

Merck KGaA, Darmstadt, Germany

Human Rights Charter

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1. Our commitment

Merck KGaA, Darmstadt, Germany, a vibrant science and technology company, operates across healthcare, life science and performance materials. We work to make a positive difference to millions of people's lives every day by creating more joyful and sustainable ways to live. Scientific exploration and responsible entrepreneurship have been key to our technological and scientific advances. This is how Merck KGaA, Darmstadt, Germany has thrived since its founding in 1668. More information on our company and business sectors is available [here](#).

At Merck KGaA, Darmstadt, Germany, we strive for responsible business conduct in our operations, the communities where we operate, our supply chain and our business relationships worldwide. Our heritage anchors us to a moral and ethical code of conduct that is reflected in our [Values](#). Respecting and supporting human rights is an integral part of this responsibility. Having negative impacts on human rights may entail legal consequences and could seriously harm our social license to operate, our competitiveness and our reputation.

This Human Rights Charter spells out our commitment to respecting human rights. It brings together and complements human rights aspects from our other [regulations and guidelines](#). The Charter has been approved by the Executive Board of Merck KGaA, Darmstadt, Germany.

Key related policies and guidelines*

- [Code of Conduct](#)
- [Social and Labor Standards Policy](#)
- [Environment, Health and Safety Policy](#)
- Security Policy
- Group Anti-Corruption Policy
- Policy for Data Protection and Personal Data Privacy
- Compliance Reporting and Investigation Policy
- [Charter on Access to Medicines in Developing Countries](#)
- [Research-related policies and principles, e.g. on fertility, stem cells and genome editing](#)
- [Responsible Sourcing Principles](#)

*Publicly available documents are hyperlinked.

We are committed to respecting human rights and supporting their realization. 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. The Charter's requirements are binding for our employees and we expect our suppliers and business partners to respect human rights and to practice human rights due diligence.

Through preventing, mitigating and remediating negative impacts on human rights we make an important contribution to the achievement of the [Sustainable Development Goals](#) (SDGs).

Our commitment is based on the [International Bill of Human Rights](#), the [UN Guiding Principles on Business and Human Rights](#) (UNGPR), the [UN Global Compact Principles](#), the [ILO Declaration on Fundamental Principles and Rights at Work and its Follow-up](#), and the [ILO MNE Declaration](#).

Where we face conflicts between our Group-wide standards and national laws, we will seek to act in accordance with the higher standard while ensuring legal compliance in our countries of operation.

2. Our due diligence processes

To know and show human rights are respected we conduct human rights due diligence.



Governance: The Executive Board of Merck KGaA, Darmstadt, Germany maintains the oversight for this Charter and related activities. Implementation is steered by the Group-



wide CR Committee. The internal Human Rights Working Group is tasked with implementing effective cross-organizational, collaborative efforts to fulfil our commitment to respect human rights as set out in this Charter. The Group comprises representatives from Corporate Responsibility, Procurement, Human Resources, Compliance, Security and Environment Health and Safety.

Roles and responsibilities: Our Board, all managers, employees, contractors and partners bear a responsibility to act in a way that respects human rights as outlined in this Charter. The Managing Directors of our legal entities are responsible for ensuring that this Charter is adhered to. We also expect our business partners and other parties linked to our operations, products or services, to respect human rights and to practice human rights due diligence.

What everyone at Merck KGaA, Darmstadt, Germany should do

- Be aware & ask questions!**
Risks to harm people exist everywhere in our operations – across countries and contexts. Even where you don't expect it.
- Avoid harm!**
Consider how our activities, products and services, including your own work, may impact people. Make sure to avoid any harm.
- Change course!**
If you feel there are risks to harm someone, change course and look for how to avoid this. If you don't know how, or there is imminent risk, raise the concern immediately with a manager.
- Select business partners with care!**
Make sure they share our commitment to respect human rights.
- Watch out!**
Where you work with other people, contractors, business partners, consumers or patients, watch out for signs of harm and raise concerns.
- Share!**
Your colleagues or people outside of Merck KGaA, Darmstadt, Germany may not know yet that they have access to the SpeakUp Line. Point them towards it.

Be alert and voice concerns – at any time!
Get in touch with your supervisor, HR, your local compliance officer or use our SpeakUp Line which is open for everyone – in and outside of Merck KGaA, Darmstadt, Germany! Via the **SpeakUp Line** you can voice concerns confidentially, whether it is about yourself, or about something you witness or suspect happening. **Make use of this opportunity!**

Stakeholder engagement: We continuously engage with stakeholders on our human rights commitments and due diligence processes (e.g. via the development and update of this Charter with input from key business functions and external stakeholders). We will continue to further develop our due diligence processes with our stakeholders – such as through the UN Global Compact and its local networks, industry specific dialogues and initiatives.



3. Specific human rights issue areas

Through our ongoing human rights due diligence processes, we have identified specific issue areas as priorities for our industry and our company. They cover our most significant risks to negatively, and opportunities to positively, impact human rights, and our greatest areas of responsibility. We will review our risk profile periodically and adapt this policy and our due diligence processes accordingly, in line with our commitment to continuous improvement.

Social and labor standards at Merck KGaA, Darmstadt, Germany

Our employees are the backbone of our business and our success depends on their health, safety, security, satisfaction and well-being.

Our [Social and Labor Standards Policy](#) sets out our commitment to respecting our employees' dignity and treating them fairly. We aim to respect the principles outlined in the policy – which cover the ILO (International Labor Organization) core labor standards among others - to the highest extent while ensuring legal compliance in our countries of operation. In case of contradictory standards provided by our local policies and the global policy, the highest standard will always apply. The policy is in effect at all Group locations and applies to all our employees.

Social and Labor Standards Policy coverage:

- Forced labor, modern slavery and human trafficking
- Child labor
- Freedom of association and the right to collective bargaining
- Fairness and respect (includes right to non-discrimination)
- Occupational Health and safety
- Working time and remuneration
- Parental leave

Access to health

Merck KGaA, Darmstadt, Germany respects the right to health and is committed to providing high-quality, safe health solutions for all. We address the health needs of underserved populations worldwide by enhancing availability, accessibility and affordability of our products, and by raising awareness in communities. This commitment is reflected in our [Charter on Access to Health in Developing Countries](#).

We recognize the importance of affordable access to medicines in low and middle income countries. We therefore register our products in low and middle income countries based on unmet needs and embrace the concept of [tiered pricing schemes](#). We [do not file or enforce](#)



[patent applications](#) in the large majority of low and middle income countries, including the least developed countries.

We work to [fight counterfeit medicines](#), which compromise access to safe and effective healthcare, particularly in low and middle income countries.

We are committed to [pursuing research and development efforts](#) on neglected tropical diseases and other priority communicable diseases such as malaria. These diseases are responsible for a large health burden in low and middle income countries and often disproportionately affect the poorest and most marginalized groups in society.

We engage with a variety of stakeholders including local communities, patient groups, access-related multi-stakeholder initiatives and programs globally, to continue to improve access to health for all.

By addressing global health needs in a business-integrated and sustainable manner, we create shared value and contribute to the achievement of the United Nations Sustainable Development Goals.

Product stewardship

The safety of our products for patients, end users and the environment is a critical priority. We therefore continually examine product safety across the entire life-cycle and take steps for necessary risk mitigation. We adhere to extremely strict safety regulations across our Group, striving for all our shipments to reach our customers and sites safely, undamaged and with the required safety information. We make the use of our products safer by providing patients and customers with up-to-date information 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. Our product authentication features go beyond legal requirements. When cases of product-related crime are identified, we cooperate with the law enforcement and public health authorities in the respective countries. In taking preventive action, we furthermore partner with representatives from Interpol and the World Customs Organization. Our guidelines, standards and processes apply to all our business sectors and markets worldwide.

For our **medicinal products** we conduct rigorous benefit-risk assessments to ensure that the benefits of our drugs always outweigh the risks for patients.

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 "Principles of Review and Approval of Promotional Materials and Other External Communications" set the standard for good and responsible marketing practices at Merck KGaA, Darmstadt, Germany. 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 all relevant regulatory requirements of our target markets, such as [REACH](#), [GHS/CLP](#) and [RoHS](#) for Europe as well as comparable regulations worldwide. We are also committed to the [Global Product](#)



[Strategy](#) of the International Council of Chemical Associations, the [Responsible Care®](#) principles of the chemical industry and the [Responsible Care Global Charter](#).

Research ethics

We are [committed](#) to conducting our preclinical research, clinical development and all our research activities adhering to the highest ethical standards.

Our Human Subjects Research and Development Policy and our processes for planning, conducting and overseeing **clinical trials** are designed to respect the human rights of trial participants, including particularly vulnerable populations. Our policy and management systems seek to ensure that we adhere to all legal, ethical and scientific standards, whether in industrialized or low and middle income countries. In addition to relevant national laws and regulations, these standards include the [Good Clinical Practice \(GCP\) guidelines](#) of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) and the [Declaration of Helsinki of the World Medical Association](#).

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. By making clinical trial information available, we are informing patients, investigators and healthcare professionals about the clinical research we sponsor, promoting the distribution of knowledge and minimizing the risk of duplication of research efforts and generally contributing towards transparency.

With respect to the topic of digital ethics and data re-use, any data collaboration efforts involving human subjects enrolled in clinical trials will conform to the same standards as our own Research Ethics guidelines, as well as supervision and monitoring of conformance from third-party entities.

We collaborate with specialist companies for the use of Artificial Intelligence (AI), which can help to speed up drug discovery and design. We will assess and address the potential human rights implications of this technology and our use of it.

Bioethics are foundational in guiding how we use the rapidly advancing knowledge and power of life sciences and novel technologies responsibly and ethically to the ultimate benefit of society, mankind and other living beings in a global environment.

Our Bioethics Advisory Panel (MBAP), consisting of renowned global bioethical experts in a broad range of sciences such as genomic medicine, bioethics, philosophy, theology and law, provides independent guidance and develops recommendations on bioethics topics. These recommendations are translated into binding policies determining how we work. In particular, we will continuously adapt our approach to genetic engineering of the human germline and reproductive cloning to the latest scientific findings and bioethical developments. Our [Guidelines](#) for stem cells and the avoidance of human cloning, fertility research and the use and handling of nanomaterial provide further guidance.

Privacy

We respect the privacy rights and protect confidential personal information of our employees, applicants, patients treated with our products, participants involved in our clinical trials, business partners, customers and other third parties. Our Group-wide



understanding of data privacy is based on European legislation, including the EU [General Data Protection Regulation](#), and also considers local data privacy requirements and needs.

We protect personal data entrusted to us by handling it properly, using it only for the intended and legitimate purposes, and considering the full rights of the individual at all times as stipulated by applicable law. Data re-use, licensing, and exchange with third parties entailing sensitive information will be protected and managed per applicable law and our relevant guidelines regarding Data Security and Privacy, as well as the appropriate consent of the individual.

We respect the dignity of others when handling their personal data, and we reject anything that stands in opposition to that commitment, for example, unlawful telephone or video recordings.

Highly sensitive information such as personal data related to health and data of children need to be particularly protected. We limit the processing of such data to the extent legally permitted to operate our business and develop new technologies and products.

Supply chain and business relationships

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 expect them to comply with our [Responsible Sourcing Principles](#) and to apply the same social and legal standards we put into practice within Merck KGaA, Darmstadt, Germany.

We use fair and transparent processes when selecting our suppliers and service providers, and regularly review our existing relationships based on risk profile and defined sustainability criteria. We do not accept any misconduct such as corruption, unfair competition, violation of environmental regulations, or substandard working conditions. We take adequate measures in the event of breaches.

We will only conduct business with suppliers who share our commitment to human rights. To help us achieve this goal, we identify the supply chains at greatest risk of adverse human rights impacts, based on country and category risk. Sourcing teams that are responsible for selecting and contracting suppliers are aware and regularly updated on CR requirements. Our supplier monitoring processes include environmental and social criteria along with human rights. Where we detect shortcomings, we are prepared to direct and guide suppliers to make improvements, and, if feasible, help them to build their capacity to fulfill the requirements. If a supplier is in breach of these criteria and cannot agree on an improvement plan, we reserve the right to end our relationship.

We assess the risk of adverse human rights impacts for different groups of contract staff and work to prevent, mitigate and address these impacts.

We expect our external business partners to uphold the [ten principles](#) of the UN Global Compact, including on human rights and anti-corruption. We employ due care in selecting these partners, especially sales-related business partners such as distributors and sales agents, and we do everything in our power to ensure that they comply with applicable laws and our company principles.



We are committed to continuously assessing and working to address additional human rights risks and impacts arising from these relationships.

Investment decisions

When projects exceed a certain cost threshold, our Investment Committee must approve the expenditure. The committee's decision considers factors such as environment safety and health. When it comes to investment projects, we are also bound by our [Code of Conduct](#), which stipulates compliance with the principles of the UN Global Compact, including on human rights and labor rights. We are working towards integrating the requirements of the UN Guiding Principles on Business and Human Rights into all our investment decisions.

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](#)). A key objective of this agreement is to ensure that countries providing genetic resources that are covered by the protocol also benefit from their use. We have common standards and processes in place to systematically assess and deal with instances of access and benefit sharing.

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.

All security functions at the group and local level as well as relevant third parties conduct their duties in line with applicable laws and good local practices. We require all third party providers to respect human rights in line with our [Responsible Sourcing Principles](#), our [Code of Conduct](#) and the Security Policy for Merck KGaA, Darmstadt, Germany. Measures such as screenings of final candidates and third party audits help us ensure good practice. We also regularly address our requirement of adherence to strict human rights regulations in the dialogue with our third party providers. We are committed to continuously improving our approach to identifying and addressing security-related human rights risks.



Bribery and corruption

Corruption is a substantial impediment to sustainable development and can have a devastating impact on the realization of human rights.

As a consequence, Merck KGaA, Darmstadt, Germany sets strict rules to prevent corruption globally. We do not offer bribes and we cannot be bribed. This clear message is reflected in our [Code of Conduct](#) and our Group Anti-Corruption Policy. In case any corruption-related questions arise our responsible staff members provide guidance and advice on how to prevent corruption and how to deal with dilemma situations.

We also engage with other stakeholders in combating bribery and corruption globally by taking an active role in the Steering Committee of the [Alliance for Integrity](#).

4. Handling of concerns and grievances

Our [SpeakUp Line](#) is our key grievance channel for any concerns, complaints and grievances regarding infringements against this Charter. All our employees and all external stakeholders can report concerns and grievances by telephone or via a web-based application in their respective national language, free of charge and anonymously. According to our internal principles stated in the Compliance Reporting & Investigation Policy, 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. We 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 events 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 grievance management systems with regard to the requirements in the UN Guiding Principles on Business and Human Rights.



5. Annex

Merck KGaA, Darmstadt, Germany human rights due diligence approach

1. Policy commitment:

This Human Rights Charter has been developed and reviewed with internal and external stakeholder and expert input.

2. Identifying actual and potential human rights impacts, including emerging risks:

Over the years, we have conducted a range of human rights risk and impact assessment processes:

- 2009: A first assessment prioritized the countries we operate in for the purpose of conducting audits on the implementation of the Social Charter, the precursor to the Human Rights Charter.
- 2012: A corporate human rights risk assessment aimed to identify the human rights and rightsholders affected by our operations, and to assess our human rights performance.
- 2014: Following the introduction of the Human Rights Charter in 2013, we conducted a human rights impact assessment in India to understand the opportunities and challenges in applying Group-wide standards to local operations.
- 2016: Merck KGaA, Darmstadt, Germany conducted a human rights self-assessment that covered all our locations globally, with the aim of improving our knowledge of our global human rights profile and identifying opportunities for targeted activities to enhance human rights due diligence worldwide. The assessment was based on our Human Rights Charter and structured in line with the process requirements for human rights due diligence set out in the UN Guiding Principles.

Ongoing risk assessments include conducting supplier assessments, audits and identifying actions on risk mitigations. We also assess the risk of adverse human rights impacts for different groups of contract staff. Additional risk assessment processes are conducted by the owners of the 'Specific human rights issue areas' set out above.

3. Addressing our impacts via clearly defined responsibilities, management processes and measures:

Actions following on from the risk assessments are conducted by the responsible functions and governance groups (see also 'Governance' and 'Roles and responsibilities' in the main due diligence section above). Relevant management processes and measures are also set out in the 'Specific human rights issue areas'.

4. Training on human rights throughout the organization and beyond:

We conduct human rights training for specific groups (e.g. Sourcing staff and EHS managers).

5. Tracking and communicating performance:



We publish our progress via our CR Report and website.

6. Ensuring effective grievance mechanisms are in place:

Among others, the SpeakUp Line is a key grievance channel for employees and external stakeholders. We continue to evaluate and improve the effectiveness of our grievance systems based on the requirements of the UN Guiding Principles on Business and Human rights.

7. Stakeholder engagement:

Continuous engagement with stakeholders on our human rights commitments and due diligence processes (e.g. to update the Human Rights Charter with input from key business functions and external stakeholders). We will continue to further develop our due diligence processes with our stakeholders – such as through the UN Global Compact and its local networks, industry specific dialogues and initiatives.

