OUR 2020 SASB DISCLOSURE

2020 SASB Disclosure of Merck KGaA, Darmstadt, Germany

This is our first Sustainability Accounting Standards Board (SASB) disclosure report that aligns with the SASB Biotechnology & Pharmaceuticals industry standard. Our reporting against the SASB standard is a voluntary disclosure to meet the increasing demands of our investors and other stakeholders. The disclosed metrics provide transparent, financially material, and meaningful information on sustainability. In order to fulfill the interests and requirements of our stakeholders in the future, we will continuously develop and expand our SASB reporting.

Sustainability Accounting Standards Board (SASB) Index

Biotechnology & Pharmaceuticals Standard

Our disclosure against the following SASB metrics essentially include our Group-wide approach. In case we refer to one particular business (e.g. our Healthcare business), we indicate this explicitly in our response.

Activity Metrics		
HC-BP-000.A	Number of patients treated	In 2020, we treated around 92 million patients with our Healthcare medicines. Additionally, we donated enough praziquantel tablets to treat around 90.5 million school-aged children in 2020.
HC-BP-000.B	Number of drugs (1) in portfolio and (2) in research and development (Phases 1-3)	For our Healthcare portfolio please see: - 2020 Annual Report (p. 15-19) For our Healthcare pipeline please see: - our website - 2020 Annual Report (p. 57-58)

Safety of Clinical Trial Participants		
HC-BP-210a.1	Discussion, by world region, of management process for ensuring quality and patient safety during clinical trials	See 2020 Sustainability Report: - Clinical trials See our website: - R&D Policies
HC-BP-210a.2	Number of FDA Sponsor Inspections related to clinical trial management and pharmacovigilance that resulted in: (1) Voluntary Action Indicated (VAI) and (2) Official Action Indicated (OAI)	In 2020 we had three FDA Good Clinical Practice (GCP) inspections related to clinical trials, none of which resulted in an VAI or OAI.
HC-BP-210a.3	Total amount of monetary losses as a result of legal proceedings with clinical trials in developing countries [€]	Not reported
Access to Medicines		
HC-BP-240a.1	Description of actions and initiatives to promote access to health care products for priority diseases and in priority countries as defined by the Access to Medicine Index	See 2020 Sustainability Report: - Health for all

HC-BP-240a.2	List of products on the WHO List of Prequalified Medicinal Products as part of its Prequalification of Medicines Programme (PQP)	Currently there is no product on the list.

Affordability & Pricing

HC-BP-240b.1	Number of settlements of Abbreviated New Drug Application (ANDA) litigation that involved payments and/or provisions to delay bringing an authorized generic product to market for a defined time period.	Not reported
HC-BP-240b.2	Percentage change in: (1) average list price and (2) average net price across U.S. product portfolio compared to previous year	Please see table on the average list price of our Healthcare US product portfolio in the appendix.
HC-BP-240b.3	Percentage change in: (1) list price and (2) net price of product with largest increase compared to previous year	We only report the percentage change in average list price across our US product portfolio. The largest increase compared to the previous year amounted to 9.7% (Mavenclad®). Please see table in the appendix.

Drug Safety		
HC-BP-250a.1	List of products listed in the Food and Drug Administration's (FDA) MedWatch Safety Alerts for Human Medical Products database	See FDA website: - Safety information and adverse event reporting program - Adverse event reporting system (FAERS) public dashboard
HC-BP-250a.2	Number of fatalities associated with products as reported in the FDA Adverse Event Reporting System [total number]	See FDA website: - Adverse event reporting system (FAERS) public dashboard
HC-BP-250a.3	Number of recalls issued, total units recalled	In 2020 we had six drug product recalls in total. None of those recalls was a global one, they affected individual countries only. One recall was related to the USA and only impacted a single batch of one product. None of the recalls was related to serious injury or fatality, all were either Class II or III. According to our internal policies, any recall type is reported and discussed with the relevant national regulatory authority, including the US FDA. All recall processes are managed under a Global Standard Procedure "Product Recall and Withdrawal Management" which is applied worldwide for medicinal products (pharmaceutical prescription, biological) and devices.

HC-BP-250a.4	Total amount of product accepted for takeback, reuse, or disposal	We do not accept takeback of products for reuse. We take back products for disposal in line with legal requirements in each country.
HC-BP-250a.5	Number of FDA enforcement actions taken in response to violations of current Good Manufacturing Practices (cGMP), by type	We had no such FDA enforcement actions in 2020.
Counterfeit Drugs		
HC-BP-260a.1	Description of methods and technologies used to maintain traceability of products throughout the supply chain and prevent counterfeiting	We comply with the requirements for product serialization, track and trace technology including barcoding and product aggregation, as mandated by existing local regulations in various regions and countries across the globe. In addition to the mandatory regulatory requirements, we apply the same technologies also in other countries. Additional anti-counterfeiting measures in the form of semi-overt and covert security features, as well as tamper evident solutions are implemented globally. See 2020 Sustainability Report: - Product-related crime

HC-BP-260a.2	Discussion of process for alerting customers and business partners of potential or known risks associated with counterfeit products	We have implemented processes and procedures to ensure all suspected counterfeit medicines are assessed by a team of experts. The scope of any notification that we provide is the outcome of the strategic alignment between relevant functions (e.g. Medical, Supply Chain, Legal, Quality, Corporate Security, Regulatory Affairs, Communications). Levels of details and format of any notification, including the HA information and collaboration, dedicated patient communication, information / awareness communication to distributors, pharmacies, physicians etc. about the presence of counterfeit or diverted product in the market, is decided on a case by case basis in accordance with the identified risks and taking into account corporate, legal and regulatory responsibilities. See 2020 Sustainability Report: - Product-related crime
HC-BP-260a.3	Number of actions that led to raids, seizure, arrests, and/or filing of criminal charges related to counterfeit products	We fully cooperate with law enforcement and other (regulatory) authorities related to the investigations and analysis of suspected counterfeit products worldwide. Intelligence about counterfeit presence in markets, is shared with the relevant authorities in order to jointly investigate measures to eliminate the issue. In addition, pro-active investigations are carried out and actions are taken to eradicate the offering of our products through illegitimate channels (e.g. internet sales, on-line pharmacies). As member of the Pharmaceutical Security Institute (PSI) and through cooperation with other pharmaceutical companies, intelligence is gathered to support investigations into the prevalence of counterfeit products. See 2020 Sustainability Report: - Product-related crime

Ethical Marketing		
HC-BP-270a.1	Total amount of monetary losses as a result of legal proceedings associated with false marketing claims	Not reported
HC-BP-270a.2	Description of code of ethics governing promotion of off-label use of products	See 2020 Sustainability Report: - Responsible interactions with health systems
Employee Recruitment, Development & Retention		
HC-BP-330a.1	Discussion of talent recruitment and retention efforts for scientists and research and development personnel	See 2020 Sustainability Report: - Good Leadership - Career with us - Diversity and inclusion
HC-BP-330a.2	(1) Voluntary and (2) involuntary turnover rate for: (a) executives/senior managers, (b) midlevel managers, (c) professionals, and (d) all others	See 2020 Sustainability Report: - Indicators: employees

Supply Chain Management		
HC-BP-430a.1	Percentage of (1) entity's facilities and (2) Tier I suppliers' facilities participating in the Rx-360 International Pharmaceutical Supply Chain Consortium audit program or equivalent third-party audit programs for integrity of supply chain and ingredients	Our Healthcare business does not participate in the Rx-360 International Pharmaceutical Supply Chain Consortium. However, our facilities are frequently audited by the respective Health authorities of the countries in which we distribute our Healthcare products. Our Life Science Business, as a major supplier to the pharmaceutical industry, participates in the Rx 360 audit program. With regards to our supplier base, we have access to sustainability audits and assessments of our suppliers through our membership in the industry initiatives "Together for Sustainability" (TfS) and "Pharmaceutical Supply Chain Initiative" (PSCI) (membership process in progress).
Business Ethics		
HC-BP-510a.1	Total amount of monetary losses as a result of legal proceedings associated with corruption and bribery	Not reported

HC-BP-510a.2	Description of code of ethics governing interactions with health care professionals	Our Code of Conduct sets and explains our company's values and our ethical integrity standards (e.g. "*We cannot be bribed, and we do not offer bribes*", "*We make our cooperation with healthcare partners transparent*", among many others). It is complemented by our Anti-Corruption Policy which stipulates that all business activities must be conducted in line with legally applicable anti-corruption standards. Specifically, with regard to our interactions with healthcare professionals, our Healthcare Ethical Guiding Principles addresses the topic with the principles "*Responsible Interactions*" and "*Safeguard Independence*". These general governance documents are complemented by more than twenty specific Standards and Policies, plus procedural and Guidance Documents covering a myriad of precise interactions and engagements with healthcare professionals. See 2020 Sustainability Report: - Compliance management - Responsible interactions with health systems

Appendix

Average list price of our Healthcare US product portfolio (HC-BP-240b.2)

Our Healthcare US product portfolio – Average list price/WAC

Product	2020 (% change vs. prior year)
Rebif®	7.5%
Mavenclad®	9.7%
Bavencio®	2.7%
Gonal-f®	7.5%
Cetrotide®	4.1%
Ovidrel®	7.5%
Serostim®	8.1%
Saizen®	5.6%

Imprint

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