

# Sustainability Accounting Standards Board (SASB) Index

## Health Care Sector Biotechnology and Pharmaceuticals Industry

The Novartis Sustainability Accounting Standards Board (SASB) Index aligns with the Biotechnology and Pharmaceutical Industry guidelines. Data and information disclosed are sourced from the Novartis 2020 Corporate Reporting suite (Annual Review; Annual Report/Form 20-F; Novartis in Society ESG Report), 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. <a href="#">Novartis Position on Responsible Clinical Trials</a> <a href="#">Novartis Commitment to Patients and Caregivers Information for patients and caregivers</a> <a href="#">Ethics in Clinical Trials</a> <a href="#">Human Rights Guideline (p.6) – Procedure to obtain participants’ free, prior and informed consent</a>
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 one FDA inspection related to clinical trial management and pharmacovigilance. No VAI or OAI was indicated. <a href="#">Novartis in Society ESG Report 2020 (data table p.57)</a>
HC-BP-210a.3	Total amount of monetary losses as a result of legal proceedings associated with clinical trials in developing countries	All material legal proceedings are disclosed within the Annual Report and accounts <a href="#">(p.F-49)</a> .

### 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	<a href="#">Novartis in Society ESG Report 2020 (p.30-53)</a> <a href="#">Novartis Access</a>
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. <a href="#">Novartis products</a> <a href="#">Sandoz products</a>

### 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	We report these changes annually within our <a href="#">Novartis in Society US Report</a> .
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 2020, Novartis initiated 27 recalls (vs. 29 in 2019 and 42 in 2018). There were no global recalls. <a href="#">Novartis in Society ESG Report 2020 (p.56 and data table p.57)</a>

SASB indicator	Novartis references
HC-BP-250a.4	Total amount of product accepted for takeback, reuse, or disposal <a href="#">Novartis in Society ESG Report 2020 (p.67)</a>
HC-BP-250a.5	Number of FDA enforcement actions taken in response to violations of current Good Manufacturing Practices (cGMP), by type Novartis received 6 FDA inspections for which one resulted in a form 483. No warning letters were received. <a href="#">Novartis in Society ESG Report 2020 (data table p.57)</a>

## COUNTERFEIT DRUGS

HC-BP-260a.1	Description of methods and technologies used to maintain traceability of products throughout the supply chain and prevent counterfeiting <a href="#">Novartis in Society ESG Report 2020 (p.58-59)</a>
HC-BP-260a.2	Discussion of process for alerting customers and business partners of potential or known risks associated with counterfeit products <a href="#">Novartis in Society ESG Report 2020 (p.58-59)</a>
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 247 incidents of suspected falsified medicines, which led to 60 successful enforcement actions and the seizure of 1.7 million medicines (unit dosage forms) by law enforcement and health authorities. <a href="#">Novartis in Society ESG Report 2020 (p.59)</a>

## ETHICAL MARKETING

HC-BP-270a.1	Total amount of monetary losses as a result of legal proceedings associated with false marketing claims All material legal proceedings are disclosed within the Annual Report and accounts <a href="#">(p.F-49)</a> .
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 <a href="#">Professional Practices Policy (p.5)</a> on Promotional and Non-Promotional Materials

## EMPLOYEE RECRUITMENT, DEVELOPMENT & RETENTION

HC-BP-330a.1	Discussion of talent recruitment and retention efforts for scientists and research and development personnel <a href="#">Novartis in Society ESG Report 2020 (p.42, p.61)</a>
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: 5.2%/10.1%; high performers voluntary turnover rate: 4.2% <a href="#">Novartis in Society ESG Report 2020 (p.71)</a>

## 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. <a href="#">Novartis in Society ESG Report 2020 (p.55)</a> <a href="#">Novartis Quality Management System (QMS)</a> <a href="#">Product and patient safety training</a> (2) <a href="#">Third-party suppliers</a> <a href="#">Novartis Audit program</a>
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## BUSINESS ETHICS

HC-BP-510a.1	Total amount of monetary losses as a result of legal proceedings associated with corruption and bribery All material legal proceedings are disclosed within the Annual Report and accounts <a href="#">(p.F-49)</a> .
HC-BP-510a.2	Description of code of ethics governing interactions with health care professionals <a href="#">Professional Practices Policy (p.5)</a> <a href="#">Payments to Healthcare Professionals</a>

## ACTIVITY METRICS

HC-BP-000.A	Number of patients treated 769 million <a href="#">Novartis in Society ESG Report 2020 (p.9)</a>
HC-BP-000.B	Number of drugs (1) in portfolio and (2) in research and development (Phases 1-3) (1) <a href="#">Novartis Global Product Portfolio (Novartis Innovative Medicines)</a> <a href="#">Sandoz</a> <a href="#">Advanced Accelerator Applications</a> (2) 160+ <a href="#">Novartis Annual Review 2020 (p.29)</a>