

B Lab Statement on Opella's Baseline Requirements

B Lab's independent Multinational Standards Advisory Council determined that to become a Certified B Corp Certification, companies with \$5 billion or more in revenue must meet minimum Baseline Requirements in addition to the other certification requirements (i.e. adopting stakeholder governance, overall verified score over 80 on B Impact Assessment, passing Disclosure Review process for controversial issues). These additional requirements recognise that the overall scale and influence of these companies also entail higher obligations to society, and are designed to ensure that B Corp Certified multinationals have strong records of performance on important aspects of their social and environmental performance in addition to achieving a score of 80 or above on the B Impact Assessment.

In December 2021, the [Guidelines for Acceptance for the Baseline Requirements](#) were created to provide transparency for stakeholders into the processes that both the B Lab Large Enterprise team and the MNC SAC will use to determine whether a company is meeting the Baseline Requirements. As companies undergo a formal review by the MNC SAC, these Guidelines ensure consistency in the review process and the creation of precedents that demonstrate concrete actions that companies can undertake to meet each of the five Baseline Requirements.

Summary of Company

[Opella](#) is a leading fast-moving consumer healthcare (FMCH) company, established in 2014 and headquartered in Paris, France. With a global presence, Opella operates in 38 countries and sells over-the-counter (OTC) medicines and vitamins, minerals, and supplement (VMS) products in over 140 countries. Opella certified as a wholly owned subsidiary of Sanofi.

Company Actions towards meeting the Baseline Requirements

1. Reporting: An annual, comprehensive impact report transparent to the public using a third-party standard (GRI, BIA, etc).

Opella releases an annual non-financial report covering material, non-financial impacts relating to all entities within the scope of certification. This report comprehensively and transparently views Opella's sustainability purpose, strategy, materiality, previous year's results, and forward-looking ambition. The [2022 and 2023 non-financial reports](#) are made available to the public, and the 2023 FY report is to GRI standards.

2. Materiality Assessment: A transparent materiality assessment and stakeholder engagement process, conducted on a regular basis (minimum every other year with mechanisms for intermediate updates as appropriate), and used to identify relevant megatrends and material topics to the company, that includes a transparent grievance/complaint mechanism, and that is overseen by the Board of Directors.

Opella conducted its first materiality assessment in 2022. In 2024, Opella updated its 2022 materiality assessment, which will be published in the FY24 Sustainability Report, to be released in 2025. Opella is committed to conducting materiality assessments in support of its sustainability



reporting regularly. A range of stakeholders was selected to ensure an appropriate representation of the expectations of all members of its ecosystem. Opella maintains continued and ongoing engagement with stakeholders to ensure we consistently incorporate insights and feedback into their process.

Opella has, in alignment with its parent company, a grievance/complaint mechanism, Speak Up!, in place for employees, customers and suppliers, as well as a separate complaints line for patients and consumers. The outcomes of the grievance/complaint mechanism are incorporated into the materiality assessment process. Opella's materiality assessments are overseen by Opella's highest governing body, Opella's Executive Committee, with the parent company (Sanofi Group) informed.

3. Materiality Issue Management: Management strategies on the most material issues relevant to the business that are overseen by the Board of Directors, and includes specific, aspirational performance goals and demonstrated progress towards those goals. Management strategies and performance goals must be made transparent to stakeholders.

In October 2024, Sanofi announced [plans to separate](#) the consumer healthcare business, expected in Q2 2025, aiming to create two distinct entities better positioned to pursue their growth strategies. Therefore, Opella is currently facing a unique circumstance where the timeline for reaching group certification and the final Baseline Requirements approval in advance of this milestone coincides with the anticipated separation of Opella from the Sanofi Group. Given the upcoming separation, Opella is taking the opportunity to update its sustainability strategy, embedding it within the core of its business. This includes ensuring alignment of the sustainability strategy with its materiality assessments, B Corp certification requirements and its reporting within future expectations imposed by the EU Corporate Sustainability Reporting Directive.

Considering the above, Opella is not meeting the Materiality Issue Management requirement at this point. B Lab worked with the company on a proposal, which was approved by the MNC SAC. The proposal requires Opella to share a compliance roadmap with B Lab, including how it is going to meet the Baseline Requirements within 90 days of separation and to submit the Materiality Issue Management requirement no later than one year after separation.

4. Tax & Government Affairs Disclosure: A disclosure statement on the company's tax philosophy/approach and government affairs (lobbying/advocacy), including the company's overall effective tax rate, that is overseen by the Board of Directors.

Opella follows the parent company's (Sanofi Group) [Tax Policy](#), which outlines Sanofi's tax strategy and responsible tax practices. This policy includes information on the approach regarding compliance, transparency, and tax risks, as well as outlines key stakeholders. Sanofi's annual effective tax rate is publicly disclosed and includes the disclosure statement and tax philosophy. Opella is responsible for tax in its jurisdictions as it has a dedicated Global Head of Tax and Heads of Tax within each region who oversee all tax-related matters for Opella's legal entities. Opella will have its dedicated policies and governance structure as an independent company after separation from Sanofi, which includes tax.



For Government Affairs, Opella follows the parent company's global lobbying policy as per the One Sanofi Approach. This policy outlines Sanofi's principles to responsible lobbying as well as providing details of the main industry-specific associations which Sanofi adheres and/or contributes to at the Group Level. Additionally, as part of Opella's B Corp certification, Opella must meet B Lab's standards for pharmaceuticals which requires companies to be reviewed and be found to not be engaged in any form of lobbying or policy advocacy that endangers consumer safety, promote an anti-competitive environment (e.g. by opposing increased transparency measures), inhibit affordable pricing or limit equitable access to medicine.

The [Sanofi Code of Conduct](#) provides details on Sanofi's adherence to national laws and regulations and its approach to conflict of interest, political contributions, corruption, bribery and the revolving door policy. The Revolving Door Policy is detailed in Opella's internal global policy on "Responsible Lobbying and Interaction with government officials". The rollout, enforcement and accountability requirement is met as Sanofi's 'One Sanofi Approach' to lobbying is overseen by Opella's Public Affairs team. The Sanofi Global Public Affairs function is accountable to report transparently at Group Level on activities related to lobbying, trade associations participation, and patient groups engagement across all four business units (which includes Opella/Consumer Healthcare).

Opella will begin its independent reporting on lobbying activities post separation from Sanofi Group in 2025, however, additional transparency of specific Opella lobbying activities is already available on the Opella.com website under the mention of '[Transparency for Public Affairs activities](#)'.

5. Human Rights Policy: A specific human rights policy that is overseen by the Board of Directors, and includes EITHER an explicit commitment to key human rights covenants (including the UN Declaration of Human Rights, UN Guiding Principles on Business and Human Rights, and ILO Principles), OR identifies the most salient human rights issues relevant to the business and its overall operations through a human rights risk assessment.

Opella follows its parent's Human Rights Policy, which commits to the key human rights covenants: The Universal Declaration of Human Rights, the United Nations Guiding Principles on Business and Human Rights, and the ILO Principles. The Human Rights Policy applies to all Sanofi (including Opella) employees, suppliers, patients and local communities and is publicly available and accessible on the Opella.com website, here: [Standards | Opella](#), along with the Code of Conduct and Speak Up! grievance mechanism. In 2025, Opella will develop and publish a Human Rights Policy as a standalone company.

The Human Rights policy also identifies Sanofi's salient human rights issues. Opella has translated Sanofi's commitment to human rights across three policies: Code of Conduct, Responsible Purchasing, and Data Protection. At the Opella level, the Business Integrity team is accountable for adherence to the Code of Conduct and Data Protection Policy, and the Procurement team is accountable for the Responsible Purchasing Policy. Overall, the Head of Consumer Healthcare is responsible for oversight of Human Rights at Opella.



Conclusion

On March 25th, 2025, the Multinational Standards Advisory Council determined that Opella meets four out of the five Baseline Requirements in full and approved of the proposal for Opella meeting the fifth requirement - around Materiality Issue Management – submitting to the MNC SAC no later than one year after separation.