

To: Director of Research, 2017 Public Comment Period, Sustainability Accounting Standards Board, 1045 Sansome St., Suite 450, 94111

Date: 29 January 2018

## Comments to SASB Exposure Draft Standard for the Biotechnology and Pharmaceuticals Industry

Dear Mr. Post,

The undersigned institutional investors, who manage assets worth more than USD 5.7 trillion, provide the following comments to SASB Exposure Draft Standard for the Biotechnology and Pharmaceuticals Industry.

- General comment

The signatory investors to the Access to Medicine Index commend SASB for the strong alignment between the Exposure Draft Standard for the Biotechnology and Pharmaceuticals Industry and the methodology of the Access to Medicine Index. As recognised by SASB in its Basis for Conclusions (October 2017), it is key that SASB metrics are “based on those already in use by issuers or are derived from standards, definitions, and concepts already in use by issuers, governments, industry associations, and others.” The methodology of the Access to Medicine Index, which is developed and ratified through a comprehensive multi-stakeholder consensus-building process, is the most authoritative framework for action for pharmaceutical companies in the field of access to medicine.

- Add “actions” and “priority diseases” to the title of HC0101-01

*Suggested change:* “HC0101-01. 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.”

*Rationale:* The explanatory notes for HC0101-01 already describe not only access to medicine “initiatives”, such as product donations, but also core business “actions”, such as R&D projects and strategies for affordable pricing. As metrics are tools for driving change as well as for measuring change, it is important that the title of the metric clarifies that the latter are within the scope of the metric. Moreover, the explanatory notes for HC0101-01 already refer to the priority diseases defined by and identified in the Access to Medicine Index, yet this reference is missing from the title of the metric. Greater emphasis on priority diseases is important as the Access to Medicine Foundation recently published the new methodology for the 2018 Access to Medicine Index, and cancer is now in scope for the first time ever.

- Align the notes for HC0101-01 with the technical areas of the Access to Medicine Index

*Suggested change:* “.02 The following issues as they relate to access to health care initiatives may be relevant for the registrant to discuss: **market influence and compliance; research and development; pricing, manufacturing and distribution; patents and licensing; capacity building; product donations. The Access to Medicine Index Methodology already offers consensus-based guidance for standardised reporting on these issues.**”

*Rationale:* It is important for companies that reporting standards and sector initiatives are aligned with each other. The methodology of the Access to Medicine Foundation is the most authoritative framework

for action for pharmaceutical companies in the field of access to medicine, developed and ratified through a multi-stakeholder consensus-building process.

- Align the notes for HC0101-01 with the new scopes of the Access to Medicine Index

For priority diseases: “.03 ... A full list is on page 27 of the Access to Medicine Index Methodology 2017.”

For priority countries: “.05 ... The full list of countries included is on Page 30 of the Access to Medicine Index Methodology 2017.”

*Rationale:* It is important to align the final SASB Standard with the latest Access to Medicine Index methodology. The current version of the Exposure Standard refers to an old version of the Access to Medicine Index Methodology.

- Add reference to the Access to Medicine Index in the title of TA01-02-01

“TA01-02-01. Total amount of losses as a result of legal proceedings associated with clinical trials, **in particular, in priority countries as defined by the Access to Medicine Index.**”

*Rationale:* The explanatory notes for TA01-02-01 already refer to the priority countries included in the Access to Medicine Index. However, this reference is missing from the title of the metric. The suggested formulation also clarifies that the metrics on “Safety of Clinical Trial Participants” should, in principle, cover all countries. Priority countries do present the most significant risks, but the result of losses is a material issue across the board.

- Change wording from “mechanisms” to “internal control framework” in the titles of HC0101-13 and HC0101-28

“HC0101-13. Description of code of ethics governing promotion of off-label use of products, including **its internal control framework** to ensure compliance.”

“HC0101-28. Description of code of ethics governing interactions with health care professionals, including **its internal control framework** to ensure compliance.”

*Rationale:* The new methodology of the Access to Medicine Index offers a comprehensive description of the mechanisms that can be used to ensure employee compliance to laws and codes of ethics, and defines them the company’s “internal control framework”. According to the methodology of the Access to Medicine Index, an internal control framework is “a series of processes and structures aimed at minimising the risk of occurrence of non-compliant activities and/or behaviour of the company’s employees and, if applicable, its company’s third parties.” The following elements are part of a robust internal control framework: “fraud-specific risk assessment; a monitoring system for compliance (other than auditing); auditing and review mechanisms, which involve the use of both internal and external resources, and apply to all third parties and all countries where it has operations, based on risk assessment; procedures for segregation of duties between: management tasks and authorisation tasks, custody of assets and verification tasks, and accounting tasks and payment tasks.”

- Add the topic of “Antimicrobial Resistance”

SASB should consider adding the topic of Antimicrobial Resistance and aligning its metrics with the methodology of the [Antimicrobial Resistance Benchmark](#) (including the environmental impacts of manufacturing antibiotics).

*Rationale:* More than 700,000 people already die every year from drug-resistant bacterial infections. This number will reach 10 million people a year worldwide – more than currently die from cancer – by 2050 unless action is taken. Society expects pharmaceutical companies, together with governments and other stakeholders, to play a crucial role in preventing this scenario, while acknowledging that biotechnology and pharmaceuticals companies find investing in the development of new antibiotics risky. Future revenues related to basic procedures in modern medicines (from chemotherapy to hip replacements) are at stake in a world where antibiotics do not work anymore and the pipeline of new antibiotics is dry.

Yours sincerely,



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