



Merck KGaA, Darmstadt, Germany

Human Rights Charter

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1. Rationale

Merck KGaA, Darmstadt, Germany is a leading global pharmaceutical, chemical and life science company with a history that began in 1668. As a family-owned business present in more than 60 countries worldwide, we aim to produce meaningful benefits for consumers, our market partners and our community.

We have been supporting the [United Nations Global Compact](#) (UNGC) since 2005, whose ten principles cover human rights, labor standards, the environment, and anti-corruption. We support the sustainability principles spelled out in the [OECD Guidelines for Multinational Enterprises](#). We also support the sustainability initiative [Chemie³](#) (Chemistry³) of the German chemical industry. Today, in times of globalization, such global principles become even more important, as we grow our sales and presence in emerging markets, internationalize our supply chains, and experience rapid technological and social change.

Merck KGaA, Darmstadt, Germany is a company striving for responsible conduct in our operations, the communities where we operate, our supply chain and our overall business relationships worldwide. We do our business on the basis of a strong ethical foundation, which has always been an integral part of our corporate culture and is reflected in our Mission Statement and our Values. Respecting and supporting human rights is an integral part of this responsibility. For us, having negative impacts on human rights might not only entail legal consequences but may also seriously harm our social license to operate, our competitiveness and our reputation. Therefore our Board, all managers, employees and contractors bear a responsibility to act in a way that respects human rights as outlined in this Charter. We also expect and encourage our business partners and other parties directly linked to our operations, products or services, to respect human rights and to practice human rights due diligence.

With this Human Rights Charter we spell out our commitment to human rights. In doing so, this Charter brings together and complements the human rights aspects from our other [regulations and guidelines](#), such as our Code of Conduct; the Environment, Health and Safety Policy; the Security Policy; the Charter on Access to Health in Developing Countries; and, our research-related policies (see full list in annex).

2. Overarching Principles

Merck KGaA, Darmstadt, Germany respects the dignity of every human being and is committed to respecting all internationally recognized human rights. It is our responsibility to avoid infringing on the human rights of others and to address adverse human rights impacts with which we are involved through our operations and business relationships - as outlined in the [UN Guiding Principles for Business and Human Rights](#). As a member of the UNGC we are also committed to supporting the realization of human rights in our sphere of influence. We understand human rights to be, at a minimum, those included in the [Universal Declaration of Human Rights](#) and its two corresponding covenants¹, [ILO Declaration on Fundamental Principles and Rights at Work](#).

To ensure human rights are respected we continue to conduct human rights due diligence, including identifying and managing actual and potential human rights impacts; revising our busi-

¹ The [International Covenant on Civil and Political Rights \(ICCPR\)](#) and the [International Covenant on Economic, Social and Cultural Rights \(ICESCR\)](#)



ness practices to address our impacts; tracking and communicating performance; and, ensuring that we have adequate mechanisms to address complaints.

Where we face conflicts between internationally recognized human rights and national laws, we will seek to act in accordance with the higher standard. We will use this Charter as a framework to guide our decision-making, while recognizing that it is the ultimate duty of governments to protect human rights.

3. Specific Provisions

While our human rights due diligence processes will ensure that we address our human rights impacts wherever we operate, there are specific areas that have been identified as priorities for our industry and our company. Based on a human rights risk assessment, we identified the following areas that cover our most significant risks and opportunities to impact human rights, and our greatest areas of responsibility².

Access to Health

Merck KGaA, Darmstadt, Germany is committed to providing high-quality safe health solutions for all. We respect the right to health and we work with a wide variety of stakeholders towards expanding access to health for underserved populations. This commitment is reflected in our Charter on Access to Health in Developing Countries. We believe that access to health is a complex issue that requires multi-stakeholder, sustainable engagement around addressing the intertwined challenges of affordability, availability, and accessibility, but also awareness towards strengthening health systems and promoting access to quality health solutions for all. There is no “one size fits all” solution and approaches need to be tailored and adapted to local needs and context.

We register our products in developing countries based on unmet needs and we embrace the concept of tiered pricing schemes tailored to make them more affordable. We adapt packaging to reduce the risk of product diversion and facilitate rational use. We are at the forefront of anti-counterfeiting and pharmacovigilance and seek innovative ways to further improve our performance. We refrain from filing patent applications in the least developed countries.

We also demonstrate our engagement all along the access value chain, from research and development efforts in neglected tropical diseases (NTDs) to capacity building initiatives and innovative alliances in developing countries. With our Praziquantel donation program we join forces with the World Health Organization (WHO) to contribute to the elimination of schistosomiasis in Sub-Saharan Africa, in line with the 2020 WHO NTD targets.

Merck KGaA, Darmstadt, Germany is a signatory to the [Guiding Principles on Access to Healthcare](#) (GPAH) and the [London Declaration on Neglected Tropical Diseases](#). We are determined, through our engagement and collaboration with a variety of stakeholders including local communities and patient groups and through engagement in access-related multi-stakeholder initiatives and programs globally, to continue to improve access to health for all. By addressing global health needs, the company contributes to the achievement of the United Nations Millennium Development Goals and is actively engaged on the post-2015 MDGs agenda.

² Human rights are indivisible and interdependent. Therefore, the issue areas addressed in this policy are ordered alphabetically. The order does not imply that one aspect is considered to be more or less relevant than another.



Bribery and Corruption

Bribery and corruption can have negative effects on the realization of human rights. Merck KGaA, Darmstadt, Germany does not tolerate bribery and corruption. No employee or member of his or her family may demand or accept from suppliers, business partners, customers or government authorities, money or gifts for personal gain that is connected with the company's business relationship with that customer/supplier/government authority. Our Code of Conduct provides detailed guidance on this issue and describes our implementation and monitoring systems.

Communities

We respect the human rights of our neighbors in areas where we operate or have facilities. When we plan, develop, acquire, run or close sites we strive to prevent any harm to the environment around us or to the human rights of surrounding communities. We aim to produce sustainable results and positive community impact, and thereby also to support the realization of human rights.

We respect the rights of indigenous peoples, as defined by applicable national and international standards, insofar as they are affected by our business activities.

We support fair and equitable access and benefit sharing, as set out in the Convention on Biological Diversity ([Nagoya Protocol](#)). In the event that we source and work with genetic resources, we will comply with access and benefit sharing requirements as defined in applicable laws.

Privacy

We respect the privacy rights and protect confidential information of our employees, patients treated with our products, participants involved in our clinical trials, business partners and customers.

Product Stewardship

With our innovative products, we are helping to resolve global challenges such as access to health and climate change, and contribute towards meeting our customers' own sustainability goals. Our products have to be safe – as long as used properly they should not pose a danger to end users or to the environment or – in the case of our medicinal products – have a negative benefit/risk balance for patients. We therefore continually examine product safety across the entire life-cycle and take steps for necessary risk mitigation. We make the use of our products safer by providing patients and customers with up-to-date informational material. We have strong processes and safeguards in place to prevent, detect and address the counterfeiting of our medicines and the diversion of our products from their legitimate use, which we will continually strengthen. With our product authentication features we go beyond legal requirements.

For our medicinal products we ensure continuous pharmacovigilance monitoring during research and development and after marketing authorization, according to applicable legislation and regulation, such as the [Guidelines on Good Pharmacovigilance Practices](#) (GVP), and in contact with the relevant health authorities. Our Pharma Code for Conducting Pharmaceutical Business and Pharmaceutical Operations sets the standard for good and responsible marketing practices at Merck KGaA, Darmstadt, Germany. This helps us ensure key players in the health care industry have continuous access to the relevant information, and that patients receive effective treatment. We will monitor this field and update our policies and processes to ensure their effectiveness and adequacy. We recognize the important role that patient organizations



play in providing support to patients and support the educational work of various patient organizations.

For our chemical and life science products, we follow regulatory requirements such as REACH and GHS and voluntary initiatives such as the [Global Product Strategy](#) of the International Council of Chemical Associations (ICCA). We have committed ourselves to the [Responsible Care®](#) principles of the chemical industry and to the Responsible Care Global Charter.

Research Ethics

We have stringent management practices in place to ensure that we abide by the relevant legal, ethical and scientific standards in all our research whether in industrialized or developing countries. We adhere to relevant external standards and guidelines, such as the [International Conference on Harmonization \(ICH\) Guidelines for Good Clinical Practice \(GCP\)](#), the Declaration of Helsinki of the World Medical Association, and the International Ethical Guidelines for Biomedical Research Involving Human Subjects of the Council for International Organizations of Medical Sciences (CIOMS). Our policy on Clinical Research and our processes for conducting and overseeing clinical trials are designed to respect the human rights of trial participants, including vulnerable populations. We require and monitor that all external research organizations conducting trials on our behalf follow our standards. We are committed to the publication of all our clinical research, irrespective of whether the results are positive or negative for our medicines. We are opposed to genetic engineering of the human germline and reproductive cloning. Our Guidelines for stem cells and human cloning, fertility research and the use and handling of nanomaterial provide further guidance. Our Bioethics Advisory Panel (MBAP), consisting of renowned scholars, provides guidance and develops recommendations on bioethics topics.

Security

Corporate Security is an integral element of our daily work and encompasses areas such as the protection of employees, immaterial and material assets, product-related crime, cybercrime, intellectual property protection and security activities along the value chain. We conduct our security risk management in compliance with national and international legal requirements. We transfer and apply relevant rules and regulations into transparent internal security standards that we strictly follow. In a continuous dialogue with law enforcement authorities and our participation in governmental and industry-driven certificate programs, we implement and maintain best practices and court-proof procedures.

Supply Chain

As a buyer of services, raw materials and manufactured goods globally, we strive to be good stewards of our supply chains and take adequate measures to ensure that our values are respected within them. We identify the supply chains at greatest risk of adverse human rights impacts, assess whether our buying and monitoring practices are sufficient to ensure that our values are respected, and make revisions if necessary. We will only conduct business with suppliers who share our commitment to human rights and to operate in a responsible manner towards their employees and their own suppliers. Our supplier selection, contracting and monitoring processes include environmental and social criteria, including human rights. Where we detect shortcomings, based on audits or other available information, we direct and guide suppliers to make improvements, and where feasible we help build their capacity to fulfil the requirements. We are prepared to end a relationship if no improvement is made. We encourage suppliers to establish their own grievance mechanisms in line with the UN Guiding Principles on Business and Human Rights. We respect the human rights of contract staff while they are



working on our behalf. Our Responsible Sourcing Principles outline the core principles we expect our suppliers to adhere to.

Workplace

Our employees are the backbone of our business and our success depends on their health, safety, security, satisfaction and well-being. At Merck KGaA, Darmstadt, Germany, respecting our employees' dignity, treating them fairly and in compliance with laws and regulations is a matter of course. As a matter of principle, we are guided by the ILO Core Labor Standards. We adhere especially to this claim with respect to the following topics and regularly audit our sites against these requirements:

Freedom of association

The company respects the right of employees to form or join organizations and to voice their concerns about important issues in a lawful manner. The right to negotiate collectively is encouraged and should not be restricted. In countries where the right to collective bargaining is restricted by law or where employees have decided not to appoint representatives, we will seek alternative means to ensure open communication and negotiation between employees and management.

No forced labor

Everyone should be working of his or her own free will; the company does not accept any form of forced labor. Employees have the right to terminate the employment relationship after giving a reasonable period of notice.

No child labor

Merck KGaA, Darmstadt, Germany only hires people who are above the minimum age of employment as stipulated in the ILO Conventions or national law whichever is higher. If child labor is detected we will provide for adequate remediation.

Non-discrimination and equal opportunity

The company does not tolerate discrimination based on gender, race, color, nationality, age, religion, sexual orientation, disability, or on any other basis prohibited by law. We recruit, hire, train and promote our employees based on this principle. We proactively fight intolerance and promote workplace diversity.

Wages and salaries

We aim to pay competitive wages that at least meet the applicable legal or industry minimum standard and ensure an adequate standard of living for our employees and their families.

Working hours

We respect the right to rest and leisure and the right to a family life. Regular working hours and overtime should not exceed the maximum legal limits.

Occupational health and safety

The company ensures the creation of safe and hygienic working conditions in compliance with the applicable laws and regulations, through our strong occupational health and safety management system which is based on the [ILO Occupational Safety and Health Convention](#) (No. 155). Our audits are oriented to the requirements of OHSAS 18001. Employees are trained so that they can contribute to a safe and hygienic working environment.



Prevention of abuse and harassment

Everyone in the company should aim to foster a working environment in which all company employees and our partners are treated in a fair manner, based on the principles of non-discrimination, respect and human dignity. No employee shall be disciplined without fair procedures.

4. Complaints Management

Complaints by employees regarding infringements against this Charter can be raised through our SpeakUp Line. All employees can report violations by telephone or via web-based application in their respective national language, free of charge and anonymously. All issues will be handled in a confidential manner, consistent with the company's need to investigate, comply with legal requirements, and cooperate with law enforcement. The company will not tolerate any form of retaliation against an employee who, in good faith, seeks advice or reports misconduct.

Subjects participating in Merck KGaA, Darmstadt, Germany-sponsored clinical trials can raise complaints by using the contact information provided on the subject information sheet.

As part of our pharmacovigilance systems, users of our drugs can report adverse reactions through their doctors or directly to the company or health authority in all countries where our products are marketed. Safety data for all our drugs in developmental and marketing status is evaluated centrally by the corporate pharmacovigilance function.

We will work to identify and fill remaining gaps in our complaints management systems with regard to the requirements in the UN Guiding Principles on Business and Human Rights.

5. Implementation of this Charter

This Charter was developed with input from key business functions and from external stakeholders and approved by our Executive Board. We will continue to engage stakeholders as our human rights commitments and due diligence processes evolve. We will learn and further develop our policies and practices - such as through the UNGC and its local networks, industry specific dialogues and initiatives.

Our implementation of this Charter is expected to strengthen over time. We will seek to identify emerging and previously unknown risks to human rights and will adapt to changes in our risk profile. We will define action plans and appropriate indicators to track and improve our performance. We aim for transparency through our Corporate Responsibility Report and our website, where we will report on progress in implementing our commitment.

With the help of management systems, we set and govern goals, actions and responsibilities in the key areas of this Charter. Where significant changes in our business are planned, such as acquisitions, divestitures, partnerships, or new market entries, we will ensure that the socio-economic impacts, including human rights risks, are assessed at an early stage, and are part of decision-making. Assessing compliance with the law and this Charter is an integral part of our



auditing activities. Merck KGaA, Darmstadt, Germany will provide appropriate training and capacity building in order to embed this policy commitment throughout the company and to ensure that our legal entities understand and implement human rights due diligence.

The Executive Board of Merck KGaA, Darmstadt, Germany maintains the general oversight for this Charter and related activities. The Managing Directors of our legal entities are responsible for ensuring that this Charter is adhered to. Implementation and periodic review of this Charter is steered by the Group-wide CR Committee.



Annex

List of related Merck KGaA, Darmstadt, Germany regulations and guidelines:

- Code of Conduct
- Charter on Access to Health in Developing Countries
 - Access to Medicines
 - R&D for Neglected Tropical Diseases
 - Intellectual Property rights
 - Pharmaceutical Products Pricing
 - Counterfeit Medicines Products
 - Pharmaceutical Products Donations and Philanthropic Activities
- Environment, Health and Safety Policy
- Fertility Research Policy
- Merck KGaA, Darmstadt, Germany Responsible Sourcing Principles
- Pharma Code for Conducting Pharmaceutical Business and Pharmaceutical Operations
- Policy on Clinical Research
- Security Policy for Merck KGaA, Darmstadt, Germany
- Stem Cells and Human Cloning Principles
- Use and Handling of Nanomaterials

