packaging and/or active pharmaceutical ingredients (APIs) and/or excipients
- Product with an incorrect concentration of the active ingredient, with unsuitable and potentially hazardous active ingredients
- Products without active ingredients, with counterfeit or incorrect labeling and/or packaging and/or brand names

Diversion into illegal distribution channels:

- Illegal export of pharmaceutical products, or misuse of chemical products and substances to produce weapons, explosives or narcotics

Black market crime:

- Selling counterfeit and/or diverted products through illegal channels or for misuse
- Theft/robbery: Warehouse theft, freight theft, vehicle theft; theft from production plants

Because criminal organizations are becoming increasingly professionalized, pharmaceutical manufacturers are facing ever-growing requirements to track and monitor their products. Effective protection systems are becoming more and more important for both the products themselves as well as the distribution channels.

Merck KGaA, Darmstadt, Germany develops and manufactures products of the utmost quality. We take action against product-related crime to prevent harm from coming to customers and patients, as well as to protect our reputation as a company. To this end, we focus on various areas in the company and support global initiatives.

Group-wide network

The Group function Corporate Security is the internal and external point of contact for all anti-counterfeiting activities of the Merck KGaA, Darmstadt, Germany and is also in charge of steering and coordinating these activities as well. Here, Corporate Security follows the "Crime relating to products of the Merck KGaA, Darmstadt, Germany" guideline, which describes the goals and strategy for handling product-related crime. At all prescription medicines division sites, we have deployed local anti-counterfeiting correspondents who act as the interface between local regulatory authorities, associations, Merck KGaA, Darmstadt, Germany functions, and Merck KGaA, Darmstadt, Germany's divisions.

Our Anti-Counterfeiting Operational Network (MACON) consists of experts from various fields such legal/trademarks, product security, export control, supply chain, and quality assurance. This network is responsible for monitoring and implementing anti-counterfeiting measures for all products worldwide. This includes coordinating preventive measures, sharing information, securing evidence, conducting investigations, and developing and implementing security systems. The network collaborates in appropriate cases with the relevant regulatory authorities and law enforcement agencies. Annually, MACON reviews and handles more than 100 cases of product-related crime.

Authenticity and tracking

Besides implementing internal quality control systems and also strictly adhering to all export and trade guidelines, we also combat counterfeit products through innovative solutions that are tailored to specific markets and target groups. With these measures, we aim to help our customers and patients determine for themselves the authenticity of a pharmaceutical product. Here, we are applying multiple approaches in parallel.

On product packaging and labels, we use security markings with protected color travel pigments of our own manufacture, which enables users to easily verify the authenticity of our products. These security features are considerably harder to counterfeit than the holograms that are frequently used.

→ Bioethics

We employ identification and shipment tracking programs such as Track and Trace, which has been instituted for certain products in certain markets. In the Mobile Anticounterfeiting System project in Nigeria, Merck KGaA, Darmstadt, Germany is partnering with a supplier to detect counterfeit medicines. In addition to this, we have also created a mobile phone/text message based identification system. After scratching off a barcode affixed to the product packaging and sending it via text message, patients immediately receive a text message back telling them whether the product is authentic or not.

We are systematically implementing the requirements of the [EU Falsified Medicines Directive](#), such as the application of a unique serial number to our pharmaceutical packaging. Furthermore, we are participating in corresponding pilot initiatives of the pharmaceutical industry.

We are collaborating closely with regulatory authorities to monitor and track chemicals that can be misused to make illegal weaponry, explosives, and narcotics. In doing so, we are abiding by a commitment of the German Chemical Industry Association (VCI), as well as implementing requirements that pertain to the use of chemicals for weapons of a chemical, biological, radioactive, or atomic nature.

In addition to this, a comprehensive auditing system for distributors and contract manufacturers ensures that GMP and GSP (Good Manufacturing Practice/Good Distribution Practices) are adhered to. This system is based on the [EMA ICH Q10](#) pharmaceutical quality assurance standard.

For our customers in the pharmaceutical industry, we offer Candurin® pearl effect pigments, which feature unique color properties that make tablets and capsules more difficult to counterfeit.

Multifaceted engagement

In our fight against product piracy, we are involved in organizations such as EFPIA, IFPMA, and VFA; we also support industry-wide initiatives, and collaborate closely with regulatory authorities at a national, regional, and international level. A particular area of emphasis is our work with the [Pharmaceutical Security Institute](#) (PSI), an organization dedicated to protecting public health by sharing information on counterfeit pharmaceuticals, and initiating enforcement actions through the appropriate authorities. When product crimes are committed, we collaborate closely with the law enforcement agencies and customs authorities in the respective countries, with Interpol, with the World Customs Organization, with health authorities – and with our competitors as well. Furthermore, Merck KGaA, Darmstadt, Germany is a member of [Rx-360](#), a consortium of global pharmaceutical manufacturers and suppliers that aims to prevent counterfeit products through the introduction of global quality control systems.

Minilab for on-site testing

Merck KGaA, Darmstadt, Germany supports the non-profit Global Pharma Health Fund, which supplies a portable analysis kit (the GPHF Minilab) to check the quality of medicines. With the Minilab, counterfeit medicines can be detected quickly, easily and cheaply, also in developing health care systems. To date, the GPHF has supplied more than 570 Minilabs at cost, to over 80 countries.

Sensitizing our employees

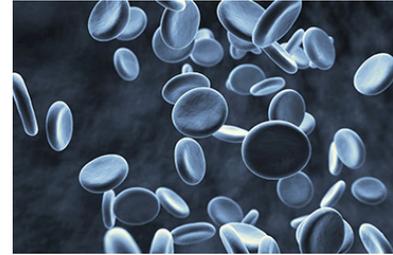
The fight against product-related crime and counterfeit products is an integral part of our risk management system. In order to minimize risks, we provide training to employees of our legal entities, as well as to business partners in the countries in which we lack our own legal entity. In 2011 and 2012, we held multi-day workshops and training seminars in Africa, China, North America, and Latin America. We furthermore conduct audits of our business partners. We are currently drafting a product crime manual and plan to sensitize employees to the topic.

Bioethics

Bioethics is concerned with fundamental questions that arise from how humans treat other creatures, both human and animal. These issues are the subject of often heated debate, in part because people's ethical positions are the reflection of their differing cultural, social, and religious backgrounds.

→ Bioethics

For Merck KGaA, Darmstadt, Germany, bioethical issues arise in the course of multiple activities; these include the use of stem cells, the use of genetically modified microorganisms, the research and application of infertility drugs, and the wide array of clinical research that we conduct.



Clinical trials

We want to alleviate human suffering by researching and developing innovative medicines. In doing so, we orient ourselves to corresponding statutory and regulatory requirements as well as industry standards. For clinical studies these standards include the Declaration of Helsinki [\[7\]](#), the clinical trial principles of the Pharmaceutical Research and Manufacturers of America (PhRMA) [\[7\]](#), and the Casebook on Ethical Issues in International Health Research [\[7\]](#) of the World Health Organization (WHO). These guidelines are rendered into internal standard operating procedures and detailed instructions that are communicated to all those involved; compliance with the guidelines is monitored. In order to give the public a clearer picture of our position, we publish our guidelines on conducting clinical trials.

Stem cell research

When clear statutory and regulatory requirements are lacking, Merck KGaA, Darmstadt, Germany collaborates closely with experts to develop appropriate guidelines. The requirements described in "Stem Cells and Human Cloning Principle" enable Merck KGaA, Darmstadt, Germany to conduct stem cell research within a strictly defined framework; they thus prevent us from violating applicable laws and regulations while enabling us to work within the framework of established ethical principles. Merck KGaA, Darmstadt, Germany is not involved in programs utilizing stem cells or human cloning for therapeutic purposes and does not pursue such approaches.

Infertility treatment research

In developing infertility treatments, Merck KGaA, Darmstadt, Germany avoids all invasive types of prenatal diagnostics. Within the framework of our "Fertility Research Policy", however, we are highly interested in improving the survival rate of fertilized embryos, thus improving the success rate for in-vitro fertilization.

Bioethics Advisory Panel

Bioethical issues are debated in a diverse social environment. Many of these questions are viewed very differently from country to country and are furthermore subject to general shifts in society. Being a global company, Merck KGaA, Darmstadt, Germany must therefore address these developments at an international level; we must detect the changes and incorporate them into our position on bioethical issues. In order to do so, Merck KGaA, Darmstadt, Germany instituted the Bioethics Advisory Panel (MBAP) in 2011, which convenes at least once a year and consists of renowned bioethics experts. Its members represent a range of pertinent disciplines such as law, theology and medical ethics.

In 2011, the panel addressed topics such as stem cell and fertility research, clinical trials and animal welfare. As a result of the discussions, our research guidelines for stem cell and fertility research as well as animal welfare have been revised and approved by the Executive Board of Merck KGaA, Darmstadt, Germany. In addition to this, the Stem Cell Research Oversight Committee was instituted at the suggestion of the Bioethics Advisory Panel.

Furthermore, the MBAP also discusses topics that prepare Merck KGaA, Darmstadt, Germany to engage in new, highly challenging projects in accordance with modern ethical standards. In 2012, clinical research in developing health care systems was therefore the focus of the panel's discussion, with the praziquantel project having received particular attention.

Within the scope of our Merck KGaA, Darmstadt, Germany is partnering with the World Health Organization (WHO) to combat the worm disease schistosomiasis in African school children. Praziquantel tablets in their current form are suitable for adults and children over the age of six; for children younger than six, it is currently not possible to properly treat the disease. Within the scope of a public-private partnership (PPP [\[7\]](#)), Merck KGaA, Darmstadt, Germany is researching a formulation of praziquantel for small children. This project makes it necessary to conduct clinical trials involving children in Africa. The children's parents and guardians must be informed of the risks of trial participation in an ethically responsible manner and give their consent. The Bioethics Advisory Panel discussed how to specifically accomplish this.

In 2013, the Bioethics Advisory Panel will discuss additional aspects of clinical research in developing health care systems and will furthermore address bioethical issues arising from developments in personalized medicine.

→ Clinical trials

Clinical trials

In our quest to thoroughly understand our pharmaceutical products throughout their entire life cycle, we ensure that patient needs are foremost at all times.

We conduct top-quality clinical research in compliance with the applicable laws and regulations. When conducting multinational, multi-site trials in both the industrialized as well as developing world, we follow the highest legal, ethical and scientific standards.

Merck KGaA, Darmstadt, Germany only conducts clinical trials if a sound, proven scientific methodology is used to investigate a scientific or medical question of relevance to patients, medical professionals, and society as a whole. We only enroll the number of participants required to answer the scientific questions being investigated.



Adhering to the highest standards

In all its research and development activities, Merck KGaA, Darmstadt, Germany adheres to the most stringent legal, ethical, scientific, and quality standards. These include:

1. The Good Clinical Practice (GCP) guidelines [GCP](#) of the International Conference on Harmonisation (ICH)
2. The Declaration of Helsinki of the World Medical Association
3. Good Laboratory/Manufacturing/Clinical/Distribution Practice (GLP/GMP/GCP/GDP)
4. "International Ethical Guidelines for Biomedical Research Involving Human Subjects [GCP](#)" of the Council for International Organizations of Medical Sciences (CIOMS)
5. The "Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases [GCP](#)" and the "Joint Position on the Publication of Clinical Trial Results in the Scientific Literature [GCP](#)", issued by the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), the European Federation of Pharmaceutical Industries and Associations (EFPIA), the Japanese Pharmaceutical Manufacturers Association (JPMA), and the Pharmaceutical Research and Manufacturers of America (PhRMA).

The principles of these and similar reference standards have been translated into legal requirements through laws and regulations that are enforced by national health authorities.

Merck KGaA, Darmstadt, Germany frequently works in partnership with third parties to provide a broad, in-depth basis for our pharmaceutical development. We expect and check that all our partners – especially contract research organizations (CROs), licensing partners and suppliers – abide by the same set of standards for conducting clinical trials.

Clinical trial governance

The Head of Global Discovery and Early Development and the Head of Global Drug Development and Medical, supported by the corresponding Operating Committees, have overall responsibility for product development and the related governance process. Our Medical Safety and Ethics Board (MSEB) makes decisions on product safety issues in order to ensure that patients' interests are being optimally served. This board, chaired by the Head of Global Drug Development and Medical as well as by the Chief Medical Officer, consists of senior physician and scientists.

Conducting clinical trials responsibly

Every clinical trial participant is important to us – both as a person and as a source of scientific findings for the treatments of tomorrow. In conducting our clinical trials, we bear in mind the great importance of trial participant safety. Prior to enrolling a single subject in an interventional clinical trial, a qualified independent ethics committee/institutional review board (EC/IRB) must therefore review and approve each and every trial. All local regulatory or governmental authorizations required in the respective country must furthermore be obtained. Before accepting participants into a clinical trial, we first ensure that they have been properly informed about the potential risks and benefits, about alternative processes or treatments, and

→ Animal testing

about the nature and duration of the clinical trial. They can ask questions about the trial and get answers from a qualified healthcare professional associated with the study.

Once a trial starts, procedures are followed to ensure that the study is conducted in accordance with Good Clinical Practice and that the data are accurately generated, documented and reported in compliance with all applicable requirements. We continuously collect, characterize and communicate the safety data for our products, promptly sharing new findings in order to appropriately manage the use of our pharmaceutical products. In addition to this, we safeguard the confidentiality of each trial participant's medical information in compliance with the applicable laws and regulations. Merck KGaA, Darmstadt, Germany transparently communicates information on its clinical trials in accordance with international transparency agreements.

Conducting clinical trials in developing health care systems

Regardless of location, Merck KGaA, Darmstadt, Germany conducts all its clinical trials in compliance with internationally agreed scientific and ethical standards, in addition to the locally applicable laws and regulations. Historically, the pharmaceutical industry has focused its development activities in the United States and Europe. However, the vast majority of the world's population resides outside these regions. Merck KGaA, Darmstadt, Germany is actively shifting its development activities to more diverse markets in order to address the health care needs in these regions as well as to support the development of their health care systems. In performing clinical trials in these developing health care systems, we apply the same principles there (sound methodology; importance of issue under investigation; quality and monitoring) that we would apply when conducting such trials in a developed health care system. When we conduct clinical trials in a developing health care system

1. We only do so in an environment that can follow Good Clinical Practice (GCP), meaning one that has appropriately set-up ethics committees and well-trained Clinical Investigators.
2. We only address diseases and test innovative medicines that are relevant for the local population.
3. We conduct clinical trials in countries where there is a reasonable expectation that the drug tested will be submitted for marketing authorization and be made available to patients/subjects after proof of efficacy and safety.
4. We also assure that enrollment into a clinical trial does not discriminate against participants on the basis of ethnic origin, gender or socio economic status.

Animal testing

Chemical and pharmaceutical companies are legally required to perform animal tests when developing new drugs; this is also required for the product safety of biological preparations as well as for chemicals in connection with the REACH [regulation](#). Animal testing provides crucial information on product efficacy and safety. Therefore, international law requires it to be performed prior to testing the effect of new drugs in humans, or prior to marketing chemicals on a large scale.

Animal testing may only be conducted if there are no recognized alternative methods available; otherwise, the alternative methods must be utilized. Animal testing is, however, still unavoidable in many fields and frequently cannot be replaced by alternative testing. All aspects of animal testing are stipulated by law and regulations, and are approved and monitored by regulatory authorities. These laws govern the treatment of laboratory animals (such as cage size, temperature, ventilation, and relative humidity), the conduct and approval of animal tests, and the reliability and expertise of all involved individuals.

Animal welfare

For Merck KGaA, Darmstadt, Germany, animal welfare is an important issue not only for ethical reasons, but also because of its influence on the quality of clinical trial results. In order to get reliable, accurate data from our studies, we need animals that are comfortable and subjected to as little stress as possible. In addition to this, we are committed to applying high, state-of-the-art quality and animal welfare standards in the housing, care and feeding of our lab animals, and we strive to continuously improve these conditions.



→ Animal testing

We promote the 3R principles of animal welfare (reduction, refinement and replacement). We therefore develop and use methods and techniques to further replace animal testing, to reduce the required number of animals, and to minimize the stress placed on them before, during and after testing.

Animal testing in pharmaceuticals and chemicals

As a pharmaceutical manufacturer, we are legally required, per government and industry regulations, to perform animal tests to prove the quality, efficacy and safety of our products prior to clinical testing. International and national laws govern the type and scope of the data to be submitted to the authorities. Animal tests are justified by the obligation to save and protect human lives and to alleviate human suffering.

For our chemicals, the EU chemicals regulation REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) that took effect in 2007 specifies that all substances manufactured in or imported to the EU must be registered and evaluated in accordance with certain requirements in order to assess their potential hazards. Depending on the amount of chemicals in question, this also includes animal testing. We minimize the number of animal tests by working with other manufacturers, importers and users in the Substance Information Exchange Forum (SIEF [\[7\]](#)) in order to share data. This allows us to avoid animal testing that is not absolutely necessary for consumer protection, or to avoid repeating animal tests that have already been conducted.

Group-wide regulations and organizational structures

Merck KGaA, Darmstadt, Germany keeps animals in its own facilities at various sites worldwide. At all of our sites where animals are kept or animal tests are performed, we have appointed responsible individuals and groups (e.g. animal care and welfare officers, institutional animal care and use committees) both on a voluntary basis as well as in response to national requirements. These units assess and assure the quality of the respective animal husbandry practices.

Our "Use, Care and Welfare of Laboratory Animals" corporate guideline, which was approved by the Executive Board in November 2011, describes our principles for the housing, care and feeding of lab animals. It also sets down the requirements we place on third parties who conduct animal testing on our behalf. In this guideline, we commit ourselves to high quality and to continually improving the housing, care and feeding of our lab animals.

Animal welfare at Merck KGaA, Darmstadt, Germany falls under the Group function Animal Science and Welfare, which has existed since January 1, 2013. The Corporate Animal Welfare Officer will create uniform animal welfare standards, conduct and/or initiate audits, and institute additional improvements to animal welfare at Merck KGaA, Darmstadt, Germany and its partners by increasing transparency throughout the Merck KGaA, Darmstadt, Germany.

As a member of Interpharma, an association of pharmaceutical companies in Switzerland, prescription medicines division has signed the Interpharma Charter on Animal Welfare.

Site accreditation

To demonstrate that we adhere to the strictest animal welfare standards, we have our laboratory animal facilities at the prescription medicines division accredited by the **Association for Assessment and Accreditation of Laboratory Animal Care International** [\[7\]](#) (AAALAC Int.). In addition to taking into account the high international quality standards of the Guide for the Care and Use of Laboratory Animals from the **Institute for Laboratory Animal Research** [\[7\]](#) (ILAR), the AAALAC accreditation also factors in national laws and guidelines as well. In the 2011–2012 period, we received full AAALAC accreditation for our animal husbandry practices at our Non-Clinical Safety and Experimental Pharmacology units in Darmstadt (Germany) and Billerica, Massachusetts (USA). Other Merck KGaA, Darmstadt, Germany laboratory animal facilities are currently preparing to undergo the accreditation process.

→ Animal testing

Employee training

In order to ensure that animals are tested, housed, fed, and cared for according to the latest standards, all employees working with laboratory animals at Merck KGaA, Darmstadt, Germany are specially trained and receive continual advanced training. The nature and scope of this training is governed by national and international legislation as well as local requirements, and the training is monitored by the responsible regulatory authorities. In addition to this, our employees participate in external continuing education programs, such as the accredited laboratory animal science courses offered by FELASA  (the Federation of European Laboratory Animal Science Association). At the site in Darmstadt, Germany, we also offer veterinarians the opportunity to complete a three-year continuing education program to specialize in laboratory animal medicine. In addition to this, we provide online training programs and classroom courses on animal welfare, "3R" and the AAALAC accreditation standard.

Using and developing alternative methods

Whenever practical and legally feasible, Merck KGaA, Darmstadt, Germany uses alternative testing methods instead of animal testing, including in-vitro tests and computer-based methods. Over the last several years, our researchers have received multiple awards for developing alternative test methods:

- 2005: The Eurotox Gerhard Zbinden Young Scientists Award
- 2006: The German Animal Welfare Research Prize awarded by the Federal Ministry of Food, Agriculture and Consumer Protection (BMELV) for Alternative Methods to Replace or Reduce Animal Tests
- 2007: The Hessian Animal Welfare Research Prize for Alternative Methods to Replace or Reduce Animal Tests
- 2008: The Eurotox Bo Holmstedt Young Scientists Award for Alternative Test Strategies according to the 3R Principles
- 2009: The Eurotox Gerhard Zbinden Young Scientists Award
- 2010: The IUTox Bo Holmstedt Scientists Award for Alternative Test Strategies according to the 3R Principles

Within the scope of our collaboration in associations such as EFPIA, VFA, Interpharma, and the 3R IQ Consortium, we are striving to obtain regulatory recognition for alternative testing methods that transcends national boundaries. There is a serious need for action here because animal testing can only be truly reduced if a new methodology gains widespread recognition at an international level. Without international recognition, both animal testing and alternative testing have to be conducted when developing pharmaceuticals intended for global distribution.

Through our work with the German Chemical Industry Association (VCI) and the German Association of Research-based Pharmaceutical Companies (VFA), we actively support the SET Foundation, and we support the 3R Foundation through our work with Interpharma. Both foundations are dedicated to finding alternative and complementary animal testing methods. We are furthermore collaborating with the European Federation of Pharmaceutical Industries and Associations (EFPIA) to devise performance indicators that can be used to evaluate the methods for 3R improvements that companies develop.

Species

Mice and rats constitute 99% of the laboratory animals used within the Merck KGaA, Darmstadt, Germany. Other animal species are only used if mandated by statutory regulations and/or if preliminary scientific testing and experience shows the results from experiments on rats and mice to be insufficiently robust. Other animal species may also be used if preliminary scientific testing and experience indicates that the results must be backed up by testing on non-rodent species as well. Statutory regulations require pharmaceuticals in development to be safety tested both on a rodent species (rat or mouse) as well as on a non-rodent species (dog, pig or monkey). In this way, potential side effects can be identified and included in the risk assessment of a substance prior to first-in-man use. In all experiments, the safety of human beings is our top priority.

Animal welfare at external partners

We procure our lab animals from special animal breeders and furthermore hire special contract research organizations to conduct animal testing on our behalf; we also collaborate or partner with industry institutes and universities. Our animal welfare policy stipulates that the same high standards that apply within Merck KGaA, Darmstadt, Germany also apply to these external partners as well. Within the scope of our work with Interpharma during the 2011–2012 period, we helped develop an audit concept for such contract institutes. An Interpharma audit has already been conducted on an animal breeder at two different sites in Germany and found the animal husbandry practices there to be of good quality.

→ Responsible marketing

Goals: Animal testing

Strategic goal	Action	By?	Status
Harmonize animal welfare throughout Merck KGaA, Darmstadt, Germany	Establish Group-wide governance for Corporate Animal Science & Welfare	End of 2014	+
	Develop a Group-wide audit concept for contract animal testing facilities	End of 2015	+
Harmonize the high quality of animal facilities at the prescription medicines division	Obtain AAALAC International accreditation for all prescription medicines division laboratory animal facilities	End of 2015	+

Legend: ■ Achieved ■ In progress ■ Not achieved + New goal

Responsible marketing

A crucial component of our business activities is the responsible marketing of our products in accordance with regulations.

In our Pharmaceuticals business, the requirements for marketing are very stringent, as they are for all interactions in the health care industry. Our number-one goal is for patients to receive effective treatment. For this to happen, all health care industry players must have continuous access to the relevant information, patients must have access to the medicines they need, and the medicines must be correctly prescribed and utilized. In order to achieve this, we adhere to strict ethical standards for the marketing of our products. These standards sometimes exceed the statutory requirements and are intended to prevent key players from being improperly influenced.



To ensure professional, transparent conduct in our pharmaceutical marketing operations, we comply not only with numerous statutory regulations, but have also defined our own code of conduct. Furthermore, we also adhere to the industry regulations of the [International Federation of Pharmaceutical Manufacturers & Associations](#) (an international umbrella organization) and the [European Federation of Pharmaceutical Industries and Associations](#) (a European umbrella organization), as well as the regulations of local industry associations.

Group-wide regulations for pharmaceutical marketing

Our Pharmaceutical Marketing Best Practices define internationally mandatory standards.

These best practices govern interactions with doctors, pharmacists and patient organizations, defining requirements for holding events and for advertising. This international standard is supplemented by country-specific regulations, whereupon the more stringent respective requirement takes precedence.

We have a Group-wide guideline that specifically applies to our pharmaceutical activities in the US market.

For employees of our German legal entities, there is also an internal guideline on interacting with physicians, hospitals, pharmacies, and other members of professional circles, as well as with patient organizations. Merck KGaA, Darmstadt, Germany is furthermore a member of the [Association for the Voluntary Self-Control of the Pharmaceutical Industry \(FSA\)](#), which has defined rules of conduct for collaboration between physicians and industry. When violations of the FSA Code are suspected, members and third parties can file complaints with an arbitration board. At the beginning of 2013, Merck KGaA, Darmstadt, Germany received a warning letter from the FSA because Merck KGaA, Darmstadt, Germany had not abided by new rules in its communication regarding a sponsoring activity.

→ Interactions in the health care industry

"Promotional Materials" is a Group-wide guideline that additionally applies to all businesses of the prescription medicines division. This guideline requires advertising materials to be examined by the Merck KGaA, Darmstadt, Germany functions Medical, Regulatory and/or Legal to ensure that they conform to global pharmaceutical regulations.

In general, Merck KGaA, Darmstadt, Germany does not use its prescription drug marketing activities to advertise directly to patients. When Merck KGaA, Darmstadt, Germany does conduct such direct-to-consumer campaigns, the provisions of our Pharmaceutical Marketing Best Practices apply, as do local requirements, which are often even more stringent.

All guidelines pertaining to marketing and advertising are part of the Group-wide compliance program. They are regularly adapted to reflect current developments and apply for all employees who work in the corresponding fields.

Within the scope of the compliance training plan, all relevant employees receive online training and participate in classroom seminars. Participation is monitored, and the results of the online training are evaluated. For instance, in 2011 and 2012, 4,345 employees participated in seminars on our Pharmaceutical Marketing Best Practices, in addition to the regular Code of Conduct training.

Marketing chemicals

Responsible marketing is also important in our Chemicals business. In order to ensure careful handling, we supply our chemicals only to commercial customers who have the proven expertise. In addition, we provide customers with information on the safe handling and use of our products. To prevent the misuse of dual-use products, Merck KGaA, Darmstadt, Germany has established an extensive safety net. Standardized export control guidelines are monitored by our central Export Control & Customs Regulations unit as well as by trade and export control officers at the local legal entities. If we suspect misuse, we refrain from doing business with that customer for safety reasons.

Interactions in the health care industry

We believe that worldwide access to medicinal product information is one of the keys to improving health care and treatment for patients. For this reason, we support scientific research as well as patient organizations and other key players in the health care industry by donating money and supplies, or through sponsoring activities. With this type of support, it is important for key players to remain neutral in order to protect the patients and ensure them the best treatment. All donations and sponsoring activities must comply with the internal and external standards that apply to our marketing operations. Within the scope of commitments we have made as members of various associations, we furthermore transparently report on the support we provide.



Support for patient organizations in Europe

Patient organizations play an important role in providing patients, their family members and their caregivers with support for and information on dealing with diseases. With these institutions, we share a common goal of improving quality of life for patients, which is why we support this important work. Merck KGaA, Darmstadt, Germany explicitly endeavors to exert no influence or control over the information that the organizations communicate to their members. For comprehensive transparency, we publish our donations to European patient organizations on our [website](#) and [update the information annually](#). This enables us to fulfill a commitment we have made through our membership in the European Federation of Pharmaceutical Industries and Associations (EFPIA).

Promoting research

To support the health care system, Merck KGaA, Darmstadt, Germany makes monetary contributions and donates supplies to institutions, organizations and associations consisting of members of professional circles. These include medical science professional associations, hospitals and university clinics. This support reflects our values and allows research institutes and related institutions to more easily do their work, which ultimately serves the common good. The contributions are not intended to influence decisions regarding treatment, prescriptions or purchasing. In compliance with the code of conduct of

→ Packaging

the German Association for the Voluntary Self-Control of the Pharmaceutical Industry (FSA), Merck KGaA, Darmstadt, Germany publishes its contributions made in Germany in excess of € 10,000 per recipient and year. The information is updated on an annual basis.

In order to promote advances in the field of medicine, Merck KGaA, Darmstadt, Germany sponsors research and advanced medical training in other countries as well. Here, the prescription medicines division supports efforts such as outstanding research projects through its [Grant for Fertility Innovation](#) and its [Grant for Multiple Sclerosis Innovation](#). Through contributions to the charitable [Serono Symposia International Foundation](#), the prescription medicines division supports the foundation's work in providing advanced medical training for scientists, physicians, nurses, pharmacists, and other health care professionals.

Increasing transparency requirements

The transparency requirements for interactions in and contributions to the health care industry are going to become more stringent in the future. Global transparency initiatives such as the Sunshine Laws in the United States and the initiatives of the European Federation of Pharmaceutical Industries and Associations (EFPIA) require the disclosure of collaborations between the pharmaceutical industry and physicians, medical organizations, and patient organizations. They are also requiring companies to disclose individual partnerships, specifically naming the physicians in question, as well as to disclose the purpose of the interaction and the amount contributed. Ensuring this sort of transparency demands a great deal from a company's internal processes. For example, the data protection law implications have to be legally reviewed, and the subsequent results of the review must be incorporated into the contract management process. Despite the high degree of time and effort, Merck KGaA, Darmstadt, Germany supports these transparency initiatives as an expression of our deep sense of responsibility. We continually adapt our systems in response to current developments such as these.

Packaging

Packaging plays an important role for our products in two ways. For one, it protects our products from external influences and ensures that they reach the customer undamaged. Secondly, packaging guarantees that the environment will not be negatively impacted by substances leaking out. The packaging has to remain safe throughout the product's entire life cycle – during transport, storage, usage, and disposal.

The development of suitable packaging therefore constitutes part of our product development process and contributes to product safety. One example is our Safebreak bottles, which are coated in plastic to prevent chemicals from leaking out if the glass breaks.

In addition to safety, efficient resource use also plays a crucial role. We identify potential areas of optimization in order to reduce material usage during packaging manufacture without compromising the quality and safety. This also aims to increase the percentage of materials that minimally impact the environment.

Packaging for life science tools division products

The life science tools division is currently using this approach to refine its packaging strategy. Another important aspect of the strategy is that we want to deliver our products in packaging that is easy for our customers to dispose of and that helps them reduce the impact of their own activities on the environment. We are therefore working to develop reusable packaging systems and to reduce the use of foam components. Here are a few examples:

- For shipping, glass reagent bottles are secured separately in the packages to prevent them from bumping into each other and breaking, a task we used to accomplish with EPS (expanded polystyrene) molded foam components. At the sites in Germany, the United States and India, we have launched an initiative to replace EPS packaging with molded fiber components consisting of cellulose and recycled paper. In Darmstadt, Germany, we will have replaced nearly all EPS molded foam packaging by the end of 2013, which means more than 600,000 molded foam components. For the switch to cellulose and recycled paper materials in India, we are conducting additional investigations because of the



→ Storage and transport

climate conditions found there. In the United States, we are furthermore looking into an alternative using corrugated cardboard.

- The majority of the cardboard boxes used to package products at US life science tools division sites are certified to the standards of the Sustainable Forestry Initiative (SFI .
- The Lab Water business field of the life science tools division has developed new packaging for the Smart and Integral ranges of the Milli-Q lab water purification systems. Here, the molded PE (polyethylene) foam components are being replaced by corrugated cardboard; less material is utilized, thus reducing the packaging costs. In addition, the polystyrene packaging used to ship the Q-Pod and E-Pod accessories has also been replaced by molded corrugated cardboard. Thanks to the improved packaging design, we are saving 18 metric tons of corrugated cardboard per year.
- In 2012, the life science tools division conducted a life cycle assessment to investigate the material usage of reusable plastic containers versus corrugated cardboard packaging for its Millistak+[®]-Pod products, which are used in the production of vaccines. It showed that a reusable container reduces the amount of material used by up to 95% per individual product delivery. It furthermore revealed other possible ways to reduce the impact of distribution on the environment.
- In the 2011–2012 period, we developed a scorecard as a tool to evaluate packaging for BioMonitoring products in order to compare the environmental impact, costs and quality of various packaging designs with one another. For instance, when we developed the packaging for the EZ-StreamTM vacuum pump, a product that is used for quality testing in the beverage industry, we compared three different packaging options. We ultimately selected the packaging with the least environmental impact that met the required quality criteria and was of a comparable cost. The design was then further refined, improving the initial design with a 28% reduction in packaging weight and an 18% reduction in volume. This has enabled 30% more products per pallet. For two other BioMonitoring products, the EZ-Fit[™] Manifold and the EZ-Pak[®] Dispenser Curve, which are also used in beverage quality testing, we have replaced the EPS foam that was formerly utilized, making the packaging now entirely recyclable.
- We have improved upon multiple aspects of the packaging for the Milliflex[®]Quantum sets, which are used for quality testing in pharmaceutical and biopharmaceutical production. We have cut down the packaging size, thus reducing the cardboard used by 15%, meaning that 26% more sets can fit per pallet. We have furthermore increased the percentage of recycled packaging material from 45% to 90%. These changes have also resulted in saving space for customers in tight lab settings.

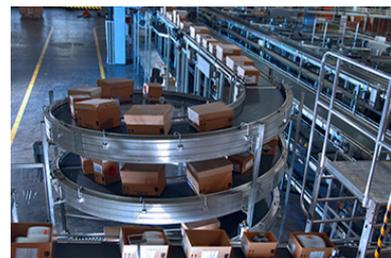
Closed system for liquid crystals packaging

In South Korea, the Performance Materials division utilizes a patented system of stainless steel canisters that are filled with liquid crystal mixtures at the Poseung site and delivered to South Korean display manufacturers. Our Standard Canisters (MSCs) can be utilized directly on the production lines without decanting. The empty canisters are then sent back to us where they are cleaned under validated conditions. The MSCs are reused within a closed system over multiple years. A reusable polypropylene box serves as outer packaging. Similar systems are in use at other liquid crystal mixture production sites in Asia.

Storage and transport

For the storage and transport of our goods, we adhere to strict safety guidelines in order to prevent risks to people and the environment.

In order to safely store substances, we have implemented global safety concepts for all our warehouses worldwide. We have based these concepts on the recommendations of the German Chemical Industry Association (VCI), which include the minimization of storage risks through segregated storage, the protection of the environment through retention capacity in the event of leaks and for extinguishing water, automatic extinguishing units adapted to the products and materials being stored, occupational safety measures, as well as optimized material and work flows in the warehouse.



→ Storage and transport

At the end of 2012, we made significant revisions to our Group-wide standards for warehouse safety. In doing so, we created the framework for selecting service providers. The "Warehouse requirements" standard defines the structural and organizational requirements for a facility. The "Warehouse Safety" standard defines the operational measures needed to prevent substance leakage, as well as fires and explosions.

According to this standard, risk evaluations must be conducted on all stored substances, including finished chemical and pharmaceutical products, raw materials, intermediates, waste, packaging material, and technical materials. In addition to this, the standard lays down mandatory rules of workplace conduct for all warehouse employees. All warehouses are to be audited thoroughly and regularly to check for compliance with safety requirements.

For shipments transported by Merck KGaA, Darmstadt, Germany or on behalf of Merck KGaA, Darmstadt, Germany, safety is our top priority. We want to ensure that shipments reach our sites and customers undamaged, with the correct labeling and documentation.

Several substances that we ship are classified as hazardous materials. Hazardous goods transport – whether by road, rail, air, or water – is heavily regulated across the globe by conventions such as the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR).

We have refined our audit concept in order to monitor compliance with the transport safety regulations at Merck KGaA, Darmstadt, Germany sites as well as the compliance of those partners involved in the transport of goods.

In Germany, we participate in the German Transport Accident Information and Emergency Response System (TUIS), which provides qualified, rapid assistance for incidents involving the transport of chemicals.

Environment Health Safety Security Quality (EQ), the Group function in charge of environmental protection at Merck KGaA, Darmstadt, Germany, are the experts in warehouse and transport safety guidelines. At the individual Merck KGaA, Darmstadt, Germany sites worldwide, local EHS managers are responsible for issues pertaining to warehouse and transport safety. Regular training is provided for our warehouse employees, as well as the employees involved in the transport of goods.

Goals: Storage & transport

Strategic goal	Action	By?	Status
Further improve warehouse and transport safety	Create a Group-wide standard for safe logistics	End of 2013	+
	Systematically share best warehouse and transport safety practices among employees worldwide	End of 2013	+
	Expand scope of transport safety audits, to include contracted service providers	End of 2014	+
	Develop additional performance indicators to assess warehouse and transport activities	End of 2014	+

Legend:  Achieved  In progress  Not achieved  New goal

→ Reuse and recycling

Reuse and recycling

We consider take-back concepts as well as environmentally sustainable utilization and disposal of chemicals and packaging to be an integral part of our corporate responsibility. By taking back used products and packaging, Merck KGaA, Darmstadt, Germany and its customers are jointly contributing to reducing the environmental impact of our products and services. This plays an important role for us at the international level as well; we are promoting this concept particularly in emerging markets.



Retrologistik®

More than 20 years ago, Merck KGaA, Darmstadt, Germany set up its own system in Germany and several other countries in order to dispose of used packaging and chemicals in a safe and environmentally sustainable manner. Called Retrologistik®, this is a well-established service that customers appreciate highly.

In 2010, we entered into a strategic alliance with the German Association for International Cooperation (GIZ ) , called Environmentally Sound Management of Chemical Waste in South East Asia. This alliance aims to establish the retrologistics concept in Indonesia, the Philippines, and Thailand in order to boost environmental awareness there as well as change how hazardous materials are handled. The transfer of Merck KGaA, Darmstadt, Germany technology and knowledge plays a crucial role here. With this project, we want to build knowledge and competencies for the environmentally sustainable storage of chemicals; we also want to help our project partners to properly classify and transport the resulting waste, as well as recycle or dispose of it. Originally scheduled to continue until 2012, the joint Merck KGaA, Darmstadt, Germany and GIZ project in Southeast Asia has been extended until summer 2013.

After three years, the strategic alliance has improved training, auditing and implementation capacity in the respective countries; it has increased the number of users who handle and dispose of their chemicals in an environmentally sustainable manner, and has boosted the number of qualified waste disposal firms.

Within the project, informational and training materials were developed and made available in the respective national languages of each country. Merck KGaA, Darmstadt, Germany and the GIZ have jointly trained more than 1,000 people as trainers, including employees of universities (Thailand) and of governmental organizations (such as the Department of Science and Technology of the Philippines as well as the Indonesia State Ministry of Environment). The trainers then act as multipliers, passing on the knowledge acquired to their institutions and countries. To date, the trained universities in Thailand have now properly disposed of eight tons of lab waste, and government labs in the Philippines have properly disposed of two tons of chemicals via a project partner.

Furthermore, lab chemicals users were trained on how to properly handle chemicals, such as when storing or disposing of them; several state-owned labs were also equipped as "model labs" to demonstrate responsible, environmentally sustainable chemical management.

This strategic alliance furthermore supports select companies in the disposal industry. For example, a washing plant for empty chemicals bottles that operates according to European standards was built in the industrial park in Kota Jababeka. This plant can be used by at least 150 companies. Great progress has also been made in implementing the retrologistics concept in the Philippines especially for photometric cuvette tests. In the region of Luzon, for instance, 25 companies are already participating in the system. To date, 3,000 test sets have been safely disposed of.

The project is being expanded to include India in order to establish a market-oriented take-back and disposal system. Founded on industry-wide self-regulation on handling hazardous waste and certified by the relevant regulatory agencies, this system is intended to be available to the entire market. After being successfully established in two pilot regions, the system is to be rolled out nationwide.

→ Reuse and recycling

Ech₂o™: Recycling program for water purification cartridges

The Lab Water business field of the life science tools division has developed the ech2o program for water purification cartridges. The program enables our customers to send back their cartridges to be recycled and thus to avoid the need for traditional disposal methods such as land fill dumping or incineration. A life cycle assessment has revealed that this can reduce the environmental impact of the cartridges by 10%-15%. More than 300 customers are already taking advantage of the program.

Biopharma take-back and recycling program

Single-use products are increasingly playing a role in the biopharmaceutical industry. Improvements in disposing of these products are a challenging task owing to a lack of recycling infrastructure, the material mix of the products, and the specific requirements for handling biologically hazardous residues. As one of the leading suppliers of products for the life science industry, the life science tools division and five customers jointly launched a take-back program in the United States in 2012.

The pilot project showed that recycling can reduce greenhouse gas emissions by up to 14% in comparison to traditional disposal methods, as confirmed by an end-of-life life cycle assessment. During the product development phase, the life science tools division takes into account obstacles to recycling identified in the course of the pilot project. This allows them to constantly improve the recycling potential of new products through measures such as simplified disassembly, or by increasing the percentage of recyclable materials.

For Ech2o and the biopharma program, the life science tools division was recognized in May 2012 with the Boston Business Journal Green Business Award and in November 2012 with the MassRecycle Business Innovation Award.

Suppliers



→ Suppliers

Suppliers

Our basic expectations for suppliers and service partners include their compliance with fundamental environmental and social standards. Therefore, we have further developed our procurement strategies in order for our supply chain worldwide to adhere more closely to environmental, compliance and social standards and to prevent violations.



Supplier Management

For our business activities we need raw materials, packaging materials, technical products, components and services; in 2012, we purchased all these commodities from more than 50,000 suppliers in over 100 countries worldwide. Of the goods and services (including R&D services) procured in 2012, totaling approximately € 4 billion, we purchased 55% from suppliers based in EU countries and 33% from suppliers in OECD countries outside the EU. Around 12% came from suppliers in non-OECD countries outside the EU.

Procurement volume 2012 in %



1 Non-OECD countries outside the EU	12%
2 OECD countries outside the EU	33%
3 EU countries	55%

Our basic expectations for suppliers and service partners include their compliance with fundamental environmental and social standards derived primarily from the ILO Core Labor Standards and the UN Global Compact. Therefore, since 2009, we have been supporting the Compliance Initiative of the German Federal Association for Materials Management, Purchasing and Logistics (BME) and have additionally signed the [BME Code of Conduct](#). This contains basic rules for combating corruption, violations of antitrust law, child labor, and minimum requirements for environmental protection in the supply chain.

► Info box: BME Code of Conduct

The BME Code of Conduct contains international cross-industry minimum standards for combating corruption, collusion in violation of anti-trust law, child labor, and forced labor, as well as for promoting ethical principles toward suppliers. It also encompasses principles for upholding human rights, for protecting health and the environment, and for fair working conditions.

In the last two years, we have refined our procurement strategies in order for our supply chain worldwide to adhere more closely to environmental, compliance and social standards, and to prevent violations. We have put into effect a new procurement guideline and published new standard operating procedures for the supplier management and purchasing process of Merck KGaA, Darmstadt, Germany. The aim is to anchor CR aspects more firmly in procurement activities in order to take them better into account in the selection, assessment and management of suppliers.

We have developed our [Responsible Sourcing Principles](#), which include not only environmental, social and compliance aspects, but also the requirements that we expect, for example, when commissioning animal studies. Our Responsible Sourcing Principles consolidate the requirements we place on our suppliers concerning responsible conduct. In addition, with these principles we also clearly highlight the responsibility of suppliers to apply our Corporate Responsibility Standards also to their upstream value chain.

→ Suppliers

In the course of 2013, we intend to integrate our Germany Responsible Sourcing Principles into the respective general terms and conditions worldwide. In this way, we are underscoring the principles we have already defined in our Code of Conduct and Social Charter by providing our suppliers with a uniform document.

Core features of our sustainable CR supplier management approach are:

- **General terms and conditions:** In our general terms and conditions, we are globally integrating the commitment to comply with the principles of our Code of Conduct and Social Charter. By the end of the first quarter of 2013, almost all legal entities had adapted their respective general terms and conditions. In the course of 2013, a reference to our Responsible Sourcing Principles will be added successively to the general terms and conditions.
- **Supplier self-disclosure:** With their self-disclosure, our suppliers provide information on their compliance with our Code of Conduct and Social Charter, as well as available (ISO) certificates. In the 2011-2012 period, we expanded the self-disclosure process started in 2010 that our suppliers have to undergo. It has now been established in Germany, Brazil, Mexico, Switzerland, Japan, and India. By the end of 2013, this will also be the case in France, the United States, China, Italy, the United Kingdom and Ireland. In these countries, we request higher-risk suppliers from whom we procure more than a defined purchasing volume to provide a self-disclosure. The global implementation process for self-disclosures has been initiated and is being successively executed with the introduction of our new computerized supplier management system.
- **Sustainability audits:** In order to monitor compliance with our Code of Conduct and Social Charter, depending on the risk potential we conduct sustainability audits at selected suppliers. A Group-wide operating procedure was created in 2012 for executing and following up audits. We select suppliers for an audit by dividing our supplier portfolio into risk groups based on the criteria country risk, product category and the sales that the supplier generates from its business with us. Suppliers in an OECD member state, for example, are classified into a lower risk group. In addition, suppliers are also audited if there are indications of a lack of compliance with our requirements. Audit observations may be classified as "critical defects", "major defects" or "minor defects". The audit results and any necessary corrective actions are communicated to the supplier. If observations are classified as critical or major, we monitor the implementation of the defined corrective actions and also initiate supplier requalification or disqualification where necessary. The audit team additionally determines the interval at which follow-up audits are to be conducted.

We conducted 36 audits in 2011 and 2012 according to the newly developed system. None of them resulted in critical defects. However, 18 audits revealed major defects, which we are tracking and monitoring. Therefore, we demanded a Corrective Action Plan (CAPA) from the suppliers concerned, which describes the measures to address the defects. This will be monitored by auditors. In addition, we will re-audit these suppliers as from 2014. Based on our risk potential analysis, we plan around 30 audits per year at suppliers with a high risk potential. These take place mainly in non-OECD countries.

› Info box: Evaluation of audit results and follow-up

Critical: Any observation rated as Critical must be rectified or mitigated as soon as possible. Proposal for corrective actions shall be submitted by the supplier to Merck KGaA, Darmstadt, Germany within one week after receiving the audit report

Major: Any observation rated as Major is believed to be significant enough to require a formal corrective action response by the supplier within one month of the receipt of the audit report

Minor: Any observation rated as Minor does not require a formal corrective action plan and the implementation of associated corrective actions will also not

Our Group function Procurement is responsible for all activities and measures that further incorporate corporate responsibility aspects into our procurement processes and supplier management process. Since 2011, Procurement has appointed a CR officer who handles purchasing activities relating to the topic of corporate responsibility and coordinates the implementation of the various sub-projects. A special intranet page informs the staff of Procurement in all countries about the guidelines and measures we apply to ensure compliance with our supply chain standards.

→ Suppliers

Responsibility in the mica supply chain

Mica is a raw material we use for one of our pigment product groups. When examining the mica supply chain, we discovered in 2008 that at the start of the supply chain mica is partly also collected by children, generally together with their parents. This is not compatible with our corporate values and the principles of our Social Charter. Consequently, we have realigned the mica supply chain in order to prevent child labor and to ensure that the principles of our Social Charter are complied with.

It was important to us to maintain our business relationships with suppliers in the regions where mica comes from and thus safeguard jobs in Jharkhand, a region in northeast India plagued by poverty and political uncertainty. Today we procure mica exclusively from mining and not from collecting. Based on information provided by our suppliers, we have introduced a system for tracking the origin of the raw material. It is regularly checked by staff from the office we recently set up in the region. We maintain regular and close contact with our business partners in Jharkhand and have informed them in detail about our values and our expectations regarding the social and environmental standards to be complied with. In addition, we conduct and commission audits at our suppliers and further processing partners. We also check that they adhere to our requirements regarding environmental protection, safety, working standards and compliance. If we observe any deviations we document them in an audit report and define corrective actions, monitoring the implementation of such corrective actions.

In addition to changing our mica procurement process, we are working to improve education and health care programs in the regions where the raw material comes from. For this purpose, we are financing three schools with an affiliated daycare center, which are now regularly attended by around 380 children, as well as a training center for tailoring and carpentry. We are improving medical care by means of a local health center. A doctor and a nurse are on daily duty, regularly visiting the surrounding villages and our schools. In addition, we support an Indian non-governmental organization with a project for developing "children-friendly villages". This aims to improve the understanding of children's rights and the general conditions for children to regularly attend school.

In the course of changing our supply chain, we regularly informed interested customers and other stakeholders on the progress made in mica procurement and the accompanying projects.

→ Suppliers

Goals: Supplier management

Strategic goal	Action	By?	Status in 2011 and 2012	Status
Sustainability in the supply chain	Introduce the new supplier management process within the most important legal entities	End of 2012	A new supplier management process has been instituted in the most important legal entities.	■
	Adapt the general terms and conditions to integrate our Responsible Sourcing Principles into all orders	End of 2013		+
	Conduct CR audits on 30 suppliers with a risk potential	End of 2013		+
	Create the technical prerequisites for obtaining supplier self-disclosures in France, the United States, China, Italy, the United Kingdom, and Ireland by implementing a new computerized supplier management system	End of 2013		+
	Collect supplier self-disclosures from higher-risk suppliers from whom we procure a volume above a defined threshold, in the countries Germany, Brazil, Mexico, Switzerland, Japan, India, France, the United States, China, Italy, the United Kingdom, and Ireland	End of 2013		+

Legend: ■ Achieved ■ In progress ■ Not achieved + New goal

Employees



In accordance with our values, we live a culture of mutual esteem and respect. We want to strengthen our company's ability to act by recruiting, developing and motivating the most suitable employees. In addition, we would like to further enhance the performance culture of our company and promote the diversity of our workforce.

Management

As of December 31, 2012, a total of 38,847 employees worked for us at 203 companies in 66 countries. In accordance with our values, we live a culture of mutual esteem and respect. Through our Social Charter, we commit ourselves to complying with fundamental labor and social standards, as well as the International Labour Organization's (ILO) core labor standards, the UN Global Compact and the Responsible Care® program of the chemical industry. Through global policies and guidelines, we ensure that these standards are implemented at our sites even beyond the legal requirements.



Strategic goals

Our strategic goals for our employees include developing a culture of goal orientation and recognition of performance, combined with a global, systematic talent development process, a performance-related, market-oriented compensation structure, as well as the recruitment and retention of talented people in the long term. For this purpose, Merck KGaA, Darmstadt, Germany has introduced global programs, for example the Performance Management Process and Global Rewards Policy, as well as the Talent and Succession Management Process. In the 2011–2012 period, we focused these programs even more on the needs of a global corporate group.

Since 2011, we have additionally increased our strategic focus on workforce diversity and fostering a culture of inclusion to benefit from that diversity, which we want to promote by means of targeted measures. These include, for example, our intention to increase the percentage of management positions held by women to between 25% and 30% by 2016.

Organization and responsibilities

Kai Beckmann, Executive Board Member and Chief Administration Officer, is responsible for Human Resources (HR). We reorganized our HR units in 2012. Group Human Resources (Group HR) steers all HR activities worldwide. Employees of Group HR in the legal entities are responsible for locally implementing these activities.

Group HR comprises the units Corporate HR, HR Business Partner and HR Services. Corporate HR develops all global policies, programs and guidelines for all HR-related topics. The HR Business Partners provide advice and support to the business units and legal entities; HR Services performs administrative services and supports all employees with regard to HR-related matters. In 2013, we will complete the transition to this structure in all local HR organizations.

Global recording of employee data and controlling

In order to measure the progress we are making in achieving our strategic goals, we collect employee data worldwide, which we record in various systems. This enables global reporting of demographic employee data and reporting lines as well as protection of sensitive data, such as salary information. We are currently introducing an integrated system called HR Suite for our global performance management, as well as for talent identification and assessment, recruitment, learning management, and compensation review. HR Suite will make our processes even more efficient and will further improve data analysis. In addition, Merck KGaA, Darmstadt, Germany regularly monitors HR-related topics by means of internal audits.

Training and sensitizing employees

In the 2011–2012 period, we redesigned our management programs so that all employees with personnel responsibility obtain a uniform understanding of, and common approach to, management activities at Merck KGaA, Darmstadt, Germany. This comprises properly applying HR processes and programs, as well as training in our Values, Code of Conduct, Social Charter, and diversity.

Outlook and goals

At the end of 2011, we launched a transformation program under the name "Fit for 2018" with the aim of securing our competitiveness in the long term. A key goal of this is to anchor an even stronger performance culture in the company. For us, this means setting clear expectations and goals for all our employees, providing regular and transparent feedback, as well

→ “Fit for 2018” transformation program

as recognizing good performance. To this end, we have redesigned our existing HR programs and processes. Our transformation program faces the challenge of driving cultural change while continuing to implement personnel restructuring measures within the scope of the efficiency programs.

“Fit for 2018” transformation program

At the end of 2011, we announced the extensive “Fit for 2018” transformation program, with which we are addressing significant market shifts, increasing competition in key product areas and efficiency deficits in our organization. The aim is to increase the competitiveness of Merck KGaA, Darmstadt, Germany. “Fit for 2018” covers all business sectors and regions of Merck KGaA, Darmstadt, Germany and consists of two phases: In 2012 and 2013, the focus is on establishing a global organization, implementing efficiency measures, and developing a long-term growth strategy. In the second phase, as of 2014, the focus will be on capturing future growth opportunities.

In order to strengthen the leadership to drive the global organization, we made altogether 51 new appointments to key positions in 2011. These included 32 positions that were filled by non-German employees and eight by female employees. In addition, we have redefined the relationships between our divisions, Group functions and legal entities. In this way, we want to streamline our organizational structure and accelerate decision-making processes.



In early 2012, we presented our plans for an efficiency program to our employees and the public. These plans include restructuring as well as reductions of the workforce across all business sectors and regions. Without first announcing detailed plans on cost and workforce reductions, we held consultations with the employee representatives in the countries concerned. A key success factor here was the unbiased approach to these talks. This enabled us to jointly reach an optimal solution for our goals in each respective case. The aim was to find socially acceptable solutions, as far as possible, and to justify them openly and fairly to our employees.

Key developments in 2012

Switzerland

In April 2012, we announced the efficiency measures for the operational business, which include the closure of the sites in Geneva and Coinsins, Switzerland. In accordance with the regulations relevant to such planning measures in Switzerland, Merck KGaA, Darmstadt, Germany called upon the employees there to submit alternative proposals by June 2012 for avoiding or reducing the planned workforce reduction. In the meantime, we held talks with the employee representatives called together at short notice at the sites in Geneva and the Canton of Vaud, as well as the UNIA trade union in Geneva and Vaud.

In mid-June, Merck KGaA, Darmstadt, Germany informed the responsible cantonal authorities and its employees of the final decision: A variety of proposals, concerning for example the social plan, had been submitted to the prescription medicines division. Nevertheless, none of the proposals about retaining the Geneva site could be incorporated into the plans. They were not reconcilable with the goal of eliminating duplicate functions in order to secure our viability over the long term.

Within the scope of restructuring measures, Merck KGaA, Darmstadt, Germany is consolidating all Group functions at corporate headquarters in Darmstadt. Pharmaceutical research and development is to be concentrated at the sites in Darmstadt (Germany), Boston (United States), Beijing (China) and Tokyo (Japan). For this purpose, around 750 of the jobs at the Geneva site are being transferred to other locations. Approximately 500 jobs have been eliminated in order to avoid duplicate structures. Around 80 jobs will be cut at the sites in the Canton of Vaud (Aubonne, Coinsins and Corsier-sur-Vevey). Production in Coinsins is being transferred to Aubonne. The closure of the Geneva site is scheduled for mid-2013, and Coinsins for 2014.

→ Attracting and developing employees

In order to cushion the impact of the changes, Merck KGaA, Darmstadt, Germany worked with the UNIA trade union and employee representatives to reach an agreement on a comprehensive social plan for the affected employees. This includes, for example, severance payments, early retirement arrangements and benefits to support employees transferring abroad or starting up their own businesses. In addition, Merck KGaA, Darmstadt, Germany made CHF 2 million available to mitigate the effects of closing the Geneva site on the local labor market. The sum is administered by a board consisting of the employee representatives and a lawyer appointed by the State Council of Geneva. Another measure is the Entrepreneur Partnership Program (EPP), which supports employees who have good ideas for starting up their own businesses. We have made € 30 million available for the EPP.

Germany

In September 2012, the company management and employee representatives reached an agreement on an efficiency program for our sites in Germany. The preceding consultation phase with employee representatives had begun in February. The aim is to reduce the workforce by around 1,100 positions in a socially acceptable manner by the end of 2015 – mainly through voluntary leaver and partial retirement programs. Forced layoffs are largely excluded until the end of 2017.

The program comprises around 100 individual initiatives aimed at increasing efficiency and focusing production on value-adding core activities. In order to strengthen the Darmstadt site, at least € 250 million in total will be invested there and at the other German sites in 2013 and 2014. Darmstadt is to be further expanded as our global corporate headquarters, meeting the most stringent competitive requirements as a modern production and R&D site. Industrial salt production in Lehrte will be discontinued.

Attracting and developing employees

As an innovative company, we need talented and well-trained employees. At all sites, we face the challenge of attracting talented people to our company and retaining qualified employees. Particularly in Europe and the United States, but also in China and other Asian countries, we must adapt to stronger competition for specialists. We are constantly seeking chemists, pharmacologists, medical scientists, biostatisticians, biochemists, business administration experts, engineers, and IT specialists, as well as people who are able and willing to take on managerial responsibility. In emerging countries, we face the particular challenge of attracting qualified executives to our company. The Corporate HR unit within Group Human Resources is responsible for developing and steering strategic measures for attracting talent and retaining employees. Employees of Corporate HR at the legal entities are implementing the measures locally.



Attracting young professionals

In 2010, we launched the "Make great things happen" campaign to position ourselves globally as an attractive employer. The campaign highlights our strengths: diverse career opportunities for contributing to the development and marketing of innovative products in an international, motivating and mutually respectful work environment. In addition, "Make great things happen" is also intended to reflect our strong social responsibility and our commitment to reconciling the demands of a career and a family as well as work and leisure. The positive impact of the campaign is confirmed by our ranking among the best employers for experienced scientists in Germany, which was completed between June and November 2012 by the company Universum following a survey of over 5,000 participants. Merck KGaA, Darmstadt, Germany reached sixth place out of 100 companies, which was an improvement of three places over 2011. By 2014, we want to revise the campaign in view of the repositioning of our company within the "Fit for 2018" program. Furthermore, in 2012 we adapted "Make great things happen" in Europe and the United States in order to especially attract potential new employees for R&D.

We also regularly present ourselves as an employer at recruitment fairs. In the 2011-2012 period, we focused our presence at fairs more strongly on potential young professionals for R&D. In addition, we make targeted use of new media, for example the business networks LinkedIn and Xing, in order to recruit experienced professionals and executives. We engage in a dialogue with students via our Facebook page. For this target group, we offer internships and mentoring programs within our company. In 2012, around 500 students completed an internship at Merck KGaA, Darmstadt, Germany in Germany.

→ Attracting and developing employees

Moreover, in 2012 Merck KGaA, Darmstadt, Germany participated as a founding partner in the "Careerloft" initiative – an online and offline exchange platform for students, graduates and companies.

In 2008, we launched a global electronic recruitment management platform. In 2011 and 2012, we introduced it across all business sectors and legal entities in Europe (except for Austria) as well as in Singapore and Thailand. At the end of 2013, it will be incorporated into the HR Suite integrated data management system and thus be available Group-wide.

Identifying talent within the company

To ensure the long-term success of our company, it is important to not only attract new, talented employees to our company, but also to retain existing staff and enable them to participate in continuing education. Here, our focus is on the personal and professional development of employees as well as career opportunities within the company.

Regular feedback discussions and employee performance evaluations are essential to a systematic development process. For this purpose, we introduced the Performance Management Process at Merck KGaA, Darmstadt, Germany in 2008, which provides for annual feedback discussions and performance evaluations for employees rated Global Grade 10 and higher in our position assessment system. Apart from evaluating employee performance, it helps us to identify individual development opportunities. In addition, we assess whether our employees' performance conforms to our values. The legal entities are responsible for applying the process also to employees in positions rated Global Grade 9 and lower. In many cases, these are subject to the regulations of the collective agreement and specific local statutory requirements. In 2011 and 2012, a total of 23,800 employees took part in the Performance Management Process.

In 2012, we refined the Performance Management Process in order to better identify new talent within the company by means of performance evaluations. The new Performance and Talent process is also meant to strengthen the performance culture at Merck KGaA, Darmstadt, Germany and to ensure that internal positions are filled in an even more efficient manner. It will be introduced incrementally starting in 2013 and is to be completed for the entire Merck KGaA, Darmstadt, Germany by the end of 2014. The process will thus replace all previous tools in the areas of talent recruitment, performance evaluation, skill development, and compensation, and will likewise become an integral element of the new HR Suite. In 2012, we were already able to fill 88% of leadership positions with internal candidates.

 2012

88%

 of leadership positions filled with
internal candidates

Vocational and advanced training

Advanced training for our employees is an investment in our future. Additionally, we want to support our employees in optimally developing their personal and professional strengths. In 2012, we continued with our advanced training approach and harmonized it globally. The objective was to ensure that employees and managers around the world develop the skills that we need in order to implement our business strategy and strengthen our culture.

This also includes offering a catalog of advanced training courses that can also be adapted to specific regional needs if required. At the same time, we also redefined good management practices based on five criteria and adapted our seminars for all management levels accordingly. This approach will be introduced globally in 2013.

The U.S. magazine "Training"  named EMD Serono in the United States as one of 125 companies that excel in employer-sponsored training and development programs.

Apart from our advanced training options, we also offer three programs designed to develop and strengthen the leadership skills of future executives. The Future Leaders program supports employees in acquiring business and leadership skills in the early phases of their career. The participants take on strategic and cross-functional projects, and they work abroad for two years. Within the scope of the nine-month International Management Program, managers are to strengthen their ability to think globally. In cooperation with top international universities, the Merck KGaA, Darmstadt, Germany University offers a multi-regional, modular one-year program. In 2011 and 2012, a total of 118 employees classified as "talent" took part in these programs. Additionally, Merck KGaA, Darmstadt, Germany cooperates globally with universities in order to support employees who wish to study for an Executive MBA. In 2011 and 2012, five employees in Europe graduated from the Executive MBA program at Ashridge Business School in the United Kingdom and the WHU-Otto Beisheim School of Management in Germany.

We view company vocational training of young people as one of the most important ways to prevent a potential shortage of trained staff due to demographic change. In Germany alone, more than 500 young people completed an apprenticeship in

→ Attracting and developing employees

one of 23 vocations at Merck KGaA, Darmstadt, Germany in both 2011 and 2012. Moreover, in Darmstadt we offer our one-year in-house work preparation program called "Start in den Beruf" (Preparing to join the workforce). In the 2011-2012 period, ten secondary school students who were previously unable to find an apprenticeship qualified themselves for the job market.

In order to ensure the quality of vocational training in technical production occupations in Darmstadt, during the 2011-2012 period Merck KGaA, Darmstadt, Germany modernized the vocational training school pilot plant at the Peter Behrens School in Darmstadt for more than € 1 million. At the vocational training facility, which spans around 200 square meters, future chemical technicians and chemical production specialists use computer simulations and technical apparatuses to familiarize themselves with large-scale production processes.

"Zeitservice" – Supporting the restructuring process

With the personnel restructuring currently underway as part of "Fit for 2018", it is particularly important to be able to find new placements for employees in other positions and units. Functioning as a hub, Zeitservice – our own internal temp agency – helps to find new jobs within the Group for employees whose positions have been eliminated. In addition, we support employees who need specific advanced training in order to meet the requirements of a new position. A team of HR staff and works council members are overseeing the entire process.

Performance-based pay

Competitive salaries and additional social benefits increase not only our attractiveness as an employer, they also serve to motivate and retain employees. At Merck KGaA, Darmstadt, Germany, compensation is based exclusively on market analyses in the relevant field and the degree of responsibility, as well as the competence and performance of the relevant employee. Initial analyses of the salaries paid to men and to women do not reveal significant differences at the same hierarchical level.

The Global Rewards Policy introduced throughout Merck KGaA, Darmstadt, Germany in 2011 defines the framework for compensation and additional benefits. Additional social benefits orient toward local legal and market conditions. These may include, for instance, sick pay or a retirement pension.

Goals: Attracting and developing talent

Strategic goal	Action	By?	Status in 2011 and 2012	Status
Introduce a performance management system	Introduce performance management systems for all employees with target agreements, feedback and coaching	End of 2013	In 2012, 98% of employees took part in a performance and development evaluation.	
	Introduce development plans for all employees with performance evaluations, target agreements, feedback and coaching	End of 2013	By the end of 2012, development plans had been instituted for 77% of employees.	
	Introduce development plans for all managers from Millipore Corporation, which was acquired in 2010	End of 2011	The Global Grading System was introduced incrementally for the employees of Millipore Corporation, which was acquired in 2010. This process had not yet reached completion as of the end of 2011, which is why the status cannot be specified for the end of 2011. At the end of 2012, development plans were instituted for 85% of the management; this process is to be completed by the end of 2013.	

→ Occupational health and safety

Goals: Attracting and developing talent

Strategic goal	Action	By?	Status in 2011 and 2012	Status
Talent & Succession Management: Fill at least 2/3 of positions at global grade 16+ with internal candidates	Use the Talent & Succession Management Process to identify suitable employees with management potential and define a process to systematically develop employees	Ongoing	In 2011, we initiated the Performance & Talent Process to systematically develop management. In 2012, 88% of the vacant management positions were filled internally.	

Legend:  Achieved  In progress  Not achieved  New goal

Occupational health and safety

As a responsible employer, it is especially important to us to prevent workplace-related illnesses and accidents.

Our Group-wide guidelines and management structures ensure uniform standards for occupational health and safety. They are oriented to the requirements of the International Labour Organization (ILO) and the Responsible Care® program of the chemical industry.



For example, in 1995 we instituted our Group-wide "EHS Policy" (Principles and Strategies for Health, Safety and the Environment), which is implemented through numerous other guidelines. At our individual sites, we furthermore have company agreements on occupational health and safety that have been entered into by employer and employee representatives.

Central EHS management with local managers

At Merck KGaA, Darmstadt, Germany, occupational health and safety is an integral part of our EHS management system. Ultimate responsibility for environmental, health, and safety matters lies with Executive Board Member Bernd Reckmann. The Group function Environment Health Safety Security Quality (EQ) manages all global activities, and local EHS managers implement them at the individual sites.

EQ monitors adherence to local environmental protection laws, regulatory requirements, standards and business requirements at our individual sites through internal and external audits oriented to the requirements of OHAS 18001 , one of the international standards for occupational health and safety management systems. We conducted 44 audits in 2011 and 17 in 2012.

Via the LION electronic data management system, data on workplace accidents is compiled at the individual sites and reported to EQ on a monthly basis. The sites are required to immediately report relevant accidents to EQ. EQ evaluates all data and informs other sites about preventive measures as needed.

We provide continual training to all employees who perform occupational healthy and safety tasks. Besides local programs, this training also includes the annual EHS congress in Darmstadt as well as the regional EHS forum. Both events inform attendees about new EHS topics as well as updated guidelines and laws, and furthermore encourage best practice sharing at an expert level.

Reducing behavior-related workplace accidents

Preventing behavior-related workplace accidents is an important aspect of operational occupational health and safety at Merck KGaA, Darmstadt, Germany. We aim to accomplish this by sensitizing our employees worldwide to potential hazards in

→ Occupational health and safety

the workplace. In 2009 and 2010, we launched the "selbst sicher" program at our Darmstadt and Gernsheim sites, and in 2011, we instituted this program Group-wide under the name "BeSafe!". It features numerous activities and awareness campaigns that are intended to reinforce our safety culture. This includes workshops for managers at the individual sites and an information exchange among EHS managers at a regional level, who then instruct employees at the sites. In addition, individual legal entities in Latin America, such as in Brazil and Mexico, hold safety competitions at specific sites that also help bolster our safety culture.

Since 2010, EQ has been presenting the Safety Excellence Award to all sites with no workplace accidents. Altogether 29 sites from all regions received this award in 2011 and 42 in 2012. We are particularly pleased that many sites were awarded this recognition for the third time.

The lost time injury rate (LTIR) is the indicator used to assess the success of our measures; our goal for 2015 is an LTIR of 2.5. We achieved an LTIR of 2.0 in 2011, and 2.3 in 2012. This shows that our activities for preventing behavior-related accidents are making a positive impact.

Goal 2015

2.5

Reduce LTIR throughout the entire Merck KGaA, Darmstadt, Germany Group

Promoting employee health

People are facing longer work lives as well as increasing demands from their careers. In view of this, we would like to bolster our employees' health as well as their capacity to perform their jobs through a wide array of health-promoting measures. Ergonomic evaluation of the workplace is one of the tasks our global EHS Management organization. At our Darmstadt site, our company medical center offers check-ups and medical services such as the early detection of diabetes and cancer, travel health advice as well as sociomedical and psychosocial advice. The medical center also provides training seminars and lectures on health-related topics.

We rely on our employees' personal responsibility and support their health awareness through local programs. At the Darmstadt site, for instance, we work with the Merck KGaA, Darmstadt, Germany company health insurance fund to offer programs and courses on healthy nutrition, exercise and relaxation. These range from back training, to yoga, to courses on how to quit smoking. We also offer courses on occupational health promotion activities, such as movement and back exercises.

Another important component of our health promotion activities is a program, which enables employees to participate in select health courses. Some of these are offered free-of-charge, and others cost a nominal fee. The courses focus on prevention through movement and back health since a large percentage of missed work is attributable to back pain. Take for example the Fitback program, in which employees can consult a physical therapist free-of-charge and have their backs examined.

Furthermore, employees in Darmstadt can participate in our company sports program. As of the end of 2012, it featured 23 different types of activities, including badminton, fitness training, ping-pong, golf, diving, and tennis.

At our company cafeterias, we furthermore offer our employees healthy food that meets the requirements of the German Society of Nutrition (DGE).

Employees of EMD Millipore at the Massachusetts and New Hampshire, USA sites can participate in a comprehensive health intervention program offered within the company. This program aims to prevent, detect early on, and/or treat diseases and injuries, especially those pertaining to the musculoskeletal system. It includes services such as special exercise/training programs, seminars, sport competitions, and ergonomic reviews of work areas. Employees who attend health intervention courses can receive up to US\$ 300 in financial incentives.

Goals: Occupational health & safety

Strategic goal	Action	By?	Status in 2011 and 2012	Status
Reduce work accidents throughout the entire Merck KGaA, Darmstadt, Germany (lost time injury rate = 2.5)	Implement the BeSafe! program; hold EHS forums on “Safety Behavior Change”	End of 2015	In 2011, we launched the BeSafe! program. Through systematic accident prevention measures (such as training and campaigns to strengthen our corporate safety culture), we attained an LTIR of 2.0 in 2011 and an LTIR of 2.3 in 2012. We are working to lastingly stabilize our LTIR.	

Legend:  Achieved  In progress  Not achieved  New goal

Diversity and inclusion

We believe that workforce diversity promotes innovation and better team performance. A good balance between different cultures, nationalities, and age groups as well as between male and female employees is conducive to our entrepreneurial success. We have therefore set ourselves the goal of furthering workforce diversity and including all employees in company operations in the best possible way (workforce inclusion). Increasing the proportion of women in management positions is important to us. Internationality and demography are two further areas of focus of our diversity activities. During the 2011-2012 period, we launched a wide variety of measures to achieve our goals.



New responsibilities – Chief Diversity Officer

Ultimate responsibility for diversity lies with Kai Beckmann, Executive Board Member and Chief Administration Officer. The Chief Diversity Officer (CDO) within Group Human Resources is responsible for strategically managing diversity. We established this new position during the 2011-2012 period. The CDO reports directly to the Chief Administration Officer.

In order to promote diversity to an even greater extent, in 2013 we plan to set up a Diversity Council comprising executives from all divisions and multiple Group functions. Its tasks will mainly include refining the diversity and inclusion strategy.

Systematically promoting women

We want to increase the percentage of female employees wherever they are underrepresented. In 2012, the 42% of the positions in our company were held by women. The ratio of female to male employees varied among the individual businesses, functions and regions. In 2012, women made up 46% of the workforce in Pharmaceuticals, 37% in Chemicals, and 42% in Group functions. In North America, 46% percent of the workforce is female, Europe 45%, the Emerging Markets 37% and Rest of World 37%. At 51%, the percentage of research and development positions held by women is highest, followed by administrative positions with 50%. The lowest percentages of women are in production (34%) and infrastructure (30%).

In 2011, we decided to increase percentage of management positions held by women to 25%-30% by 2016. In the same year, Merck KGaA, Darmstadt, Germany joined with all 29 other DAX 30 companies in signing a voluntary commitment to increase the proportion of management positions held by women. The participating companies report on their progress every year.

Goal 2016

25-30%

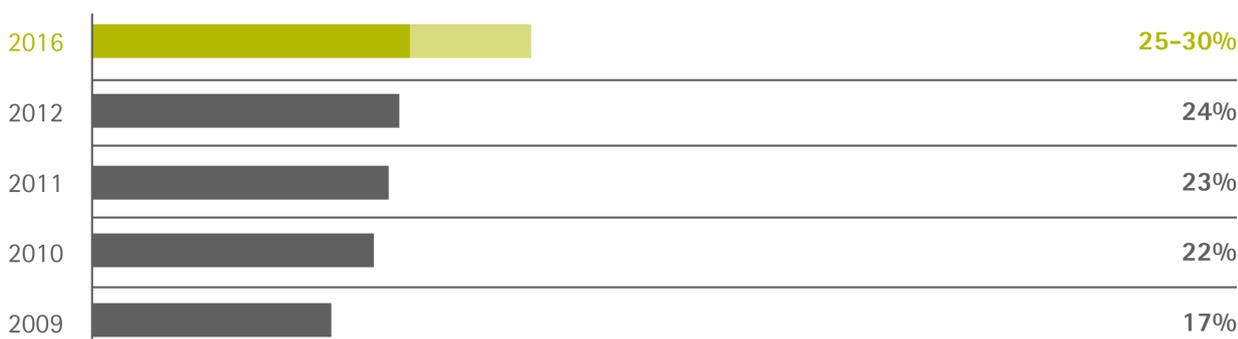
Management positions held by women

→ Diversity and inclusion

At local level, we have implemented numerous measures designed to increase the percentage of women in the entire workforce and to specifically increase the number holding management positions. For one, we facilitate the work-life balance for our employees in many countries, for instance by offering flexible working hours and childcare options. Furthermore, women benefit from special advanced training measures, seminars, mentoring programs and networks. During the 2011-2012 period, we conducted the "Women in Mentoring" program. Altogether, 15 women took part, with each being mentored by a female executive. Since 2000, Merck KGaA, Darmstadt, Germany has been supporting local mentoring programs such as the "Cross-Company Mentoring" industry initiative or the "Hessisches Mentorinnen Netzwerk für Frauen in Naturwissenschaft und Technik", a local German initiative. In order to promote exchanges among women in management positions within the Merck KGaA, Darmstadt, Germany, we initiated an internal "Women in Leadership" program at corporate headquarters in Darmstadt. In addition, we set up the Group-wide "International Women's Network" in 2012. Our Chief Diversity Officer and the Executive Board Member with responsibility for Human Resources engage in regular exchanges with these groups.

The overall percentage of management positions held by women was 24% in 2012. The percentage was higher at the legal entities than at corporate headquarters in Darmstadt; it is also higher in Pharmaceuticals than in Chemicals. In certain Group functions such as IT, women account for a lower proportion of management positions. The results in the 2011-2012 period show that we are not far from achieving our strategic goal of 25%-30% women in management positions by 2016. In 2013, we will launch further local and global measures to promote women in management with a special focus on women with little or no management experience.

Management positions held by women



 Percentage of management positions held by women

Promoting internationality

As a global company, we promote the international and intercultural diversity of our workforce. People from a total of 121 different nations work at Merck KGaA, Darmstadt, Germany. Only 26% of our workforce is from Germany. Altogether our executive staff includes representatives of 57 nationalities, and 61% of our management positions were held by non-German citizens.

In order to promote the internationality of our workforce, we pursue two goals when making appointments to new positions. Firstly, we aim to increase the number of local employees at all sites across all hierarchical levels. And secondly, we want to offer our employees international development opportunities. Furthermore, we help our employees to acquire intercultural competencies. For this purpose, we promote intercultural training courses and international teamwork throughout Merck KGaA, Darmstadt, Germany. We offer special cultural immersion courses to executives working outside of their home countries. This includes for example language courses and international networks.

Demographic change

In Germany, several other EU countries and the United States, we must prepare ourselves for demographic change. In these countries, the average age of our employees exceeds 40 – and we assume that this average will continue to increase. In Europe, we are using various programs to address these demographic challenges. We seek young professionals for our company in order to meet our long-term human resources needs. We also promote the employability of our workforce and are active in the area of employee retention. This includes adapting workplaces to the needs of older people and establishing a health management program to maintain their ability to do their job. One example is the health management program in

→ Work-life balance

cooperation with the company health insurance fund at the Darmstadt site in Germany. Employees older than 40 receive special support in the form of the "Leben nach Herzenslust (Living Life to the Full)" program when starting or resuming sports activities.

Monitoring and controlling

Each quarter, we collect data on gender distribution, nationality and demographics for internal evaluation purposes. We analyze these data at divisional and Group function level, as well as for key countries and groups of young professionals and executives. We present selected data in our Annual Report and Corporate Responsibility Report as well as jointly with the other 29 DAX 30-listed companies.

Training and sensitizing employees

The topics of diversity and inclusion are integral components of all training courses for Human Resources staff. For instance in 2012, we informed our international recruiting team on the relevance of these topics to us and trained them accordingly. The aim of the workshop was to develop a common understanding of diversity and to discuss measures to adapt our recruiting activities. In addition, we have added the topics of diversity and inclusion to the curricula of our management courses offered to all employees with leadership responsibility.

Preventing discrimination

Our commitment to diversity also means that we do not tolerate discrimination anywhere in the world within our company – whether based on age, ethnic origin, skin color, nationality, religion, sexual orientation or disability.

This rule is defined in our Code of Conduct. Cases of discrimination can be reported to supervisors or to Group Human Resources, Legal or Compliance. Employees can also report discrimination cases anonymously via the Speak-up Line, a global, toll-free telephone hotline. Our compliance organization is responsible for processing the cases. Confirmed cases can lead to disciplinary measures or consequences stipulated by labor law. In 2011 and 2012, two cases of suspected discrimination were reported via the Speak-up Line. However, a review of the cases revealed that our regulations were not breached in either of them.

Goals: Diversity and inclusion

Strategic goal	Action	By?	Status in 2011 and 2012	Status
Increase the percentage of management positions (Global Grade 14+) held by women to 25%-30%	Increase the percentage of management positions held by women through numerous initiatives that move women into those positions	End of 2016	23% of management positions were held by women in 2011; 24% were held by women in 2012, a 2% increase over 2010.	

Legend:  Achieved  In progress  Not achieved  New goal

Work-life balance

As a family-friendly company, we want to help our employees to achieve a good balance between their professional and personal objectives. For instance, we help them to maintain and strengthen their motivation and performance potential. In addition, we further their trust in our company. Therefore, our employees can make use of flexible working models and childcare options, making it easier for them to achieve their personal goals. We also offer our employees ways to better reconcile the demands of a career while caring for family members as well as health management support.



→ Work-life balance

Flexible working models

In Germany and other countries, we offer numerous working model options. These include individualized working hours and locations.

In 2011 and 2012, our employees made use of more than 20 different part-time models, for instance varying weekly working hours and individually agreed working days. Globally, approximately 6% of our employees worked part-time.

At the Massachusetts sites of EMD Millipore in the United States, we introduced a new work concept called "FlexWorks". Participation is voluntary and enables both full-time and part-time workers to decide for themselves when and where they work while meeting their contractually agreed working hours. In our view, this not only promotes the work effectiveness of our people, it also enables us to lower power consumption for unused offices and helps our employees avoid the stress of commuting. As of the end of 2012, 147 employees were taking part in the program. Only one month after the project started, the commuting savings amounted to an average of 72 km (or 70 minutes) per participating employee.

In 2012, Merck KGaA, Darmstadt, Germany introduced a new working model at the Darmstadt, Gernsheim and Grafing sites in Germany based on a working time honor system. Initially, we piloted the model in 14 areas of the company. Altogether, 350 non-exempt and exempt employees took part in the program, enabling them to flexibly shape their working hours and location. As of mid-2013, all exempts in Germany with qualifying positions can make use of the program.

Entitlement to parental leave

At numerous sites, our employees are able to take parental leave; this possibility is also provided for by law in some countries, such as Germany and the United States. Often, we offer our employees better conditions than those required by law.

In the United States, employees are legally entitled to a 12-week unpaid leave of absence per year in the event of the birth of a child or illness of a family member. In these cases, EMD Millipore offers its employees financial support. Overall, EMD Millipore offers eight weeks of paid maternity leave, two weeks of paid paternity leave, and five weeks of paid leave when adopting a child. Moreover, EMD Millipore will reimburse up to US\$ 5,000 in adoption fees.

The number of employees working for our German companies in Darmstadt, Gernsheim and Grafing (representing around 24% of Merck KGaA, Darmstadt, Germany employees in 2012) who were on parental leave totaled 401 as of December 31, 2011 and 434 as of December 31, 2012. Fathers represented 30% of these totals. Parents returning to work after parental leave can find information on possible childcare options on the intranet. In addition, presentations and meetings with parents are held by us in Germany. Contacts are available at the Darmstadt site for individual consultations.

Childcare options

At various sites, our employees benefit from childcare options that we subsidize. A daycare center for children from the ages of one to twelve years has been operating at the Darmstadt site in Germany for more than 40 years. It is supported by the family of owners. The center is open year-round from 6:30 a.m. to 5:15 p.m. and offers 100 daycare slots. At the end of 2013, a further 50 slots are going to be made available. In addition, the operating hours will be extended. At our headquarters in Darmstadt, employees can also make use of our emergency childcare service if their regular childcare provider happens to be unavailable. For employees at the Gernsheim site in Germany, five slots are available at a public daycare center.

We have been offering vacation camps for the children of employees at the Darmstadt site since 2008 and considerably expanded the offer in 2011 and 2012. In 2012, a total of 275 vacation camp slots were available to parents, who could book them either on a daily or weekly basis. The vacation camp program consists of sports activities, art and research projects.

In the United States, EMD Millipore offers its employees assistance in finding the best childcare solution.

Reconciling demands of career and family

In an aging society, more and more employees will be required to care for family members with special needs. In Darmstadt, we have therefore been offering special information and consultation possibilities since 2009. This includes the services of the local Merck KGaA, Darmstadt, Germany company health insurance fund, which provides information such as contacts to nursing staff and offers seminars on the challenges and costs of nursing care. In the United States, EMD Millipore supports its employees financially by enabling nursing care to be paid out of gross income.

→ Dialogue and co-determination

Award for family-friendliness

In 2012, the charitable Hertie Foundation recognized our sites in Darmstadt and Gernsheim, Germany for the third consecutive time as being "family-friendly". The distinction is based on an audit on family-friendliness, which was conducted using predefined criteria and is valid for three years.

Dialogue and co-determination

We believe that we can strengthen our employees' trust in the company through open and honest communication. We therefore inform them regularly about the latest developments.

Information and communication channels

We provide employees Group-wide with a broad range of information on the latest topics, which we publish in different languages on the intranet. In 2012, we introduced the possibility for our employees to comment on the news items directly online. We set up an additional intranet platform for the "Fit for 2018" transformation program; the platform provides information as well as a discussion forum. In addition, numerous additional information media and dialogue forums are in place. Examples include the international employee newspaper "pro" as well as newsletters issued by the divisions and Group functions. Our "ChemForum", a dialogue-promoting event for all employees working in the Chemicals divisions, was held 13 times in the 2011-2012 period.



Employee representatives and co-determination

We foster employee participation, co-determination and dialogue in our company. The Euroforum is our employee representative body at the European level and also serves as an information and advisory platform for a direct dialogue between employees and senior management up to the Executive Board level. Topics that are addressed regularly include the economic and financial situation of Merck KGaA, Darmstadt, Germany in Europe, the employment situation, and also significant changes within our company.

Moreover, the individual sites have other forms of employee representation, such as local works councils and unions. Local works councils as well as a central Group works council represent our employees in Germany, for instance. Senior executives are represented by the Senior Executives Committee.

During the 2011-2012 period, the "Fit for 2018" transformation program was a topic debated extensively by all employee representative bodies. In May 2012, around 30 Euroforum participants from 14 countries spoke with the Executive Board about the impact of the program on the workforce. In 2013, our employees at the Aubonne, Coinsins, Eysins and Corsier-sur-Vevey sites in Switzerland elected employee representative bodies for the first time in order to utilize this communication channel with a view to the further implementation of "Fit for 2018".

Employee surveys

We introduced the "Pulse" survey in 2009, initially conducting it every year and as of 2011 every two years. Through this survey, our employees have the opportunity to rate us as an employer and to express their concerns anonymously. The results are used to devise and implement concrete measures. In 2011, the results of the survey were slightly inferior to those of previous years. We ascribe this sentiment to "Fit for 2018"; at the time of the survey, the first measures from the program had already been instituted at the prescription medicines division. The next Group-wide survey will take place in 2014. We are monitoring employee sentiment during the current reorganization process by conducting smaller, short-term surveys. For example, the prescription medicines division conducted this type of survey in 2012. We are planning to conduct employee surveys in additional units in 2013.

→ Dialogue and co-determination

Further possibilities for dialogue and exchange

Our employees have other options for dialogue and feedback, for instance the annual employee appraisal.

At the Darmstadt site in Germany, we want to use the company suggestion scheme to hone our competitive edge. We reward employees for the suggestions that are implemented by paying them bonuses based on the cost savings or the contribution to occupational safety, environmental protection and quality improvement. Our employees submitted 4,111 suggestions in 2011 and 3,128 in 2012 for improvement. These led to savings amounting to € 1.9 million in 2011 and € 2.0 million in 2012. For this, they received bonuses totaling € 1.1 million in 2011 and € 0.8 million in 2012. Around 70% of the suggestions for improvement related to production areas; the remaining 30% comprised suggestions pertaining to analysis, technology and logistics. The suggestions helped significantly in many instances to optimize production processes and occupational safety or to lower waste quantities and emission levels.

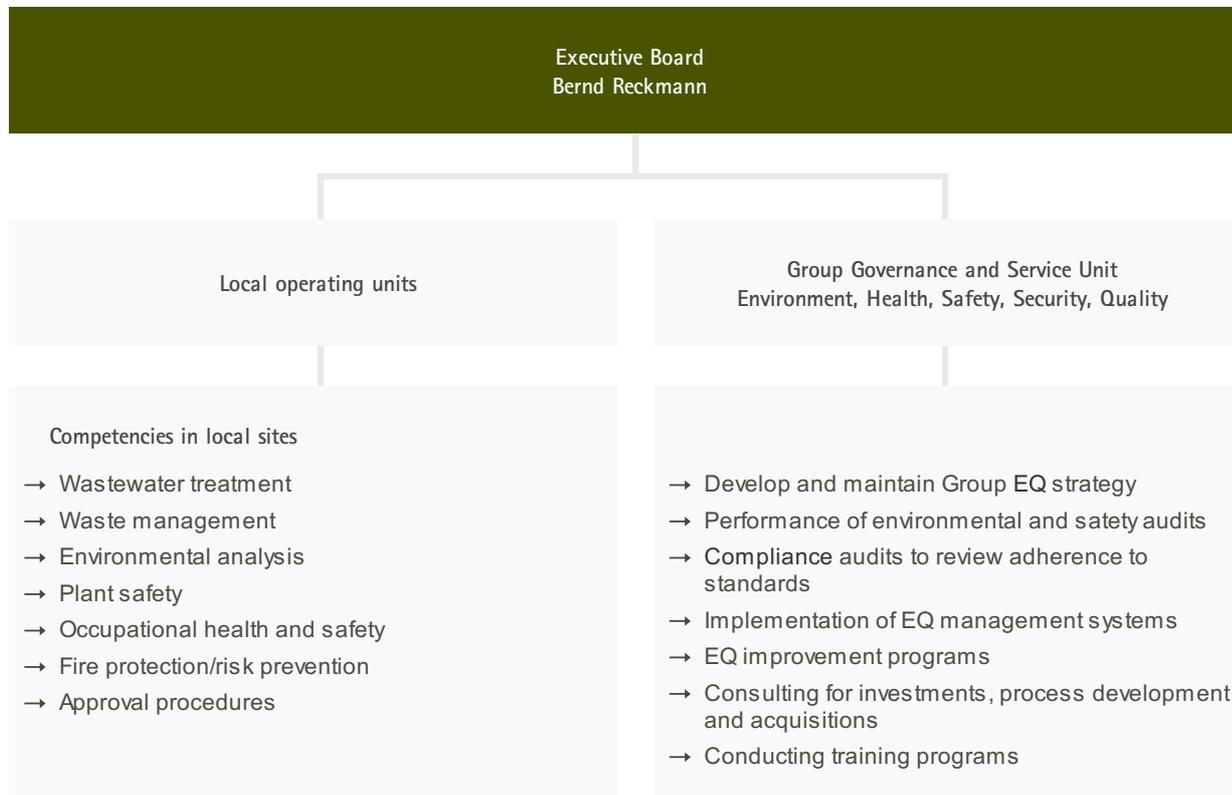
Environment



Our responsibility to protect the environment is derived from our values and our corporate strategy. We have instituted Group-wide principles, strategies and organizational structures for corporate environmental protection and have also implemented a certified environmental management system for our Group-wide activities. In this way, we aim to reduce our emissions and waste while also ensuring that resources such as energy, water and raw materials are utilized as efficiently as possible. Process safety is a key prerequisite here.

→ Management of company environmental protection measures

Management of company environmental protection measures



Our responsibility to protect the environment is derived from our Values and our corporate strategy. We aim to continually improve our performance and reduce our impact on the environment by applying the precautionary principle. This especially includes utilizing resources such as energy, water and raw materials both efficiently and economically. Furthermore, we strive to lower our emissions and waste so that we can reduce our costs as well as our impact on the environment. As part of our contribution to climate protection, we have set a goal of reducing our direct and indirect greenhouse gas emissions by 20% by 2020, measured against the 2006 baseline.

Our Corporate "EHS Policy" provides the framework for principles, strategies, and organizational structures for environment, health and safety at Merck KGaA, Darmstadt, Germany. The policy is implemented through internal guidelines and instruction manuals such as our EHS, Security and Quality Manual, which tells our employees how to apply the EHS principles in their day-to-day work. Our guidelines are based on the Responsible Care Charter, which the chemical industry drafted in 2005.

Overall responsibility for environment, health, and safety is born by Executive Board Member Bernd Reckmann. The function Environment Health Safety Security Quality (EQ) is responsible for globally steering all environmental measures. At the individual sites, the local EHS managers are in charge of operational environmental protection measures.

Through internal and external audits, EQ monitors adherence to local environmental protection laws, regulatory requirements, standards and business requirements. During the 2011-2012 period, the Millipore sites acquired in summer 2010 were integrated into EQ's structural organization and processes. Reporting was harmonized as well. Environmentally relevant data are regularly collected at the individual sites via the LION electronic data management system; the data are then reported to EQ, mostly on a yearly basis, but sometimes several times a year, or even monthly.

We manage our Group-wide environmental protection activities through an environmental management system that complies with ISO 14001. All production sites are required to implement this environmental management system, which is annually certified by an accredited organization. Since 2009, Merck KGaA, Darmstadt, Germany has held an ISO 14001:2004 Group certificate for its environmental management system, which covered 49 sites at the end of 2012. New

→ Climate protection

production sites must subsequently set up and implement a certifiable environmental management system that conforms to Group standards. This has been accomplished for the majority of the Millipore sites acquired in 2010. At the remaining four Millipore production sites, enough progress has been made in setting up the corresponding management systems that they are scheduled to be externally certified and added to the Group certificate in 2013.

In both 2011 and 2012, we successfully passed the audit that is conducted every year in November as part of the certification process. During the audits, the certifier identified only a few areas with potential for improvement at select sites, after which appropriate action plans were defined to address them.

All employees with environmental protection responsibilities are trained on a continuous basis and obtain additional qualifications. Besides local programs, this training also includes the annual international EHS Congress in Darmstadt as well as the regional EHS Forum. Both events inform attendees about new EHS issues as well as updates to guidelines and laws; they furthermore encourage best practice sharing at an expert level.

Spending on environment, health and safety totaled € 141 million in 2011 and € 146 million in 2012. These totals also include investments made during the respective years.

Goals: Environmental management

Strategic goal	Action	By?	Status in 2011 and 2012	Status
Obtain ISO 14001:2004 Group certificate	Certify all production sites to ISO 14001:2004; certify the Millipore sites acquired in July 2010	Ongoing	New production sites were successively added to the Group certificate. Four Millipore production sites are scheduled to be externally certified and added to the Group certificate in 2013.	

Legend:  Achieved  In progress  Not achieved  New goal

Climate protection

Climate change and its consequences, one of the key challenges facing society in the 21st century, are already impacting life on earth today.

Being a responsible company, we are resolute in our quest to help reduce greenhouse gas emissions, which we are accomplishing by lowering our greenhouse gas emissions and by offering products that help our customers reduce their own emissions in turn. Within the scope of the Carbon Disclosure Project, we have been reporting for several years now in detail to our stakeholders – in particular customers, NGOs and shareholders – regarding our activities, measures, and achievements. In addition, our engagement in climate protection activities is also of financial benefit since improved energy-efficiency means that we save on energy costs. Pressure from a growing number of statutory regulations governing greenhouse gas emissions – such as those found in emissions trading systems – has also encouraged us to take action. Furthermore, our customers are likewise increasingly expecting us to engage in climate protection activities.



Steering activities centrally

The Merck KGaA Darmstadt, Germany function Environment Health Safety Security Quality (EQ) is responsible for globally steering all climate protection measures. At our individual sites, operational units are responsible for implementing climate protection measures.

→ Climate protection

Strategic goal and EDISON program

In 2009, we set the goal of reducing our greenhouse gas emissions by 20%, measured against the 2006 baseline. In order to achieve this goal, we initiated the EDISON (Energy Efficiency and Climate Protection) program, which consolidates the climate protection activities of Merck KGaA, Darmstadt, Germany. 20 sites worldwide are responsible for around 80% of the greenhouse gas emissions at Merck KGaA, Darmstadt, Germany, which is why EDISON is focusing on these sites. The reduction of our energy-related emissions is one of our primary measures. To this end, we are working to reduce greenhouse gas emissions from our own energy generation as well as to enhance the energy efficiency of research and production processes. Furthermore, we wish to lower process-related emissions through measures such as a quality control process at the life science tools division. Improving our building management in terms of energy-related aspects is another measure that will contribute.

Goal 2020

-20%

Greenhouse gas emissions

EQ collaborates with a cross-divisional working group founded in 2011 to create and implement climate protection projects. This working group develops measures itself and evaluates site-related project proposals using a method it created to systematically evaluate projects. In 2012, the Executive Board of Merck KGaA, Darmstadt, Germany earmarked € 10 million for projects. Of the more than 130 approved projects, we have initiated or successfully implemented around half. This includes the construction of a biomass power plant at our site in Goa, India, and the cogeneration plant in Gernsheim, Germany that will go on line in mid-2013.

The Executive Board has also earmarked € 10 million for 2013 as well. Some of this will be used to continue projects that were launched in 2012, and some of it will go to support the 73 new projects that were submitted by the EDISON working group in September 2012 and were approved. Through approximately 200 individual projects, we are aiming to reduce emissions by around 64,000 metric tons of CO₂ per year in the medium term.

Energy management is another component of EDISON. In 2012, our production sites in Darmstadt and Gernsheim, responsible for around 40% of our global energy consumption, were certified to ISO 50001 "Energy management systems".

The economical use and energy efficiency of company cars also constitutes part of our climate protection measures. The Group-wide company car guidelines are being revised this year and will establish solid upper limits for vehicle CO₂ emissions.

Climate protection figures for 2011 and 2012

We produced 521,000 metric tons of greenhouse gas emissions in 2011, and 516,000 metric tons in 2012. In 2012, the sites that produced the most emissions included the Darmstadt and Gernsheim sites in Germany, the Jaffrey, New Hampshire and Savannah, Georgia sites in the United States, the Cork site in Ireland, and the Molsheim site in France. Greenhouse gas emissions are reported in line with the Greenhouse Gas (GHG) Protocol, an international standard for greenhouse gas emissions reporting. Merck KGaA, Darmstadt, Germany currently reports Scopes 1 and 2 of the GHG protocol. Scope 1 covers direct emissions that the company produces itself through fossil fuel combustion or through its own processes. Scope 2 pertains to emissions from consumption of purchased electricity, heat or steam. Scope 3 includes emissions such as those from the manufacture and transportation of raw materials, products, and waste, or from employee business travel. Due to the complexity of Scope 3 emissions reporting, Merck KGaA, Darmstadt, Germany is currently only reporting on Scope 3 emissions from business travel (plane and train travel, rental cars).

The Darmstadt and Gernsheim sites in Germany were also our largest CO₂ producers in 2011 and 2012. With the cogeneration plant in Darmstadt and the heating plant in Gernsheim, these two sites are subject to the EU Emissions Trading System. The final carbon credit allowances have not yet been defined for the third trading period (2013-2020). However, based on the current status, Merck KGaA, Darmstadt, Germany will have to purchase additional allowances.

Increasing employee awareness

We want climate protection to be lived throughout the whole company. At several sites, Merck KGaA, Darmstadt, Germany calls on employees to contribute their own ideas for saving energy and conserving resources. In the United States, the life science tools division also supports employees' personal climate protection activities, such as incentives for installing solar panels in their homes. With global campaigns such as the Energy Month campaign, the life science tools division is increasing employees' environmental awareness.

→ Resource consumption

In order to keep our employees informed, we publish a selection of climate protection facts and figures on our intranet. Furthermore, various tools such as energy checklists or best practice examples are also available to help employees share information and learn from one another. We also continuously provide information on climate protection at Merck KGaA, Darmstadt, Germany in our employee newspaper and in an employee newsletter. In addition to this, we give our employees tips, such as how to reduce fuel consumption by modifying their driving habits. As an incentive to use public transportation. Our Darmstadt site offers a job ticket, for which the company covers part of the cost. More than 3000 employees take advantage of this offer.

Goals: Climate protection

Strategic goal	Action	By?	Status in 2011 and 2012	Status
20% reduction of direct and indirect greenhouse gas emissions (Scope 1 and 2) of Merck KGaA, Darmstadt, Germany (2006 baseline)	Systematically examine the energy consumption at the individual sites	End of 2020	The production plants in Darmstadt and Gernsheim were systematically examined in terms of energy savings potential. In addition to this, energy checks were conducted at the Altdorf, Semoy, Taicang, Savannah, and Eppenheim sites.	■
	Identify and implement potential ways to save energy	End of 2020	Nearly 70 projects to save energy or reduce greenhouse gas emissions have been initiated, and some of them have already reached completion.	■
	Reduce process-related emissions	End of 2020	We have made progress in reducing process-related emissions. Despite increased production volume, we managed to lower emissions slightly.	■

Legend: ■ Achieved ■ In progress ■ Not achieved + New goal

Resource consumption

For our business activities, we require resources such as energy, water, and raw materials, as well as numerous other materials, which we mostly utilize for production purposes. Given that resources are becoming ever scarcer and more costly, efficient energy and material use is a crucial factor in staying competitive.

Through our Group-wide program to continually improve business processes, called Operational Excellence (OE), we are aiming to achieve the most economic, efficient level of operation in all our production facilities. All Merck KGaA, Darmstadt, Germany production sites were included in the program in 2011 and 2012. In previous years, the program focused primarily on globalizing structures and processes, as well as enhancing efficiency. For example, utility management (with an emphasis on energy management) became mandatory for chemical production in 2012, after having already been applied to pharmaceutical production in 2011.



Energy consumption

In 2012, Merck KGaA, Darmstadt, Germany consumed 1,438 GWh of energy, which represents a slight decrease compared to 2011 (1,446 GWh).

Merck KGaA, Darmstadt, Germany also operates its own plants to generate power and steam, such as the gas turbine power plant in Darmstadt and the heating plant in Gernsheim. The power plant in Darmstadt is a cogeneration plant, which means

→ Water protection

that the heat created from generating power is then utilized for other purposes. Using a generator, a gas turbine transforms natural gas into power; the waste heat from the turbine and the hot exhaust resulting from combustion are then utilized to create steam and warm water for production.

In mid-2013, a cogeneration plant is also scheduled to go on line in Gernsheim, which will save around 6,000 metric tons of carbon dioxide per year.

Water consumption

We utilized 17.6 million cubic meters of fresh water in 2011, and 16.2 million cubic meters in 2012, consisting of 33% groundwater, 43% surface water, and 24% water from the public water supply. No sensitive water sources were impacted by our water intake.

The largest percentage of water, 86%, was utilized in Europe; 8% was used in Asia, Australia and Africa, 5% in North America, and 1% in Latin America.

Material consumption

Merck KGaA, Darmstadt, Germany especially utilizes production materials such as chemical and pharmaceutical raw materials. In addition, we also employ operating supplies and packaging materials such as folding boxes, glass bottles and ampules.

We generally quantify the weight of purchased materials used directly in our chemicals and pharmaceuticals. We utilized 389 metric kilotons of these materials in 2011, and 360 metric kilotons in 2012. The portfolio of our life science tools division includes numerous devices and work instruments for whose production we need semifinished and finished materials such as ready-assembled electronic components or casing for devices. We record these in unit numbers.

The figures do not include packaging materials and operating supplies such as energy or lubricants.

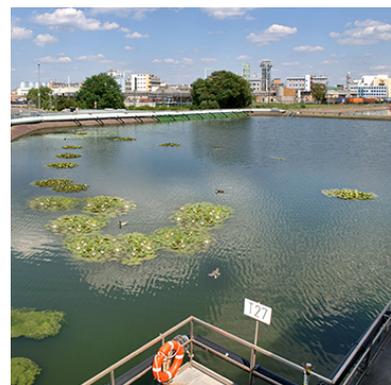
Water protection

At Merck KGaA, Darmstadt, Germany, water is used in production primarily for cooling, as process water, or for exhaust air purification. After being used, the water may contain eutrophication substances, heavy metals, or active pharmaceutical ingredients (APIs). The treatment of this wastewater, and thus the prevention of environmental pollution, is a fundamental part of our corporate environmental protection measures worldwide.

The function Environment Health Safety Security Quality (EQ), which is in charge of environmental protection, bears overall responsibility for water protection. At the individual Merck KGaA, Darmstadt, Germany sites worldwide, the local EHS managers are in charge of this. Our employees regularly receive training and obtain additional qualifications.

In 2011–2012, Merck KGaA, Darmstadt, Germany made significant revisions to its Group-wide "Water Protection" standard. Based on our Responsible Care obligations, this standard defines the processes and responsibilities required for clean wastewater at Merck KGaA, Darmstadt, Germany, and also covers the hiring of third parties to handle it.

The standard also requires all sites to estimate the specific risks and effects of wastewater, as well as to assess these risks and effects using ecotoxicological data. The individual sites must develop and implement a water pollution response plan that features specific measures to prevent wastewater or reduce its volume. This plan takes into account API emissions, among others, and also defines the documentation process for wastewater volume, point of origin, and local limits.



→ Waste management

The standard also provides strict guidelines for wastewater handling via external service providers. The wastewater quality to be attained is, if not already specified in law, contractually defined, as are the responsibilities involved. Furthermore, service providers are regularly audited.

Waste management

For Merck KGaA, Darmstadt, Germany, waste management is a key aspect of its corporate environmental protection activities. This includes measures to prevent and reduce waste, as well as recycling when possible and disposing of waste properly. Proper waste handling with regard to occupational safety and storage on site is also of key importance.

During the process development phase, we pay particular attention to making the processes efficient, to minimizing the resulting waste, and to ensuring that the materials utilized pose as little danger to people and the environment as possible. We also work to optimize existing production processes. Efficient resource use is an important goal here, for cost-related reasons as well.



The function Environment Health Safety Security Quality (EQ), which is in charge of environmental protection, bears overall responsibility for waste management. Local EHS managers are in charge of this at the individual sites worldwide. EHS managers receive regular training from EQ. The type and quantity of waste is logged and documented at all sites.

With our Group-wide "Waste Management" standard, we have introduced a uniform waste management framework for all Merck KGaA, Darmstadt, Germany sites. This standard defines organizational structures and processes and is regularly updated – the last update was in August 2011.

The majority of waste is recycled or disposed of externally. As the generator of the waste, Merck KGaA, Darmstadt, Germany is ultimately responsible for the final disposal of the waste and selects its service providers with extreme care. The terms and conditions for disposal are contractually defined. Service providers are also required to properly document the disposal process. They are regularly audited by Merck KGaA, Darmstadt, Germany, especially if they handle hazardous waste. When possible, waste such as solvents is also processed and recycled in-house.

Waste by disposal method



Waste for disposal

1 Landfill waste	10%
2 Incinerated waste	43%

Recycled waste

3 Recycled solid waste	34%
4 Recycled energy	13%

We produced less waste in 2012 than in 2011 (2012: 189,000 metric tons, 2011: 199,000 metric tons). As in the past several years, waste from construction and renovation projects had a strong influence on waste volume also in 2012, with 34% of the total waste volume consisting of construction, excavation and demolition waste (2011: 36%). Due to a major demolition and renovation project at the Darmstadt site, large quantities of hazardous waste had to be disposed of in 2012. At the same time, the volume of recyclable non-hazardous waste declined. A large portion of this waste was generated in 2011 during a major construction project in Darmstadt that was completed in 2012. This impacted the recycling rate, which dropped from 60% in 2011 to 47% in 2012.

→ Process and plant safety

Process and plant safety

Plant and process safety has high priority at Merck KGaA, Darmstadt, Germany. Safety system failures can lead to the release of chemicals, which can in turn impact people and the environment as well as result in financial damage, such as from production stoppages.

The function Environment Health Safety Security Quality (EQ), in charge of environmental protection, are the experts in plant and process safety guidelines as well as all related topics. At the individual Merck KGaA, Darmstadt, Germany sites worldwide, local EHS managers have been appointed to handle issues pertaining to plant and process safety.

We apply the same uniform standard to plant and process safety across the globe. Our Group-wide "Plant and Process Safety" standard mandates safety-related requirements to be applied to the entire life cycle of a plant – including construction, normal operation, modifications, maintenance, repair, and shutdown. This standard applies to production plants and warehouses. Before a plant goes on line, a safety concept is always developed for each plant, which is then continuously updated. It contains an overview of potential risks and the corresponding protective measures.



The Group-wide standard "Spillage Control" defines the organizational measures for preventing spillage during storage and transport, and also details how to handle hazardous materials. The Group-wide standard operating procedure "Risk Management Process" defines how to identify and assess risks, as well as how to develop and implement measures to minimize them.

In order to continuously identify potential for improvement, we assess the plant and process safety for each site using the EHS performance indicators. This gives us a comprehensive overview of safety at our sites. Here, we use lagging indicators to analyze incidents retrospectively and leading indicators to make a perspective analysis of near-incidents.

Data on spillage at our plants are evaluated using process safety indicators and are also incorporated into the overarching EHS indicators. In 2011, we registered 41 substance spills in total due to incidents at 108 production, research and storage sites. In 2012, 36 incidents were registered at 107 sites. Each individual incident was investigated at the respective site. Appropriate countermeasures were taken in order to prevent the same scenario – or a similar one – from recurring. Information on the incidents is regularly communicated so that all production sites can learn from the situation and implement preventive measures.

Since plant and process safety involves the interaction of man and machine, we consider it highly important for our employees to be well-trained and to receive further training on a regular basis. In 2012, a new internal continuing education program was set up for site managers – as well as for production, engineering and EHS managers at the individual sites – and rolled out within the Chemicals divisions. The primary topics here included systematic risk identification in processing plants, explosion protection, and static electricity.

Biodiversity

Since the signing of the [Convention on Biological Diversity](#), the concept of biodiversity has included diversity within species, between species and of ecosystems. This convention, signed in 1992 at the United Nations Conference on Environment and Development ([UNCED](#)) in Rio de Janeiro, has the following three main goals: conservation of biological diversity, sustainable use of its components, and fair and equitable sharing of benefits arising out of the utilization of genetic resources.



The loss of biodiversity is one of the greatest challenges of our time. Ecosystems provide us with services and resources such as sufficient quantities of good-quality water that are absolutely essential to our business operations worldwide. We therefore consider it extremely important to protect biodiversity.

Our production sites are located in established industrial and commercial zones, and the corresponding operating permits are reviewed via audits. In order to prevent substances that could negatively impact biodiversity from being released into the environment, we plan and operate our facilities according to strict Group-wide safety requirements. In our Group-wide standards, we have defined measures for processing waste and production wastewater. We have furthermore implemented a Group-wide program called EDISON to reduce greenhouse gas emissions

We improve the habitats for animals and plants at our sites, for instance by increasing the amount of unsealed surface area. This is, however, not always possible since we seal certain surfaces to protect them from any leakage that may occur.

In 1995, we developed a green open space concept for our Darmstadt site in Germany. Around 30% of the premises have now been greened. The green areas are designed to improve the functionality of the production areas as well as enhance the ecological value of the open areas. In 2008, we signed an agreement with the city of Darmstadt that established the framework for increasingly taking nature conservation into account. This agreement applies to the industrial use of the site and its better integration into the urban surroundings. The stipulated planning guidelines require, for example, an increase in the percentage of native plants.

When planning new sites and facilities, we consider environmental aspects such as aeration, land use structures that contribute to a favorable microclimate, and energy-efficient building concepts. For example, when planning the expansion of our site in Corsier-sur-Vevey, Switzerland, we conducted a biodiversity study. To protect the bordering alpine meadows, we developed a landscape plan in which the meadows are tended to by a local farmer.

When we acquire new sites and investigate their environmental situation, we also take into consideration information from public sources such as neighbors or NGOs. We assume responsibility for the pollution we have caused and investigate our sites before selling them.

Society



Taking responsibility toward society is an integral part of our entrepreneurial approach. We are convinced that we can make an important contribution to society with our knowledge, our skills and our products.

→ Management

Management

Merck KGaA, Darmstadt, Germany sees itself as part of the community, not only at its individual locations, but also globally. In the context of our business activities, we play an important role in the community at our respective locations. We create jobs and invest in the qualification and social security of our employees. Many companies supply us locally with their goods and services. In addition to this, we engage ourselves in charitable initiative – in many cases together with our employees.

Our corporate social responsibility engagement primarily focuses on those areas in which we have specific expertise stemming from our core businesses. We are thus engaged in health care projects and support education, specifically in the natural sciences. We provide disaster relief in emergency situations, especially in those regions in which we also have operations.

To increase the effectiveness of our projects, we have consolidated our resources into three global lighthouse projects:

- Through our Praziquantel Donation Program, we are partnering with the World Health Organization (WHO ) to combat the worm disease schistosomiasis in African school children.
- The Global Pharma Health Fund is a non-profit initiative funded by Merck KGaA, Darmstadt, Germany to fight counterfeit medicines in developing and emerging countries.
- The Deutsche Philharmonie is the musical ambassador of our company.

In addition, our legal entities are engaged in local projects. We have defined criteria for selecting projects, and the decisions concerning specific projects are made by our local legal entities. Our Group Communications in Darmstadt is responsible for coordinating and executing the global lighthouse projects. The Executive Board receives regular reports on the progress of the projects. We conduct annual global surveys in order to ascertain the regional distribution of our social engagement, to determine our goals and focus, and to track the development of our activities over time. In 2011, we invested a total of € 7.9 million in corporate social engagement activities, and in 2012 we invested € 11.8 million.

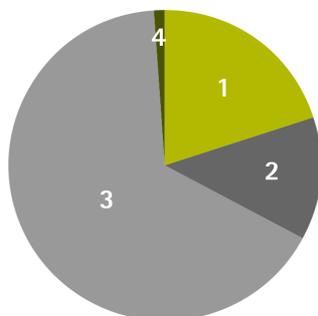
2012

11.8 million

In 2012, we invested a total of € 11.8 million in corporate social engagement activities.

Of the total monetary and supply donations made by our legal entities in 2012, 49% were made in emerging markets (Latin American and Asia, excluding Japan), 41% in Europe, 9% in North America, and 1% in the rest of the world.

Spending on local social engagement by region* in 2012 in %



1 Europe	20%
2 North America	13%
3 Emerging markets	66%
4 Rest of world	1%

* Excluding lighthouse projects.

This figure does not include activities that primarily serve to market our products. We document donations to patient organizations in Europe separately and publish this information on our website.

As part of a Bertelsmann Foundation project on corporate social engagement, we collaborated on the development of the "IOOI" method  (Input, Output, Outcome, Impact), a way of gauging and assessing social engagement. We have applied this method to our donation program to combat schistosomiasis, thus evaluating the progress of the project.

→ Global projects: Fighting schistosomiasis with praziquantel

Global projects: Fighting schistosomiasis with praziquantel

Over 200 million people in Africa suffer from the widespread tropical worm disease schistosomiasis. It is estimated that more than 200,000 die each year as a result of this chronic parasitic condition, which makes it the most common tropical disease in Africa after malaria. Schistosomiasis is widespread primarily in the tropical and subtropical areas of sub-Saharan Africa. In these regions, a vast majority of the population has no access to clean water and sanitary installations.



The disease is caused by flatworms and is spread through stagnant water. People become infected by the worm larvae in the water, while bathing, fishing, playing, washing their clothes, or working agricultural land. These larvae penetrate human skin and enter the blood vessels, where they grow into adult worms. The female's eggs infest inner organs such as the intestines, bladder, spleen, or liver, and often cause severe inflammation. Symptoms include severe abdominal pain, diarrhea, and bloody urine or stool. The infection rate is especially high among children, and the chronic symptoms that result are particularly serious. Schistosomiasis stunts growth, causes learning disabilities and leads to anemia.

Merck KGaA, Darmstadt, Germany has been supporting the World Health Organization (WHO ) since 2007 in the fight against schistosomiasis in Africa. Our efforts are thus in line with the United Nations Millennium Development Goals. In addition, they are part of the initiative to fight neglected tropical diseases that was launched by the Bill & Melinda Gates Foundation in early 2012. Merck KGaA, Darmstadt, Germany donates tablets containing the active ingredient praziquantel to WHO, which then distributes these mainly to African school children. Since the start of our Praziquantel Donation Program, over 100 million tablets have been donated. A total of more than 28 million children have been treated. In 2012 alone, Merck KGaA, Darmstadt, Germany supplied WHO with over 27 million praziquantel tablets. In 2012, an estimated seven million children were treated for schistosomiasis (final figures will be available mid-2013).

28 million

28 million children have been treated to date within the scope of our Praziquantel Donation Program to combat schistosomiasis.

Praziquantel is the only active ingredient with which all forms of schistosomiasis can be treated. In addition, praziquantel is well-tolerated. WHO has therefore included it on its Model List of Essential Medicines. Merck KGaA, Darmstadt, Germany developed praziquantel in the 1970s as part of a research collaboration. Our plant in Mexico produces the tablets under the brand name Cesol 600®; we organize and finance the transport to Africa, and WHO coordinates local distribution.

Program expansion

Originally, our program was scheduled to end in 2017. However, Merck KGaA, Darmstadt, Germany decided at the end of 2011 to continue its efforts indefinitely. The goal, agreed upon in conjunction with WHO, is to eliminate the worm disease in Africa. To this end, Merck KGaA, Darmstadt, Germany intends to increase the number of tablets donated in the medium term, raising the total to 250 million annually. This will allow around 100 million children to be treated each year.

This planned donation has a value of approximately US\$ 23 million per year; in 2012, Merck KGaA, Darmstadt, Germany invested US\$ 2.85 million (2011: US\$ 2.3 million) in the donation program. These figures include the logistics costs to ship the tablets from the production site in Mexico to Africa, but not the costs for the awareness program or the research into a pediatric formulation.

→ Global projects: Fighting schistosomiasis with praziquantel

Educating people

In addition to the tablet donation, Merck KGaA, Darmstadt, Germany is also supporting an awareness program at schools in Africa; it uses [comic booklets](#) and [posters](#) to explain the causes of schistosomiasis, teaching pupils how to prevent the disease. In 2011, a pilot project was launched at schools in Senegal and Malawi; through 1,100 brochures and 130 posters, the project reached around 1,100 school children. WHO is currently adapting the materials based on the experience gained from the pilot regions. In 2013, the program is being launched in Senegal with 750,000 brochures and in Malawi with 250,000 brochures.

Optimizing the formulation

As part of the donation program expansion, Merck KGaA, Darmstadt, Germany is also working to optimize the formulation of the drug. For instance, pharmaceutical experts are currently developing a fruity coating intended to make it easier for children to take the tablets.

Research

Within the scope of a [public-private partnership \(PPP\)](#), Merck KGaA, Darmstadt, Germany is researching a formulation of praziquantel for small children. Praziquantel tablets in their current form are suitable for adults and children over the age of six; for children younger than six, it is currently not possible to properly treat the disease. We believe that a pediatric formulation of praziquantel will be a significant step toward eliminating schistosomiasis in Africa. The partners of this public-private partnership, which was founded in July 2012, include Merck KGaA, Darmstadt, Germany, [TI Pharma](#), [Astellas Pharma Inc.](#), and the Swiss Tropical and Public Health Institute ("[Swiss TPH](#)") in Basel.

Managing and monitoring

Our Praziquantel Donation Program (MPDP) is being conducted in partnership with WHO, with Merck KGaA, Darmstadt, Germany and WHO each contributing their particular expertise. Merck KGaA, Darmstadt, Germany produces the tablets and handles the costs for transporting the tablets to Africa. WHO manages, monitors, and documents the local distribution of the Praziquantel tablets and works with local authorities to implement the treatment at schools. WHO supplies the local data on morbidity rates and treatment frequency in the countries in which our Praziquantel Donation Program has been rolled out. The data for each country can be found in [the WHO PCT databank](#). A steering committee consisting of representatives from WHO and Merck KGaA, Darmstadt, Germany convenes several times a year in order to review the program's progress and decide on its future course. The last meeting was held in Kenya in November 2012.

Evaluation

As part of a Bertelsmann Foundation project on corporate social engagement, we collaborated on the development of the "[IOOI](#)" method (Input, Output, Outcome, Impact), a way of gauging and assessing social engagement. We have applied this method to our donation program to combat schistosomiasis, which allows us to evaluate the progress of the project.

Praziquantel: Evaluation

	Indicators	Measuring instruments
Impact	1% infection rate = Schistosomiasis has been eliminated as a public health issue.	Scientific studies conducted by WHO
Outcome	Infection rate	In 2013, WHO is conducting scientific studies in select countries; reviewing the scope of treatment via the WHO PCT online databank.
Output	Number of school children who received praziquantel in one year.	Medical experts and teachers document the treatment of school children. WHO consolidates these data into reports on the distribution of the tablets in the individual countries.

→ Global projects: Fighting schistosomiasis with praziquantel

Praziquantel: Evaluation

	Indicators	Measuring instruments
Input	Number of tablets supplied by Merck KGaA, Darmstadt, Germany to the individual countries.	A logistics partner delivers the tablets to Africa and reports on their distribution.

Goals: Praziquantel

Strategic goal	Action	By?	Status in 2011 and 2012	Status
Eliminate the worm disease schistosomiasis in Africa	Provide tablets containing praziquantel free of charge to treat school children in Africa	Ongoing	More than 100 million tablets were donated from the beginning of the project to the end of 2012. More than 28 million children were treated in total (figure not yet final; figures for 2012 will not be finalized until July 2013). In 2011 and 2012, over seven million children were treated. 2011: 25 million tablets provided to nine countries in Africa 2012: 27 million tablets provided to eight countries in Africa	
	Run an awareness program to explain the causes of schistosomiasis and potential preventive measures.	End of 2013	Until mid-2012, instructional materials were tested in Senegal and Malawi as part of a pilot project. In 2013, the awareness program will be initiated in both countries, taking into account experience from the pilot projects.	
	Incrementally increase the number of tablets donated annually by a factor of ten, up to 250 million	End of 2016	Currently searching for additional API suppliers.	
	Research a new formulation of praziquantel for children under 6 years old		In July 2012, a public-private partnership (PPP) was founded. Milestone: Preclinical development is to be completed by 2014; clinical development is scheduled to start in 2014.	
	Optimize the praziquantel formulation	End of 2014	Development of a film coating to make the tablets easier for patients to swallow and to make them even more resistant to long transport times.	

Legend:  Achieved  In progress  Not achieved  New goal

→ Global projects: Combating counterfeit medicines with the Minilab

Global projects: Combating counterfeit medicines with the Minilab

Substandard and counterfeit medicines pose a deadly hazard. Interpol estimates that up to 30% of all medicines in developing health care systems fall into this category. The Global Pharma Health Fund (GPHF ) , a non-profit initiative funded by Merck KGaA, Darmstadt, Germany, is dedicated to fighting counterfeit medicines: the Minilab developed by the GPHF is able to detect counterfeit medicines quickly, easily and cheaply. Two test kits each weighing around 30 kilograms contain a large number of test methods that state health care workers in developing countries can use to inspect pharmaceuticals. Reference samples are used to test the identity and concentration of altogether 63 active ingredients in total, ranging from anti-malarial drugs to antibiotics up to analgesics and antipyretics.



The GPHF developed the Minilab specifically for use in regions with a simple infrastructure. The rapid analyses do not rely on external power sources and normal drinking water suffices for the tests. There is currently no other product like it. To date, the GPHF has supplied 578 Minilabs at cost to 86 countries. More than half of these countries are in Africa, and one third of them are in Asia. The Minilabs are primarily utilized by local health authorities, often in collaboration with labs for governmental drug inspection centers

Merck KGaA, Darmstadt, Germany participates in external research with the aim of increasing the number of medicines that can be tested. In 2011 and 2012, the GPHF developed testing methods for seven other pharmaceuticals each and updated the user manuals accordingly. The GPHF also offers training courses in order to familiarize users with the test procedures. In 2012, training courses were held in Russia, Myanmar, Angola, Germany, and Indonesia.

A total of 77 Minilabs were supplied in 2011 and 100 in 2012. In addition to selling them at cost, which is handled via a distribution partner, both the GPHF and Merck KGaA, Darmstadt, Germany donate Minilabs in individual cases. In 2012, Merck KGaA, Darmstadt, Germany donated ten Minilabs to the Angolan Ministry of Health, and the GPHF donated five labs to the Ministry of Health of Zambia, five to the Ministry of Health and Welfare of Tanzania, and one to the Ghanaian Ministry of Health.

Goals: Minilab

Strategic goal	Action	By?	Status in 2011 and 2012	Status
Combat counterfeit medicines by providing and further developing the mobile GPHF Minilab	Develop new test methods for five active ingredients and add the descriptions of the new test methods to the user manuals	End of 2011	2011: Seven new test methods were developed. 2012: Five training seminars were conducted on using the GPHF Minilab, and seven new test methods were developed.	
	Conduct three training seminars on using the GPHF Minilab, sell 50 Minilabs, develop seven new test methods	End of 2013		

Legend:  Achieved  In progress  Not achieved  New goal

→ Global projects: Philharmonic Orchestra

Global projects: Philharmonic Orchestra

We also have a long tradition of cultural engagement. We consider classical music in particular to be the universal language that brings people together; as such, it is an important part of our culture, which is represented by Philharmonic Orchestra, our musical ambassador. The concerts of this professional ensemble are highly popular, with more than 20,000 people attending them per year. They represent an integral part of the cultural life in the vicinity of our corporate headquarters in Darmstadt, Germany. Special events for children and youth as well as collaboration with schools, such as the annual orchestra workshop held for the first time in 2010, aim to make classical music more accessible to young people.



Furthermore, Philharmonic Orchestra regularly invites international guest ensembles to Darmstadt and also goes on international concert tours itself.

In 2011, the orchestra toured India, with more than 10,000 people attending the classical music concerts in Mumbai, Pune, New Delhi, Goa, Hyderabad, Bangalore, and Chennai. Our Philharmonic Orchestra thus helps to present our corporate culture to employees, customers and many other people. In summer 2013, our Philharmonic Orchestra will be participating in an international jazz festival in Istanbul.

Local responsibility

It is also imperative to show responsibility at the local level: In accordance with our values, we call upon all of our legal entities to assume responsibility for their local communities. After all, they foster an open dialogue with their neighbors and therefore know where Merck KGaA, Darmstadt, Germany can make the most valuable contributions. The individual companies can orient their activities toward our Group-wide framework, which defines the following areas of focus for local engagement: health, education, environment, culture, and sports in the vicinity of our sites. In 2011 and 2012, the legal entities participated in more than 120 projects. These are often long-term projects that are sponsored by Merck KGaA, Darmstadt, Germany for multiple years. Numerous initiatives are either supported or even started up by employees. In 2011, 3,675 employees strengthened corporate engagement at Merck KGaA, Darmstadt, Germany by making donations or doing volunteer work for charitable purposes, and in 2012 6,987 employees did so.



Examples include constructing and running a hospital on the island of Baba Bhit in Pakistan, as well as sponsoring projects to help integrate disadvantaged youth in Brazil. The legal entities in India and China award scholarships that enable young people to receive a good education, which they could otherwise not afford without support. Employees at our legal entity in Guatemala are building houses for underprivileged people in collaboration with a charitable organization. In addition to this, we provide disaster relief; in 2011, this went to the victims of the earthquake and tsunami in Japan as well as the victims of the flooding in Thailand.

➤ More examples of local engagement can be found on our website [☞](#)

Facts and figures



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In this chapter, we present the facts and figures of our report. The report profile specifies the reporting framework, shows how data was collected, and describes how the content of the report was determined. We use indicators to facilitate comparison of our ecological, economic and social performance. The figures have been subjected to a limited assurance audit. We have compiled our goals, prizes and awards into a single overview. The GRI Index documents Merck KGaA, Darmstadt, Germany's fulfillment of the requirements of the GRI guidelines on sustainability reporting. In the Communication on Progress for the Global Compact, we describe the implementation of the Compact's ten principles.

→ Report profile

Report profile

This is our sixth Corporate Responsibility (CR) Report. We have a long tradition of reporting on topics pertaining to our corporate responsibility. Since as early as 1993, we have been reporting on how we fulfill this obligation; initially, we published environmental reports, but then in 2003, we started publishing a full Corporate Responsibility report every two years. Our goal is to inform people about our activities, successes and challenges. At the same time, our CR Report documents the progress we've made in implementing the principles of the United Nations Global Compact ("Communication on Progress").

Reporting framework

This CR Report covers the 2011 and 2012 fiscal years and pertains to Merck KGaA, Darmstadt, Germany with its 203 sites in 66 countries. Any deviations from this reporting framework are indicated in each specific case.

Systems for collecting and consolidating data

Since 2005, we have been using the Group-wide electronic Location Information Online System (LION) to collect environmental data as well as occupational health and safety data. The data is input locally at the individual sites and approved after being reviewed. In order to ensure that the data is reliable, the function Environment Health Safety Security Quality (EQ) furthermore checks the feasibility of the data.

We compile environmentally relevant performance indicators from all Merck KGaA, Darmstadt, Germany production sites, as well as relevant warehouse and research sites. In assessing the relevance of the warehouse and research sites, we take into account the sites' environmental impact as well as the number of employees there. LION's scope of consolidation therefore covers all Merck KGaA, Darmstadt, Germany sites that relevantly impact the environment.

For the indicators on occupational health and safety, we have furthermore incorporated additional warehouse sites and branch offices into our data collection process, covering more than 95% of all employees.

To improve data quality, we help the sites optimize their data collection processes as well as the associated quality control. The processes and the reported data are audited by EQ and examined in the course of internal EHS audits.

The data on employees and social engagement pertain to Merck KGaA, Darmstadt, Germany. Employee master data is continually updated in an SAP-based database. Other employee data, for example data pertaining to core ILO standards, and data on social engagement are queried on an annual basis.

Some employee data is only reported for the sites in Darmstadt, Gernsheim and Grafing (all in Germany), which employed 24% of our employees in 2012. We indicate accordingly when this is the case.

Determining report content

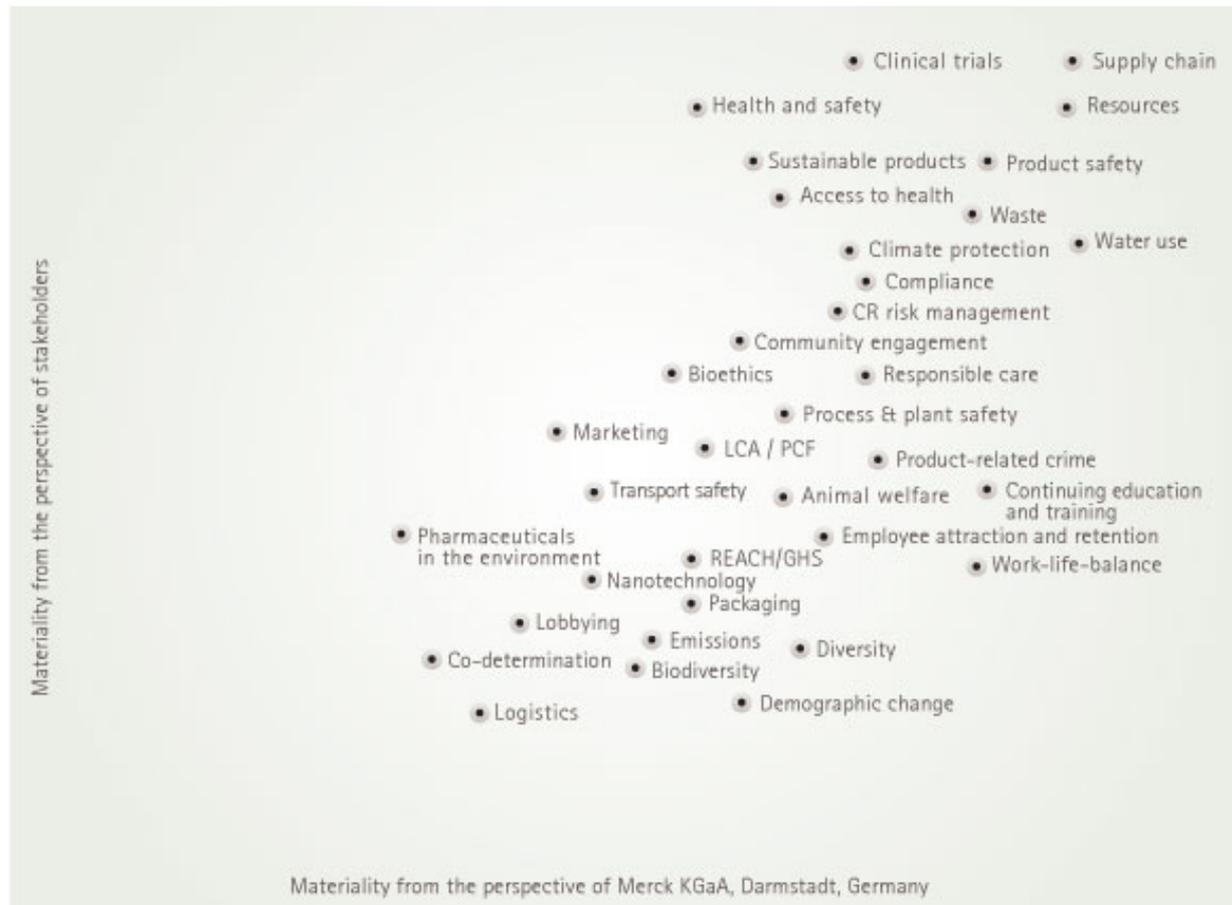
The content of our CR report is oriented to the internationally recognized G3.1 Guidelines of the Global Reporting Initiative (GRI). This report meets the criteria for an A+ application level (confirmed by GRI).

We have furthermore taken into consideration the requirements of the capital market for assessing companies' contributions to sustainability. In summer 2012, we conducted a materiality analysis to determine the CR topics of relevance to Merck KGaA, Darmstadt, Germany. Both online and via telephone, we surveyed 85 stakeholders, including customers, non-governmental organizations, Merck KGaA, Darmstadt, Germany employees, and scientists. Internal workshops were then held to assess the results in terms of their materiality for the company. The results of the materiality analysis are presented in the materiality matrix. The higher and farther to the right a topic is in the matrix, the more important it is for our stakeholders as well as for our business activities.

We have derived the content of this CR Report from the results of the materiality analysis. The report addresses all topics identified as material.

→ Report profile

Materiality analysis



External audit

KPMG AG Wirtschaftsprüfungsgesellschaft has audited the annual financial statements and management report of the Merck KGaA, Darmstadt, Germany and issued an unqualified opinion. Furthermore, after undergoing a limited assurance audit, Merck KGaA, Darmstadt, Germany has obtained an independent audit certificate for the non-financial key performance indicators.

Point of contact:

We are happy to receive your feedback and answer your questions.

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Our next CR report is scheduled for publication in April 2015.

Indicators

The figures presented below pertain to Merck KGaA, Darmstadt, Germany, unless otherwise indicated.

You can find further information on our reporting framework and data collection systems in our [report profile](#).

The following indicators have undergone a limited assurance audit by KPMG AG Wirtschaftsprüfungsgesellschaft.



Indicators in this chapter:

- › Indicators: Economics
- › Indicators: Compliance
- › Indicators: Employees
- › Indicators: Environment
- › Indicators: Society

→ Indicators: Economics

Indicators: Economics

Total revenues, sales, operating result (EBIT), and R&D costs broken down by division (€ million)

	Prescription medicines division	Consumer Health	Performance Materials	Life science tools division	Group**
2011*					
Total revenues	5,920.0	496.2	1,467.4	2,392.8	10,276.4
Sales	5,564.4	494.2	1,464.7	2,382.6	9,905.9
Total operating result (EBIT)	342.2	46.9	691.0	235.4	1,132.1
Research and development costs	1,224.5	22.8	132.8	133.4	1,514.0
2012					
Total revenues	6,405.2	475.2	1,675.6	2,619.9	11,172.9
Sales	5,995.8	472.6	1,674.2	2,598.2	10,740.8
Total operating result (EBIT)	508.3	4.3	598.5	233.2	963.6
Research and development costs	1,187.3	19.4	137.4	166.1	1,511.3

* The previous year's figures have been adjusted (see Annual Report 2012, Accounting Policies [↗](#)).

** As a non-operating segment, Corporate and Other is not shown here (see Annual Report 2012, Segment Reporting [↗](#)).

2012 was a highly successful year for Merck KGaA, Darmstadt, Germany, shaped by significant changes. Total sales rose by 8.7% to € 11,173 million due to organic growth of 4.8%, growth from currency effects of 3.6% and a 0.3% increase resulting from acquisition effects (see Annual Report 2012, Financial Position and Results of Operations [↗](#)).

In 2012, Merck KGaA, Darmstadt, Germany reported a 14.9% decline in the operating result (EBIT [↗](#)) to € 964 million, while the operating result excluding depreciation and amortization (EBITDA [↗](#)) was down 13.6% to € 2,360 million, primarily due to the one-time restructuring costs (see Annual Report 2012, Financial Position and Results of Operations [↗](#)).

At € 1,511 million, R&D spending remained roughly at the 2011 level (see Annual Report 2012, Financial Position and Results of Operations [↗](#)).

→ Indicators: Compliance

Indicators: Compliance

Internal audits on corruption and Social Charter

	2008	2009	2010	2011	2012
Number of audits relating to corruption	36	32	34	28	40
Number of audits relating to Social Charter	–	–	26	26	40

Compliance violations reported via the SpeakUp Line

	2008	2009	2010	2011	2012
Number of reported compliance incidents	Not recorded	14	21	29	20
Number of confirmed cases	Not recorded	3	3	5	5

Compliance training seminars

	2008	2009	2010	2011	2012
Number of employees trained in anti-corruption policies and procedures*	556	6,400	8,600	13,399	22,890
% of employees trained on the topic of anti-corruption	2	19	21	33	59
Number of employees Global Grade 10 or higher who are trained on the topic of anti-corruption**	Not recorded	Not recorded	Not recorded	7,540	10,164
% of employees Global Grade 10 or higher who are trained on the topic of anti-corruption**	Not recorded	Not recorded	Not recorded	53	60
% of employees Global Grade 9 or lower who are trained on the topic of anti-corruption**	Not recorded	Not recorded	Not recorded	22	58

* Until 2010, anti-corruption training was part of Code of Conduct training seminars.

In order to address the special responsibility held by employees of a certain management level, as well as by employees with HR responsibility, these employees are increasingly receiving anti-corruption training. This includes all employees rated Global Grade (GG) 10 or higher.

→ Indicators: Employees

Indicators: Employees

Workforce structure

Number of total employees

As of Dec. 31	2008	2009	2010	2011	2012
Total employees	32,800	33,062	40,562	40,676	38,847
Men	Not recorded	19,097	23,171	23,347	22,505
Women	Not recorded	13,965	17,391	17,329	16,342

The "Fit for 2018" efficiency program made a major impact on HR work in 2012. In the majority of countries in which Merck KGaA, Darmstadt, Germany is represented, structural requirements and agreements were reached with the respective social partners in order to create a socially responsible approach to workforce reduction. For example, a partial retirement program and a voluntary leaver program were offered in Germany, with around 1,200 employees participating by the end of 2012. Compared to 2011, the total number of employees in 2012 decreased by 1,829, or 4.5%.

Number of employees according to hierarchical level

As of Dec. 31	2008	2009	2010	2011	2012
Total employees	32,800	33,062	40,562	40,676	38,847
Senior Management (Global Grade above 17)	Not recorded	Not recorded	51*	49*	54
Low and middle management (Global Grade 14-17)	Not recorded	Not recorded	1,354*	1,355*	1,719
Other employees (Global Grade below 14)	Not recorded	Not recorded	39,157*	39,272*	37,074

* Figures do not entirely include the employees of the Millipore Corporation, which was acquired in July 2010. The Global Grading System was instituted there incrementally.

Average number of employees according to functional areas

	2008	2009	2010	2011	2012
Entire Group	Not recorded	32,850	36,347	40,570	39,939
Production	Not recorded	6,956	8,327	9,317	9,486
Logistics	Not recorded	1,773	1,927	2,054	1,665
Marketing and sales	Not recorded	10,582	11,541	12,322	12,353
Administration	Not recorded	3,750	4,378	4,696	4,416
Research and development	Not recorded	3,627	4,116	4,632	4,558
Infrastructure and other	Not recorded	6,162	6,058	7,549	7,461

→ Indicators: Employees

Number of employees by region

As of Dec. 31	2008	2009	2010	2011	2012
Total	32,800	33,062	40,562	40,676	38,847
Employees in Europe	*	*	*	21,830	20,777
thereof women	*	*	*	9,832	9,261
Employees in North America	*	*	*	4,964	4,848
thereof women	*	*	*	2,314	2,225
Employees in Emerging markets**	*	*	*	12,229	11,642
thereof women	*	*	*	4,565	4,274
Employees in Rest of world	*	*	*	1,653	1,580
thereof women	*	*	*	618	582

* No retroactive calculation based on the new regional structure.

** Latin America and Asia excluding Japan.

Full-time and part-time employees

As of Dec. 31	2008	2009	2010	2011	2012
% of full-time employees	94	94	94	94	94
% of part-time employees	6	6	6	6	6

In 2012, the percentage of women working full-time at Merck KGaA, Darmstadt, Germany was 39% (2011: 40%); in 2012, the percentage of women working part-time was 90% (2011: 92%).

In 2011, 11% of employees worked part-time at the Darmstadt, Gernsheim and Grafing sites in Germany, with 13% working part-time there in 2012.

Temporary and permanent contracts

As of Dec. 31	2008	2009	2010	2011	2012
Total employees	32,800	33,062	40,562	40,676	38,847
Number of employees with permanent contracts	Not recorded	Not recorded	Not recorded	39,261	37,732
Number of employees with temporary contracts	Not recorded	Not recorded	Not recorded	1,415	1,115

Only 3% of Merck KGaA, Darmstadt, Germany employees have temporary contracts.

In 2012, 42% of Merck KGaA, Darmstadt, Germany employees with permanent contracts were women (2011: 42%); 46% of the employees with temporary contracts were women (2011: 49%).

→ Indicators: Employees

Staff turnover

	2008	2009	2010	2011	2012
Total turnover rate	Not recorded	Not recorded	Not recorded	13.42	13.34
Turnover rate by gender					
Men	Not recorded	Not recorded	Not recorded	12.80	12.87
Women	Not recorded	Not recorded	Not recorded	14.26	13.99
Turnover rate by age group					
Up to 29 years old	Not recorded	Not recorded	Not recorded	21.74	21.76
30 to 49 years old	Not recorded	Not recorded	Not recorded	11.63	12.19
50 or older	Not recorded	Not recorded	Not recorded	11.79	10.01
Turnover rate by region					
Europe	Not recorded	Not recorded	Not recorded	8.65	9.22
North America	Not recorded	Not recorded	Not recorded	14.73	12.59
Emerging markets	Not recorded	Not recorded	Not recorded	20.85	20.93
Rest of world	Not recorded	Not recorded	Not recorded	16.55	14.24

The table contains unadjusted turnover rates, calculated as follows: Number of employees departing x 100/average workforce in %.

The adjusted turnover rate excludes employees who leave due to parental leave or a long-term illness, as well as employees who are transitioning to the non-working phase of partial retirement.

Staff turnover

	2008	2009	2010	2011	2012
Turnover rate of employees who were hired during the 18 months preceding Dec. 31 of the respective year	Not recorded	Not recorded	Not recorded	12.23	14.07
Turnover rate by gender					
Men	Not recorded	Not recorded	Not recorded	13.49	15.20
Women	Not recorded	Not recorded	Not recorded	10.42	12.34
Turnover rate by age group					
Up to 29 years old	Not recorded	Not recorded	Not recorded	16.25	16.20
30 to 49 years old	Not recorded	Not recorded	Not recorded	9.18	12.73
50 or older	Not recorded	Not recorded	Not recorded	8.51	9.69
Turnover rate by region					
Europe	Not recorded	Not recorded	Not recorded	7.16	8.16
North America	Not recorded	Not recorded	Not recorded	7.30	7.91
Emerging markets	Not recorded	Not recorded	Not recorded	17.11	19.06
Rest of world	Not recorded	Not recorded	Not recorded	5.67	11.90

Merck KGaA, Darmstadt, Germany records the new employee turnover rate over the course of 18 months because 12 months is too short a time to become truly familiar with a new position, especially when it comes to management positions.

The turnover rate is calculated as follows: (Number of newly hired employees within the preceding 18 months that left Merck KGaA, Darmstadt, Germany within the same period)/(average number of employees in the preceding 18 months)*100

→ Indicators: Employees

The figures exclude employees who leave due to parental leave or a long-term illness, as well as employees who are transitioning to the non-working phase of partial retirement.

Core labor standards of the International Labour Organization (ILO)

As of Dec. 31	2008	2009	2010	2011	2012
% of full-time employees (standard contract, excluding exempts) with contractually stipulated working hours of maximally 48 hours/week ¹	99	99	99	99	99
% of full-time employees (standard contract) with at least 15 vacation days/year ²	93	95	94	96	95
% of female employees with access to maternity leave programs ³	89	97	100	100	100
% of employees with the right to collective bargaining ⁴	78*	76*	96	96	97
% of sites that rule out complicity in child labor as described in ILO Convention 138	100	100	100	100	100
Age of youngest employees, excluding apprentices	17	17	17	18	18

1 ILO: Hours of Work (Commerce and Offices) Convention, 1930 (No. 30).

2 ILO: Holidays with Pay Convention (Revised), 1970 (No. 132).

3 ILO: Holidays with Pay Convention (Revised), 1952 (No. 103).

4 ILO: Freedom of Association and Protection of the Right to Organize Convention, 1948 (No. 87).

* Since 2010, Merck KGaA, Darmstadt, Germany has been recording the percentage of employees who have a right to collective bargaining. In the years prior to this, we recorded the employees who were subject to collective bargaining.

Local minimum wage

	2008	2009	2010	2011	2012
% of sites that guarantee a salary above the local minimum wage*	94	94	100	99	100

* Minimum wage as stipulated by law, or derived from other provisions such as collective agreements.

The Global Rewards Policy applies to all Merck KGaA, Darmstadt, Germany legal entities worldwide and guarantees a systematic compensation structure. Base pay is oriented to the median base pay, and short-term variable compensation is based on the third quartile of the relevant reference market. The overall compensation package thus exceeds the market median.

→ Indicators: Employees

Occupational health and safety

Work-related accidents

	2008	2009	2010	2011	2012
Lost Time Injury Rate (LTIR)	3.9	3.5	3.0	2.0	2.3
Number of deaths	1	0	1	0	0

Merck KGaA, Darmstadt, Germany employees have been included in the calculation of the indicators, but supervised employees of external companies and independent contractors have not been taken into account.

Using the LTIR, we record work-related accidents of Merck KGaA, Darmstadt, Germany employees that involve at least one day of missed work. A work-related accident is an injury that results from the type of work, in the course of doing said work, and that has no internal cause (cumulative trauma). Work-related accidents are considered relevant if they occur on the premises, on business trips, during a transport accident, in the course of external influences (e.g. natural disasters), or due to criminal acts involving personal injury. Commuting accidents and accidents during company sporting activities are not included. First-aid incidents are generally not included in the LTIR since these usually do not result in more than one day of missed work.

Through systematic accident prevention measures (such as training and campaigns to strengthen our corporate safety culture), we attained an LTIR of 2.0 in 2011 and an LTIR of 2.3 in 2012. We are working to lastingly stabilize the LTIR.

For Merck KGaA (24% of the employees of the Merck KGaA, Darmstadt, Germany Group), we report work-related illnesses if these have been diagnosed and certified by a physician. In the 2011–2012 period, one case of work-induced illness was reported. We do not keep track of the number of work-related illnesses throughout Merck KGaA, Darmstadt, Germany.

Continuing education and training

Spending on advanced training for employees (€)

	2008	2009	2010	2011	2012
Average continuing education spending per employee	1,064	1,102	1,152	982	699

Due to savings measures within the "Fit for 2018" efficiency program, average continuing education spending per employee in 2012 decreased by 29% relative to 2011, and 2011 spending decreased by 15% relative to 2010. Aside from this, the increasing trend toward e-learning has also contributed to a reduction in training costs.

Apprentices*

As of Dec. 31	2008	2009	2010	2011	2012
Number of apprentices	503	520	513	523	528
% of apprentices	5.6	5.7	5.9	5.6	5.7

* Only pertains to the Darmstadt, Gernsheim and Grafing sites in Germany (which accounted for around 24% of Merck KGaA, Darmstadt, Germany employees in 2012).

→ Indicators: Employees

Employees who regularly receive a performance and development evaluation

As of Dec. 31	2008	2009	2010	2011	2012
% of employees who regularly receive a performance and development evaluation	Not recorded	Not recorded	88	98	98

Our globally uniform Performance Management process requires annual feedback discussions and performance assessments for all employees that are rated above Global Grade 10 in our position assessment system. Apart from evaluating employee performance, it helps us to identify individual development opportunities. To date, 23,800 employees worldwide have been involved in the process.

For all other employees that do not participate online in this globally uniform process, other methods of performance assessment are available. Thus in 2012, 98% of employees took part in a performance and development evaluation.

Diversity and inclusion

Percentage of women

As of Dec. 31	2008	2009	2010	2011	2012
% of women in the entire workforce	42	43	43	43	42
% of management positions held by women (Global Grade 14 or above)*	Not recorded	17	22*	23*	24
% of women in the prescription medicines division and Consumer Health divisions	Not recorded	Not recorded	47	47	46
% of women in the Performance Materials and life science tools divisions	Not recorded	Not recorded	33	38	37

* These figures do not entirely include the employees of the Millipore Corporation, which was acquired in July 2010. The Global Grading System was instituted there incrementally.

Since 2009, we have been continually increasing the percentage of management positions held by women. 23% of management positions were held by women in 2011, and 24% were held by women in 2012.

We aim to increase the percentage of management positions (Global Grade 14 or above) held by women to at least 25%–30% by 2016, and we are on the right track to reaching this goal.

Internationality of employees

	2008	2009	2010*	2011*	2012
Number of nationalities	117	111	128	125	121
Number of nationalities in management positions (Global Grade 14 or above)	Not recorded	56	55	54	57

* These figures do not entirely include the employees of the Millipore Corporation, which was acquired in July 2010. The Global Grading System was instituted there incrementally.

→ Indicators: Employees

Internationality of employees

	2008	2009	2010*	2011*	2012
% of non-Germans in management positions (Global Grade 14 or above)	Not recorded	58	57	56	61

* These figures do not entirely include the employees of the Millipore Corporation, which was acquired in July 2010. The Global Grading System was instituted there incrementally.

Employee age, by individual region

	Worldwide	North America	Europe (including Germany)	Germany	Emerging markets	Rest of world
2011						
Up to 29 years old	6,856	543	2,764	1,581	3,306	243
thereof women	3,014	269	1,371	661	1,274	100
30 to 49 years old	26,513	2,996	14,407	6,526	8,002	1,108
thereof women	11,563	1,397	6,664	2,509	3,064	438
50 or older	7,307	1,425	4,659	2,793	921	302
thereof women	2,752	648	1,797	951	227	80
Average age	39.7	43.1	41.2	41.9	35.4	39.8
Total employees	40,676	4,964	21,830	10,900	12,229	1,653
2012						
Up to 29 years old	5,957	508	2,354	1,466	2,878	217
thereof women	2,476	226	1,104	593	1,067	79
30 to 49 years old	25,329	2,843	13,592	6,361	7,835	1,059
thereof women	11,027	1,339	6,290	2,478	2,976	422
50 or older	7,561	1,497	4,831	2,961	929	304
thereof women	2,839	660	1,867	1,022	231	81
Average age	40.2	43.6	41.8	42.3	36.0	40.3
Total employees	38,847	4,848	20,777	10,788	11,642	1,580

Employees with disabilities* (%)

As of Dec. 31	2008	2009	2010	2011	2012
Employees with disabilities*	4.2	4.1	4.1	4.2	4.9

* Only pertains to the Darmstadt, Gernsheim and Grafing sites in Germany (which accounted for around 24% of Merck KGaA, Darmstadt, Germany employees in 2012). The figures for 2009-2011 have been retroactively adjusted (calculations based on the German Social Code IX - SGB IX).

→ Indicators: Employees

Insurance and retirement benefits for employees

Insurance and pension systems for employees

	2008	2009	2010	2011	2012
% of employees who are obliged to contribute to a statutory pension system	87	90	95*	98	99
% of employees in a company pension plan (also in addition to the statutory pension plan)	70	67	68	68	68
% of employees with company accident insurance	99	97	100	100	100
% of employees with statutory health insurance	82	78	88	88	87
% of employees with employer-funded health insurance	82	82	88	88	93

* Due to new data provided these figures have been retroactively adjusted.

Long-term benefit obligations and retirement pensions (€ million)

	2008	2009	2010	2011	2012
Present value of all benefit obligations as of Dec. 31	1,586	1,878	2,356	2,490	2,830
Pension expenses	93	98	132	168	159

Depending on the legal, economic and fiscal circumstances prevailing in each country, differing retirement benefit systems are provided for the employees of the Merck KGaA, Darmstadt, Germany. As a rule, these systems are based on length of service and salary of the employees. Pension obligations of Merck KGaA, Darmstadt, Germany include both defined benefit and defined contribution plans and comprise both obligations from current pensions and accrued benefits for pensions payable in the future. At Merck KGaA, Darmstadt, Germany, defined benefit plans are funded and unfunded. These provisions also contain other post-employment benefits, such as accrued future health care costs for retirees in the United States (see Annual Report 2012, Notes to the Provisions for pensions and other post-employment benefits).

Reconciling the demands of a career and family

Flexible working hours

	2008	2009	2010	2011	2012
% of employees with the option of working flexible hours	Not recorded	Not recorded	57	58	69

→ Indicators: Employees

Parental leave in Germany*

As of Dec. 31	2008	2009	2010	2011	2012
Number of employees with a right to parental leave	Not recorded	Not recorded	Not recorded	237	299
Thereof women (recorded via maternity leave in the respective year)	Not recorded	Not recorded	Not recorded	82	139
Thereof men (recorded via special paternity leave in the respective year)	Not recorded	Not recorded	Not recorded	155	160
Number of employees who took parental leave	234	162	426	401	434
Thereof women	Not recorded	Not recorded	Not recorded	283	303
Thereof men	Not recorded	Not recorded	Not recorded	118	131
Number of employees on parental leave who worked part time during their leave	Not recorded	Not recorded	Not recorded	123	137
Thereof women	Not recorded	Not recorded	Not recorded	117	135
Thereof men	Not recorded	Not recorded	Not recorded	6	2
Number of employees who returned from parental leave	Not recorded	Not recorded	Not recorded	144	162
Thereof women	Not recorded	Not recorded	Not recorded	58	62
Thereof men	Not recorded	Not recorded	Not recorded	86	100
Number of employees still working for Merck KGaA, Darmstadt, Germany one year after their return from parental leave	Not recorded	Not recorded	Not recorded	140	***
Thereof women	Not recorded	Not recorded	Not recorded	55	***
Thereof men	Not recorded	Not recorded	Not recorded	85	***

* Figures only pertain to the Darmstadt, Gernsheim and Grafing sites in Germany (which accounted for around 24% of Merck KGaA, Darmstadt, Germany employees in 2012). For 2008 and 2009, the figures were calculated based on the data as of Dec. 31 of the respective year; since 2010, the data from the entire year has provided the basis for the calculation, which also includes those employees who took parental leave during the calendar year, but who had returned by Dec. 31.

** Since parental leave can be taken for a period ranging from one month to three years, it is possible for employees to be recorded across a period of up to four calendar years. This explains why the number of employees on parental leave exceeds the number of employees who have a right to it.

*** Figure will be available on Dec. 31, 2013.

→ Indicators: Environment

Indicators: Environment

Environmental management

Spending on environmental protection, safety and health (€ million)

	2008	2009	2010	2011	2012
Spending	131	131	140	141	146

These figures include both investments in as well as internal and external spending on waste and wastewater management, water, occupational safety, fire protection, noise reduction, air pollution prevention, decontamination, preservation of nature and the landscape, climate protection, and energy efficiency.

Greenhouse gas emissions

Total greenhouse gas emissions (metric kilotons) (Scope 1 and 2 of the GHG Protocol)

	2006	2007	2008	2009	2010	2011	2012
Total CO ₂ eq emissions	542	598	513	489	556	521	516
Direct CO ₂ eq emissions	318	370	303	302	352	318	319
Indirect CO ₂ eq emissions	224	228	210	187	204	203	197

Portfolio-adjusted in line with the Greenhouse Gas (GHG) Protocol.
eq = equivalents.

Our response to the Carbon Disclosure Project contains a detailed description of our calculation methods.

Greenhouse gas emissions in 2011 decreased 6% relative to 2010. Our EDISON program is thus already making progress. These figures do not include emissions from using biomass to create energy. In 2012, emissions totaled 5.1 metric kilotons (2011: 4.9 metric kilotons).

Other relevant indirect greenhouse gas emissions (Scope 3 of the GHG Protocol)

	2008	2009	2010	2011	2012
From air travel (metric kilotons)*	35	34	29	47	48
From rail travel (metric tons)**	147	138	160	121	122
From rental car travel (metric tons)***	Not recorded	Not recorded	Not recorded	Not recorded	848

* Estimated at around 70%-80% of air travel within Merck KGaA, Darmstadt, Germany. The flight-related CO₂ emissions recorded in this manner are calculated using [atmosfair](#) (except for 2010).

** Recorded Germany-wide. Data is provided by Deutsche Bahn AG.

*** Emissions from rental car use in Europe and North America.

eq = equivalent.

→ Indicators: Environment

Other air emissions

Emissions of ozone-depleting substances (metric tons)

	2008	2009	2010	2011	2012
Total emissions of ozone-depleting substances	1.3	0.8	0.7	1.0	1.9
CFC-11eq*	Not recorded	Not recorded	0.04	0.06	0.1

* CFC-11eq is a unit of measure used to compare the potential of various substances to deplete the ozone. Reference figure 1 indicates the potential of CFC-11 and CFC-12 to cause the depletion of the ozone layer.

Other air emissions (metric kilotons)

	2008	2009	2010	2011	2012
VOC (Volatile organic compounds)	1.9	0.2	0.2	0.2	0.2
Nitrogen oxide	0.2	0.1	0.2	0.1	0.2
Sulfur dioxide	0.05	0.03	0.03	0.02	0.02
Dust	0.02	0.02	0.02	0.03	0.03

The VOC, nitrogen oxide, sulfur dioxide and dust emissions reported here are production-related. These figures do not include emissions from vehicles. Emissions are determined partially based on measurements and partially based on calculations or estimates. Only some sites are required to measure individual parameters.

Transport

Transport of finished goods, broken down by means of transportation*

	2008	2009	2010	2011	2012
% Truck	63	60	58	58	58
% Boat	32	35	36	36	36
% Airplane	5	5	6	6	6

* Pertains to goods shipped by Merck KGaA, Darmstadt, Germany sites in Germany. These figures pertain to the total weight of the transported products. Indicated here is the primary means of transport.

In shipping finished goods from production sites to local warehouses of the legal entities, we are working to reduce the use of air shipping in favor of sea shipping. In doing so, we cut costs and reduce the CO₂ emissions incurred by transporting goods.

In 2012, this switch led to savings of 2,000 metric tons of CO₂.

→ Indicators: Environment

Resource consumption

Energy consumption (in GWh)					
	2008	2009	2010	2011	2012
Total energy consumption	1,435	1,322	1,455	1,446	1,438
Direct energy consumption	913	835	922	917	933
Natural gas	810	752	811	808	829
Liquid fossil fuels*	95	68	97	97	91
Biomass	8	15	14	12	13
Indirect energy consumption	522	487	533	529	505
Electricity	503	466	509	508	488
Steam	19	21	24	21	17

Energy consumption (in TJ)					
	2008	2009	2010	2011	2012
Total energy consumption	5,166	4,759	5,238	5,206	5,177
Direct energy consumption	3,287	3,006	3,319	3,301	3,359
Natural gas	2,916	2,707	2,920	2,909	2,984
Liquid fossil fuels*	342	245	349	349	328
Biomass	29	54	50	43	47
Indirect energy consumption	1,879	1,753	1,919	1,905	1,818
Electricity	1,811	1,678	1,832	1,829	1,757
Steam	68	75	87	76	61

Portfolio-adjusted in line with the Greenhouse Gas Protocol.

* Light and heavy fuel oil, liquified petroleum gas (LPG), diesel and unleaded gas.

At our sites in Billerica, Massachusetts (USA), Bedford, Massachusetts (USA), Molsheim (France), Tel Aviv (Israel), and Rome (Italy), we use photovoltaics to produce power.

Water consumption (in millions of m ³)					
	2008	2009	2010	2011	2012
Total water consumption	21.3	16.2	18.0	17.6	16.2
Surface water (rivers, lakes)	11.3	7.6	8.7	8.3	7.0
Groundwater	6.6	5.7	5.5	5.7	5.3
Drinking water (from local suppliers)	3.4	2.9	3.8	3.6	3.9
Rain water and other sources	0.02	0.02	0.02	0.02	0.01

→ Indicators: Environment

The water utilized also includes cooling water that is only ever heated and that never comes into contact with chemical substances. A large portion of the cooling water (around 7 million m³) is used for cooling and heating purposes at the prescription medicines division site in Geneva. Here, water from Lake Geneva is utilized to air-condition this administrative and laboratory site. Other buildings in the neighboring district are connected to the system. The lake water covers a large portion of the site's energy requirements.

These figures do not include the groundwater that we utilize in relation to safety measures at the Gernsheim site in Germany. Here, the water is fed back directly into natural circulation.

Wastewater

Wastewater volume and quality

	2008	2009	2010	2011	2012
Total wastewater volume (millions of m ³)	9.5	9.3	8.8	11.1	8.4*
Chemical oxygen demand (metric tons of O ₂)	1,441	745	967	911	929
Phosphorous (metric tons)	9	6	9	8	7
Nitrogen (metric tons)	52	48	61	73	76
Zinc (kg)	703	808	283	248	267
Chromium (kg)	31	18	20	21	21
Copper (kg)	30	38	40	34	37
Nickel (kg)	50	38	39	101	101
Lead (kg)	45	32	38	40	35
Cadmium (kg)	9	8	10	10	10
Mercury (kg)	2	1	1	1	1
Arsenic (kg)	7	8	7	6	3

* Unlike previous years, the wastewater figures for 2012 do not include groundwater that we utilize for safety measures at the site in Gernsheim, Germany, which is fed back directly into natural circulation. In addition, the figures likewise exclude rainwater at the Gernsheim site.

The wastewater volume includes indirect discharge into both public and Merck KGaA, Darmstadt, Germany-owned wastewater treatment plants, as well as direct discharge (such as rainwater and cooling water). The wastewater volume does not include the water taken from Lake Geneva (around 7 million m³) that is exclusively used for cooling and heating and then fed directly back again.

Wastewater from the neighboring municipality of Biebesheim is also treated at the wastewater treatment plant at the Gernsheim site in Germany. The communal wastewater from Biebesheim is included in the wastewater volume as well as in the emissions stated in the table.

Emissions are determined partially based on measurements and partially based on calculations or estimates. Only some sites are required to measure individual parameters.

→ Indicators: Environment

Waste

Hazardous and non-hazardous waste (metric kilotons)

	2008	2009	2010	2011	2012
Total waste	216*	162	194*	199*	189
Hazardous waste disposed	56	45	47	43	63
Non-hazardous waste disposed	22	21	27	36	38
Hazardous waste recycled	41	26	29	41	44
Non-hazardous waste recycled	97	70	91	79	44

* Due to new data provided, these figures have been retroactively adjusted.

Waste by disposal method

	2008	2009	2010	2011	2012
Total waste (metric kilotons)	216*	162	194*	199*	189
Waste for disposal (metric kilotons)	78	66	74	79	101
Landfill waste (metric kilotons)	10	12	13	14	19
Incinerated waste (metric kilotons)	68	54	61	65	82
Recycled waste (metric kilotons)	138	96	120	120	88
Recycled solid waste (metric kilotons)	115	79	100	97	64
Recycled energy (metric kilotons)	23	17	20	23	24
Recycling rate (%)	64	59	62	60	47

* Due to new data provided, these figures have been retroactively adjusted.

In 2011 and 2012, waste from construction and renovation projects constituted a large portion of the waste volume (2011: 36%, 2012: 34%). Due to a major demolition and renovation project at the Darmstadt site in Germany, large quantities of hazardous waste had to be disposed of in 2012. This impacted the recycling rate, which dropped to 47%. At the same time, the volume of recyclable non-hazardous waste declined. A large portion of this waste was generated in 2011 during a major construction project in Darmstadt that was completed in 2012.

→ Indicators: Society

Indicators: Society

Spending on social engagement (€ million)

	2008	2009	2010	2011	2012
Total spending	5.3	6.2	6.9	7.9	11.8

For spending on social engagement, we calculate product donations at their fair value, except for the praziquantel donated within our Praziquantel Donation Program, whose value is calculated according to the WHO Guidelines for Medicine Donations.

The increase in spending from 2011 to 2012 is largely attributable to the Erbitux[®] China Patients Aid Program (ECPAP), in which we work with the Beijing Red Cross Foundation to provide this drug free-of-charge to low-income patients with colorectal cancer. The program has reached 510 patients in 97 hospitals across 35 cities in China.

Spending on local social engagement, by region (%)*

	2008	2009	2010	2011	2012
Europe	45	56	29	39	20
North America	7	11	17	23	13
Emerging markets	34	28	49	37	66
Rest of world	14	5	5	1	1

* Excluding lighthouse projects.

Focus of local social engagement (%)*

	2008	2009	2010	2011	2012
Health	–	–	–	28	30
Support for culture and sports activities near our sites	20	15	14	18	28
Education	23	19	21	22	16
Environment	–	–	–	5	9
Other	11	27	27	17	14
Disaster relief	5	6	3	10	3
Aid to socially disadvantaged people	41	33	35	–	–

* Excluding lighthouse projects, based on number of projects.

In 2011, we reviewed the focuses of our social engagement. Many of our projects in the different focal areas support socially disadvantaged people. In order to clearly categorize our activities, we have therefore stopped using "Aid for socially disadvantaged people" as a sub-category. We have added "Health" and "Environment" as focal areas.

→ Indicators: Society

 Motivations for our social engagement (%)*

	2008	2009	2010	2011	2012
Charitable activities	57	58	56	52	32
Community investment	16	19	20	24	52
Commercial initiatives in the community	27	23	24	24	16

* Excluding lighthouse projects, based on total spending.

We assign the motivations for our engagement to categories based on the model of the London Benchmarking Group and the guidelines of the Bertelsmann Foundation for corporate social engagement. Projects that primarily aim to make improvements within the community are classified as "Community investment". Projects that are predominantly aimed at company-relevant factors such as image or personnel recruitment are classified as "Commercial initiatives in the community". "Charitable activities" comprises any other projects that benefit a charitable organization, but cannot be assigned to either of the other two motivation categories due to missing data or their narrow scope.

→ Goals

Goals

Strategy and management

Goals: CR strategy and management

Strategic goal	Action	By?	Status in 2011 and 2012	Status
Improve management of CR topics	Establish a CR Committee	End of 2011	The CR Committee was founded in 2011. It convened four times in 2011 and 2012.	

Legend:  Achieved  In progress  Not achieved  New goal

Products

Goals: Product safety

Strategic goal	Action	By?	Status in 2011 and 2012	Status
Establish a globally uniform hazard and risk communication system for all relevant Merck KGaA, Darmstadt, Germany chemicals in the supply chain, incorporating the principles of prevention	Implementation of REACH:	End of 2011	The program SciDeEx®  has been published on our website.	
	Publish the SciDeEx® calculation program on our Chemicals portal			
	Provide all mixtures with new safety data sheets in accordance with REACH Annex II	End of 2012	All safety data sheets were converted to the new format by the deadline.	
	Register substances produced in quantities ranging from 100-1,000 metric tons per year (phase 2 of REACH implementation) and register non-phase-in substances	Mid-2013	For more than 75 substances, and thus a majority of the relevant substances, the work has already been done. Merck KGaA, Darmstadt, Germany is on schedule in terms of reaching its goal.	
	Register substances produced in quantities ranging from 1-100 metric tons per year (phase 3 of REACH implementation) and register non-phase-in substances	Mid-2018	We have started the process of registering substances for phase 3.	
Implementation of GHS/CLP:	Classify mixtures and sets according to the CLP regulation	Mid-2015	We have started the process of classifying mixtures.	

→ Goals

Goals: Product safety

Strategic goal	Action	By?	Status in 2011 and 2012	Status
	Implementation of the Global Product Strategy (GPS): Within the scope of GPS, provide product safety summaries for all hazardous substances registered under REACH	End of 2020	The first product safety summaries are available on the website of the International Council of Chemical Associations (ICCA ). In parallel to the registration of substances for REACH, Merck KGaA, Darmstadt, Germany will produce further product safety summaries in order to achieve the goal for all substances.	
	Projects for hazard communication: Update safety data sheets for non-hazardous materials	End of 2020	We have started updating the safety data sheets.	
	Increase the number of safety data sheets prepared to a globally uniform standard	End of 2020	A Group-wide standard is currently being developed.	

Goals: Animal testing

Strategic goal	Action	By?	Status in 2011 and 2012	Status
Harmonize animal welfare throughout Merck KGaA, Darmstadt, Germany	Establish Group-wide governance for Corporate Animal Science & Welfare	End of 2014		
	Develop a Group-wide audit concept for contract animal testing facilities	End of 2015		
Harmonize the high quality of animal facilities at the prescription medicines division	Obtain AAALAC International accreditation for all prescription medicines division laboratory animal facilities	End of 2015		

Goals: Storage & transport

Strategic goal	Action	By?	Status in 2011 and 2012	Status
Further improve warehouse and transport safety	Create a Group-wide standard for safe logistics	End of 2013		
	Systematically share best warehouse and transport safety practices among employees worldwide	End of 2013		
	Expand scope of transport safety audits, to include contracted service providers	End of 2014		
	Develop additional performance indicators to assess warehouse and transport activities	End of 2014		

→ Goals

Goals: Product safety

Strategic goal	Action	By?	Status in 2011 and 2012	Status
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Legend:  Achieved  In progress  Not achieved  New goal

Suppliers

Goals: Supplier management

Strategic goal	Action	By?	Status in 2011 and 2012	Status
Sustainability in the supply chain	Introduce the new supplier management process within the most important legal entities	End of 2012	A new supplier management process has been instituted in the most important legal entities.	
	Adapt the general terms and conditions to integrate our Responsible Sourcing Principles into all orders	End of 2013		
	Conduct CR audits on 30 suppliers with a risk potential	End of 2013		
	Create the technical prerequisites for obtaining supplier self-disclosures in France, the United States, China, Italy, the United Kingdom, and Ireland by implementing a new computerized supplier management system	End of 2013		
	Collect supplier self-disclosures from higher-risk suppliers from whom we procure a volume above a defined threshold, in the countries Germany, Brazil, Mexico, Switzerland, Japan, India, France, the United States, China, Italy, the United Kingdom, and Ireland	End of 2013		

Legend:  Achieved  In progress  Not achieved  New goal

Employees

Goals: Attracting and developing talent

Strategic goal	Action	By?	Status in 2011 and 2012	Status
Introduce a performance management system	Introduce performance management systems for all employees with target agreements, feedback and coaching	End of 2013	In 2012, 98% of employees took part in a performance and development evaluation.	

→ Goals

Goals: Attracting and developing talent

Strategic goal	Action	By?	Status in 2011 and 2012	Status
	Introduce development plans for all employees with performance evaluations, target agreements, feedback and coaching	End of 2013	By the end of 2012, development plans had been instituted for 77% of employees.	
	Introduce development plans for all managers from Millipore Corporation, which was acquired in 2010	End of 2011	The Global Grading System was introduced incrementally for the employees of Millipore Corporation, which was acquired in 2010. This process had not yet reached completion as of the end of 2011, which is why the status cannot be specified for the end of 2011. At the end of 2012, development plans were instituted for 85% of the management; this process is to be completed by the end of 2013.	
Talent & Succession Management: Fill at least 2/3 of positions at global grade 16+ with internal candidates	Use the Talent & Succession Management Process to identify suitable employees with management potential and define a process to systematically develop employees	Ongoing	In 2011, we initiated the Performance & Talent Process to systematically develop management. In 2012, 88% of the vacant management positions were filled internally.	

Goals: Occupational health & safety

Strategic goal	Action	By?	Status in 2011 and 2012	Status
Reduce work accidents throughout Merck KGaA, Darmstadt, Germany (lost time injury rate = 2.5)	Implement the BeSafe! program; hold EHS forums on "Safety Behavior Change"	End of 2015	In 2011, we launched the BeSafe! program. Through systematic accident prevention measures (such as training and campaigns to strengthen our corporate safety culture), we attained an LTIR of 2.0 in 2011 and an LTIR of 2.3 in 2012. We are working to lastingly stabilize our LTIR.	

Goals: Diversity and inclusion

Strategic goal	Action	By?	Status in 2011 and 2012	Status
Increase the percentage of management positions (Global Grade 14+) held by women to 25%-30%	Increase the percentage of management positions held by women through numerous initiatives that move women into those positions	End of 2016	23% of management positions were held by women in 2011; 24% were held by women in 2012, a 2% increase over 2010.	

Legend:  Achieved  In progress  Not achieved  New goal

→ Goals

Environment

Goals: Environmental management

Strategic goal	Action	By?	Status in 2011 and 2012	Status
Obtain ISO 14001:2004 Group certificate	Certify all production sites to ISO 14001:2004; certify the Millipore sites acquired in July 2010	Ongoing	New production sites were successively added to the Group certificate. Four Millipore production sites are scheduled to be externally certified and added to the Group certificate in 2013.	

Goals: Climate protection

Strategic goal	Action	By?	Status in 2011 and 2012	Status
20% reduction of direct and indirect greenhouse gas emissions (Scope 1 and 2) of Merck KGaA, Darmstadt, Germany (2006 baseline)	Systematically examine the energy consumption at the individual sites	End of 2020	The production plants in Darmstadt and Gernsheim were systematically examined in terms of energy savings potential. In addition to this, energy checks were conducted at the Altdorf, Semoy, Taicang, Savannah, and Eppelheim sites.	
	Identify and implement potential ways to save energy	End of 2020	Nearly 70 projects to save energy or reduce greenhouse gas emissions have been initiated, and some of them have already reached completion.	
	Reduce process-related emissions	End of 2020	We have made progress in reducing process-related emissions. Despite increased production volume, we managed to lower emissions slightly.	

Legend:  Achieved  In progress  Not achieved  New goal

Society

Goals: Praziquantel

Strategic goal	Action	By?	Status in 2011 and 2012	Status
Eliminate the worm disease schistosomiasis in Africa	Provide tablets containing praziquantel free of charge to treat school children in Africa	Ongoing	More than 100 million tablets were donated from the beginning of the project to the end of 2012. More than 28 million children were treated in total (figure not yet final; figures for 2012 will not be finalized until July 2013). In 2011 and 2012, over seven million children were treated. 2011: 25 million tablets provided to nine countries in Africa 2012: 27 million tablets provided to eight countries in Africa	
	Run an awareness program to explain the causes of schistosomiasis and potential preventive measures.	End of 2013	Until mid-2012, instructional materials were tested in Senegal and Malawi as part of a pilot project. In 2013, the awareness program will be initiated in both countries, taking into account experience from the pilot projects.	
	Incrementally increase the number of tablets donated annually by a factor of ten, up to 250 million	End of 2016	Currently searching for additional API suppliers.	
	Research a new formulation of praziquantel for children under 6 years old		In July 2012, a public-private partnership (PPP) was founded. Milestone: Preclinical development is to be completed by 2014; clinical development is scheduled to start in 2014.	
	Optimize the praziquantel formulation	End of 2014	Development of a film coating to make the tablets easier for patients to swallow and to make them even more resistant to long transport times.	

Goals: Minilab

Strategic goal	Action	By?	Status in 2011 and 2012	Status
Combat counterfeit medicines by providing and further developing the mobile GPHF Minilab	Develop new test methods for five active ingredients and add the descriptions of the new test methods to the user manuals	End of 2011	2011: Seven new test methods were developed. 2012: Five training seminars were conducted on using the GPHF Minilab, and seven new test methods were developed.	

→ Goals

Goals: Praziquantel

Strategic goal	Action	By?	Status in 2011 and 2012	Status
	Conduct three training seminars on using the GPHF Minilab, sell 50 Minilabs, develop seven new test methods	End of 2013		+

Legend:  Achieved  In progress  Not achieved  New goal

→ Awards and recognition

Awards and recognition



Awards and recognition in the 2011–2012 period

Name	For what?	When?
Sustainability ratings in the capital market		
Carbon Disclosure Project	The Carbon Disclosure Project (CDP) is an independent not-for-profit organization that works on behalf of investors to motivate companies to transparently report their greenhouse gas emissions and water consumption. In the Carbon Disclosure Leadership Index, which assesses the extent and transparency of a company's reporting, Merck KGaA, Darmstadt, Germany scored 80 out of 100 possible points. In the Carbon Disclosure Performance Index, which rates a company's performance in reducing emissions, Merck KGaA, Darmstadt, Germany received a B rating on a scale of A to E, thus clearly placing it among the top-ranking companies from Germany, Austria and Switzerland.	2012
FTSE4Good Index	Since 2008, Merck KGaA, Darmstadt, Germany shares have been included in the FTSE4Good Index, the leading international sustainability index that annually evaluates companies' ecological and ethical conduct.	2011 and 2012
oekom research sustainability rating	The sustainability rating agency oekom research AG has given Merck KGaA, Darmstadt, Germany a C+ on a scale of A+ (top grade) to D-, which means Merck KGaA, Darmstadt, Germany has once more achieved prime status. This puts Merck KGaA, Darmstadt, Germany in tenth place in the pharmaceuticals & biotechnology sector. A total of 69 companies were evaluated.	2011
Sustainalytics sustainability rating for DAX® 30 companies	In a study comparing the sustainability performance of the 30 largest publicly traded German companies, Merck KGaA, Darmstadt, Germany holds 14th place (2009: 11th place). The analysis conducted by Sustainalytics followed the ESG method, which focuses on environmental, social and governance aspects.	2011
STOXX® Global ESG Leaders index	Since October 2011, Merck KGaA, Darmstadt, Germany shares have been included in the STOXX Global ESG Leaders sustainability index, which rates companies based on key environmental, social and governance criteria.	2011 and 2012
Awards for product responsibility		
Access to Medicine Index	In the Access to Medicine Index, Merck KGaA, Darmstadt, Germany rose to eighth place (2011: 17th place). This index rates pharmaceutical companies with regard to their activities to improve access to medicines in developing health care systems. The index is published every two years by the Access to Medicine Foundation, an international not-for-profit organization.	2012

→ Awards and recognition

Awards and recognition in the 2011–2012 period

Name	For what?	When?
Bio-IT World Best Practices Award 	Our cross-divisional Innospire initiative received the Bio-IT World Best Practices Award for the “Knowledge Management” category. The award is granted by the Cambridge Healthtech Institute in the United States.	2012
Boston Business Journal Green Business Award	The life science tools division’s Lab Water business field developed the ech2o-program for recycling water filter cartridges, which was recognized with the Boston Business Journal Green Business Award in May 2012.	2012
Customer service for MS patients	The MS LifeLines®  initiative in the United States, sponsored by EMD Serono  and Pfizer, was recognized by the J.D. Power and Associates Call Center Program for outstanding customer service to the MS community.	2012
MassRecycle Business Innovation Award	As one of the leading suppliers of products for the life science industry, our life science tools division and five customers jointly launched a take-back program for single-use products in the United States in 2012. The program was honored in November 2012 with the MassRecycle Business Innovation Award.	2012
R&D Magazine 100 Award 	The Samplicity® filtration system from the life science tools division was chosen by R&D Magazine as one of the 100 most technologically significant products introduced into the marketplace in the United States.	2012
Awards for our performance as an employer		
Work and Family audit	The charitable Hertie Foundation recognized the Merck KGaA, Darmstadt, Germany sites in Darmstadt and Gernsheim, Germany for the third consecutive time as being “family-friendly”. The distinction is based on an audit conducted on family-friendliness using predefined criteria and is valid for three years.	2012
Top employer in the Netherlands	The prescription medicines division was recognized by the Corporate Research Foundation as a top employer in the Netherlands.	2011
Top Employer in the Greater Toronto Area 	The prescription medicines division was recognized by “The Globe and Mail” as one of the top employers in the Greater Toronto Area.	2011
Ranking of the best employers in Germany for senior scientists	Merck KGaA, Darmstadt, Germany attained sixth place in the ranking of the best employers in Germany for senior scientists.	2012
Ranking of the top 125 companies for continuing education 	EMD Serono was recognized by “Training Magazine” as one of the companies in the United States that excel at employee development.	2012
Recognition of our social engagement		
Capital Philanthropy Award	The prescription medicines division was presented the Capital Philanthropy Award in China for its Erbitux China Patients Aid Program. This award is among the most renowned ones given in Beijing for charitable activities. A total of 70 companies were recognized as a Philanthropic Enterprise Beijing.	2012
Golden Bee CSR China Honor Roll	In recognition of Merck KGaA, Darmstadt, Germany’s exemplary corporate social engagement, Merck KGaA, Darmstadt, Germany was admitted to the Golden Bee CSR China Honor Roll.	2012

→ Awards and recognition

Awards and recognition in the 2011–2012 period

Name	For what?	When?
Recognition as an “Empresa con Prácticas Transparentes (EPT)” in Mexico	CETIFARMA , the Consejo de Etica y Transparencia de la Industria Farmacéutica en México (Council for ethics and transparency in the pharmaceutical industry), recognized Merck KGaA, Darmstadt, Germany in Mexico for its ethical and transparent conduct.	2012

Further awards and recognition can be found in the printed version of our [Annual Report 2011](#) (back page) and our [Annual Report 2012](#) (p. 210).

GRI Index

The CR Report 2012 is based on the guidelines of the [Global Reporting Initiative GRI](#) (Version G3.1). It meets the criteria for an A+ application level (confirmed by GRI). The following GRI Index provides an overview of the GRI indicators, the scope to which Merck KGaA, Darmstadt, Germany reports them, and where the corresponding contents can be found.

In addition, the table presents the UN Global Compact (UNGC) principles. Interested readers can use the references to learn about the progress Merck KGaA, Darmstadt, Germany has made in implementing the principles (Communication on Progress).

More in this chapter:

- › GRI Index: Company and report profile
- › GRI Index: Economic performance indicators
- › GRI Index: Environmental performance indicators
- › GRI Index: Social performance indicators

Legend:

● ● ●	This indicator is fully reported.
● ●	This indicator is not fully reported.
●	This indicator is currently not reported.
+	Indicators shown in light gray are additional indicators and may be addressed optionally.

→ GRI index: Company and report profile

GRI index: Company and report profile

UNGC	GRI indicator	Comments	Reference	Status
1.	Strategy and Analysis			
1.1	Statement from the Chief Executive Officer about the relevance of sustainability		Letter from Karl-Ludwig Kley, CR strategy	● ● ●
1.2	Impact of business activity and its risks as well as opportunities for the company		CR strategy	● ● ●
2.	Organizational Profile			
2.1	Name		Company profile	● ● ●
2.2	Primary brands, products and services		Company profile, Products	● ● ●
2.3	Operational structure		Company profile	● ● ●
2.4	Location of headquarters		Company profile	● ● ●
2.5	Countries where the organization operates		Company profile, Share ownership by country ↗	● ● ●
2.6	Nature of ownership and legal form		Company profile	● ● ●
2.7	Markets served		Company profile	● ● ●
2.8	Scale of organization		Number of employees, Products and sites, Net sales ↗ , Capitalization ↗	● ● ●
2.9	Significant changes regarding size, structure or ownership		Scope of consolidation ↗ , Fit for 2018	● ● ●
2.10	Awards		Awards and recognition	● ● ●
3.	Report Parameters			
3.1	Reporting period		Report profile	● ● ●
3.2	Date of publication of the most recent reports		Report profile	● ● ●
3.3	Reporting cycle		Report profile	● ● ●
3.4	Contact person for questions regarding the report		Report profile	● ● ●
3.5	Process for defining report content		Report profile	● ● ●
3.6	Boundary of the report		Report profile	● ● ●
3.7	Specific limitations on the scope or boundary of the report		Report profile	● ● ●
3.8	Organizational units included in reporting		Report profile	● ● ●
3.9	Data measurement techniques and the bases of calculations		Report profile	● ● ●
3.10	Explanation of any restatements of information	Data has been adjusted in individual cases; the corresponding changes are indicated.	Report profile	● ● ●
3.11	Explanation of changes to the report parameters		Report profile	● ● ●
3.12	GRI Index			● ● ●
3.13	External assurance of the report		GRI index: Company and report profile	● ● ●
4.	Corporate Governance, Commitments and Engagement			
4.1	Governance structure of the organization, including committees		Executive bodies ↗ , Diversity, Articles of Association ↗	● ● ●
4.2	Independence of the Chief Executive Officer		Executive bodies ↗ , Articles of Association ↗	● ● ●
4.3	Independent members of the Executive Board		Executive bodies ↗ , Articles of Association ↗	● ● ●
4.4	Mechanics for shareholders and employees to provide recommendations and directions		Shareholder: Articles of Association ↗ , Employees: Dialogue and co-determination	● ● ●
4.5	Linkage between compensation for members of the Executive Board and executive employees and the organization's performance		Compensation Report ↗	● ● ●

→ GRI index: Company and report profile

4.6	Processes in place to ensure conflicts of interest are avoided	Compliance, Corporate Governance Practices ↗	● ● ●
4.7	Qualification and experience of members of the Executive Board	Executive bodies ↗ , Articles of Association ↗ , Objectives of the Supervisory Board ↗ , Diversity ↗	● ● ●
4.8	Internally developed statements of mission or values, codes of conduct and principles	Company values and external initiatives, Compliance	● ● ●
4.9	Procedures of the Executive Board for overseeing and controlling the organization's sustainability performance	CR strategy	● ● ●
4.10	Processes for evaluating the performance of the members of the Executive Board	Articles of Association ↗ , Supervisory Board ↗ , Board of Partners ↗	● ● ●
4.11	Explanation of how the precautionary approach is addressed	CR strategy, Environmental management	● ● ●
4.12	Externally developed charters, principles or initiatives	Company values and external initiatives	● ● ●
4.13	Memberships in associations and advocacy organizations	Stakeholder dialogue	● ● ●
4.14	Stakeholder groups engaged by the organization	Stakeholder dialogue	● ● ●
4.15	Basis for selection of stakeholders	Stakeholder dialogue	● ● ●
4.16	Approaches to stakeholder engagement	Stakeholder dialogue	● ● ●
4.17	Topics and concerns of stakeholders	Stakeholder dialogue, Fit for 2018, Report profile	● ● ●

→ GRI index: Economic performance indicators

GRI index: Economic performance indicators

UNGC	GRI indicator	Comments	Reference	Status	
	Management approach		Economic performance  , Products and climate protection, Pension plans  , Supplier selection, Local executives, Indirect economic impacts: Access to health, Procurement of mica raw material, Dialogue and co-determination, Retrologistics	● ● ●	
Aspect: Economic performance					
	EC1	Direct economic value generated and distributed	Income Statement  , Cash Flow Statement  , Figures by division, country and region  , Community investments, Personnel expenses 	● ● ●	
7,8,9	EC2	Financial implications for the organization's activities due to climate change	In our response to the Carbon Disclosure Project, we describe the opportunities and risks that we see for Merck KGaA, Darmstadt, Germany as a result of climate change. Owing to the complexity of contents and the different probabilities of occurrence, we cannot make any meaningful estimate of the financial implications.	Climate protection, Carbon Disclosure Project	● ● ●
1	EC3	Company retirement pension		Pension plans  , Indicators: Employees	● ● ●
	EC4	Financial assistance received from government		Accounting policies for property, plant and equipment  , Property, plant and equipment  , Research and development spending 	● ● ●
Aspect: Market presence					
1	EC5 	Ratio of standard entry level salary compared to local minimum salary	According to the requirement of our Social Charter, all sites guarantee a salary above the local minimum salary.	Attracting and developing employees, Social Charter, Indicators: Employees	● ●
	EC6	Locally based suppliers	Merck KGaA, Darmstadt, Germany does not have any specific, global policies and guidelines that are generally applicable for purchasing with local suppliers. We procure our raw materials globally, depending on availability and supply. However, there are cases in which local suppliers have a competitive advantage owing to their spatial proximity, for example technical purchases as well as purchases of packaging materials.		● ● ●
6	EC7	Local hiring	We promote local hiring of employees and international appointments at all levels of the hierarchy. The percentage of local executives is not recorded as it is not relevant to strategic personnel planning at Merck KGaA, Darmstadt, Germany.	Diversity, Indicators: Employees	● ●
Aspect: Indirect economic impacts					
	EC8	Infrastructure investments and services provided for public purposes		Investments in infrastructure: Vocational school's technical unit, Hospital in Pakistan, Education and health care opportunities in India, Charitable activities: Social engagement, Indicators: Society	● ● ●
	EC9 	Indirect economic impacts		Access to health, Procurement of mica raw material, Dialogue and co-determination, Retrologistics	● ● ●

→ GRI index: Environmental performance indicators

GRI index: Environmental performance indicators

UNGC	GRI indicator	Comments	Reference	Status	
7, 8, 9	Management approach		Environmental management, Sustainable products, Transport safety	● ● ●	
Aspect: Materials					
8	EN1	Materials used	Where possible and appropriate, as for example in the case of packaging, we use recycled materials. Overall, the possibilities for using recycled materials in our portfolio are limited. Since this indicator is not applicable to Merck KGaA, Darmstadt, Germany, we do not record Group-wide data on this.	Resource consumption, Packaging	● ●
8,9	EN2	Percentage of materials used that are recycled input materials	Where possible and appropriate, as for example in the case of packaging, we use recycled materials. Overall, the possibilities for using recycled materials in production are limited, as we are at the beginning of value chains with our business model. Since this indicator is not applicable to Merck KGaA, Darmstadt, Germany, Group-wide data are not recorded.	Packaging	● ●
Aspect: Energy					
8	EN3	Direct energy consumption		Indicators: Environment	● ● ●
8	EN4	Indirect energy consumption	Merck KGaA, Darmstadt, Germany currently only records purchased secondary energy – this is primarily electricity and, to a lesser extent, heat/steam. Details on the local energy mix, including the respective percentage of primary energy, renewable energy, etc. are currently not available. Data on local energy efficiency in electricity or heat generation are currently not available either. Merck KGaA, Darmstadt, Germany production sites are located in countries with a widely varying energy mix. Our Darmstadt and Gernsheim sites in Germany have a high energy consumption. At these sites, fossil energy (coal, gas, etc.) accounts for approx. 61%, nuclear energy approx. 18% and renewable energies approx. 21% of the energy mix. Renewable energies account for a higher share in electricity generation at production sites in Switzerland, and nuclear energy in France and Japan. Based on an estimated global energy efficiency of 37% for the conversion and distribution of generated electricity, this results in a primary energy consumption of 1318 GWh for 2012. Based on an estimated global energy efficiency of 85% for heat/steam, this results in a primary energy consumption of 20 GWh for 2012. This gives a total primary energy consumption of 1,338 GWh for 2012. (The calculation is based on factors stated in "Handbuch für betriebliches Energiemanagement – Systematisch Energiekosten senken" ("Manual for energy management in practice – Systematically reducing energy costs") published by DENA, 12/2012).	Indicators: Environment	● ● ●

→ GRI index: Environmental performance indicators

8,9	EN5 +	Energy savings and energy efficiency	In 2012, we implemented projects enabling us to save approx. 8.9 MWh of energy and thus avoiding approx. 3,460 metric tons of CO ₂ .	Examples of climate protection projects	● ● ●
8,9	EN6 +	Energy-efficient products and services		Examples of products from our Performance Materials division 	● ● ●
8,9	EN7 +	Initiatives to reduce indirect energy consumption	We use a variety of measures to reduce indirect energy consumption. These include encouraging the use of public transportation and carpooling at some sites. Our business travel policy for Germany allows air travel for only a limited number of routes. The use of video and telephone conferencing is encouraged within the company. We can quantify the energy savings for only some of these measures. Based on our present knowledge, we will not be able to comprehensively report robust data in the coming years either, as the data situation – at our company as well as our business partners – is not sufficient for meaningful reporting in this respect.	Climate protection, Work-life balance	● ● ●
Aspect: Water					
8	EN8	Total withdrawal of water		Indicators: Environment	● ● ●
8	EN9 +	Water sources		Resource consumption	● ● ●
8, 9	EN10 +	Water recycled and reused	At Merck KGaA, Darmstadt, Germany, cooling water for production processes is recycled and, in some processes, production wastewater is prepared for reuse. At our largest site, Darmstadt in Germany, for example, more than 10 million m ³ of cooling water is recycled. The cooling water is circulated several times. Only approx. 1% of this water quantity needs to be replaced in the recycling process (to compensate for any losses caused by evaporation or sludge water from the cooling towers). These water quantities are not systematically recorded for the Merck KGaA, Darmstadt, Germany.		● ● ●
Aspect: Biodiversity					
8	EN11	Land in protected areas and areas of high biodiversity value	None.	Biodiversity	● ● ●
8	EN12	Impacts of products and services on protected areas		Biodiversity	● ● ●
8	EN13 +	Habitat protected or restored	This indicator is not relevant to our business activities, as our production sites are located only in declared industrial areas.		●
8	EN14 +	Strategy, objectives and actions for managing biodiversity	see EN13	Biodiversity	●
8	EN15 +	Endangered plant and animal species	see EN13		●
Aspect: Emissions, effluents and waste					
8	EN16	Direct and indirect greenhouse gas emissions		Indicators: Environment	● ● ●
8	EN17	Other relevant greenhouse gas emissions	In our response to the Carbon Disclosure Project, we assessed the relevance of various Scope 3 emissions.	Carbon Disclosure Project 	● ● ●
7, 8, 9	EN18	Reduction of greenhouse gas emissions	In our response to the Carbon Disclosure Project 2013, we describe projects to reduce greenhouse gas emissions.	Carbon Disclosure Project  , Climate protection, Indicators: Environment	● ● ●
8	EN19	Emissions of ozone-depleting substances		Indicators: Environment	● ● ●
8	EN20	NO _x , SO _x and other significant air emissions		Indicators: Environment	● ● ●

→ GRI index: Environmental performance indicators

8	EN21	Total water discharge		Water protection, Indicators: Environment	● ● ●
8	EN22 +	Total waste and disposal method		Waste management, Indicators: Environment	● ● ●
8	EN23	Significant spills	There were no significant spills.	Process and plant safety	● ● ●
8	EN24 +	Transport of hazardous waste		Waste management	● ●
8	EN25 +	Waters and habitats significantly affected by discharges of water and runoff	There were no significant discharges. At the Darmstadt site, the discharge of purified wastewater into the Darmbach (a stream in the Darmstadt area) accounts for over 5% of the average annual discharge volume. This has been permitted by the relevant authorities. It involves no significant impacts on the water or related habitats.		● ● ●
Aspect: Products and services					
7, 8, 9	EN26	Initiatives to mitigate environmental impacts of products and services		Sustainable products	● ● ●
8, 9	EN27	Reclaim and recycling of product packaging	We take back product packaging and have developed special return systems for this. We do not record precise percentages owing to the large number of our products (more than 60,000) and their wide diversity.	Reuse and recycling	● ● ●
Aspect: Compliance					
8	EN28	Fines and sanctions for non-compliance with laws and regulations	There were no significant incidents of non-compliance during the 2011-2012 period.		● ● ●
Aspect: Transport					
8	EN29 +	Environmental impacts of transportation		Transport safety, Indicators: Environment	● ●
Aspect: Overall					
7, 8, 9	EN30 +	Total environmental protection expenditures and investments		Indicators: Environment	● ● ●

→ GRI index: Social performance indicators

GRI index: Social performance indicators

Labor practices and decent work: Management approach and indicators

UNGC	GRI indicator	Comments	Reference	Status	
1, 3, 6	Management approach		HR Management, Dialogue and co-determination, Occupational health and safety, Attracting and developing employees, Diversity	● ● ●	
Aspect: Labor/Management relations					
	LA1	Total workforce	We do not currently record data on supervised workers, e.g. temps, in our data systems for employees. We are working to record these data in the future, making them available in 2014.	Indicators: Employees, Code of Conduct 	● ●
6	LA2	Rate of employee turnover		Attracting and developing employees, Indicators: Employees	● ● ●
	LA3 +	Benefits provided		Attracting and developing employees, Indicators: Employees	● ● ●
	LA15	Parental leave		Indicators: Employees	● ● ●
Aspect: Employer-employee relationship					
1, 3	LA4	Employees covered by collective bargaining agreements	We currently report the percentage of employees who qualify to be covered by collective bargaining agreements at Merck KGaA, Darmstadt, Germany. In the next report we will present the percentage of employees who are actually covered by collective bargaining agreements.	Dialogue and co-determination, Indicators: Employees	● ●
3	LA5	Minimum notice periods regarding significant operational changes	The regulations on notice periods vary worldwide. As we comply with the applicable regulations, we have not defined a Group-wide uniform notice period.	Dialogue and co-determination, Fit for 2018	● ● ●
Aspect: Occupational health and safety					
1	LA6 +	Workforce represented in health and safety committees	Occupational health and safety committees are stipulated by law in Germany. Therefore, all employees of the sites in Germany (Darmstadt, Gernsheim, and Grafing) are represented in health and safety committees working at site level. This accounts for approx. 24% of the total workforce.		● ● ●
1	LA7	Injuries, occupational diseases, lost days, days of absence and work-related deaths	We have defined the lost time injury rate (LTIR) as an important indicator at Merck KGaA, Darmstadt, Germany. Therefore, we do not present any separate figures on workplace accidents, lost days and days of absence. The LTIR is currently not broken down by gender and region. We intend to include a breakdown by region in the next report. Occupational diseases are reported for Merck KGaA, Darmstadt, Germany in Germany if they have been medically diagnosed and certified. One case of an occupational diseases was reported in the 2011-2012 period.	Indicators: Employees, Occupational health and safety	● ●
1	LA8	Health care and counseling		Occupational health and safety	● ● ●
1	LA9 +	Health and safety agreements with trade unions	For our sites in Germany there is a company agreement on occupational health and safety.		● ● ●

→ GRI index: Social performance indicators

Aspect: Training and education				
	LA10	Average annual further training per employee	The costs of training and education for our employees are currently recorded and reported. The average number of hours of advanced training are currently not recorded, but are to be made available in the next fiscal year.	Indicators: Employees, Attracting and developing employees, Training on specific topics: Compliance, Occupational safety, Diversity, Animal welfare, Company environmental protection, Product-related crime ●
	LA11 +	Skills management and lifelong learning		Attracting and developing employees, Fit for 2018 ●●●
	LA12 +	Employee performance and career development reviews		Attracting and developing employees, Indicators: Employees ●●●
Aspect: Diversity and equal opportunity				
1, 6	LA13	Composition of governance bodies and breakdown of employees by diversity criteria	As there is no globally uniform definition of the term "minority", we do not record any data on this. Moreover, the recording of our employees' personal data is strictly regulated in many countries in which we operate.	Executive Board  , Supervisory Board  , Objectives of the Supervisory Board  , Indicators: Employees ●●
Aspect: Equal remuneration for women and men				
1, 6	LA14	Ratio of basic salary of men to women	The salaries at Merck KGaA, Darmstadt, Germany are linked to the job descriptions that are defined in the global grade system. This system has fixed salary bands that are identical for men and women. Bonuses that we pay within the scope of our performance-oriented compensation are paid on the basis of target agreement and achievement. A performance management system steers the process.	Attracting and developing employees ●●●

Human Rights: Management approach and indicators

UNGC	GRI indicator	Comments	Reference	Status
1, 2, 3, 4, 5, 6	Management approach		Human rights, Compliance, HR Management, Safety of our drugs, Clinical trials, Supplier management	●●●
Aspect: Investment and procurement practices				
1, 2, 3, 4, 5, 6	HR1	Investment agreements that include human right clauses	In all decisions relating to mergers and acquisitions, we screen our potential partners for their compliance with human rights. A special focus is on labor standards and environmental aspects.	Supplier management ●●●
1, 2, 3, 4, 5, 6	HR2	Suppliers that have undergone screening on human rights and actions taken		Supplier management, Clinical trials ●●●
1, 2, 3, 4, 5, 6	HR3	Employee training on human rights	We train our employees on diverse topics that show a relationship to human rights. Interdisciplinary training is currently not carried out on the topic of human rights.	Diversity, Product-related crime, Access to health, Supplier management, Compliance ●●●
Aspect: Non-discrimination				
1, 2, 6	HR4	Number of incidents of discrimination and actions taken		Diversity ●●●
Aspect: Freedom of association and collective bargaining				
1, 2, 3	HR5	Risks to the right to exercise freedom of association and collective bargaining in business activity		Human rights, Compliance, Supplier management ●●●
Aspect: Child labor				
1, 2, 5	HR6	Risk of child labor in business activity		Human rights, Compliance, Supplier management ●●●
Aspect: Forced and compulsory labor				
1, 2, 4	HR7	Risk of forced or compulsory labor in business activity		Human rights, Compliance, Supplier management ●●●
Aspect: Security practices				

→ GRI index: Social performance indicators

1, 2	HR8 +	Security personnel trained in aspects of human rights	Security personnel are currently not being trained in aspects of human rights. We are developing the corresponding training modules, which are scheduled to start in 2014.		●
Aspect: Rights of indigenous people					
1, 2	HR9 +	Incidents of violations involving rights of indigenous people	There were no significant incidents of non-compliance during the 2011-2012 period.		● ● ●
Aspect: Assessment					
1, 2	HR10	Percentage and total number of operations that have been subject to human rights reviews and/or impact assessments		Compliance, Human rights	● ● ●
Aspect: Remediation					
1, 2	HR11	Number of grievances related to human rights filed, addressed, and resolved through formal grievance mechanisms		Compliance, Human rights, Supplier management, Product safety	● ● ●

Society: Management approach and indicators

UNGC	GRI indicator	Comments	Reference	Status	
1, 2, 3, 4, 5, 6, 7, 8, 9, 10		Management approach	Compliance, Stakeholder dialogue, Dialogue and co-determination		
Aspect: Society					
	S01	Programs that assess the impact of operations on society	Company strategy ↗ , CR strategy, Stakeholder dialogue, Social engagement	● ● ●	
	S09	Operations with significant potential or actual negative impacts on local communities	Company environmental protection, Supplier management, Reuse and recycling	● ● ●	
	S010	Prevention and mitigation measures implemented in operations with significant potential or actual negative impacts on local communities	Compliance, Supplier management, Dialogue and co-determination, Stakeholder dialogue	● ● ●	
Aspect: Corruption					
10	S02	Analysis of risks related to corruption in business units	Compliance	● ● ●	
10	S03	Training in anti-corruption	Compliance	● ● ●	
10	S04	Incidents of corruption and actions taken	Compliance	● ● ●	
Aspect: Public policy					
1, 2, 3, 4, 5, 6, 7, 8, 9, 10	S05	Political positions and lobbying	Merck KGaA, Darmstadt, Germany acts according to the political positions published. This also applies to direct dialog with politicians and to representatives of political interests through associations.	Stakeholder dialogue	● ● ●
10	S06 +	Contributions to political parties and politicians	Merck KGaA, Darmstadt, Germany does not make financial contributions to holders of or candidates for political office, political parties or related organizations. This is defined in our Code of Conduct. In the United States, EMD Political Action Committees (PACs) have been set up via which our employees support political candidates and organizations with donations. These are not donations by the company, but donations by the employees. The contributions donated are reported to the U.S. Federal Election Commission and published.	Code of Conduct ↗ , Publication of donations made via PACs (EMD Serono) ↗	● ● ●
Aspect: Anti-competitive behavior					
10	S07 +	Number of legal actions as a result of anti-competitive behavior	Merck KGaA, Darmstadt, Germany is currently involved in two antitrust proceedings.	Risk Report ↗	● ● ●
Aspect: Compliance					

→ GRI index: Social performance indicators

S08	Fines and sanctions for non-compliance with laws and regulations	There were no significant incidents of non-compliance during the 2011-2012 period.	● ● ●
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Product responsibility: Management approach and indicators

UNGC	GRI indicator	Comments	Reference	Status
1, 7, 8	Management approach		Product safety, Responsible marketing, Compliance	● ● ●
Aspect: Customer health and safety				
1	PR1	Analysis of the health and safety impact of products and services	Product safety, Sustainable products	● ● ●
1	PR2 +	Incidents of non-compliance with regulations on health protection and safety	Risks arising from litigation and legal proceedings are published in the Risk Report contained in the Annual Report.	● ●
Aspect: Product and service labeling				
8	PR3	Labeling of products and services	Product safety	● ● ●
8	PR4 +	Non-compliance with regulations concerning labeling of products and services	Risks arising from litigation and legal proceedings are published in the Risk Report contained in the Annual Report.	● ●
	PR5 +	Measurement of customer satisfaction and results	The results of customer surveys are confidential.	● ●
Aspect: Marketing communications				
	PR6	Responsible marketing	Responsible marketing	● ● ●
	PR7 +	Non-compliance with regulations on marketing	Risks arising from litigation and legal proceedings are published in the Risk Report contained in the Annual Report.	● ●
Aspect: Customer privacy				
1	PR8 +	Total number of substantiated complaints by customers regarding breaches of data protection	A corporate directive regulates data protection within Merck KGaA, Darmstadt, Germany. In line with increasing requirements, we resolved to expand our data protection organization. We received no significant complaints from external parties or regulatory agencies.	● ● ●
Aspect: Compliance				
	PR9	Fines and sanctions for non-compliance with laws and regulations	During the 2011-2012 period we recorded a normal course of business without any significant fines.	● ● ●

Global Compact Communication on Progress

2012 Communication on Progress regarding the implementation of the Global Compact Principles

The Global Compact (GC) is a UN initiative founded in 2000. Signatories of the initiative commit themselves to ten principles based on key UN conventions regarding human rights, labor standards, environmental protection, and anti-corruption. At the same time, the compact obliges the signatories to actively engage themselves in propagating the principles within their own sphere of influence.



Merck KGaA, Darmstadt, Germany has been a Global Compact participant since 2005. The following table presents the key measures that Merck KGaA, Darmstadt, Germany took in 2011 and 2012 to implement the principles of the Global Compact.

www.unglobalcompact.org

Global Compact COP

UNGC Principles	Relevant GRI indicators	Key actions in 2011 and 2012	Link
Principle 1: Support and respect human rights	EC5, LA4, LA6-9, LA13-14, HR1-9, SO5, PR1-2, PR8	<ul style="list-style-type: none"> → Human rights risk assessment → Supplier management further developed in terms of CR aspects; creation of the "Responsible Sourcing Principles" → Increase in praziquantel donations to eliminate schistosomiasis 	Human rights, Supplier management, Praziquantel
Principle 2: Rule out complicity in human rights abuses	HR1-9, SO5	<ul style="list-style-type: none"> → Internal audits conducted on the Social Charter → Human rights risk assessment → Supplier management further developed in terms of CR aspect; creation of the "Responsible Sourcing Principles" 	Compliance, Human rights, Supplier management
Principle 3: Uphold freedom of association	LA4-5, HR1-3, HR5, SO5	<ul style="list-style-type: none"> → Internal audits conducted on the social charter → Human rights risk assessment → Supplier management further developed in terms of CR aspects; creation of the "Responsible Sourcing Principles" 	Compliance, Human rights, Supplier management
Principle 4: Eliminate all forms of forced and compulsory labor	HR1-3, HR7, SO5	<ul style="list-style-type: none"> → Internal audits conducted on the Social Charter → Human rights risk assessment → Supplier management further developed in terms of CR aspects; creation of the "Responsible Sourcing Principles" 	Compliance, Human rights, Supplier management

Global Compact COP

UNGC Principles	Relevant GRI indicators	Key actions in 2011 and 2012	Link
Principle 5: Abolition of child labor	HR1-3, HR6, SO5	<ul style="list-style-type: none"> → Internal audits conducted on the Social Charter → Human rights risk assessment → Supplier management further developed in terms of CR aspects; creation of the "Responsible Sourcing Principles" 	Compliance, Human rights, Supplier management
Principle 6: Eliminate discrimination	EC7, LA2, LA13-14, HR1-4, SO5	<ul style="list-style-type: none"> → Internal audits conducted on the social charter → Corporate goal to increase percentage of management positions held by women 	Compliance, Diversity and inclusion
Principle 7: Take a precautionary approach to environmental challenges	EC2, EN18, EN26, EN30, SO5	<ul style="list-style-type: none"> → ISO 14001 Group certificate for company environmental management → EHS standards implemented and updated (e.g. for process and plant safety, storage and transport, water protection, and waste management) → Product safety measures (e.g. REACH, GHS, Global Product Strategy) 	Environmental management, Process and plant safety, Storage and transport, Water protection, Waste management, Product safety
Principle 8: Promote greater environmental responsibility	EN1-30, SO5, PR3-4	<ul style="list-style-type: none"> → EHS standards implemented and updated (e.g. for process and plant safety, storage and transport, water protection, and waste management) → Initiation of EDISON climate protection program → Energy checks conducted at sites → Product labeling → Packaging take-back programs 	Process and plant safety, Storage and transport, Water protection, Waste management, Climate protection, Product safety, Reuse and recycling
Principle 9: Encourage diffusion of environmentally friendly technologies	EN2, EN5-7, EN10, EN18, EN26-27, EN30, SO5	<ul style="list-style-type: none"> → Product life cycle analyses → Innovative products developed 	Sustainable products, Performance Materials 
Principle 10: Anti-corruption measures	SO2-6	<ul style="list-style-type: none"> → Internal audits conducted on corruption → Anti-corruption training 	Compliance

Glossary

3R principle

The 3R principle applies internationally as the guiding principle for all animal testing. By using methods to replace animal experiments (replacement), reducing the required number of animals (reduction), and improving the test methods (refinement), the number of laboratory animals used as well the stress placed on them before, during and after testing are to be kept to an absolute minimum.

AAALAC

The Association for Assessment and Accreditation of Laboratory Animal Care International is a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs.

ATM (Access to Medicine)

Access to Medicine

Access to Medicine Index

The index is a ranking of world's 20 largest pharmaceutical companies on their efforts to increase access to medicine for societies in need. It is published every two years by the Access to Medicine Foundation.

API

Active pharmaceutical ingredient.

Audit

An audit is a process performed by a trained auditor to monitor a management system.

Schistosomiasis

Schistosomiasis is a parasitic disease that is spread in warm lakes and ponds by snails that serve as intermediate hosts.

Biodiversity

The term is used to describe the diversity of ecosystems, habitats and landscapes on earth, the diversity of the species and the genetic diversity within a biological species or population.

CAPA

Corrective action and preventive action

Carbon Disclosure Project

The Carbon Disclosure Project (CDP) is an independent not-for-profit organization that works on behalf of investors to motivate companies to transparently report their greenhouse gas emissions and water consumption.

CLP

The European CLP regulation (Classification, Labelling and Packaging of Substances and Mixtures) is based on the Globally Harmonized System (GHS) of Classification and Labeling of Chemicals.

CO₂eq

CO₂-equivalent: Indicates how much a specified quantity of a specific greenhouse gas contributed to the greenhouse effect. Carbon dioxide serves as the comparable value.

Compliance

This term refers to compliance with laws and regulations as well as with voluntary codices that are internal to Merck KGaA, Darmstadt, Germany. Compliance is an element of diligent corporate governance.

→ Glossary

Corporate Governance

This term covers compliance with laws and regulations; the application of recognized standards and recommendations; the development of and adherence to internal guidelines; as well as the creation and implementation of guideline and control structures.

CRO

Contract research organization

Demographic change

The term describes the development of a population, such as the change in the age structure. In Germany, several other EU countries and the United States, the average age of the population is on the rise.

Dual-use products

Dual-use products are goods that are normally used for civilian purposes, but that may also have military applications.

EBIT

Earnings before interest and taxes on income. Equals the operating result.

EDISON

Company-wide program that consolidates Merck KGaA, Darmstadt, Germany's climate protection activities.

EFPIA

The European Federation of Pharmaceutical Industries and Associations (EFPIA) is a European umbrella organization representing individual pharmaceutical companies as well national associations of research-based pharmaceutical companies.

EHS

Environment, Health and Safety: This abbreviation describes environmental management, health protection and occupational safety throughout the company.

EMA

European Medicines Agency: an official body of the European Union, headquartered in London. It is responsible for evaluating and monitoring medicines and plays a key role in the marketing authorization of medicinal products.

EQ

Environment Health Safety Security Quality: A Merck KGaA, Darmstadt, Germany function

Eutrophication

Eutrophication substances cause an overabundance of nutrients in the ecosystem.

Falsified Medicines Directive

The EU Falsified Medicine Directive, adopted in June 2011, aims to help prevent counterfeit medicines from entering the supply chain.

FDA

Food and Drug Administration: U.S. government agency responsible for protecting and advancing public health, especially as concerns food and drugs.

Total revenues

Sum of sales as well as royalty, license and commission income. Royalties are earned primarily through patents held by the prescription medicines division.

GHG Protocol

The Greenhouse Gas (GHG) Protocol is the most widely used accounting and reporting system for greenhouse gas emissions.

GHS

Globally Harmonized System of Classification and Labelling of Chemicals: An international standard system for classifying chemicals, including packaging labels and safety data sheets.

→ Glossary

Global Compact

The Global Compact is an initiative launched by the United Nations in 2003. Its signatories commit themselves to ten principles on human rights, labor standards, environmental protection, and anti-corruption, which are based on key UN conventions.

Global Grade

Merck KGaA, Darmstadt, Germany works with the Global Grading system from Towers Watson to evaluate positions. A total of 23 different global grades are available for evaluating all the positions of Merck KGaA, Darmstadt, Germany to create comparability of the positions throughout the Group.

Global Product Strategy

The Global Product Strategy is an initiative of the International Council of Chemical Associations (ICCA) through which participating companies of the chemical industry make a commitment to comprehensive product responsibility.

GMP

Good Manufacturing Practices are rules and procedures that help ensure that pharmaceuticals are of the required quality. GMPs pertain to the methods, facilities and control processes utilized for manufacturing, processing, packaging, and/or storing pharmaceuticals.

GPHF

Global Pharma Health Fund e.V. is a charitable organization funded by Merck KGaA, Darmstadt, Germany. The organization's goal is to promote health care within the scope of development assistance, especially with respect to the fight against counterfeit medicines through the use of the GPHF-Minilab®.

Global Reporting Initiative (GRI)

The GRI is a global network of stakeholders and experts that has created guidelines for producing sustainability reports with the aim of achieving comparability among these reports. The GRI G3 is the third generation of the guidelines. Apart from information on planning, contents and quality of reporting, it contains a list of the required data on management approach and indicators that are to be communicated as part of sustainability reporting.

Good Clinical Practice

Good Clinical Practices (GCP) are rules and procedures for conducting clinical drug trials involving human subjects.

ICCA

International Council of Chemical Associations.

IFPMA

The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) is the global umbrella organization for research-based pharmaceutical companies as well as pharmaceutical associations.

ICH

The aim of the "International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use" (ICH) is to promote uniform assessment criteria for product registration in Europe, the United States and Japan. The ICH makes recommendations toward achieving greater harmonization in the interpretation and application of technical guidelines and requirements for pharmaceutical product registration. This includes, for instance, Good Clinical Practice (GCP) guidelines for clinical trials of pharmaceuticals and Good Manufacturing Practice (GMP) guidelines for flawless manufacturing.

Interventional studies

Interventional studies are "investigations conducted on humans with the purpose of researching or proving the clinical or pharmacological effects of medicines, or of determining their side effects, or of investigating their absorption, distribution, metabolism, or excretion, in order to discern the safety and/or efficacy of the drug". (German Federal Drug Law (AGM), section 4, para. 23).

→ Glossary

International Labour Organization (ILO)

The ILO is a United Nations agency dealing with labor issues, in particular the formulation and implementation of international labor and social standards, especially the core ILO labor standards. The agency's work focuses on an inclusive, democratically governed globalization process and the creation of decent employment opportunities as a fundamental prerequisite for prosperity.

Interpharma

A federation of research-based pharmaceutical companies in Switzerland

In Vitro

"In vitro" refers to procedures involving components of an organism that have been isolated from their usual biological surroundings (e.g. test tube experiments)

ISAE 3000

ISAE 3000 (the International Standard for Assurance Engagements other than Audits or Reviews of Historical Financial Information), published by the International Auditing and Assurance Standards Board (IAASB), is currently the far most internationally applied corporate responsibility standard.

ISO 14001

This international environmental management standard sets globally recognized requirements for environmental management systems.

ISO 50001

This international standard defines globally recognized requirements for energy management systems.

Least Developed Countries

Least Developed Countries (LDC) are countries that, according to the United Nations, exhibit the lowest indicators of socioeconomic development.

LED

The abbreviation for "light-emitting diode", an electrical semiconductor. When an electrical current passes through the light-emitting diode in the diode's forward direction, the diode emits visible light, infrared light (for infrared diodes), or ultraviolet light in a wavelength determined by the semiconductor material and the doping.

Life Cycle Assessment (LCA)

A life cycle assessment (also known as ecobalance) is a systematic analysis of the environmental impact of products throughout their entire life cycle.

Liquid Crystals (LC)

These specialty chemicals are used in LC displays (LCD), for example, in flat-panel televisions, notebooks, mobile telephones, etc.

LTIR

Lost time injury rate: indicator for workplace safety. The number of workplace accidents with one or more days of lost time per million hours worked.

mutagen

A substance that changes the DNA of an organism.

Neglected Tropical Disease

Neglected tropical diseases (NTD) are conditions that occur primarily in developing countries. NTDs include schistosomiasis, intestinal worms, trachoma, lymphatic filariasis, and onchocerciasis. This group of diseases is called "neglected" because despite the large number of people affected, they have historically received less attention and research funding than other diseases.

→ Glossary

NGO

Non-governmental organization

OECD

Organization for Economic Co-operation and Development, with headquarters in Paris, is a forum of 34 countries committed to the principles of democracy and market economy.

Ecotoxicology

Ecotoxicology focuses on the effects of substances on the ecosystem.

OLED

Organic light-emitting diodes. New technology for displays and lighting used, for example, in mobile telephones, MP3 players, and since recently also in televisions and lamps.

Pharmacovigilance

Pharmacovigilance is the continual, systematic monitoring of a drug's safety.

Product Carbon Footprint (PCF)

A product carbon footprint quantifies the total amount of greenhouse gas emissions that a product causes throughout its entire life cycle, making transparent to what extent a product adversely affects the climate.

PS-VA

Polymer-stabilized vertical alignment: A polymer layer pre-aligns the molecules inside the display in a certain direction. In the black state, the liquid crystals are not exactly vertical, but slightly tilted, which allows the liquid crystals to switch more quickly. The light transmittance of the display is significantly higher, thus reducing the backlighting, one of the most costly components to produce.

Public-Private Partnership (PPP)

A public-private partnership is a collaboration between public sector (government) organizations, private companies and/or non-profit organizations.

REACH

Registration, Evaluation, Authorization and Restriction of Chemicals: This is an EU regulation that was adopted in mid-2007 in order to further improve chemical safety.

RoHS

(Restriction of Hazardous Substances) This EU directive, which was adopted in 2002, serves to limit the use of certain hazardous materials, such as lead and cadmium, in the manufacture of various types of electrical and electronic equipment in the European Union.

Security

The term stands for technical, organizational and personnel measures to avoid dangers that occur knowingly and willingly. This serves to protect employees and the environment as well as company knowledge.

Stakeholder

Stakeholders are people or organizations that have a legitimate interest in a company, entitling them to make justified demands. Stakeholders include people such as employees, business partners, neighbors to sites, and shareholders.

Stem cells

Stem cells are undifferentiated cells with the potential to develop into many different cell types that carry out different functions.

Sunshine Laws

The Sunshine Provisions of the Patient Protection and Affordable Care Act aim to create more transparent relationships between manufacturers of drugs, medical devices and medical aids on the one hand and doctors and teaching hospitals on the other.

→ Glossary

Greenhouse gases

Greenhouse gases are gases in the atmosphere that contribute to global warming. Greenhouse gases can be either naturally occurring or caused by humans (such as CO₂ emissions caused by burning fossil fuels).

UK Bribery Act

The UK Bribery Act is an anti-corruption law in the United Kingdom. It applies not only to UK companies, but also to all companies that do business in the United Kingdom in any way.

Essential medicines

Essential medicines as defined by the World Health Organization are "those drugs that satisfy the health care needs of the majority of the population."

UNIA

UNIA is a Swiss trade union that spans multiple sectors of industry.

VCI

The Verband der Chemischen Industrie (German Chemical Industry Association) represents the economic-political interests of 1,600 German chemical companies.

VfA

The German Association of Research-Based Pharmaceutical Companies represents the interests of 44 international research-based companies and over 100 subsidiaries in health care, research and economic policy.

VOC

(Volatile Organic Compounds) A collective term for organic chemical compounds that evaporate readily and are gaseous even at low temperatures.

WHO

The World Health Organization is a specialized agency of the United Nations. WHO is the directing and coordinating authority for public health within the United Nations system.

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