Sustainability Accounting Standards Board (SASB) Index

Health Care Sector

Biotechnology and Pharmaceuticals Industry

The first Novartis Sustainability Accounting Standards Board (SASB) Index aligns with the Biotechnology and Pharmaceutical Industry guidelines. Data and information disclosed are sourced from the Novartis 2019 Corporate Reporting suite (Annual Review; Annual Report/Form 20-F; Novartis in Society ESG Report), 2019 Environmental, Social and Governance Index, and Novartis public policies and positions.

SASB indicator		Novartis references
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	We have mechanisms in place to protect all trial participants, when consenting to the research, during the conduct of the trial and after completion. We have additional processes in place to protect vulnerable patients. We ensure voluntary informed consent to the research, including the right to withdraw from the trial at any time and the right to withdraw consent for the collection and use of their personal data. Novartis Position on Responsible Clinical Trials Novartis Commitment to Patients and Caregivers What should I know before joining a clinical trial? Ethics in Clinical Trials Human Rights Guideline - Procedure to obtain participants' free, prior and informed consent (p.6)
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)	Novartis received 19 FDA inspections for which 10 resulted in a Form 483. In each case, corrective and preventative actions were taken. Novartis ESG Index - Regulatory warnings, (p.11)
HC-BP-210a.3	Total amount of monetary losses as a result of legal proceedings associated 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	Novartis in Society Report 2019 (p.20-38) Novartis Access

HC-BP-240a.2	List of products on the WHO List of Prequalified Medicinal Products as part of its Prequalification of Medicines Programme (PQP)	Novartis has tuberculosis and malaria products on the WHO List of Prequalified Medicinal Products. Novartis products Sandoz products
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	For US product portfolio – % change vs. prior year (1) Average list price: 4.9% (2) Average net price: 2.9% Novartis in Society US Report 2019 (p.9)
HC-BP-240b.3	Percentage change in: (1) list price and (2) net price of product with largest increase compared to previous year	Not reported
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	Available via FDA Adverse Event Reporting website
HC-BP-250a.2	Number of fatalities associated with products as reported in the FDA Adverse Event Reporting System	Available via FDA Adverse Event Reporting website
HC-BP-250a.3	Number of recalls issued, total units recalled	In 2019, Novartis initiated 29 recalls (vs. 42 in 2018 and 47 in 2017); 27 of the initiated recalls only had a local impact. Out of these 29 recalls, Novartis initiated 2 global recalls, both for generic products: One for Ranitidine in 27 countries due to contamination with traces of N-Nitrosodimethylamine (NDMA) and one for Amoxicilline/Potassium Clavulanate powder for oral suspension in 18 countries, a precautionary recall due to sealing defects of a very small number of bottles. Novartis ESG Index - Product Recalls (p.10) Novartis Annual Report 2019 (p.57)
HC-BP-250a.4	Total amount of product accepted for takeback, reuse, or disposal	Novartis in Society Report 2019 (p.48)

HC-BP-250a.5	Number of FDA enforcement actions taken in response to violations of current Good Manufacturing Practices (cGMP), by type	177 inspections were completed in 2019, and all but six were deemed acceptable (96.6%). Out of the 177 inspections, Novartis received 19 FDA inspections for which 10 resulted in a Form 483. In each case, corrective and preventative actions were taken. Novartis ESG Index - Regulatory warnings (p.11)
Counterfeit Drugs		
HC-BP-260a.1	Description of methods and technologies used to maintain traceability of products throughout the supply chain and prevent	Novartis in Society Report 2019 (p.41-42)
HC-BP-260a.2	Discussion of process for alerting customers and business partners of potential or known risks associated with counterfeit products	Novartis in Society Report 2019 (p.41-42)
HC-BP-260a.3	Number of actions that led to raids, seizure, arrests, and/or filing of criminal charges related to counterfeit products	We investigated 268 incidents of suspected falsified medicines (i.e., a 23% increase compared to 2018), which led to 61 successful enforcement actions and the seizure of over 2 million falsified medicines (unit dosage forms) by law enforcement and health authorities. Novartis in Society Report 2019 (p.41-42)
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	Procedures for off-label requests outlined; further information on ethical marketing contained in P3 Guideline on Promotional and Non-Promotional Materials Professional Practices Policy (P3) (p.5)
Employee Recruitment, Development & Retention		
HC-BP-330a.1	Discussion of talent recruitment and retention efforts for scientists and research and development personnel	Next Generation Scientist program & career development fellowship Novartis Annual Review 2019 (p.38) In addition to the focus on D&I, our talent strategy aims to anticipate future business priorities. Internal promotion has played a vital role in revitalizing the company's leadership as we transform our culture, with four out of 10 new ECN members in the last two years coming from within the organization. Among the company's top 293 leaders, 38% were appointed during the past year and 82% of these positions were filled internally. We are also stepping up external recruitment, both to refill the talent pipeline and to develop our capabilities in key areas such as data science. Novartis Annual Review 2019 (p.20)

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	Voluntary/overall turnover rate: 7%/14%; high performers voluntary turnover rate: 5.4% Novartis in Society Report 2019 (p.53)
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	(1) For the manufacture of medical devices, we hold the relevant certifications from ISO and other notified bodies. For all manufacturing, supply and distribution of Novartis pharmaceutical products, we hold the relevant manufacturing licenses and GMP/GxP certificates issued by the appropriate health authorities (FDA, EMEA, WHO, SwissMedic), that confirm after inspection that our duties, including our quality management systems, comply with their regulatory requirements. All Novartis employees in Manufacturing and Quality Assurance are continuously trained to maintain the skills and knowledge needed to manufacture medicine safely, compliantly and effectively. These trainings include: Aseptic Operator, Enhanced Third-party Oversight, Investigation Certification Program and Quality Management Systems. Novartis in Society Report 2019 (p.41) Novartis ESG Index (p.8) (2) Not reported
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	Professional Practices Policy (P3) (p.5) Payments to Healthcare Professionals
Activity metrics		
HC-BP-000.A	Number of patients treated	799 million Novartis Annual Review 2019 (p.9)
HC-BP-000.B	Number of drugs (1) in portfolio and (2) in research and development (Phases 1-3)	(1) Novartis Global Product Portfolio (Novartis Innovative Medicines) Sandoz Advanced Accelerator Applications (2) 160+ Novartis Annual Review 2019 (p.27)