B Impact Assessment™

Opella
2025 Aggregated Disclosure Report

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Note: Opella achieved B Corp certification as a wholly-owned subsidiary of Sanofi, prior to becoming a standalone company.

Disclosure Materials

Certified B Corporations must complete a Disclosure Questionnaire to identify potentially sensitive issues related to the company (e.g. historical fines, sanctions, material litigation, or sensitive industry practices).

This component does not affect the company's score on the B Impact Assessment. If the company answers affirmatively to any items in the Disclosure Questionnaire that B Lab deems relevant for public stakeholders, then, as a condition of their certification, the company must:

1) Be transparent about details of the disclosure issues identified on the company's public B Impact Report
2) Describe how the company has addressed this issue
3) Demonstrate that management practices are in place to avoid similar issues from arising in the future, when necessary.

In all cases, the Standards Advisory council reserves the right to refuse certification if the company is ultimately deemed not to uphold the spirit and integrity of the community.

In addition to the voluntary indication of sensitive issues in the Disclosure Questionnaire, companies pursuing Certification also are subject to a background check by B Lab staff. Background checks include a review of public records, news sources, and search engines for company names, brands, executives/founders, and other relevant topics.

Sensitive issues identified through background checks may or may not be within the scope of questions in the Disclosure Questionnaire, but undergo the same review process and are subject to the same possible review by the Standards Advisory Council, including ineligibility for B Corp Certification, required remediation, or disclosure.

This document contains a copy of the company's completed Disclosure Questionnaire and related disclosure documentation provided by the company

Opella France & Russia

Disclosure Report

Date Submitted: April, 2025

Disclosure Questionnaire

Industries and Products

	Yes	No
Please indicate if the company is involved in production of or trade in any of the following. Select Yes for all options that apply.		
Animal Products or Services	☐	☑
Biodiversity Impacts	☐	☑
Chemicals	☑	☐
Disclosure Alcohol	☐	☑
Disclosure Firearms Weapons	☐	☑
Disclosure Mining	☐	☑
Disclosure Pornography	☐	☑
Disclosure Tobacco	☐	☑
Energy and Emissions Intensive Industries	☑	☐
Gambling	☐	☑
Genetically Modified Organisms	☐	☑
Illegal Products or Subject to Phase Out	☐	☑
Industries at Risk of Human Rights Violations	☐	☑
Monoculture Agriculture	☐	☑
Nuclear Power or Hazardous Materials	☐	☑
Payday, Short Term, or High Interest Lending	☐	☑
Water Intensive Industries	☑	☐
Tax Advisory Services	☐	☑

Outcomes & Penalties

	Yes	No
Please indicate if the company has had any formal complaint to a regulatory agency or been assessed any fine or sanction in the past five years for any of the following practices or policies. Check all that apply.		
Anti-Competitive Behavior	☐	☑
Breaches of Confidential Information	☐	☑
Bribery, Fraud, or Corruption	☐	☑
Company has filed for bankruptcy	☐	☑
Consumer Protection	☐	☑
Financial Reporting, Taxes, Investments, or Loans	☐	☑
Hazardous Discharges Into Air/Land/Water (Past 5 Yrs)	☐	☑
Labor Issues	☐	☑
Large Scale Land Conversion, Acquisition, or Relocation	☐	☑
Litigation or Arbitration	☐	☑
On-Site Fatality	☑	☐
Penalties Assessed For Environmental Issues	☐	☑
Political Contributions or International Affairs	☐	☑
Recalls	☑	☐
Significant Layoffs	☐	☑
Violation of Indigenous Peoples Rights	☐	☑
Other	☐	☑

Practices

	Yes	No
Please indicate if the following statements are true regarding whether or not the company engages in the following practices. Check all that apply. If the statement is true, select "Yes." If false, select "No."		
Animal Testing	☑	☐
Company/Suppliers Employ Under Age 15 (Or Other ILO Minimum Age)	☐	☑
Company prohibits freedom of association/collective bargaining	☐	☑
Company workers are prisoners	☐	☑
Conduct Business in Conflict Zones	☐	☑
Confirmation of Right to Work	☐	☑
Does not transparently report corporate financials to government	☐	☑
Employs Individuals on Zero-Hour Contracts	☐	☑
Facilities located in sensitive ecosystems	☑	☐
ID Cards Withheld or Penalties for Resignation	☐	☑
No formal Registration Under Domestic Regulations	☐	☑
No signed employment contracts for all workers	☐	☑
Overtime For Hourly Workers Is Compulsory	☐	☑
Payslips not provided to show wage calculation and deductions	☐	☑
Sale of Data	☐	☑
Tax Reduction Through Corporate Shells	☐	☑
Workers cannot leave site during non-working hours	☐	☑
Workers not Provided Clean Drinking Water or Toilets	☐	☑
Workers paid below minimum wage	☐	☑
Workers Under Bond	☐	☑
Other	☑	☐

Supply Chain Disclosures

	Yes	No
Please indicate if any of the following statements are true regarding your company's significant suppliers.		
Business in Conflict Zones	☐	☑
Child or Forced Labor	☐	☑
Negative Environmental Impact	☐	☑
Negative Social Impact	☐	☑
Other	☐	☑

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Environmentally Intensive Industry

Topic	Water Intensive Industry
Summary of Issue	Opella France & Russia's legal entities are part of Opella, the consumer healthcare business unit of Sanofi, a pharmaceutical company. Opella France & Russia is the last cluster to achieve certification and includes the following assessments: 1 - Opella France (HQ, corporate office, two manufacturing sites and one distribution centre) 2 - Opella Russia (Corporate office) Opella France & Russia operate in the pharmaceutical industry which is recognised by B Lab as a water-intensive industry due to manufacturing and cleaning processes. The company does not consider itself to be a water intensive industry and continues to minimise water use. The company's manufacturing facilities are located in France, in Compiègne & Lisieux. Both sites use municipal water supply and are not water stressed regions.
Size/Scope of Issue **(e.g. $ financial implication, # of individuals affected)**	In the previous fiscal year, 100% of the production at Opella France & Russia was medicines/drugs, food/dietary supplements, and cosmetics. Considering local contexts, each manufacturing site has its own water intensity as described below. 1. Compiègne's manufacturing facility has a water intensity of 0,46 L per unit of product produced for its standard manufacturing processes. 2. Lisieux's manufacturing facility has a water intensity of 0,05 L per unit of product produced for its standard manufacturing processes.
Impact on Stakeholder(s)	As a water intensive industry, the manufacturing of pharmaceutical products poses risks such as water stress or depletion of local water sources if water used is not appropriately managed. The company uses municipality water supply for pharmaceutical production and utilities. The main stakeholders affected are other water users in the regions of operation, such as local water authorities & regulators, residents, other industrial plants, farmers, and the

	local biodiversity.
Implemented Management Practices	According to the company, Compiegne and Lisieux sites are not water intensive. The company does not carry out an assessment of how it compares to other peers in the industry regarding water use and management. All sites use global corporate standards to manage water, and globally, Opella has the target of reducing water consumption by 20% in 2030, compared to 2019 levels as a benchmark. As an example, Compiègne site is working on a water roadmap, including projects related to recycling wastewater (water reuse).The site has reduced its water consumption by more than 10% in the last 2 years. Opella's sustainability strategy is based on water stewardship principles: increasing water efficiency, assessing risks in each local watershed and defining a strategy aligned with local communities to properly manage the watershed the company relies on.
Management Comments	As of June 2024, Opella no longer operates a distribution centre in France

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Environmentally Intensive Industries

Topic	Chemical Intensive industries
Summary of Issue	Opella France & Russia's legal entities are part of Opella, the consumer healthcare business unit of Sanofi, a pharmaceutical company. Opella France & Russia is the last cluster to achieve certification and includes the following assessments: 1 - Opella France (HQ, corporate office) 2 - Opella Russia (Corporate office) Opella France & Russia operate in the pharmaceutical industry which is recognised by B Lab as a chemical intensive industry. The company does not consider itself to be a chemical intensive industry and works to minimize the chemicals it uses. The company is not involved in the production, operation, trade or sale of chemicals that meet the European Union's list of Substances of Very High Concern (SVHC). The cluster manufacturing sites (Compiègne & Lisieux) use limited quantities of SVHC substance as lab chemicals for quality control purposes. All product formulas are approved by the appropriate competent authorities, go through quality control and quality assurance, and are subject to monitoring in terms of quality, safety & efficacy. The level of the ingredients in the finished products remain adequate for the safe and intended use of consumers.
Size/Scope of Issue **(e.g. $ financial implication, # of individuals affected)**	The use of chemicals for quality control purposes at the manufacturing and R&D sites is below 1 ton/year. Therefore, these facilities would be exempted from restriction and authorization linked to REACH regulation.
Impact on Stakeholder(s)	The primary potential impacts of chemical use in pharmaceutical products are potential negative effects on the environment and potential negative health impacts on workers exposed to chemical ingredients. Risks to workers exposed to chemical ingredients are mitigated through appropriate controls such as engineering controls and respiratory protection. In the last five years, Opella France & Russia has not experienced any significant incidents and/or fines related to environmental or worker impacts of its chemical use.
Implemented	Opella does not conduct an assessment and comparison with

Management Practices	other companies regarding its chemical use. All chemicals used are handled, stored, disposed of, and transported following corporate standards, local legal requirements, Standard Operating Procedures, and local Permits. Furthermore, wastewater is managed by complying with all local legal requirements, Standard Operating Procedures and Permits, assuring all wastewater parameters are within the defined local regulation limits. At the global level, the company has implemented a program to identify substances of potential future concern in our formula and plan their substitution or removal whenever possible from a technical or regulatory standpoint. This program includes a list of materials or substances to be banned, avoided, or restricted in Opella products. All product formulas are approved by local Health Authorities, go through quality control and quality assurance, and are subject to monitoring in terms of quality, safety & efficacy. Given the restricted regulation of the sector, the level of ingredients in the finished products remains adequate for the safe and intended use of consumers. Lastly, Compiègne site has in place a Waste Water treatment Plant (WWTP) to guarantee the removal of chemicals in the waste water.
Management Comments	As of June 2024, Opella no longer operates a distribution centre in France

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Other - Mandatory Animal Testing

Issue Date	Ongoing
Topic	Opella France & Russia, the consumer healthcare business unit of Sanofi, a pharmaceutical company, manufactures and sells medicines and other consumer health products which may require animal testing, but does not develop new drugs (eg. new drug molecules) that require regular animal testing.
Summary of Issue	Opella France & Russia's legal entities are part of Opella, the consumer healthcare business unit of Sanofi, a pharmaceutical company. Opella France & Russia is the last cluster to achieve certification and includes the following assessments: 1 - Opella France (HQ, corporate office, two manufacturing sites and one distribution centre) 2 - Opella Russia (Corporate office) As a company that manufactures pharmaceutical products, Opella is legally obligated to ensure the quality, safety, and efficacy of its medicines and other consumer healthcare products, for which animal testing is required in research and production. Opella does not engage in the regular practice of animal testing: It is only conducted when specifically required by regulatory authorities and no alternative methods can be applied. Animal studies would only be performed in rare situations to evaluate and assess major safety concerns, if literature/data was unavailable for the study endpoints needed, and when specifically required by Regulatory Authorities or to verify the rationale, safety, and efficacy of the combination of two or more ingredients and when no alternative methods can be applied. Animal studies would therefore generally only be conducted as a final resort if no alternatives are available or when required by Regulatory Authorities. Although rare, the method remains legally required and it is an integral part of comprehensive research and testing strategy that also include non-animal methods, digital and clinical research. In Russia, animal testing is performed since abnormal toxicity test is required for parenteral forms obtained from herbal raw materials, according to Eurasian economic union Pharmacopeia. According to Federal Law № 61 this test is conducted externaly,

	by a local certified laboratory, on only one batch of one product per year and it does not concern the product development process. In the last five years, both France (HQ) and Russia outsourced its animal testing needs to third-party laboratories.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	The value spent on animal testing represents less than 0.02% of the company's total revenue.
Impact on Stakeholders	Animal testing and experimentation is widely used to develop and test the safety of new drug molecules. Many of these experiments can cause pain to the animals involved or reduce their quality of life in other ways. Opella does not develop new drug molecules as stated above and it would only perform animal testing in rare situations when required by Regulatory Authorities. Animal testing and experimentation is widely used to develop and test the safety of new drug molecules. When the execution of this study is mandatory for regulatory or safety reasons the company implements practices to promote animal welfare and prevent animal pain and distress in housing and procedure conditions.
Implemented Management Practices	Opella does not engage in the regular practice of animal testing. It only conducts when the regulatory and scientific merit is established and under strict ethical over-sight. Sanofi at a group level has a policy for the protection of animals that includes a 3R principle towards animal testing; seeking to exceed regulation and standards. The company tests products on animals only: - when a non-animal method is unsuited for the required use or not accepted by the authorities (replacement) - with the smallest number of animals necessary for quality science (reduction) - with the implementation of state-of-the-art practices to promote animal welfare and prevent animal pain and distress in housing and procedure conditions (refinement). Sanofi has Animal Ethics Committees with principles to ensure impartiality and independence of the ethical review. Opella rarely authorizes animal testing and only when the regulatory and scientific merit is established and under strict ethical over-sight. If animal testing is authorized, Sanofi monitors compliance by third parties (breeders, contract research organizations, not-for-profit collaborations).

	In addition to the legal obligations, Sanofi has set internal standards to align requirements across the world and to ensure high welfare considerations. All Sanofi sites maintain or seek independent accreditation of their animal care and use programs through recognized expert organizations such as AAALAC International. Sanofi applies the same principles to subcontractors and breeders; their animal welfare program is assessed by Sanofi professionals to ensure the consistency of the animal care. External partners are expected to comply with animal welfare laws and commit to the spirit of the Sanofi policy on the protection of animals. Sanofi professionals will evaluate animal care and use programs of external partners on a regular basis and approve those that comply with Sanofi standards. Sanofi is also a signatory of the Marseille Declaration, a pharmaceutical industry declaration on animal housing and use (see link below). External stakeholders can raise concerns in relation to animal testing directly to the Chief Veterinary Officer through Sanofi.com.
Report	- Sanofi-policy-on-the-protection-of-animals-2018-EN.pdf - Marseille-Declaration-2022-signed.pdf (sanofi.com) - Responsible use of animals in research and production (sanofi.com)
Management Comments	As of June 2024, Opella no longer operates a distribution centre in France

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Environmentally Intensive Industry

Topic	Energy Intensive industries
Summary of Issue	Opella France & Russia's legal entities are part of Opella, the consumer healthcare business unit of Sanofi, a pharmaceutical company. Opella France & Russia is the last cluster to achieve certification and includes the following assessments: 1 - Opella France (HQ, corporate office, two manufacturing sites and one distribution centre) 2 - Opella Russia (Corporate office) Opella France & Russia operates in the pharmaceutical industry which has been recognised by B Lab as an energy-intensive industry. Of the company's total energy use, the most energy intensive activities are related to the manufacturing sites. Regarding Opella's consolidated operations, the company uses electricity and natural gas as the main sources of energy, with the majority of sites using renewable electricity (87% at the end of 2023 with the objective to have 100% of the sites by 2025). Accordingly, the company relies on Power Purchase Agreements (PPAs), self-generated solar photovoltaic energy and renewable electricity certificates. Furthermore, some sites use a mix of biogas and natural gas for its operations.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	In the previous fiscal year, 100% of Opella Russia & France was derived from the production of self-medication medicines/drugs, food/dietary supplements, and cosmetics. Considering local contexts, each manufacturing site has its own energy intensity as described below. 1. Compiègne's manufacturing facility has an energy intensity of 0,33 kWh per product produced for its standard manufacturing processes. 2. Lisieux's manufacturing facility has an energy intensity of 0,05 kWh per product produced for its standard manufacturing processes.
Impact on Stakeholders	Energy-intensive activities, such as manufacturing activities, pose an environmental risk due to the related emissions derived from energy use. The extent of environmental impact is dependent on the energy sources utilised and the management practices in place to manage energy use.

Implemented Management Practices	Energy consumption and emission reductions are managed at site levels and coordinated at the global level to reach ambitious targets. The company uses the following best practices to minimise energy use and carbon emissions: • Energy efficiency • Renewable Electricity • Decarbonizing heat through electrification and new technologies While the company already decreased its Scope 1 & 2 emissions by 57% in 2023 compared to a 2019 baseline, the objective is to reach 65% emissions reduction & use 100% renewable electricity by 2025. Opella intends to establish a new science-based target (covering Scopes 1, 2 and 3). As part of this process, Opella is working to develop new baseline emissions data of our Scope 3 emissions.
Management Comments	As of June 2024, Opella no longer operates a distribution centre in France

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Recalls

Issue Date	2020-2024
Topic	Mandatory and voluntary recalls
Summary of Issue	Opella France & Russia's legal entities are part of Opella, the consumer healthcare business unit of Sanofi, a pharmaceutical company. Opella France & Russia is the last cluster to achieve certification and includes the following assessments: 1 - Opella France (HQ, corporate office, two manufacturing sites and one distribution centre) 2 - Opella Russia (Corporate office) In the last five years, Opella France & Russia had seven (7) recalls across France and two (2) recalls in Russia. France - Precautionary recall of Doliprane 2.4 suspension (medicinal product) in 2019. Lack of graduation on the dosing pipette. - Mandatory recall of Decontractyl comprime + Decontratctyl baume (both medicinal products) in 2019. Decision following a reassessment of the risk-benefit ratio to withdraw the Market Authorization. - Precautionary recall of Phytoxil Junior (medicinal device) in 2020. Lack of graduation on the dosing cup. - Mandatory recall of Bronchokod Enfants 2% (medicinal product) in 2021. Stability issues on finished products. Product is discontinued. - Precautionary recall of Decontractoll Roll On (cosmetic product) in 2022. New European Guidelines. Product is discontinued. - Precautionary recall of PHOSPHALUGEL, oral suspension in sachet (medicinal product) in 2022. Impurities detected with a level above the permitted daily exposure. - Precautionary recall of Maxilase Coated Tablet (medicinal product) in 2024. Stability issue on the finished product. Russia - Precautionary recall of Nospa Tablets in 2020. Recall due to incorrect labelling and expiration dates on the packaging. - Precautionary recall of Phosphalugel 16 g oral gel (sachet 6; sachet 20) in 2021. Recall due to out of specification (OOS) on an API test (Active Pharmaceutical Test).

Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	The recalls represent less than 1% of the overall company's production.
Impact on Stakeholders	None of the recalls resulted in consumer illness or injury.
Implemented Management Practices	Recalls are managed according to global procedures in line with international and local regulatory requirements. Each recall is managed by the Quality department and includes root cause analysis and corrective and preventative actions, as appropriate. The company has a global procedure called; “Escalation of Quality Events and Management of Quality Alerts” to address recall issues. It details the internal management of recalls and requires that all quality events and alerts are reported in a timely, structured, and concise way so that the risk assessment and associated mitigation plan is shared at the appropriate management level and subsequently managed with the adequate level of priority. France - Doliprane 2.4 suspension (2019): Improvement of in-process controls in manufacturing sites. - Decontractyl comprimé (2019) + Decontractyl baume (2019): Product is discontinued. - Phytoxil Junior (2020): A new measuring cup was put in place. - Bronchokod Enfants 2% (2021): Product is discontinued. - Decontractoll Roll On (2022): Product is discontinued. - PHOSPHALUGEL, oral suspension in sachet (2022): Improvement of in-process controls in manufacturing site - Maxilase Coated Tablet (2024): Improvement of in-process controls in manufacturing site. Russia - Nospa (2020). Actions on manufacturing site level, additional check of artworks and printing lines before manufacturing. - Phosphalugel (2021) Additional testing of API before manufacturing at site level.
Management Comments	As of June 2024, Opella no longer operates a distribution centre in France.

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Facilities located in sensitive ecosystems

Topic	The company has one manufacturing facility at Compiègne in the Hauts-de-France region [Northern France] which is considered a sensitive ecosystem.
Summary of Issue	Opella France & Russia's legal entities are part of Opella, the consumer healthcare business unit of Sanofi, a pharmaceutical company. Opella France & Russia is the last cluster to achieve certification and includes the following assessments: 1 - Opella France (HQ, corporate office, two manufacturing sites and one distribution centre) 2 - Opella Russia (Corporate office) The company's manufacturing facility at Compiègne is located in an area considered of high biodiversity significance since due to its location adjacent to the following sensitive ecosystems: - Massif Forestier De Compiègne (site code: FR2200382- part of Natura 2000) - Forêts picardes : Compiègne, Laigue, Ourscamps (site code: FR22212001 - part of Natura 200)
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	The company's manufacturing facility at Compiègne represents 76% of the cluster's total area (size of facilities in m2).
Impact on Stakeholders	Having facilities & operations near protected/sensitive ecosystems can potentially impact the quality of the ecosystem (flora, fauna and the natural dynamics of these natural systems) Potential impacts derived from the company's operations are noise & light pollution, potential spills, air / soil / water pollution.
Implemented Management Practices	A biodiversity assessment was conducted by a third-party expert (Ramboll) in 2022 based on the methodology “BIODIVERSITY INDICATORS FOR SITE-BASED IMPACTS” developed by UNEP-WCMC, Conservation International and Fauna & Flora International which highlighted threatened species in the vicinity of the site. In case of changes impacting the biodiversity, an environmental impact study is performed and measures are taken to reduce and/or mitigate the impact on the biodiversity.

	Opella has a global commitment to "protect biodiversity at our sites, particularly those located near sensitive natural areas. By 2025, our priority sites with the highest potential impacts on local biodiversity will implement specific biodiversity management plans. This approach will be extended to all our sites located near biodiversity-sensitive areas by 2030." The organization has a Biodiversity Management standard which describes the management of biodiversity by each site. As aligned with Sanofi's public commitments to Nature, the subsidiary's objective is to reduce the impacts on biodiversity of its direct operations – in particular at sites exposed to high risks for biodiversity. This standard sets out the following minimum requirements: - Design: biodiversity risks need to be considered for the design of new facilities/buildings or in case of revamping existing ones, - Operational: biodiversity risks need to be considered in its daily operations to reduce the local pressure of its activities on biodiversity and implement the best practices promoting biodiversity.

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Other Disclosure

Topic	Negative News involving the company's OTC products
Summary of Issue	Opella France & Russia's legal entities are part of Opella, the consumer healthcare business unit of Sanofi, a pharmaceutical company. Opella France & Russia is the last cluster to achieve certification and includes the following assessments: 1 - Opella France (HQ, corporate office, two manufacturing sites and one distribution centre) 2 - Opella Russia (Corporate office) In France, a small number of the company's OTC products were cited on three (3) occasions in media articles which challenge the efficacy or possible adverse effects of these products. - Episode 1 (2020) Product: Maxilase Prescrire, an independent monthly medical journal featured an article discussing drugs included in an annual blacklist. The article is not a complaint received by the company and does not involve the authorities. The article states alpha-amylase (Maxilase and equivalents brands), may cause allergic reactions which may be serious or even fatal. - Episode 2 (2023) Product: Toplexil & Bisolvan Prescrire, an independent monthly medical journal featured an article which listed: "various drugs used to relieve a cough, sometimes annoying but benign, expose to disproportionate adverse effects." Toplexil and Bisolvon were identified in the list. The article is not a complaint received by the company and does not involve the authorities. - Episode 3 (2023) Product: Dolirhume The French National Agency for the Safety of Medicine

	issued a warning in 2023 that certain drugs (including Dolirhume), used to treat colds are no longer being recommended in their oral form due to the low risk of causing heart attacks and strokes.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	These brands represent <7% of revenues in the company's total portfolio.
Impact on Stakeholders	No impact (health or financial) on the company's stakeholders reported.
Implemented Management Practices	All company medicinal products have a Marketing Authorization, granted by the Health Authorities following the evaluation of a dossier, based on benefit-risk balance (including data regarding safety, quality and efficacy). This balance between benefit and risk is examined throughout the product's lifecycle by means, among other things, of a Periodic Benefit Risk Evaluation Report. As per the regulation, the company closely monitors the safety of its product through its Pharmacovigilance system. If there is new safety data, these are added to the product labelling for Healthcare Professionals and patients (in agreement with the authorities). Toplexil, Bisolvon and Maxilase Marketing Authorizations are maintained to date and no complaint or alert calling into question this balance (safety or efficacy) has been sent by the Health Authorities. For Dolirhume, the latest evaluation on pseudoephedrine was performed by the European Health Agency (following a request from the French Health Authority). This evaluation has again confirmed that the balance benefit-risk of pseudoephedrine remains positive and recommended to keep the concerned Marketing Authorization on the market. Despite this, the French Health Authority continues to advise against the use of pseudoephedrine in self-medication, while maintaining the Marketing Authorizations valid. The company acknowledged the French Health Authority's decision to make medicines containing pseudoephedrine available on prescription only.
Report	- Report 1

	- Report 2 - Report 3 - Report 4
Management Comments	As of June 2024, Opella no longer operates a distribution centre in France.

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: On-site fatality

Issue Date	2022
Topic	Fatality in the context of Occupational Health and Safety
Summary of Issue	Opella France & Russia's legal entities are part of Opella, the consumer healthcare business unit of Sanofi, a pharmaceutical company. Opella France & Russia is the last cluster to achieve certification and includes the following assessments: 1 - Opella France (HQ, corporate office, two manufacturing sites and one distribution centre) 2 - Opella Russia (Corporate office) The company experienced an on-site fatality involving an employee in France.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	The company reported one fatality in the last 5 years.
Impact on Stakeholders	The primary impact was on the individual and their family. Additionally, fatalities and accidents have emotional, mental, and financial repercussions for the employee's family, friends, and colleagues.
Resolution	The case is undergoing investigation. No further details can be shared.
Implemented Management Practices	Not applicable - case is under investigation.
Other Management Comments	As of June 2024, Opella no longer operates a distribution centre in France
Related Incidents (Yes/No)	No.

Opella Brazil

Disclosure Report

Date Submitted: December, 2024

Disclosure Questionnaire

Industries and Products

	Yes	No
Please indicate if the company is involved in production of or trade in any of the following. Select Yes for all options that apply.		
Animal Products or Services	☐	☑
Biodiversity Impacts	☐	☑
Chemicals	☑	☐
Disclosure Alcohol	☐	☑
Disclosure Firearms Weapons	☐	☑
Disclosure Mining	☐	☑
Disclosure Pornography	☐	☑
Disclosure Tobacco	☐	☑
Energy and Emissions Intensive Industries	☑	☐
Gambling	☐	☑
Genetically Modified Organisms	☐	☑
Illegal Products or Subject to Phase Out	☐	☑
Industries at Risk of Human Rights Violations	☐	☑
Monoculture Agriculture	☐	☑
Nuclear Power or Hazardous Materials	☐	☑
Payday, Short Term, or High Interest Lending	☐	☑
Water Intensive Industries	☑	☐
Tax Advisory Services	☐	☑

Outcomes & Penalties

	Yes	No
Please indicate if the company has had any formal complaint to a regulatory agency or been assessed any fine or sanction in the past five years for any of the following practices or policies. Check all that apply.		
Anti-Competitive Behavior	☐	☑
Breaches of Confidential Information	☐	☑
Bribery, Fraud, or Corruption	☐	☑
Company has filed for bankruptcy	☐	☑
Consumer Protection	☑	☐
Financial Reporting, Taxes, Investments, or Loans	☐	☑
Hazardous Discharges Into Air/Land/Water (Past 5 Yrs)	☐	☑
Labor Issues	☐	☑
Large Scale Land Conversion, Acquisition, or Relocation	☐	☑
Litigation or Arbitration	☑	☐
On-Site Fatality	☐	☑
Penalties Assessed For Environmental Issues	☐	☑
Political Contributions or International Affairs	☐	☑
Recalls	☐	☑
Significant Layoffs	☐	☑
Violation of Indigenous Peoples Rights	☐	☑
Other	☐	☑

Practices

	Yes	No
Please indicate if the following statements are true regarding whether or not the company engages in the following practices. Check all that apply. If the statement is true, select "Yes." If false, select "No."		
Animal Testing	☑	☐
Company/Suppliers Employ Under Age 15 (Or Other ILO Minimum Age)	☐	☑
Company prohibits freedom of association/collective bargaining	☐	☑
Company workers are prisoners	☐	☑
Conduct Business in Conflict Zones	☐	☑
Confirmation of Right to Work	☐	☑
Does not transparently report corporate financials to government	☐	☑
Employs Individuals on Zero-Hour Contracts	☐	☑
Facilities located in sensitive ecosystems	☐	☑
ID Cards Withheld or Penalties for Resignation	☐	☑
No formal Registration Under Domestic Regulations	☐	☑
No signed employment contracts for all workers	☐	☑
Overtime For Hourly Workers Is Compulsory	☐	☑
Payslips not provided to show wage calculation and deductions	☐	☑
Sale of Data	☐	☑
Tax Reduction Through Corporate Shells	☐	☑
Workers cannot leave site during non-working hours	☐	☑
Workers not Provided Clean Drinking Water or Toilets	☐	☑
Workers paid below minimum wage	☐	☑
Workers Under Bond	☐	☑
Other	☐	☑

Supply Chain Disclosures

	Yes	No
Please indicate if any of the following statements are true regarding your company's significant suppliers.		
Business in Conflict Zones	☐	☑
Child or Forced Labor	☐	☑
Negative Environmental Impact	☐	☑
Negative Social Impact	☐	☑
Other	☐	☑

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Environmentally Intensive Industry

Topic	Water Intensive Industry
Summary of Issue	Opella Brazil is part of Opella, the consumer healthcare business unit of Sanofi, a pharmaceutical company. Opella Brazil's operations include the entity's offices in São Paulo (SP, Brazil) and a manufacturing site in Suzano (SP, Brazil). Opella Brazil operates in the pharmaceutical industry which is recognised by B Lab as a water-intensive industry due to manufacturing and cleaning processes, although the company does not consider itself to be a water intensive industry and continues to minimise water use. Of the company's total water use, the most water intensive activities are related to the manufacturing site. The company uses municipality water, water wells and (in extraordinary situations) water trucks for manufacturing and cleaning, with water reduction efforts deployed at the site. Suzano is located in São Paulo State, Brazil which is not classified as a high water stressed area according to the World Resources Institute (WRI).
Size/Scope of Issue **(e.g. $ financial implication, # of individuals affected)**	In the previous fiscal year, 100% of Opella Brazil was derived from the production of medicines/drugs, food/dietary supplements, and cosmetics. The entity's manufacturing facility has a water intensity of 0.628 m3 per K/unit of product produced for its standard manufacturing processes.
Impact on Stakeholder(s)	As a water intensive industry, the manufacturing of pharmaceutical products poses risks such as water stress or depletion of local water sources if water used is not appropriately managed. The company uses municipality water supply for pharmaceutical production and utilities. The main stakeholders affected are other water users in the regions of operation, such as local water authorities & regulators, residents, other industrial plants, farmers, and the local biodiversity.
Implemented	The company does not carry out an assessment of how it

Management Practices	compares to other peers in the industry regarding water use and management. All sites use global corporate standards to manage water and globally, Opella has the target of reducing water consumption by 20% in 2030, compared to 2019 levels as a benchmark. Opella's sustainability strategy is based on water stewardship principles: increasing water efficiency, assessing risks in each local watershed and defining a strategy aligned with local communities to properly manage the watershed the company relies on.

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Environmentally Intensive Industries

Topic	Chemical Intensive industries
Summary of Issue	Opella Brazil is part of Opella, the consumer healthcare business unit of Sanofi, a pharmaceutical company. Opella Brazil's operations include the entity's offices in São Paulo (SP, Brazil) and a manufacturing site in Suzano (SP, Brazil). Opella Brazil operates in the pharmaceutical industry which has been recognised by B Lab as a chemical intensive industry. The company is not involved in the production, operation, trade or sale of chemicals that meet the European Union's list of Substances of Very High Concern (SVHC). The company uses SVHC lab chemicals for quality control purposes on its sites. All product formulas are approved by local Health Authorities, go through quality control and quality assurance, and are subject to monitoring in terms of quality, safety & efficacy. The level of the ingredients in the finished products remain adequate for the safe and intended use of customers.
Size/Scope of Issue **(e.g. $ financial implication, # of individuals affected)**	The use of SVHC substances for quality control purposes at the manufacturing sites is below 1 ton/year. Therefore, these facilities are exempted from restriction and authorization linked to REACH regulation.
Impact on Stakeholder(s)	The primary potential impacts of chemical use in pharmaceutical products are potential negative effects on the environment and potential negative health impacts on workers exposed to chemical ingredients. Risks to workers exposed to chemical ingredients are mitigated through appropriate controls such as engineering controls and respiratory protection. In the last five years, Opella Brazil has not experienced any significant incidents and/or fines related to environmental or worker impacts of its chemical use.
Implemented Management Practices	All chemicals used are handled, stored, disposed of, and transported following corporate standards, local legal requirements, Standard Operating Procedures, and local Permits. Furthermore, wastewater is managed by complying

	with all local legal requirements, Standard Operating Procedures and Permits, assuring all wastewater parameters are within the defined local regulation limits. At the global level, the company has implemented a program to identify substances of potential future concern in our formula and plan their substitution or removal whenever possible from a technical or regulatory standpoint. This program includes a list of materials or substances to be banned, avoided, or restricted in Opella products. Moreover, Opella Brazil has documented HSE requirements to minimize the use of carcinogens, mutagens, reprotoxic and volatile organic compounds. All product formulas are approved by local Health Authorities, go through quality control and quality assurance, and are subject to monitoring in terms of quality, safety & efficacy. Given the restricted regulation of the sector, the level of ingredients in the finished products remains adequate for the safe and intended use of consumers. At the local level, the company does not conduct an assessment and comparison with other companies regarding chemical use.

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Other - Mandatory Animal Testing

Issue Date	Ongoing
Topic	Opella Brazil is a subsidiary of Opella and sells consumer healthcare products. Opella Brazil manufactures and sells but does not develop new drugs (eg. new drug molecules), therefore Opella Brazil is not required to perform animal testing.
Summary of Issue	Opella Brazil is part of Opella, the consumer healthcare business unit of Sanofi, a pharmaceutical company. Opella Brazil's operations include the entity's offices in São Paulo (SP, Brazil) and a manufacturing site in Suzano (SP, Brazil). As a company that manufactures pharmaceutical products, Opella is legally obligated to ensure the quality, safety, and efficacy of its medicines and other consumer healthcare products, for which animal testing is required in research and production. As a subsidiary of Opella, Opella Brazil can market over the counter (OTC) products because they have already been proven to be safe and effective. Opella does not engage in the regular practice of animal testing: It is only conducted when specifically required by regulatory authorities and no alternative methods can be applied. Animal studies would only be performed in rare situations to evaluate and assess major safety concerns, if literature/data was unavailable for the study endpoints needed, and when specifically required by Regulatory Authorities or to verify the rationale, safety, and efficacy of the combination of two or more ingredients and when no alternative methods can be applied. Animal studies would therefore generally only be conducted as a final resort if no alternatives are available or when required by Regulatory Authorities. In Opella Brazil, no animal testing was performed in the last five years since Opella Brazil does not research and develop new drug molecules and it only manufactures and sells Over the Counter (OTC) products which have already been proven to be safe and effective.
Size/Scope of Issue ***(e.g. $ financial implication, # of***	Opella Brazil did not conduct animal testing in past 5 years. However, the company currently sells medicines that had to go

individuals affected)	through animal testing previously.
Impact on Stakeholders	Animal testing and experimentation is widely used to develop and test the safety of new drug molecules and/or food products. Many of these experiments can cause pain to the animals involved or reduce their quality of life in other ways. Opella Brazil does not develop new drug molecules and as stated above would only perform animal testing in rare situations when required by Regulatory Authorities. Animal testing and experimentation is widely used to develop and test the safety of new drug molecules. When the execution of this study is mandatory for regulatory or safety reasons the company implements practices to promote animal welfare and prevent animal pain and distress in housing and procedure conditions.
Implemented Management Practices	Opella does not engage in the regular practice of animal testing. It only conducts when the regulatory and scientific merit is established and under strict ethical over-sight. Sanofi at a group level has a policy for the protection of animals that includes a 3R principle towards animal testing; seeking to exceed regulation and standards. The company tests products on animals only: - when a non-animal method is unsuited for the required use or not accepted by the authorities (replacement) - with the smallest number of animals necessary for quality science (reduction) - with the implementation of state-of-the-art practices to promote animal welfare and prevent animal pain and distress in housing and procedure conditions (refinement). Sanofi has Animal Ethics Committees with principles to ensure impartiality and independence of the ethical review. Opella rarely authorizes animal testing and only when the regulatory and scientific merit is established and under strict ethical over-sight. If animal testing is authorized, Sanofi monitors compliance by third parties (breeders, contract research organizations, not-for-profit collaborations). In addition to the legal obligations, Sanofi has set internal standards to align requirements across the world and to ensure high welfare considerations. All Sanofi sites maintain or seek independent accreditation of their animal care and use programs through recognized expert organizations such as AAALAC International. Sanofi applies the same principles to subcontractors and breeders; their animal welfare program is assessed by Sanofi professionals to ensure the consistency of

	the animal care. External partners are expected to comply with animal welfare laws and commit to the spirit of the Sanofi policy on the protection of animals. Sanofi professionals will evaluate animal care and use programs of external partners on a regular basis and approve those that comply with Sanofi standards. Sanofi is also a signatory of the Marseille Declaration, a pharmaceutical industry declaration on animal housing and use (see link below). External stakeholders can raise concerns directly to the Chief Veterinary Officer through Sanofi.com.
Report	- Sanofi-policy-on-the-protection-of-animals-2018-EN.pdf - Marseille-Declaration-2022-signed.pdf (sanofi.com) - Responsible use of animals in research and production (sanofi.com)

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Environmentally Intensive Industry

Topic	Energy Intensive industries
Summary of Issue	Opella Brazil is part of Opella, the consumer healthcare business unit of Sanofi, a pharmaceutical company. Opella Brazil's operations include the entity's offices in São Paulo (SP, Brazil) and a manufacturing site in Suzano (SP, Brazil). Opella Brazil operates in the pharmaceutical industry which has been recognised by B Lab as an energy-intensive industry. Of the company's total energy use, the most energy intensive activities are related to the manufacturing site. The company tracks energy and emissions on a local level. Regarding Opella's consolidated operations, the company uses electricity and natural gas as the main sources of energy, with the offices in São Paulo (SP, Brazil) and manufacturing site in Suzano (SP, Brazil) using renewable electricity (100% in 2023; aligning with the objective to have 100% of sites worldwide using renewable electricity by 2025). Accordingly, the company relies on Power Purchase Agreements (PPAs), self-generated solar photovoltaic energy and renewable electricity certificates.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	In the previous fiscal year, 100% of Opella Brazil was derived from the production of medicines/drugs, food/dietary supplements, and cosmetics. The entity's manufacturing facility has an energy intensity of 0.23 kWh per product produced for its standard manufacturing processes.
Impact on Stakeholders	Energy-intensive activities, such as manufacturing activities, pose an environmental risk due to the related emissions derived from energy use. The extent of environmental impact is dependent on the energy sources utilised and the management practices in place to manage energy use.
Implemented Management Practices	Energy consumption and emission reductions are managed at site levels and coordinated at the global level to reach ambitious targets.

	The company uses the following best practices to minimise energy use and carbon emissions: • Energy efficiency • Renewable Electricity • Decarbonizing heat through electrification and new technologies While the company already decreased its Scope 1 & 2 emissions by 57% in 2023 compared to a 2019 baseline, the objective is to reach 65% emissions reduction & use 100% renewable electricity by 2025. Opella intends to establish a new science-based target (covering Scopes 1, 2 and 3). As part of this process, Opella is working to develop new baseline emissions data of our Scope 3 emissions.

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Consumer Protection

Issue Date	2019-2023
Topic	Consumer protection (Undue advertising & lack of Consumer Safety Standards)
Summary of Issue	Opella Brazil is part of Opella, the consumer healthcare business unit of Sanofi, a pharmaceutical company. Opella Brazil's operations include the entity's offices in São Paulo (SP, Brazil) and a manufacturing site in Suzano (SP, Brazil). In the last five years, Opella Brazil experienced five (5) minor cases related to consumer advertising and technical complaints. No cases led to risk or harm to consumers. However, minor fines for two (2) closed cases were issued under the ANVISA damage prevention clause and three (3) cases are ongoing due to the company's appeal. - Case 1 (Dorflex® Icy Hot Arnica) A regulatory fine (Anvisa) related to advertisement issues on the product's website. The company was notified in 2016 & the case closed in 2021. - Case 2 (Dorflex®) A regulatory fine (Anvisa) related to potential issue in the product's secondary packaging. The company was notified in 2017 & the case closed in 2021. - Case 3 (Novalgina®) A regulatory notification (2019) followed by an infraction notice (Anvisa) in 2022 related to technical complaints involving Novalgina family products. Opella Brazil filed an appeal to Anvisa in September 2022. The case is ongoing. - Case 4 (Novalgina®) A regulatory fine related to product safety. A foreign body was detected inside the ampoule of Novalgina® injectable which imposed a mandatory product recall in 2021. In 2022 ANVISA issued the relevant infraction notice imposing a fine. Opella Brazil filed an appeal to ANVISA in January 2023. The case is ongoing.

	- Case 5 (Enterogermina®) A regulatory infraction related to advertisement issues on the product's website and social media account pages. The company was notified in 2021 and the infraction notice was issued in March 2023. Opella Brazil filed an appeal in April/2023. The case is ongoing. The company reaffirms that the entire process of development, manufacturing, and distribution of Opella's products undergoes regular inspection by the health authorities, as well as regulatory approval of all products. The company takes laws, regulations and consumer protection very seriously.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	The fines imposed in the two (2) closed cases are minor, together they represent less than 0,01% of the company's revenues.
Resolution	Two (2) cases are closed with fines issued under the ANVISA damage prevention clause. The other three (3) cases are still ongoing.
Impact on Stakeholders	The five (5) cases resulted in no harm to consumers. The two cases related to Consumer Safety Standards (Case 3 & 4 Novalgina®) resulted in no consumer illness or injury. The cases related to advertisements issues did not result in damages to consumers.
Implemented Management Practices	For the closed cases, the company has paid minor fines and amended the advertising as required. For the ongoing cases, despite not being closed, the company has implemented a Corrective and Preventative Action (CAPA) plan.

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Litigation & Arbitration cases

Issue Date	2019-2023
Topic	Labor litigation dispute
Summary of Issue	Opella Brazil is part of Opella, the consumer healthcare business unit of Sanofi, a pharmaceutical company. Opella Brazil's operations include the entity's offices in São Paulo (SP, Brazil) and a manufacturing site in Suzano (SP, Brazil). In the last five years, Opella Brazil experienced two (2) labor litigation cases regarding wage and hour disputes.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	Both cases represent less than 0.1% of the company's revenues.
Resolution	Case 1 was settled. Case 2 ruling was unfavourable
Impact on Stakeholders	The two cases relate to labor disputes. In labor dispute cases, the main stakeholders affected are the company's employees and direct collaborators (independent contractors & outsourced staff).
Implemented Management Practices	The company has established a workflow to evaluate labor practices for outsourced providers and avoid related situations. The company developed new programs for variable salaries in collaboration with internal departments.

Opella Africa, Middle East and Asia [AMEA]

Disclosure Report

Date Submitted: November, 2024

Disclosure Questionnaire

Industries and Products

	Yes	No
Please indicate if the company is involved in production of or trade in any of the following. Select Yes for all options that apply.		
Animal Products or Services	☐	☑
Biodiversity Impacts	☐	☑
Chemicals	☑	☐
Disclosure Alcohol	☐	☑
Disclosure Firearms Weapons	☐	☑
Disclosure Mining	☐	☑
Disclosure Pornography	☐	☑
Disclosure Tobacco	☐	☑
Energy and Emissions Intensive Industries	☑	☐
Gambling	☐	☑
Genetically Modified Organisms	☐	☑
Illegal Products or Subject to Phase Out	☐	☑
Industries at Risk of Human Rights Violations	☐	☑
Monoculture Agriculture	☐	☑
Nuclear Power or Hazardous Materials	☐	☑
Payday, Short Term, or High Interest Lending	☐	☑
Water Intensive Industries	☑	☐
Tax Advisory Services	☐	☑

Outcomes & Penalties

	Yes	No
Please indicate if the company has had any formal complaint to a regulatory agency or been assessed any fine or sanction in the past five years for any of the following practices or policies. Check all that apply.		
Anti-Competitive Behavior	☐	☑
Breaches of Confidential Information	☐	☑
Bribery, Fraud, or Corruption	☐	☑
Company has filed for bankruptcy	☐	☑
Consumer Protection	☐	☑
Financial Reporting, Taxes, Investments, or Loans	☐	☑
Hazardous Discharges Into Air/Land/Water (Past 5 Yrs)	☐	☑
Labor Issues	☐	☑
Large Scale Land Conversion, Acquisition, or Relocation	☐	☑
Litigation or Arbitration Case A Case B	☑	☐
On-Site Fatality	☑	☐
Penalties Assessed For Environmental Issues	☐	☑
Political Contributions or International Affairs	☐	☑
Recalls	☑	☐
Significant Layoffs	☐	☑
Violation of Indigenous Peoples Rights	☐	☑
Other	☑	☐

Practices

	Yes	No
Please indicate if the following statements are true regarding whether or not the company engages in the following practices. Check all that apply. If the statement is true, select "Yes." If false, select "No."		
Animal Testing	☑	☐
Company/Suppliers Employ Under Age 15 (Or Other ILO Minimum Age)	☐	☑
Company prohibits freedom of association/collective bargaining	☐	☑
Company workers are prisoners	☐	☑
Conduct Business in Conflict Zones	☐	☑
Confirmation of Right to Work	☐	☑
Does not transparently report corporate financials to government	☐	☑
Employs Individuals on Zero-Hour Contracts	☐	☑
Facilities located in sensitive ecosystems	☐	☑
ID Cards Withheld or Penalties for Resignation	☐	☑
No formal Registration Under Domestic Regulations	☐	☑
No signed employment contracts for all workers	☐	☑
Overtime For Hourly Workers Is Compulsory	☐	☑
Payslips not provided to show wage calculation and deductions	☐	☑
Sale of Data	☐	☑
Tax Reduction Through Corporate Shells	☐	☑
Workers cannot leave site during non-working hours	☐	☑
Workers not Provided Clean Drinking Water or Toilets	☐	☑
Workers paid below minimum wage	☐	☑
Workers Under Bond	☐	☑
Other	☐	☑

Supply Chain Disclosures

	Yes	No
Please indicate if any of the following statements are true regarding your company's significant suppliers.		
Business in Conflict Zones	☐	☑
Child or Forced Labor	☐	☑
Negative Environmental Impact	☐	☑
Negative Social Impact	☐	☑
Other	☐	☑

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Recalls

Issue Date	2019 - 2024 (updated 2025)
Topic	Mandatory and voluntary recalls
Summary of Issue	Opella AMEA includes the assessment of the following entities: - Opella Japan (Corporate, Manufacturing & R&D, distribution centers) - Opella Australia (Corporate office, Manufacturing & R&D), Opella South Korea (Corporate Office), Opella Hong Kong (Corporate Office) - Opella Egypt, Turkey, Saudi Arabia, UAE (Corporate Offices) - Opella Tunisia (Manufacturing & Corporate Office), Opella South Africa (Corporate Office) - Opella Vietnam (Manufacturing, Corporate Office), Opella Philippines, Thailand, Indonesia, Singapore, Malaysia (Corporate Offices) - Opella China (Corporate Office). - Opella India (Corporate Office). In the last five years, Opella AMEA had recalls across Japan, South Korea, Australia, Vietnam, Thailand and India. Out of all these recalls, one (1) mandatory recall, and the remaining voluntary recalls. **Japan** Year: 2022 Product: A single product with multiple names (S. Tac Rhinitis Capsule 12/ New Long-Acting S-Tac Niscap) Voluntary recall: Due to an out of specification result for a dissolution test in the annual stability monitoring (of the product). There have been no adverse events attributed to this product. **South Korea** Year: 2021 Product: Dulcolax Suppository Mandatory recall: Violation of Pharmaceutical Act Article 56, 76. Class 3(minor) - Incorrect expiring date. There have been no adverse events attributed to this product. **Australia** Year: 2023 Product: BISOLVON PHOLCODINE DRY FORTE 4mg/mL oral

	liquid bottle (200mL) Voluntary recall: Recall was led by a review of EMA (European Medicines Agency) of medicines containing Pholcodine that are used to treat non-productive dry coughs. Pholcodine, which is the active ingredient in recalled product and also in many other cough medicines available in the market, is linked to a risk of perianaesthetic anaphylactic reaction related to Neuromuscular Blocking Agents (NMBAs).There have been no adverse events attributed to this product. **Vietnam** Year: 2022 Product: Phosphalugel Voluntary recall: Recall was due to out of specification (OOS) on an API test (Active Pharmaceutical Test). Result non-compliant with ICHQ3D. There have been no adverse events attributed to this product. **Thailand** Year: 2022 Product: Bisolvon 8 mg/ 5 mL (Case I- batch no. 20020121) & Bisolvon 8 mg/ 5 mL (Case II- batch no. 21020087.) Mandatory recall: Bisolvon 8mg/ 5 ml. Out of specification results found during the stability testing at 18 months. After reporting to the authority, Thai FDA classified this quality defect as Class II and issued a mandatory recall letter to the company. Voluntary recall: Bisolvon 8mg/ 5 ml. Out of trend result during the stability testing. The company initiated a letter for voluntary recall to the Thai FDA. The quality defect is classified as class II. There have been no adverse events attributed to this product. In April 2021, the manufacturing of this product ceased. The product is no longer sold by Opella Thailand. **India** Year: 2024 Product: Depura Kids, Depura Sugar Free, Allegra & Combiflam Voluntary recall 1: Depura Kids and Depura Sugar Free. Following a consumer complaint in February 2024, as a precautionary measure, the company decided to voluntarily recall Depura Kids and Depura Sugar Free from the market given potential microbiological contamination of particular batches of the products recalled. Voluntary recall 2: Allegra and Combiflam. In May 2024 a consumer complaint was received for Allegra Suspension, which was manufactured at the same factory site as Depura Kids and Depura Sugar free. Following a thorough investigation, the

	company took an abundant precautionary measure to conduct a voluntary recall of Allegra Suspension and Combiflam Suspension from the market. Both recalls were classified internally as category II abiding with the Indian regulations. There have been no adverse events attributed to this product.
Size/Scope of Issue (e.g. $ financial implication, # of individuals affected)	The four recalls represent approximately 1% of the overall company's production.
Impact on Stakeholder(s)	None of the recalls resulted in consumer illness or injury. No Pharmacovigilance (PV) cases were retrieved from the impacted period.
Implemented Management Practices	Recalls are managed according to global procedures in line with international and local regulatory requirements. Each recall is managed by the Quality department and includes root cause analysis and corrective and preventative actions, as appropriate. The company has a global procedure called; “Escalation of Quality Events and Management of Quality Alerts” to address recall issues. It details the internal management of recalls and requires that all quality events and alerts are reported in a timely, structured, and concise way so that the risk assessment and associated mitigation plan is shared at the appropriate management level and subsequently managed with the adequate level of priority.
Management Comments	Opella’s affiliate in **Hong Kong, Sunstone China LTD (“Sunstone”)**, was included in the initial scope of companies and territories verified for the AMEA certification. However, Sunstone is no longer an active legal entity and has stopped its operation effective as of 31 May 2024. The company **Opella Healthcare South Africa (“OHSA”)** was included in the initial scope of companies and territories verified for the AMEA certification. Following a shares transaction effective as of October 1st, 2024, OHSA is no longer an Opella company.

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: On-site fatality

Issue Date	2019 (updated in 2025)
Topic	Fatality in the context of Occupational Health and Safety
Summary of Issue	Opella AMEA includes the assessment of the following entities: - Opella Japan (Corporate, Manufacturing & R&D, distribution centers) - Opella Australia (Corporate office, Manufacturing & R&D), Opella South Korea (Corporate Office), Opella Hong Kong (Corporate Office) - Opella Egypt, Turkey, Saudi Arabia, UAE (Corporate Offices) - Opella Tunisia (Manufacturing & Corporate Office), Opella South Africa (Corporate Office) - Opella Vietnam (Manufacturing, Corporate Office), Opella Philippines, Thailand, Indonesia, Singapore, Malaysia (Corporate Offices) - Opella China (Corporate Office). - Opella India (Corporate Office). The company experienced an off-site fatality involving an employee in India due to a road accident during work-related travel. The incident resulted in one fatality and one serious injury.
Size/Scope of Issue **(e.g. $ financial implication, # of individuals affected)**	- The company reported one on-site fatality in the last 5 years.
Impact on Stakeholder(s)	The primary impact was on the individual and their family. Additionally, fatalities and accidents have emotional, mental, and financial repercussions for the employee's family, friends, and colleagues.
Resolution	A police report was filed the same day, and the incident was reported to state emergency and medical agencies. An external third-party conducted the investigation and determined the incident resulted from multiple factors.
Implemented Management Practices	The implementation of a detailed Corrective Action Plan, including new safety programs and training modules. HSE requirements, along with the agenda, are circulated to all stakeholders when travel is required.

Related Incidents (Yes/No)	No.

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Environmentally Intensive Industries

Topic	Water Intensive Industry
Summary of Issue	Opella AMEA operates in the pharmaceutical industry which is recognised as a water-intensive industry due to manufacturing and cleaning processes. Opella AMEA includes the assessment of the following entities: - Opella Japan (Corporate office, Manufacturing & R&D, distribution centers) - Opella Australia (Corporate office, Manufacturing & R&D), Opella South Korea (Corporate Office), Opella Hong Kong (Corporate Office) - Opella Egypt, Turkey, Saudi Arabia, UAE (Corporate Offices) - Opella Tunisia (Manufacturing & Corporate Office), Opella South Africa (Corporate Office) - Opella Vietnam (Manufacturing, Corporate Office), Opella Philippines, Thailand, Indonesia, Singapore, Malaysia (Corporate Offices) - Opella China (Corporate Office). - Opella India (Corporate Office). The company's manufacturing facilities are located at 1. Narita, Japan; 2. Brisbane, Australia; 3. Megrine, Tunisia; and 4. Ho Chi Minh, Vietnam. 1. At Narita's facility, the company uses municipal water for production and utilities, with some recovery efforts deployed at the site. The region is not a water stressed region. 2. At Brisbane's facility, the company uses municipal water for production and utilities, with some rainwater recovery efforts deployed at the site for gardening needs. The region is not a water stressed region. 3. At Megrine's facility, the company uses municipal water for production and utilities. The region is considered a water stressed area, and the company is working on a water use reduction plan. 4. At Ho Chi Minh's facility, the company uses municipal water for production and utilities. The region is considered a water stressed area, and the company is working on a water use reduction plan.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	In the previous fiscal year, 100% of the production at Opella AMEA was medicines/drugs, food/dietary supplements, and cosmetics.

	Considering local contexts, each manufacturing site has its own water intesity as described below. Narita's manufacturing facility has a water intensity of 0.21 L per unit of product produced for its standard manufacturing processes. Brisbane's manufacturing facility has a water intensity of 0.007 L per unit of product produced for its standard manufacturing processes. Megrine's manufacturing facility has a water intensity of 0.98 L per unit of product produced for its standard manufacturing processes. Ho Chi Minh's manufacturing facility has a water intensity of 1.12 L per unit of product produced for its standard manufacturing processes.
Impact on Stakeholders	As a water intensive industry, the manufacturing of pharmaceutical products poses risks such as water stress or depletion of local water sources if water used is not appropriately managed. The company uses mostly municipal water supply for pharmaceutical production and utilities. The main stakeholders affected are other water users in the regions of operation, such as local water authorities & regulators, residents, other industrial plants, farmers, and the local biodiversity.
Implemented Management Practices	The company does not carry out an assessment of how it compares to other peers in the industry regarding water use and management. All sites use global corporate standards to manage water and globally, Opella has the target of reducing water consumption by 20% in 2030, compared to 2019 levels as a benchmark. Opella's sustainability strategy is based on water stewardship principles: increasing water efficiency, assessing risks in each local watershed and defining a strategy aligned with local communities to properly manage the watershed the company relies on.
Management Comments	Opella's affiliate in **Hong Kong, Sunstone China LTD ("Sunstone")**, was included in the initial scope of companies and territories verified for the AMEA certification. However, Sunstone is no longer an active legal entity and has stopped its operation effective as of 31 May 2024. The company **Opella Healthcare South Africa ("OHSA")** was included in the initial scope of companies and territories verified for the AMEA certification. Following a shares transaction effective as of October 1st, 2024, OHSA is no longer an Opella

	company.

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Environmentally Intensive Industry

Topic	Chemical Intensive industries
Summary of Issue	Opella AMEA operates in the pharmaceutical industry which it is recognised as a chemical intensive industry. Opella AMEA includes the assessment of the following entities: - Opella Japan (Corporate office, Manufacturing & R&D, distribution centers) - Opella Australia (Corporate office, Manufacturing & R&D), Opella South Korea (Corporate Office), Opella Hong Kong (Corporate Office) - Opella Egypt, Turkey, Saudi Arabia, UAE (Corporate Offices) - Opella Tunisia (Manufacturing & Corporate Office), Opella South Africa (Corporate Office) - Opella Vietnam (Manufacturing & Corporate Office), Opella Philippines, Thailand, Indonesia, Singapore, Malaysia (Corporate Offices) - Opella China (Corporate Office). - Opella India (Corporate Office). The company is not involved in the production, operation, trade or sale of chemicals that meet the European Union's list of Substances of Very High Concern (SVHC). All manufacturing and R&D facilities (Narita, Brisbane, Megrine, Ho Chi Minh) use limited quantities of SVHC substances as lab chemicals for quality control purposes. The use in each facility is below 1 ton/year and therefore exempted from REACH registration. All product formulas are approved by the appropriate Competent Authorities, go through quality control and quality assurance, and are subject to monitoring in terms of quality, safety & efficacy. The level of the ingredients in the finished products remain adequate for the safe and intended use of consumers.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	The use of chemicals for quality control purposes at the manufacturing and R&D sites is below 1 ton/year. Therefore, these facilities would be exempted from restriction and authorization linked to REACH regulation.
Impact on Stakeholders	The primary potential impacts of chemical use in pharmaceutical products are potential negative effects on the environment and potential negative health impacts on workers exposed to chemical ingredients. Risks to workers exposed to chemical

	ingredients are mitigated through appropriate controls such as engineering controls and respiratory protection. In the last five years, Opella AMEA has not experienced any significant incidents and/or fines related to environmental or worker impacts of its chemical use.
Implemented Management Practices	Opella does not conduct an assessment and comparison with other companies regarding its chemical use. All chemicals used are handled, stored, disposed of, and transported following corporate standards, local legal requirements, Standard Operating Procedures, and local Permits. Furthermore, wastewater is managed by complying with all local legal requirements, Standard Operating Procedures and Permits, assuring all wastewater parameters are within the defined local regulation limits. At the global level, the company has implemented a program to identify substances of potential future concern in our formula and plan their substitution or removal whenever possible from a technical or regulatory standpoint. This program includes a list of materials or substances to be banned, avoided, or restricted in Opella products. Moreover, Opella AMEA has documented HSE requirements to minimize the use of Carcinogens, Mutagens, Reprotoxic and volatile organic compounds. All product formulas are approved by local Health Authorities, go through quality control and quality assurance, and are subject to monitoring in terms of quality, safety & efficacy. Given the restricted regulation of the sector, the level of ingredients in the finished products remains adequate for the safe and intended use of consumers.
Management Comments	Opella's affiliate in **Hong Kong, Sunstone China LTD ("Sunstone")**, was included in the initial scope of companies and territories verified for the AMEA certification. However, Sunstone is no longer an active legal entity and has stopped its operation effective as of 31 May 2024. The company **Opella Healthcare South Africa ("OHSA")** was included in the initial scope of companies and territories verified for the AMEA certification. Following a shares transaction effective as of October 1st, 2024, OHSA is no longer an Opella company.

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Other - Mandatory Animal Testing

Issue Date	Ongoing
Topic	Opella AEMA's legal entities are part of Opella, the consumer healthcare business unit of Sanofi, a pharmaceutical company. Opella AMEA manufactures and sells but does not develop new drugs (e.g. new drug molecules), therefore Opella AMEA does not require the use of animal testing.
Summary of Issue	Opella AEMA legal entities are part of Opella, the consumer healthcare business unit of Sanofi, a pharmaceutical company. Opella AMEA includes the assessment of the following entities: 1 - Opella Japan (Corporate office, Manufacturing & R&D, distribution centers) 2 - Opella Australia (Corporate office, Manufacturing & R&D), Opella South Korea (Corporate Office), Opella Hong Kong (Corporate Office) 3 - Opella Egypt, Turkey, Saudi Arabia, UAE (Corporate Offices) 4 - Opella Tunisia (Manufacturing & Corporate Office), Opella South Africa (Corporate Office) 5- Opella Vietnam (Manufacturing, Corporate Office), Opella Philippines, Thailand, Indonesia, Singapore, Malaysia (Corporate Offices) Cluster 6- OpellaChina (Corporate Office). 7 - Opella India (Corporate Office). As a company that manufactures pharmaceutical products, Opella is legally obligated to ensure the quality, safety, and efficacy of its medicines and other consumer healthcare products, for which animal testing is required in research and production. Opella AMEA can market over the counter (OTC) products because they have already been proven to be safe and effective. Opella does not engage in the regular practice of animal testing: It is only conducted when specifically required by regulatory authorities and no alternative methods can be applied. Animal studies would only be performed in rare situations to evaluate and assess major safety concerns, if literature/data was unavailable for the study endpoints needed, and when specifically required by Regulatory Authorities or to verify the rationale, safety, and efficacy of the combination of two or more ingredients and when no alternative methods can be applied. Animal studies would therefore generally only be

	conducted as a final resort if no alternatives are available or when required by Regulatory Authorities. In Opella AMEA, no animal testing was performed in the last five years. Opella AMEA does not research and develop new drugs molecules. They manufacture and sell Over the Counter (OTC) products which have already been proven to be safe and effective.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	Opella AMEA did not conduct animal testing in the past 5 years. However, the company currently sells medicines that had to go through animal testing previously.
Impact on Stakeholders	Opella AMEA does not develop new drug molecules and as stated above would only perform animal testing in rare situations when required by Regulatory Authorities. Animal testing and experimentation is widely used to develop and test the safety of new drug molecules. Many of these experiments can cause pain to the animals involved or reduce their quality of life in other ways. When the execution of this study is mandatory for regulatory or safety reasons the company implements practices to promote animal welfare and prevent animal pain and distress in housing and procedure conditions.
Implemented Management Practices	Opella does not engage in the regular practice of animal testing. It only conducts when the regulatory and scientific merit is established and under strict ethical over-sight. Sanofi at a group level has a policy for the protection of animals that includes a 3R principle towards animal testing; seeking to exceed regulation and standards. The company tests products on animals only: - when a non-animal method is unsuited for the required use or not accepted by the authorities (replacement) - with the smallest number of animals necessary for quality science (reduction) - with the implementation of state-of-the-art practices to promote animal welfare and prevent animal pain and distress in housing and procedure conditions (refinement). Sanofi has Animal Ethics Committees with principles to ensure impartiality and independence of the ethical review. Opella rarely authorizes animal testing and only when the regulatory and scientific merit is established and under strict ethical over-sight. If animal testing is authorized, Sanofi monitors compliance by third parties (breeders, contract research organizations, not-for-profit collaborations). In addition to the legal obligations, Sanofi has set internal

	standards to align requirements across the world and to ensure high welfare considerations. All Sanofi sites maintain or seek independent accreditation of their animal care and use programs through recognized expert organizations such as AAALAC International. Sanofi applies the same principles to subcontractors and breeders; their animal welfare program is assessed by Sanofi professionals to ensure the consistency of the animal care. External partners are expected to comply with animal welfare laws and commit to the spirit of the Sanofi policy on the protection of animals. Sanofi professionals will evaluate animal care and use programs of external partners on a regular basis and approve those that comply with Sanofi standards. Sanofi is also a signatory of the Marseille Declaration, a pharmaceutical industry declaration on animal housing and use (see link below). External stakeholders can raise concerns in relation to animal testing directly to the Chief Veterinary Officer through Sanofi.com.
Report	Sanofi Animal Protection Factsheet Sanofi Policy on Animal Protection Signed Marseille Declaration
Management Comments	Opella's affiliate in **Hong Kong, Sunstone China LTD ("Sunstone")**, was included in the initial scope of companies and territories verified for the AMEA certification. However, Sunstone is no longer an active legal entity and has stopped its operation effective as of 31 May 2024. The company **Opella Healthcare South Africa ("OHSA")** was included in the initial scope of companies and territories verified for the AMEA certification. Following a shares transaction effective as of October 1st, 2024, OHSA is no longer an Opella company.

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Penalties & Complaints

Issue Date	2019
Topic	Penalties and complaints related to a Remediation Order from the Labor Standards Inspection Office
Summary of Issue	Opella AMEA includes the assessment of the following clusters: - Opella Japan (Corporate office, Manufacturing & R&D, distribution centers) - Opella Australia (Corporate office, Manufacturing & R&D), Opella South Korea (Corporate Office), Opella Hong Kong (Corporate Office) - Opella Egypt, Turkey, Saudi Arabia, UAE (Corporate Offices) - Opella Tunisia (Manufacturing & Corporate Office), Opella South Africa (Corporate Office) - Opella Vietnam (Manufacturing, Corporate Office), Opella Philippines, Thailand, Indonesia, Singapore, Malaysia (Corporate Offices) - Opella China (Corporate Office). - Opella India (Corporate Office). In the last five years, Opella AMEA had one (1) formal complaint from the Labor Standards Inspection Office (Japan). Specifically, Opella Japan received a Remediation Order from the Labor Standards Inspection Office followed by an accident in the Narita Laboratory in May 2019. This incident occurred when an intense chemical reaction occurred after a contingent worker mixed the waste liquid of an experiment into the wrong plastic waste bottle. During the clean-up phase of the operation the contingent worker was injured as the chemical reaction continued to the point of rupturing the plastic bottle and ejecting the chemical waste across the room and in to the face of the worker who had at that stage removed their PPE needed for the previous laboratory work. The contingent worker suffered a serious eye injury, after medical treatment the individual made a full recovery. In March 2019, the company submitted a written report to the Labor Standards Inspection Office to notify them about the incident.

Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	No penalty was issued. The company received a Remediation Order that included corrective recommendations and safety and health guidance. 1 individual affected.
Impact on Stakeholders	The main stakeholders affected are the company's employees, who were vulnerable to different types of accidents due to lack of appropriate Health & Safety measures and compliance.
Resolution	The company completed all the improvements actions instructed in the corrective recommendation and guidance before the instructed due date. Accordingly, the company submitted "the Remediation Improvement Report" to the Labor Standards Inspection Office in Jun 2019.
Implemented Management Practices	In order to prevent similar recurrence, the company reviewed the procedures for the treatment of experimental waste by referring to the Safety Data Sheet (SDS) of each reagent and combinations that may explode when mixed. Information and training were carried out to employees. In accordance with Article 25 of the Organic Law, the categories of organic solvents used are color-coded and displayed in an easily visible place. A notice was posted in accordance with Article 38 (3) of the Special Substances Control Law at the workshop where specially controlled substances were handled.
Related Incidents	No related incidents
Management Comments	Opella's affiliate in **Hong Kong, Sunstone China LTD ("Sunstone")**, was included in the initial scope of companies and territories verified for the AMEA certification. However, Sunstone is no longer an active legal entity and has stopped its operation effective as of 31 May 2024. The company **Opella Healthcare South Africa ("OHSA")** was included in the initial scope of companies and territories verified for the AMEA certification. Following a shares transaction effective as of October 1st, 2024, OHSA is no longer an Opella company.

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Environmentally Intensive Industry

Issue Date	Ongoing
Topic	Energy Intensive industries
Summary of Issue	Opella AMEA includes the assessment of the following entities: - Opella Japan (Corporate, Manufacturing & R&D, distribution centers) - Opella Australia (Corporate office, Manufacturing & R&D), Opella South Korea (Corporate Office), Opella Hong Kong (Corporate Office) - Opella Egypt, Turkey, Saudi Arabia, UAE (Corporate Offices) - Opella Tunisia (Manufacturing & Corporate Office), Opella South Africa (Corporate Office) - Opella Vietnam (Manufacturing, Corporate Office), Opella Philippines, Thailand, Indonesia, Singapore, Malaysia (Corporate Offices) - Opella China (Corporate Office). - Opella India (Corporate Office). Opella AMEA operates in the pharmaceutical industry which has been recognised by B Lab as an energy-intensive industry. Of the company's total energy use, the most energy intensive activities are related to the manufacturing sites. Regarding Opella's consolidated operations, the company uses electricity and natural gas as the main sources of energy, with the majority of sites using renewable electricity (87% in 2023 with the objective to have 100% of the sites by 2025). Accordingly, the company relies on Power Purchase Agreements (PPAs), self-generated solar photovoltaic energy and renewable electricity certificates. Furthermore, some sites use a mix of biogas and natural gas for its operations.
Size/Scope of Issue ***(e.g. $ financial implication, # of***	In the previous fiscal year, 100% of Opella CEE was derived from the production of self-medication medicines/drugs,

individuals affected)	food/dietary supplements, and cosmetics. Considering local contexts, each manufacturing site has its own energy intensity as described below. 1. Narita's manufacturing facility has an energy intensity of 0.30 kWh per product produced for its standard manufacturing processes. 2. Brisbane's manufacturing facility has an energy intensity of 0.78 kWh per product produced for its standard manufacturing processes. 3. Megrine's manufacturing facility has an energy intensity of 0.63 kWh per product produced for its standard manufacturing processes. 4. Ho Chi Minh's manufacturing facility has an energy intensity of 0.38 kWh per product produced for its standard manufacturing processes.
Impact on Stakeholders	Energy-intensive activities, such as manufacturing activities, pose an environmental risk due to the related emissions derived from energy use. The extent of environmental impact is dependent on the energy sources utilised and the management practices in place to manage energy use.
Implemented Management Practices	Energy consumption and emission reductions are managed at site levels and coordinated at the global level to reach ambitious targets. The company uses the following best practices to minimise energy use and carbon emissions: • Energy efficiency • Renewable Electricity • Decarbonizing heat through electrification and new technologies While the company already decreased its Scope 1 & 2 emissions by 57% in 2023 compared to a 2019 baseline, the objective is to reach 65% emissions reduction & use 100% renewable electricity by 2025. Opella intends to establish a new science-based target (covering Scopes 1, 2 and 3). As part of this process, Opella is working to develop new baseline emissions data of our Scope 3 emissions.
Report	
Management Comments	Opella’s affiliate in Hong Kong, Sunstone China LTD

	(“Sunstone”), was included in the initial scope of companies and territories verified for the AMEA certification. However, Sunstone is no longer an active legal entity and has stopped its operation effective as of 31 May 2024. The company Opella Healthcare South Africa (“OHSA”) was included in the initial scope of companies and territories verified for the AMEA certification. Following a shares transaction effective as of October 1st, 2024, OHSA is no longer an Opella company.

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Litigation, Arbitration, and/or Penalties

Issue Date	2018
Topic	Penalties related to possible violations of the U.S. Foreign Corrupt Practices Act (FCPA)
Summary of Issue	Sanofi agreed to pay penalties following an investigation into allegations that its subsidiaries in Kazakhstan and the Middle East engaged in corrupt practices to secure business deals. The investigation was conducted by the U.S. Securities and Exchange Commission (SEC) and the Department of Justice (DOJ). The subsidiaries implicated in the investigation operated in Kazakhstan, Jordan, Lebanon, Bahrain, Kuwait, Qatar, Yemen, Oman, the United Arab Emirates, and the Palestinian territory between 2006 and 2015. This investigation includes the subsidiaries prior to the carve-in of Opella as a standalone business unit so it includes CHC.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	In the settlement, Sanofi agreed to pay $25 million in penalties.
Impact on Stakeholders	Overall, the risks associated with corruption extend beyond legal and financial implications to encompass broader reputational damage and erosion of stakeholder trust, which can have lasting negative effects on the company's sustainability and success. The compliance with the FCPA is essential for mitigating these risks and safeguarding the interests of stakeholders. It requires robust internal controls, effective compliance programs, and a culture of ethical conduct throughout the organization.
Resolution	In September 2018, Sanofi reached a civil settlement with the US Securities and Exchange Commission (SEC) fully resolving the SEC's investigation into possible violation of the US FCPA. Sanofi did not admit any wrongdoing in connection with the settlement but agreed to pay $25 million in penalties and to a two-year period of self-reporting on the effectiveness of its enhanced internal controls, which ended in January 2021.
Implemented Management Practices	Opella shared that abides by overarching Sanofi Group policies and procedures in relation to Code of Ethics, anti-corruption, and bribery, lobbying and advocacy, in interactions with

	healthcare organizations/professionals and ethical marketing. All Opella employees and any third party working on behalf of Sanofi CHC must comply with the relevant, appropriate procedure. The company also has policies and procedures designed to help ensure that they, their officers, employees, agents, intermediaries and other third parties, comply with applicable laws and regulations (including, but not limited to, the US Foreign Corrupt Practices Act, the UK Bribery Act, the OECD Anti-Bribery Convention, the French Anti-Corruption measure law, the French duty of vigilance law and any other applicable local anti-bribery laws and regulations).
Report	- Sanofi Charged With FCPA Violations - Sanofi reaches civil settlement with US SEC
Management Comments	*"The investigation is concluded by this settlement. Sanofi has implemented a comprehensive and rigorous global anti-bribery and corruption compliance program, encompassing, among other things, clear policies and procedures, comprehensive training and awareness programs, detailed internal controls, periodic internal audits, and a helpline able to receive calls and reports in 28 different languages. All of these elements support prevention, detection, remediation and discipline of potential misconduct. We expect every employee to follow and respect the Company's policies, procedures and its internal control mechanisms and provide the foundations for them to do so. In short, integrity is one of the core values of Sanofi and it guides our actions every day."*

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Litigation, Arbitration, and/or Penalties

Issue Date	June - August 2023
Topic	Administrative penalty related to Sanofi's advertisements
Summary of Issue	Sanofi's antihistaminic drug, Allegra, was suspended from advertising for 2 months (from June 2023 to Aug 2023) by the Ministry of Food and Drug Safety in Korea due to omitting some facts about the drug in previous advertisements.The company shared that as a result of a competitor petition, Sanofi South Korea received an administrative penalty for not following the review process for the inclusion of its recent "Consumer Selected Brand of the Year award" emblem for Allegra on its advertising material.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	There was no penalty associated with the matter. The company faced a two month suspension period on the advertisement.
Impact on Stakeholders	The company's advertisements might be unclear, misleading, and/or confusing, especially for clients in the pharmaceutical industry, if not properly managed and aligned with local regulations and procedures.
Resolution	After the two month suspension period, the Company revised the said advertisement to align with the guideline. The Company is able to use the revised advertisement.
Implemented Management Practices	The company's internal investigation concluded the root cause to be a new recruit failing to file for the necessary approval and a gap in their training plan. As a corrective action, retraining was done for all employees including the new recruit in line with their Promotional review Standard Operating Procedure.
Management Comments	Opella's affiliate in Hong Kong, Sunstone China LTD ("Sunstone"), was included in the initial scope of companies and territories verified for the AMEA certification. However, Sunstone is no longer an active legal entity and has stopped its operation effective as of 31 May 2024. The company Opella Healthcare South Africa ("OHSA") was included in the initial scope of companies and

	territories verified for the AMEA certification. Following a shares transaction effective as of October 1st, 2024, OHSA is no longer an Opella company.
Related Incidents (Yes/No)	No.

Opella CEE (Central and Eastern Europe)

Disclosure Report

Date Submitted: September, 2024

Disclosure Questionnaire

Industries and Products

	Yes	No
Please indicate if the company is involved in production of or trade in any of the following. Select Yes for all options that apply.		
Animal Products or Services	☐	☑
Biodiversity Impacts	☐	☑
Chemicals	☑	☐
Disclosure Alcohol	☐	☑
Disclosure Firearms Weapons	☐	☑
Disclosure Mining	☐	☑
Disclosure Pornography	☐	☑
Disclosure Tobacco	☐	☑
Energy and Emissions Intensive Industries	☑	☐
Gambling	☐	☑
Genetically Modified Organisms	☐	☑
Illegal Products or Subject to Phase Out	☐	☑
Industries at Risk of Human Rights Violations	☐	☑
Monoculture Agriculture	☐	☑
Nuclear Power or Hazardous Materials	☐	☑
Payday, Short Term, or High Interest Lending	☐	☑
Water Intensive Industries	☑	☐
Tax Advisory Services	☐	☑

Outcomes & Penalties

	Yes	No
Please indicate if the company has had any formal complaint to a regulatory agency or been assessed any fine or sanction in the past five years for any of the following practices or policies. Check all that apply.		
Anti-Competitive Behavior	☐	☑
Breaches of Confidential Information	☐	☑
Bribery, Fraud, or Corruption	☐	☑
Company has filed for bankruptcy	☐	☑
Consumer Protection	☐	☑
Financial Reporting, Taxes, Investments, or Loans	☐	☑
Hazardous Discharges Into Air/Land/Water (Past 5 Yrs)	☐	☑
Labor Issues	☐	☑
Large Scale Land Conversion, Acquisition, or Relocation	☐	☑
Litigation or Arbitration	☐	☑
On-Site Fatality	☐	☑
Penalties Assessed For Environmental Issues	☐	☑
Political Contributions or International Affairs	☐	☑
Recalls	☐	☑
Significant Layoffs	☐	☑
Violation of Indigenous Peoples Rights	☐	☑
Other	☐	☑

Practices

	Yes	No
Please indicate if the following statements are true regarding whether or not the company engages in the following practices. Check all that apply. If the statement is true, select "Yes." If false, select "No."		
Animal Testing	☑	☐
Company/Suppliers Employ Under Age 15 (Or Other ILO Minimum Age)	☐	☑
Company prohibits freedom of association/collective bargaining	☐	☑
Company workers are prisoners	☐	☑
Conduct Business in Conflict Zones	☑	☐
Confirmation of Right to Work	☐	☑
Does not transparently report corporate financials to government	☐	☑
Employs Individuals on Zero-Hour Contracts	☐	☑
Facilities located in sensitive ecosystems	☐	☑
ID Cards Withheld or Penalties for Resignation	☐	☑
No formal Registration Under Domestic Regulations	☐	☑
No signed employment contracts for all workers	☐	☑
Overtime For Hourly Workers Is Compulsory	☐	☑
Payslips not provided to show wage calculation and deductions	☐	☑
Sale of Data	☐	☑
Tax Reduction Through Corporate Shells	☐	☑
Workers cannot leave site during non-working hours	☐	☑
Workers not Provided Clean Drinking Water or Toilets	☐	☑
Workers paid below minimum wage	☐	☑
Workers Under Bond	☐	☑
Other	☐	☑

Supply Chain Disclosures

	Yes	No
Please indicate if any of the following statements are true regarding your company's significant suppliers.		
Business in Conflict Zones	☐	☑
Child or Forced Labor	☐	☑
Negative Environmental Impact	☐	☑
Negative Social Impact	☐	☑
Other	☐	☑

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Operations located in Conflict Zones

Topic	Company operates and has suppliers located in Conflict Zones
Summary of Issue	Opella CEE's legal entities are part of the Opella, the consumer health care business unit of Sanofi, a pharmaceutical company. Opella CEE includes the assessment of the following entities: 1 - Opella Hungary-Poland (HQ, Manufacturing & R&D) 2 - Opella Czech-Slovakia-Ukraine-Romania (wholesale/retail) Opella CEE has ongoing operations in Ukraine, which is in an ongoing conflict due to the military aggression launched by the Russian Federation. Opella CEE is currently working in line with the Martial Law and continues to to supply / make available essential medicinal products to the society in Ukraine. As part of its operations in Ukraine, the company also has direct suppliers related to marketing services and external workforce. Patients' health and well-being is a priority for Opella CEE and thus it continues operations in Ukraine supplying / making available essential medicinal products to the society. Opella CEE, in accordance with the national legislation and regulations imposed by the Martial Law, does not operate directly or indirectly in the territories within Ukraine that is currently occupied by the aggressor. The company also supplies / makes available essential medicinal products in countries outside of this military conflict.
Size/Scope of Issue **(e.g. $ financial implication, # of individuals affected)**	In the fiscal year end of 2023, 6% of Opella CEE's total revenue was generated through sales in Ukraine, while suppliers in Ukraine represent 2% of Opella CEE"s total expenses.
Impact on Stakeholder(s)	Business activities located in conflict zones are considered high-risk as they are more likely to cause or contribute to the conflict and/or sociopolitical instability. Countries classified as conflict zones are more likely to have a weak rule-of-law or a corrupt judicial system, which could undermine the effectiveness of operational grievance

	mechanisms for these businesses and their suppliers. In addition, the safety of the company's workers and other potential human rights violations are at risk.
Implemented Management Practices	The company has taken measures to help its employees in Ukraine. Other team members working with Sanofi (including Oppela) from neighboring countries are supporting the colleagues and their families from Ukraine who have made the difficult decision to leave the country. Opella CEE based in Ukraine has moved supplies from high-risk areas to safer warehouse locations and has established new shipping centers in lower-risk zones; and embraced new partnerships to keep on top of logistics. The company is also committed to helping its patients and clinicians access sites safely, stay connected with each other through migration and disruption, and access their investigational medicines. Additionally, Opella CEE follows a set of Standards which provide a framework to enable it to work effectively with customers, patients and other stakeholders in accordance with the company's Code of Conduct and all relevant applicable laws, regulations, and industry guidelines. The Code has a section on the company's stand against bribery and corruption which ensures that the company's operations are not tied to the conflicts surrounding Ukraine and do not in any way exacerbate the conflicts. The company also has a Suppliers Code of Conduct in place. The company's suppliers and service providers undergo a risk based due diligence aiming at assessing any potentially exposure to corruption and/or any other illicit/ inappropriate practices.
Report	https://www.sanofi.com/en/media-room/our-response-to-the-situation-in-ukraine
Management Comments	Opella CEE is currently working in line with the martial law and continues to supply / make available essential medicinal products to the society in Ukraine. Opella also supplies / makes available essential medicinal products in countries outside of this military conflict.Patients' health and well-being is a priority for Opella and thus continues operations in Ukraine supplying /

	making available essential medicinal products to the society. Opella CEE, in accordance with the national legislation, does not operate directly or indirectly in the territories occupied by the aggressor. In daily operations Opella CEE in Ukraine follows all relevant Standards and Procedures applied for compliant cooperation with partners. The company also has a Suppliers Code of Conduct in place. The company's suppliers and service providers undergo a risk based due diligence aiming at assessing any potentially exposure to corruption and/or any other illicit/ inappropriate practices.

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Environmentally Intensive Industry

Issue Date	Ongoing
Topic	Water Intensive Industry
Summary of Issue	Opella CEE's legal entities are part of Opella, the consumer healthcare business unit of Sanofi, a pharmaceutical company. Opella CEE includes the assessment of the following entities: 1 - Opella Hungary-Poland (HQ, Manufacturing & R&D) 2 - Opella Czech-Slovakia-Ukraine-Romania (wholesale/retail) Opella CEE operates in the pharmaceutical industry which is recognised by B Lab as a water-intensive industry due to manufacturing and cleaning processes, although the company does not consider itself to be a water intensive industry and continues to minimise water use. Of the company's total water use, the most water intensive activities are in the manufacturing sites; Rzeszów facility in Poland, and Veresegyhaz facility in Hungary. - At Rzeszów's facility, the company uses municipality water for manufacturing and cleaning, with water reduction efforts deployed at the site, including the elimination of detergents from cleaning processes. The region is a medium-high water risk area. - At Veresegyhaz's facility, the company uses municipality water for manufacturing and cleaning, with water reduction efforts deployed at the site and consumption below 10,500 cubic meters per quarter. The region is a low water risk area.
Size/Scope of Issue **(e.g. $ financial implication, # of individuals affected)**	In the previous fiscal year, 100% of Opella CEE was derived from the prodution of self-medication medicines/drugs, food/dietary supplements, and comestics. Considering local contexts, each manufacturing site has its own water intesity as described below. - Rzeszów's manufacturing facility has a water intensity of 0.277 L per unit of product produced for its standard manufacturing processes. - Veresegyhaz's manufacturing facility has a water intensity of 0.288L per unit of product produced for its standard manufacturing processes.

Impact on Stakeholder(s)	As a water intensive industry, the manufacturing of pharmaceutical products poses risks such as water stress or depletion of local water sources if water used is not appropriately managed. The company uses municipality water supply for pharmaceutical production and utilities. The main stakeholders affected are other water users in the regions of operation, such as local water authorities & regulators, residents, other industrial plants, farmers, and the local biodiversity.
Implemented Management Practices	The company does not carry out an assessment of how it compares to other peers in the industry regarding water use and management. All sites use global corporate standards to manage water and globally, Opella has the target of reducing water consumption by 20% in 2030, compared to 2019 levels as a benchmark. Opella sustainability strategy is based on water stewardship principles: increasing water efficiency, assessing risks in each local watershed and defining a strategy aligned with local communities to manage properly the watershed the company relies on.

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Environmentally Intensive Industries

Issue Date	Ongoing
Topic	Chemical Intensive industries
Summary of Issue	Opella CEE's legal entities are part of Opella, the consumer healthcare business unit of Sanofi, a pharmaceutical company. Opella CEE includes the assessment of the following entities: 1 - Opella Hungary-Poland (HQ, Manufacturing & R&D) 2 - Opella Czech-Slovakia-Ukraine-Romania (wholesale/retail) Opella CEE operates in the pharmaceutical industry which has been recognised by B Lab as a chemical intensive industry. The company is not involved in the production, operation, trade or sale of chemicals that meet the European Union's list of Substances of Very High Concern (SVHC). The company uses SVHC lab chemicals for quality control purposes on its sites. All product formulas are approved by local Health Authorities, go through quality control and quality assurance, and are subject to monitoring in terms of quality, safety & efficacy. The level of the ingredients in the finished products remain adequate for the safe and intended use of customers.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	The use of SVHC substances for quality control purposes at the manufacturing sites is below 1 ton/year. Therefore, these facilities are exempted from restriction and authorization linked to REACH regulation.
Impact on Stakeholders	The primary potential impacts of chemical use in pharmaceutical products are potential negative effects on the environment and potential negative health impacts on workers exposed to chemical ingredients. Risks to workers exposed to chemical ingredients are mitigated through appropriate controls such as engineering controls and respiratory protection. In the last five years, Opella CEE has not experienced any significant incidents and/or fines related to environmental or worker impacts of its chemical use.
Implemented Management Practices	All chemicals used are handled, stored, disposed of, and transported following corporate standards, local legal

	requirements, Standard Operating Procedures, and local Permits. Furthermore, wastewater is managed by complying with all local legal requirements, Standard Operating Procedures and Permits, assuring all wastewater parameters are within the defined local regulation limits. At the global level, the company has implemented a program to identify substances of potential future concern in our formula and plan their substitution or removal whenever possible from a technical or regulatory standpoint. This program includes a list of materials or substances to be banned, avoided, or restricted in Opella products. Moreover, Opella CEE has documented HSE requirements to minimize the use of Carcinogens, Mutagens, Reprotoxic and volatile organic compounds. All product formulas are approved by local Health Authorities, go through quality control and quality assurance, and are subject to monitoring in terms of quality, safety & efficacy. Given the restricted regulation of the sector, the level of ingredients in the finished products remains adequate for the safe and intended use of consumers. At the local level, the company does not conduct an assessment and comparison with other companies regarding chemical use.

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Other - Mandatory Animal Testing

Issue Date	Ongoing
Topic	Opella CEE is a subsidiary of Opella and sells consumer healthcare products. Opella CEE manufactures and sells but does not develop new drugs (e.g. new drug molecules), therefore Opella CEE does not require the use of animal testing.
Summary of Issue	Opella CEE's legal entities are part of Opella, the consumer healthcare business unit of Sanofi, a pharmaceutical company. Opella CEE includes the assessment of the following entities: 1 - Opella Hungary-Poland (HQ, Manufacturing & R&D) 2 - Opella Czech-Slovakia-Ukraine-Romania (wholesale/retail) As a company that manufactures pharmaceutical products, Opella is legally obligated to ensure the quality, safety, and efficacy of its medicines and other consumer healthcare products, for which animal testing is required in research and production. As a subsidiary of Opella, Opella CEE can market over the counter (OTC) products because they have already been proven to be safe and effective. Opella does not engage in the regular practice of animal testing: It is only conducted when specifically required by regulatory authorities and no alternative methods can be applied. Animal studies would only be performed in rare situations to evaluate and assess major safety concerns, if literature/data was unavailable for the study endpoints needed, and when specifically required by Regulatory Authorities or to verify the rationale, safety, and efficacy of the combination of two or more ingredients and when no alternative methods can be applied. Animal studies would therefore generally only be conducted as a final resort if no alternatives are available or when required by Regulatory Authorities. In Opella CEE, no animal testing was performed in the last five years. Opella CEE does not research and develop new drug molecules. Opella CEE manufactures and sells Over the Counter (OTC) products which have already been proven to be safe and effective.
Size/Scope of Issue ***(e.g. $***	Opella CEE did not conduct animal testing in past 5 years.

financial implication, # of individuals affected)	However, the company currently sells medicines that had to go through animal testing previously.
Impact on Stakeholders	Animal testing and experimentation is widely used to develop and test the safety of new drug molecules and/or food products. Many of these experiments can cause pain to the animals involved or reduce their quality of life in other ways. Opella CEE does not develop new drug molecules and as stated above would only perform animal testing in rare situations when required by Regulatory Authorities. Animal testing and experimentation is widely used to develop and test the safety of new drug molecules. When the execution of this study is mandatory for regulatory or safety reasons the company implements practices to promote animal welfare and prevent animal pain and distress in housing and procedure conditions.
Implemented Management Practices	Opella does not engage in the regular practice of animal testing. It only conducts when the regulatory and scientific merit is established and under strict ethical over-sight. Sanofi at a group level has a policy for the protection of animals that includes a 3R principle towards animal testing; seeking to exceed regulation and standards. The company tests products on animals only: - when a non-animal method is unsuited for the required use or not accepted by the authorities (replacement) - with the smallest number of animals necessary for quality science (reduction) - with the implementation of state-of-the-art practices to promote animal welfare and prevent animal pain and distress in housing and procedure conditions (refinement). Sanofi has Animal Ethics Committees with principles to ensure impartiality and independence of the ethical review. Opella rarely authorizes animal testing and only when the regulatory and scientific merit is established and under strict ethical over-sight. If animal testing is authorized, Sanofi monitors compliance by third parties (breeders, contract research organizations, not-for-profit collaborations). In addition to the legal obligations, Sanofi has set internal standards to align requirements across the world and to ensure high welfare considerations. All Sanofi sites maintain or seek independent accreditation of their animal care and use programs through recognized expert organizations such as AAALAC International. Sanofi applies the same principles to subcontractors and breeders; their animal welfare program is

	assessed by Sanofi professionals to ensure the consistency of the animal care. External partners are expected to comply with animal welfare laws and commit to the spirit of the Sanofi policy on the protection of animals. Sanofi professionals will evaluate animal care and use programs of external partners on a regular basis and approve those that comply with Sanofi standards. Sanofi is also a signatory of the Marseille Declaration, a pharmaceutical industry declaration on animal housing and use (see link below). External stakeholders can raise concerns directly to the Chief Veterinary Officer through Sanofi.com.
Report	- Sanofi-policy-on-the-protection-of-animals-2018-EN.pdf - Marseille-Declaration-2022-signed.pdf (sanofi.com) - Responsible use of animals in research and production (sanofi.com)

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Environmentally Intensive Industry

Issue Date	Ongoing
Topic	Energy Intensive industries
Summary of Issue	Opella CEE's legal entities are part of Opella, the consumer healthcare business unit of Sanofi, a pharmaceutical company. Opella CEE includes the assessment of the following entities: 1 - Opella Hungary-Poland (HQ, Manufacturing & R&D) 2 - Opella Czech-Slovakia-Ukraine-Romania (wholesale/retail) Opella CEE operates in the pharmaceutical industry which has been recognised by B Lab as an energy-intensive industry. Of the company's total energy use, the most energy intensive activities are in the manufacturing sites; Rzeszów facility in Poland, and Veresegyhaz facility in Hungary. Regarding Opella's consolidated operations, the company uses electricity and natural gas as the main sources of energy, with the majority of sites using renewable electricity (87% in 2023 with the objective to have 100% of the sites by 2025). Accordingly, the company relies on Power Purchase Agreements (PPAs), self-generated solar photovoltaic energy and renewable electricity certificates. Furthermore, some sites use a mix of biogas and natural gas for its operations.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	In the previous fiscal year, 100% of Opella CEE was derived from the production of self-medication medicines/drugs, food/dietary supplements, and cosmetics. Considering local contexts, each manufacturing site has its own energy intensity as described below. - Rzeszów's manufacturing facility has an energy intensity of 0.24 kWh per product produced for its standard manufacturing processes. - Veresegyhaz's manufacturing facility has an energy intensity of 0.13 kWh per product produced for its standard manufacturing processes.
Impact on Stakeholders	Energy-intensive activities, such as manufacturing activities, pose an environmental risk due to the related emissions derived from energy use. The extent of environmental impact is dependent on the energy sources utilised and the management

	practices in place to manage energy use.
Implemented Management Practices	Energy consumption and emission reductions are managed at site levels and coordinated at the global level to reach ambitious targets. The company uses the following best practices to minimise energy use and carbon emissions: • Energy efficiency • Renewable Electricity • Decarbonizing heat through electrification and new technologies While the company already decreased its Scope 1 & 2 emissions by 57% in 2023 compared to a 2019 baseline, the objective is to reach 65% emissions reduction & use 100% renewable electricity by 2025. Opella intends to establish a new science-based target (covering Scopes 1, 2 and 3). As part of this process, Opella is working to develop new baseline emissions data of our Scope 3 emissions.

Sanofi CHC Western Europe

Disclosure Report

Date Submitted: March, 2024

Disclosure Questionnaire

Industries and Products

	Yes	No
Please indicate if the company is involved in production of or trade in any of the following. Select Yes for all options that apply.		
Animal Products or Services	☐	☑
Biodiversity Impacts	☐	☑
Chemicals	☐	☑
Disclosure Alcohol	☐	☑
Disclosure Firearms Weapons	☐	☑
Disclosure Mining	☐	☑
Disclosure Pornography	☐	☑
Disclosure Tobacco	☐	☑
Energy and Emissions Intensive Industries	☐	☑
Gambling	☐	☑
Genetically Modified Organisms	☐	☑
Illegal Products or Subject to Phase Out	☐	☑
Industries at Risk of Human Rights Violations	☐	☑
Monoculture Agriculture	☐	☑
Nuclear Power or Hazardous Materials	☐	☑
Payday, Short Term, or High Interest Lending	☐	☑
Water Intensive Industries	☐	☑
Tax Advisory Services	☐	☑

Outcomes & Penalties

	Yes	No
Please indicate if the company has had any formal complaint to a regulatory agency or been assessed any fine or sanction in the past five years for any of the following practices or policies. Check all that apply.		
Anti-Competitive Behavior	☐	☑
Breaches of Confidential Information	☐	☑
Bribery, Fraud, or Corruption	☐	☑
Company has filed for bankruptcy	☐	☑
Consumer Protection	☐	☑
Financial Reporting, Taxes, Investments, or Loans	☐	☑
Hazardous Discharges Into Air/Land/Water (Past 5 Yrs)	☐	☑
Labor Issues	☐	☑
Large Scale Land Conversion, Acquisition, or Relocation	☐	☑
Litigation or Arbitration	☐	☑
On-Site Fatality	☐	☑
Penalties Assessed For Environmental Issues	☐	☑
Political Contributions or International Affairs	☐	☑
Recalls	☑	☐
Significant Layoffs	☐	☑
Violation of Indigenous Peoples Rights	☐	☑
Other	☐	☑

Practices

	Yes	No
Please indicate if the following statements are true regarding whether or not the company engages in the following practices. Check all that apply. If the statement is true, select "Yes." If false, select "No."		
Animal Testing	☑	☐
Company/Suppliers Employ Under Age 15 (Or Other ILO Minimum Age)	☐	☑
Company prohibits freedom of association/collective bargaining	☐	☑
Company workers are prisoners	☐	☑
Conduct Business in Conflict Zones	☐	☑
Confirmation of Right to Work	☐	☑
Does not transparently report corporate financials to government	☐	☑
Employs Individuals on Zero-Hour Contracts	☐	☑
Facilities located in sensitive ecosystems	☐	☑
ID Cards Withheld or Penalties for Resignation	☐	☑
No formal Registration Under Domestic Regulations	☐	☑
No signed employment contracts for all workers	☐	☑
Overtime For Hourly Workers Is Compulsory	☐	☑
Payslips not provided to show wage calculation and deductions	☐	☑
Sale of Data	☐	☑
Tax Reduction Through Corporate Shells	☐	☑
Workers cannot leave site during non-working hours	☐	☑
Workers not Provided Clean Drinking Water or Toilets	☐	☑
Workers paid below minimum wage	☐	☑
Workers Under Bond	☐	☑
Other	☐	☑

Supply Chain Disclosures

	Yes	No
Please indicate if any of the following statements are true regarding your company's significant suppliers.		
Business in Conflict Zones	☐	☑
Child or Forced Labor	☐	☑
Negative Environmental Impact	☐	☑
Negative Social Impact	☐	☑
Other	☐	☑

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Other - Mandatory Animal Testing

Issue Date	Ongoing
Topic	Sanofi Consumer Healthcare (CHC) Western Europe is a cluster of subsidiaries of Sanofi CHC that sells consumer healthcare products. Sanofi CHC Western Europe does not perform research and development activities (e.g. new drug molecules) that require the use of animal testing.
Summary of Issue	As a company that manufactures, and sells pharmaceutical products, Sanofi CHC is legally obligated to ensure the quality, safety, and efficacy of its medicines and other consumer healthcare products. As a subsidiary of Sanofi, Sanofi CHC Western Europe sells consumer healthcare products which have already been proven to be safe and effective and therefore do not require the generation of new animal safety data for their registration procedure. In summary, Sanofi CHC Western Europe would only perform animal studies in rare situations when required by Regulatory Authorities to evaluate and assess major safety concerns and if no alternative methods can be applied including if literature/data was unavailable for the study endpoints needed, and if performing human testing was unethical.
Size/Scope of Issue (e.g. $ financial implication, # of individuals affected)	Sanofi CHC Western Europe has not conducted any animal testing on its products portfolio over the past 5 years. However, the company sells healthcare products such as Over the Counter Products that rely on animal data generated previously to demonstrate the efficacy and safety of the treatment and/or to satisfy Regulatory Authorities requests.
Impact on Stakeholder(s)	Sanofi CHC Western Europe does not develop new drug molecules and as stated above would only perform animal testing in rare situations when required by Regulatory Authorities due to safety concerns. Animal testing and experimentation is widely used to develop and test the safety of new drug molecules. When the execution of this study is mandatory for regulatory or safety reasons the company implement practices to promote animal welfare and

	prevent animal pain and distress in housing and procedure conditions.
Implemented Management Practices	Sanofi CHC Western Europe does not carry out animal testing at the local level. Sanofi at a group level has a policy for the protection of animals that includes a 3R principle towards animal testing; seeking to exceed regulation and standards. The company tests products on animals only: - when a non-animal method is unsuited for the required use or not accepted by the authorities (replacement) - with the smallest number of animals necessary for quality science (reduction) - with the implementation of state-of-the-art practices to promote animal welfare and prevent animal pain and distress in housing and procedure conditions (refinement). Sanofi has animal ethics committees with principles to ensure impartiality and independence of the ethical review. Sanofi CHC rarely authorizes animal testing and only when the regulatory repectively scientific merit is established and under strict ethical over-sight. If animal testing is authorized, Sanofi CHC monitors compliance by third parties (breeders, contract research organizations, not-for-profit collaborations). External partners are expected to comply with animal welfare laws and commit to the spirit of the Sanofi policy on the protection of animals. Sanofi professionals will evaluate animal care and use program of external partners on a regular basis and approve those that comply with Sanofi standards. In addition to the legal obligations, Sanofi has set internal standards to align requirements across the world and to ensure high welfare considerations. All Sanofi sites maintain or seek independent accreditation of their animal care and use programs through recognized expert organizations such as AAALAC International. Sanofi applies the same principles to subcontractors and breeders; their animal welfare program is assessed by Sanofi professionals to ensure the consistency of the animal care. Further information can be found in the Sanofi Animal Protection Factsheet and Animal Protection Policy (links below).

	Sanofi is also a signatory of the pharmaceutical industry declaration on animal housing and use, Marseille Declaration (see link below) External stakeholders can raise concerns in relation to animal testing directly to the Chief Veterinary Officer through Sanofi.com.
Report	Sanofi Animal Protection Factsheet Sanofi Policy on Animal Protection Signed Marseille Declaration

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Recalls

Issue Date	2022 & 2023
Topic	Mandatory and voluntary recalls
Summary of Issue	In the last five years, Sanofi CHC Western Europe experienced two (2) mandatory recalls and one (1) voluntary recall. - Recall 1 (Dexa-Rhinospray N Dexamethasone/ Tramazoline Nasal Spray) Mandatory recall in Belgium & Luxembourg. During routine stability tests, out - of -specifications results for 2 impurities were detected in 2 different batches. Voluntary recall in Belgium & Luxembourg. - Recall 2 (Selsun 1% Shampoo) Voluntary recall in Greece. Publication of an amendment of the EU regulation (1272 / 2008) which banned substances, which is part of several formulas of Selsun 1% (shampoo). Two fragrances used in the formulation of Selsun products were impacted. Because of this regulation, starting from 1 March 2022, all cosmetic products that include this substance must not be sold to the consumer anymore on the European market. - Recall 3 (Dexarhina spray) Mandatory recall in Greece. Out of Specifications results have been identified during long-term stability testing. The recalls were all duly managed as per the global procedure in force, which is in line with international and local regulatory requirements. Each recall was properly managed by the Quality Department including root cause analysis and corrective and preventative action.
Size/Scope of Issue **(e.g. $ financial implication, # of individuals affected)**	Recall 1 represented around 0.001% of the company's overall production. Recall 2 represented around 0.3% of the company's overall production. Recall 3 represented around 0.2% of the company's overall production.
Impact on Stakeholder(s)	None of the recalls resulted in consumer illness or injury. - Recall 1 (Dexa-Rhinospray N Dexamethasone/ Tramazoline Nasal Spray) No consumers were affected. All other quality attributes tested

	for both these batches met specifications. Retain samples of the same batches met the specifications for the two impurities. - Recall 2 (Selsun 1% Shampoo) No consumers were affected. - Recall 3 (Dexarhina spray) No consumers were affected.
Implemented Management Practices	Recalls are managed according to global procedures in line with international and local regulatory requirements. Each recall is managed by the Quality department and includes root cause analysis and corrective and preventative actions. The company has a set of global procedures to address quality alerts and recalls, defining the management and timely reporting and escalation of quality alerts and related mitigation plans. Summary of Corrective and preventative actions: - Recall 1 (Dexa-Rhinospray N Dexamethasone/ Tramazoline Nasal Spray - The product was transferred to a new CMO. - Recall 2 (Selsun 1% Shampoo) - The product was discontinued. - Recall 3 (Dexarhina spray - The product was transferred to a new CMO.

Sanofi CHC Hispanic Latin America

Disclosure Report

Date Submitted: December, 2023

Disclosure Questionnaire

Industries and Products

	Yes	No
Please indicate if the company is involved in production of or trade in any of the following. Select Yes for all options that apply.		
Animal Products or Services	☐	☑
Biodiversity Impacts	☐	☑
Chemicals	☑	☐
Disclosure Alcohol	☐	☑
Disclosure Firearms Weapons	☐	☑
Disclosure Mining	☐	☑
Disclosure Pornography	☐	☑
Disclosure Tobacco	☐	☑
Energy and Emissions Intensive Industries	☐	☑
Gambling	☐	☑
Genetically Modified Organisms	☐	☑
Illegal Products or Subject to Phase Out	☐	☑
Industries at Risk of Human Rights Violations	☐	☑
Monoculture Agriculture	☐	☑
Nuclear Power or Hazardous Materials	☐	☑
Payday, Short Term, or High Interest Lending	☐	☑
Water Intensive Industries	☑	☐
Tax Advisory Services	☐	☑

Outcomes & Penalties

	Yes	No
Please indicate if the company has had any formal complaint to a regulatory agency or been assessed any fine or sanction in the past five years for any of the following practices or policies. Check all that apply.		
Anti-Competitive Behavior	☐	☑
Breaches of Confidential Information	☐	☑
Bribery, Fraud, or Corruption	☐	☑
Company has filed for bankruptcy	☐	☑
Consumer Protection	☐	☑
Financial Reporting, Taxes, Investments, or Loans	☐	☑
Hazardous Discharges Into Air/Land/Water (Past 5 Yrs)	☐	☑
Labor Issues	☐	☑
Large Scale Land Conversion, Acquisition, or Relocation	☐	☑
Litigation or Arbitration	☐	☑
On-Site Fatality	☐	☑
Penalties Assessed For Environmental Issues	☐	☑
Political Contributions or International Affairs	☐	☑
Recalls	☑	☐
Significant Layoffs	☐	☑
Violation of Indigenous Peoples Rights	☐	☑
Other	☐	☑

Practices

	Yes	No
Please indicate if the following statements are true regarding whether or not the company engages in the following practices. Check all that apply. If the statement is true, select "Yes." If false, select "No."		
Animal Testing	☑	☐
Company/Suppliers Employ Under Age 15 (Or Other ILO Minimum Age)	☐	☑
Company prohibits freedom of association/collective bargaining	☐	☑
Company workers are prisoners	☐	☑
Conduct Business in Conflict Zones	☐	☑
Confirmation of Right to Work	☐	☑
Does not transparently report corporate financials to government	☐	☑
Employs Individuals on Zero-Hour Contracts	☐	☑
Facilities located in sensitive ecosystems	☑	☐
ID Cards Withheld or Penalties for Resignation	☐	☑
No formal Registration Under Domestic Regulations	☐	☑
No signed employment contracts for all workers	☐	☑
Overtime For Hourly Workers Is Compulsory	☐	☑
Payslips not provided to show wage calculation and deductions	☐	☑
Sale of Data	☐	☑
Tax Reduction Through Corporate Shells	☐	☑
Workers cannot leave site during non-working hours	☐	☑
Workers not Provided Clean Drinking Water or Toilets	☐	☑
Workers paid below minimum wage	☐	☑
Workers Under Bond	☐	☑
Other	☐	☑

Supply Chain Disclosures

	Yes	No
Please indicate if any of the following statements are true regarding your company's significant suppliers.		
Business in Conflict Zones	☐	☑
Child or Forced Labor	☐	☑
Negative Environmental Impact	☐	☑
Negative Social Impact	☐	☑
Other	☐	☑

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Environmentally Intensive Industries

Issue Date	Ongoing
Topic	Water Intensive Industries
Summary of Issue	Sanofi CHC Mexico operates in the pharmaceutical industry which has been recognised as a water-intensive industry due to manufacturing and cleaning processes. The company's manufacturing facility is located in a water stress area- Ocoyoacac municipality, in the state of Mexico (Lerma-Chapala Basin). Issues related to water use and management are water stressed, water depletion, and water quality at the local water bodies. The company's main water source is deep wells located at the manufacturing facility which the company has permits to extract. Furthermore, the company also uses municipality water as a backup. The main risks identified by the company related to the facility's water management are: - Physical risk (water scarcity and water quality) - Regulatory risk (lack of regulations) - Reputational risk (biodiversity importance).
Size/Scope of Issue (e.g. $ financial implication, # of individuals affected)	In the previous fiscal year, 100% of Sanofi CHC Mexico's revenues was derived from the sale of over-the-counter medicines/drugs, food/dietary supplements, and cosmetics. In the last fiscal year, the company consumed 56,777 m3/year of water. Sanofi CHC Mexico has a water intensity of 0,51 liters of water per unit of product product.
Impact on Stakeholder(s)	The company has a plant in Ocoyoacac, a municipality in the State of Mexico. Considering the current situation of the Lerma-Chapala Basin, with the aforementioned risks identified, the company's operations contribute to the risk of water stress and depletion of the local basin if water management is not appropriate. The main stakeholders affected are other water users in the region, such as local water authorities & regulators, residents, other industrial plants & farmers, as well as the local

	biodiversity.
Implemented Management Practices	Sanofi CHC's sustainability strategy is based on water stewardship principles: increasing water efficiency, assessing risks in each local watershed, and defining a strategy aligned with local communities to manage properly the watershed the company relies on. Globally Sanofi CHC has the target of reducing water consumption by 20% by 2030, with 2019 levels as a benchmark. All Sanofi CHC's production sites will contribute to this global reduction, including the Ocoyocac manufacturing facility. At Ocoyoaca site, the company has the following practices in place: - Initial filtration system (after water is withdrawn from the well) - Wastewater treatment plant for chemical water and biological water. - Treated wastewater is discharged into the river or stored in a tank for the fire protection system. - The wastewater effluent is analyzed weekly and monthly for internal control, and quarterly for local regulatory compliance, all analyses are carried out by a laboratory accredited by the authorities In an effort to contribute to the global sustainability strategy, Sanofi Mexico is adopting the following measures: - Implementation of AWS Standard Indicators 1.3.2, 1.3.3 and 1.5.3 to gather additional data on site and watershed balance - Installation of additional flow meters to better quantify site water withdrawals, reuse, consumption and improvement areas - Development of a water efficiency roadmap - Development of analysis/scenario of flood events to determine site exposure to flood risk

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Environmentally Intensive Industries

Issue Date	Ongoing
Topic	Chemical Intensive Industries
Summary of Issue	Sanofi CHC Mexico operates in the pharmaceutical industry which has been recognized as a chemical-intensive industry. The company is not involved in the production, operation, trade, or sale of chemicals that meet the European Union's list of Substances of Very High Concern (SVHC) under REACH. At Ocoyoacac's manufacturing plant, the company uses SVHC lab chemicals for quality control purposes. While REACH regulation is only applicable in the EU, resulting in Sanofi CHC Mexico not being required to comply with the REACH requirements, no formula produced in the Ocoyoacac site contains ingredients listed as SVHC according to the REACH criteria.
Size/Scope of Issue **(e.g. $ financial implication, # of individuals affected)**	The use of chemicals for quality control purposes at the Ocoyoacac site is below 1 ton/year. Given the reported use is below 1 ton/year, the facility is exempted from restriction and authorization (processes linked to SVHCs) in Mexico.
Impact on Stakeholder(s)	The primary potential impacts of chemical use in pharmaceutical products are potential negative effects on the environment and potential negative health impacts on workers exposed to chemical ingredients. Risks to workers exposed to chemical ingredients are mitigated through appropriate controls such as engineering controls and respiratory protection. In the last five years, Sanofi CHC Mexico has not experienced any significant incidents and/or fines related to environmental or worker's health impacts for chemical use.
Implemented Management Practices	All of the chemicals used are handled, stored, disposed of, and transported following corporate standards, local legal requirements, Standard Operating Procedures, and local Permits. Furthermore, wastewater is managed by complying with all local legal requirements, Standard Operating Procedures and Permits, assuring all wastewater parameters are within the defined local regulation limits. At the global level, the company has implemented a program to identify substances of potential future concern in our formula

	and plan their substitution or removal whenever possible from a technical or regulatory standpoint. This program includes a list of materials or substances to be banned, avoided, or restricted in Sanofi CHC products. Moreover, Sanofi CHC Mexico has documented HSE requirements to minimize the use of Carcinogens, Mutagens, Reprotoxic and volatile organic compounds. All product formulas are approved by Mexican Health Authorities, go through quality control and quality assurance, and are subject to monitoring in terms of quality, safety & efficacy. Given the restricted regulation of the sector, the level of ingredients in the finished products remains adequate for the safe and intended use of consumers. At the local level, the company does not conduct an assessment and comparison with other companies regarding chemical use.

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Facilities located in sensitive ecosystems

Issue Date	Ongoing
Topic	The company has a manufacturing facility in Ocoyoacac, which is considered a sensitive ecosystem.
Summary of Issue	As a subsidiary of Sanofi Consumer Healthcare, this company manufactures pharmaceutical products in a facility located near the following sensitive ecosystems in Ocoyoacac, a municipality in Mexico: - Ciénegas del Lerma / 5 km from site. - Parque Estatal Santuario del Agua Subcuenca Tributaria Río San Lorenzo / 8 km from site. - Parque Nacional Insurgente Miguel Hidalgo y Costilla "La Marquesa" / 15 km from site.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	In terms of area, 100% of the company's facilities are located near sensitive ecosystems. Other than that, 82% of the company's manufacturing, in terms of value, also happens in this area.
Impact on Stakeholders	Having facilities/operations near protected/sensitive ecosystems can potentially impact the flora, fauna and quality of the ecosystem (e.g. noise & light pollution from the facilities, spills, air / soil / water pollution owing to company's operations). Also, there is a risk of negatively impacting the local communities.
Resolution	Sanofi Consumer Healthcare Mexico implements the following practices to address the risk associated with operations close to sensitive ecosystems: The company conducts a biodiversity assessment that considers the following criteria: (1) Proximity with natural/semi-natural areas, (2) Proximity with regulated/classified sensible areas, (3) Proximity with wetlands, (4) Potential interaction with an ecological corridor, (5) Potential presence of protected species / sensible habitats, (6) Anthropic pressure. The last assessment was developed in 2022 and the company intends to update it every 3 years. Globally, Sanofi Consumer Healthcare has a global

	commitment to "protect biodiversity at our sites, particularly those located near sensitive natural areas. By 2025, our priority sites with the highest potential impacts on local biodiversity will implement specific biodiversity management plans. This approach will be extended to all our sites located near biodiversity-sensitive areas by 2030." The organization has a Biodiversity Management standard which describes the management of biodiversity by each site. As aligned with Sanofi's public commitments to Nature, the subsidiary's objective is to reduce the impacts on biodiversity of its direct operations – in particular at sites exposed to high risks for biodiversity. This standard sets out the following minimum requirements: - Design: biodiversity risks need to be considered for the design of new facilities/buildings or in case of revamping existing ones, - Operational: biodiversity risks need to be considered in its daily operations to reduce the local pressure of its activities on biodiversity and implement the best practices promoting biodiversity. - The company reported there were no stakeholders' concerns raised in relation to this site.
Implemented Management Practices	Sanofi Consumer Healthcare Mexico implements the following practices to address the risk associated with operations close to sensitive ecosystems: The company conducts a biodiversity assessment that considers the following criteria: (1) Proximity with natural/semi-natural areas, (2) Proximity with regulated/classified sensible areas, (3) Proximity with wetlands, (4) Potential interaction with an ecological corridor, (5) Potential presence of protected species / sensible habitats, (6) Anthropic pressure. The last assessment was developed in 2022 and the company intends to update it every 3 years. Globally, Sanofi Consumer Healthcare has a global commitment to "protect biodiversity at our sites, particularly those located near sensitive natural areas. By 2025, our priority sites with the highest potential impacts on local biodiversity will implement specific biodiversity management plans. This approach will be extended to all our sites located near biodiversity-sensitive areas by 2030."

	The organization has a Biodiversity Management standard which describes the management of biodiversity by each site. As aligned with Sanofi's public commitments to Nature, the subsidiary's objective is to reduce the impacts on biodiversity of its direct operations – in particular at sites exposed to high risks for biodiversity. This standard sets out the following minimum requirements: - Design: biodiversity risks need to be considered for the design of new facilities/buildings or in case of revamping existing ones, - Operational: biodiversity risks need to be considered in its daily operations to reduce the local pressure of its activities on biodiversity and implement the best practices promoting biodiversity. - The company reported there were no stakeholders' concerns raised in relation to this site.
Report	Environmental Sustainability and Resilience commitments

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Animal Testing

Issue Date	Ongoing
Topic	Required animal testing by regulatory authorities
Summary of Issue	Sanofi Consumer Healthcare Mexico is legally required to perform animal testing on two products of its portfolio. Four batches are required to be tested per year. This is due to safety concerns and is required by the Health Authority In very rare circumstances, the company may need to perform animal testing to ensure the efficacy of a specific product. However, this has not been done in the past 5 years. No product development occurs in Sanofi CHC Mexico.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	Two products are required to be tested in animals, representing 4.7% of Sanofi CHC Mexico's portfolio. These products were divested in 2023 so are no longer part of CHC.
Impact on Stakeholders	Sanofi CHC Mexico does not develop new drug molecules. The company used to perform animal testing in rare situations when it was required by Regulatory Authorities due to safety concerns. From mid-2023 no products from Sanofi CHC need to be tested on animals, as the products have been divested. Animal testing and experimentation are widely used to develop and test the safety of new drug molecules. Many of these experiments can cause pain to the animals involved or reduce their quality of life in other ways.
Implemented Management Practices	Sanofi CHC Mexico follows the principles laid out in the publicly available information on Sanofi's global position on animal testing "Responsible use of animals in research and production". This policy includes, but is not limited to, the following practices: - Any use of animals is overseen by ethics committees that monitor the care and use of animals, as well as the active implementation of the "3Rs" (replacement, reduction and refinement of animals in research and production), to which Sanofi has been committed for decades. Our approach is to use animals only in the absence of adequate alternative methods to achieve an identical result (Replace), to use the smallest number necessary for quality science (Reduce), and to use state-of-the-art practices to protect animal welfare and prevent animal pain and distress in living and procedural conditions (Refine),

	- Sanofi has signed the French Transparency Charter on the use of animals for scientific and regulatory purposes. This engagement has followed the signature of the Belgian agreement. Sanofi is globally committed to making information on the use of animals for scientific or regulatory purposes accessible to the general public. All animal testing conducted in Sanofi CHC Mexico is outsourced. The outsourced services are certified by Health Authorities in Mexico to be in compliance with Mexican regulations. In addition to the legal obligations, external partners (contract research organizations, breeders and suppliers, and any other partners) are expected to comply with animal welfare laws and commit to the spirit of the Sanofi Policy on the Protection of Animals. External stakeholders can raise concerns and questions directly to the Chief Veterinary Officer through this contact form.
Report	1. Sanofi Animal Protection Factsheet 2. Marsaille Declaration

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Recalls

Issue Date	2020 & 2022
Topic	Mandatory and voluntary recalls
Summary of Issue	Sanofi CHC SOCOPAC had two voluntary recalls and one mandatory recall over the last 5 years. - Selsun 2,5% shampoo Sanofi CHC Peru has decided to prune the product, resulting in a mandatory recall per local regulation. - Buscapina Compositum N tablets. As a precautionary measure, Sanofi CHC Panama conducted a voluntary recall in Panama due to a wrong leaflet in the product - Hyoscine butylbromide+Metamizol instead of Hyoscine butylbromide+Paracetamol. - Buscapina Fem 20mg/400mg tablets. Out Of Specification (OOS) results for microbial testing was found for an already released batch on the market. As a precautionary measure, Sanofi CHC Colombia conducted a voluntary recall in Colombia.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	Selsun 2,5% shampoo Sanofi CHC Peru. The recall included 42 batches of the product. Buscapina Compositum N tablets. The recall included 3 batches of the product. Buscapina Fem 20mg/400mg tablets. The recall included 1 batche of the product
Impact on Stakeholders	None of the recalls resulted in consumer illness or injury. - Selsurin 2,5% shampoo The assessment resulted in no risk to patient/subject/consumer. - Buscapina Compositum N tablets. The Health Hazard Evaluation (HHE) concluded that the main theoretical safety risk would be the use in non-appropriate population due to missing information for paracetamol. - Buscapina Fem 20mg/400mg tablets. The Health Hazard Evaluation (HHE) concluded that the cumulative weighted evidence is insufficient to confirm the risk(s) due to Out of Specificication (OOS) of microbial contamination of affected batch of Buscapina fem tablet.
Implemented	There are no similarities between the recall events. Recalls are

Management Practices	managed by a global procedure which is in line with international and local regulatory requirements. Each recall is managed by the Quality department and includes root cause analysis and corrective and preventative action, as appropriate. The company has a global procedure called; “Escalation of Quality Events and Management of Quality Alerts” to address recall issues. It details the internal management of recalls and requires that all quality events and alerts are reported in a timely, structured, and concise way so that the risk assessment and associated mitigation plan is shared at the appropriate management level and subsequently managed with the adequate level of priority.
Related Incidents (Yes/No)	No.

Sanofi CHC Italy

Disclosure Report

Date Submitted: November, 2023

Disclosure Questionnaire

Industries and Products

	Yes	No
Please indicate if the company is involved in production of or trade in any of the following. Select Yes for all options that apply.		
Animal Products or Services	☐	☑
Biodiversity Impacts	☐	☑
Chemicals	☑	☐
Disclosure Alcohol	☐	☑
Disclosure Firearms Weapons	☐	☑
Disclosure Mining	☐	☑
Disclosure Pornography	☐	☑
Disclosure Tobacco	☐	☑
Energy and Emissions Intensive Industries	☐	☑
Gambling	☐	☑
Genetically Modified Organisms	☐	☑
Illegal Products or Subject to Phase Out	☐	☑
Industries at Risk of Human Rights Violations	☐	☑
Monoculture Agriculture	☐	☑
Nuclear Power or Hazardous Materials	☐	☑
Payday, Short Term, or High Interest Lending	☐	☑
Water Intensive Industries	☑	☐
Tax Advisory Services	☐	☑

Outcomes & Penalties

	Yes	No
Please indicate if the company has had any formal complaint to a regulatory agency or been assessed any fine or sanction in the past five years for any of the following practices or policies. Check all that apply.		
Anti-Competitive Behavior	☐	☑
Breaches of Confidential Information	☐	☑
Bribery, Fraud, or Corruption	☐	☑
Company has filed for bankruptcy	☐	☑
Consumer Protection	☐	☑
Financial Reporting, Taxes, Investments, or Loans	☐	☑
Hazardous Discharges Into Air/Land/Water (Past 5 Yrs)	☐	☑
Labor Issues	☐	☑
Large Scale Land Conversion, Acquisition, or Relocation	☐	☑
Litigation or Arbitration	☑	☐
On-Site Fatality	☐	☑
Penalties Assessed For Environmental Issues	☐	☑
Political Contributions or International Affairs	☐	☑
Recalls	☑	☐
Significant Layoffs	☐	☑
Violation of Indigenous Peoples Rights	☐	☑
Other	☐	☑

Practices

	Yes	No
Please indicate if the following statements are true regarding whether or not the company engages in the following practices. Check all that apply. If the statement is true, select "Yes." If false, select "No."		
Animal Testing	☑	☐
Company/Suppliers Employ Under Age 15 (Or Other ILO Minimum Age)	☐	☑
Company prohibits freedom of association/collective bargaining	☐	☑
Company workers are prisoners	☐	☑
Conduct Business in Conflict Zones	☐	☑
Confirmation of Right to Work	☐	☑
Does not transparently report corporate financials to government	☐	☑
Employs Individuals on Zero-Hour Contracts	☐	☑
Facilities located in sensitive ecosystems	☑	☐
ID Cards Withheld or Penalties for Resignation	☐	☑
No formal Registration Under Domestic Regulations	☐	☑
No signed employment contracts for all workers	☐	☑
Overtime For Hourly Workers Is Compulsory	☐	☑
Payslips not provided to show wage calculation and deductions	☐	☑
Sale of Data	☐	☑
Tax Reduction Through Corporate Shells	☐	☑
Workers cannot leave site during non-working hours	☐	☑
Workers not Provided Clean Drinking Water or Toilets	☐	☑
Workers paid below minimum wage	☐	☑
Workers Under Bond	☐	☑
Other	☐	☑

Supply Chain Disclosures

	Yes	No
Please indicate if any of the following statements are true regarding your company's significant suppliers.		
Business in Conflict Zones	☐	☑
Child or Forced Labor	☐	☑
Negative Environmental Impact	☐	☑
Negative Social Impact	☐	☑
Other	☐	☑

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Environmentally Intensive Industries

Issue Date	Ongoing
Topic	Water Intensive Industries
Summary of Issue	Sanofi CHC Italy operates in the pharmaceutical industry which is recognised as a water-intensive industry due to manufacturing and cleaning processes. The company's manufacturing facility is located at Origgio, in Lombardy region, Northern Italy. Although the region is not a water stress area, the company is working on a water use reduction plan. The company's plant (biotechnological) uses municipal water for production and underground water for the plant utilities and serves as a global hub for the production of key brands under Sanofi CHC's portfolio.
Size/Scope of Issue (e.g. $ financial implication, # of individuals affected)	In the previous fiscal year, 100% of Sanofi CHC Italy was derived from the production of self-medication medicines/drugs, food/dietary supplements, and cosmetics. Sanofi CHC Italy has a water intensity of 0.77 liter per unit of product produced for its standard manufacturing processes.
Impact on Stakeholder(s)	As a water intensive industry, the manufacturing of pharmaceutical products poses risks such as water stress or depletion of local water sources if water used is not appropriately managed. The company uses municipal water supply for pharma production and underground water supply for the plant's utilities. The main stakeholders affected are other water users in the region, such as local water authorities & regulators, residents, other industrial plants, farmers, and the local biodiversity.
Implemented Management Practices	The company does not carry out an assessment of how it compares to other peers in the industry regarding water use and management. Globally, Sanofi CHC has the target of reducing water consumption by 20% by 2030, with 2019 levels as a benchmark. Sanofi CHC's sustainability strategy is based on water stewardship principles: increasing water efficiency, assessing

	risks in each local watershed and defining a strategy aligned with local communities to properly manage the watershed the company relies on.

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Environmentally Intensive Industries

Issue Date	Ongoing
Topic	Chemical Intensive Industries
Summary of Issue	Sanofi CHC Italy operates in the pharmaceutical industry which it is recognized as a chemical intensive industry. The company is not involved in the production, operation, trade or sale of chemicals that meet the European Union's list of Substances of Very High Concern (SVHC). At Origgio manufacturing plant, the company does use SVHC lab chemicals for quality control purposes. All product formulas are approved by the Italian Health Authorities, go through quality control and quality assurance, and are subject to monitoring in terms of quality, safety & efficacy. The level of the ingredients in the finished products remain adequate for the safe and intended use of consumers.
Size/Scope of Issue **(e.g. $ financial implication, # of individuals affected)**	The use of chemicals for quality control purposes at the Origgio site is approximately 1 ton/year. Given the reported use is below 1 ton/year, the facility is exempted from restriction and authorization (processes linked to SVHCs) in the EU.
Impact on Stakeholder(s)	The primary potential impacts of chemical use in pharmaceutical products are potential negative effects on the environment and potential negative health impacts on workers exposed to chemical ingredients. Risks to workers exposed to chemical ingredients are mitigated through appropriate controls such as engineering controls and respiratory protection. In the last five years, Sanofi CHC Italy has not experienced any significant incidents and/or fines related to environmental or worker impacts of its chemical use.
Implemented Management Practices	All chemicals used are handled, stored, disposed of, and transported following corporate standards, local legal requirements, Standard Operating Procedures, and local Permits. Furthermore, wastewater is managed by complying with all local legal requirements, Standard Operating Procedures and Permits, assuring all wastewater parameters are within the defined local regulation limits. At the global level, the company has implemented a program to

	identify substances of potential future concern in our formula and plan their substitution or removal whenever possible from a technical or regulatory standpoint. This program includes a list of materials or substances to be banned, avoided, or restricted in Sanofi CHC products. Moreover, Sanofi CHC Italy has documented HSE requirements to minimize the use of Carcinogens, Mutagens, Reprotoxic and volatile organic compounds. All product formulas are approved by Italian Health Authorities, go through quality control and quality assurance, and are subject to monitoring in terms of quality, safety & efficacy. Given the restricted regulation of the sector, the level of ingredients in the finished products remains adequate for the safe and intended use of consumers. At the local level, the company does not conduct an assessment and comparison with other companies regarding chemical use.

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Recalls

Issue Date	2018, 2019, 2022
Topic	Mandatory and voluntary recalls
Summary of Issue	In the last five years, Sanofi CHC Italy experienced one (1) mandatory recall and six (6) voluntary recalls for several reasons as detailed below. - Recall 1 (Zerinol 300 mg + 2mg) Mandatory recall. Reduction of the shelf-life of the finished product from "60 months" to "36 months". In June 2022, the company initiated a Mandatory recall for batches that have reached the expiry date of 36 months. This product is no longer part of Sanofi Consumer Healthcare Italy's portfolio. - Recall 2 Voluntary recall. Impurity found in one of the medicine's excipients. - Recall 3, Recall 4 & Recall 5 Voluntary recalls. Presence of foreign bodies inside the products. - Recall 6 Voluntary recall. Possible contamination of the product with impurity. - Recall 7 Voluntary recall. Presence of a substance banned from cosmetic products following a new cosmetics regulation. This product is no longer part of Sanofi Consumer Healthcare Italy's portfolio. Such recalls were all duly managed as per the global procedure in force, which is in line with international and local regulatory requirements. Each recall was properly managed by the Quality Department that focused on root cause analysis and corrective and preventative action, as appropriate.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	Recall 1 represented around 6.5% of the company overall production. Recall 2 represented around 0.1% of the company overall production. Recall 3 represented around 0.04% of the company overall production. Recall 4 represented around 0.1% of the company overall

	production. Recall 5 represented around 0.1% of the company overall production. Recall 6 represented around 1.7% of the company overall production. Recall 7 represented around 0.1% of the company overall production.
Impact on Stakeholders	None of the recalls resulted in consumer illness or injury. - Mandatory Recall 1 (Zerinol 300 mg + 2mg) No risks for consumers were identified. The recall was not related to product quality and no further stability out of specification (OOS) has been registered on this product since 2018. - Voluntary Recall 2 It may have caused temporary adverse health consequences. - Voluntary Recall 3 It may have posed a constraint for users but it is not likely to cause adverse health consequences. - Voluntary Recall 4 & Recall 5 It may have caused a mistreatment or a temporary health problem. - Voluntary Recall 6 It may have caused risk to health. - Voluntary Recall 7 It may have posed a constraint for users but it is not likely to cause adverse health consequences.
Implemented Management Practices	Recalls are managed by a global procedure which is in line with international and local regulatory requirements. Each recall is managed by the Quality department and includes root cause analysis and corrective and preventative action, as appropriate. The company has a global procedure called; “Escalation of Quality Events and Management of Quality Alerts” to address recall issues. It details the internal management of recalls and requires that all quality events and alerts are reported in a timely, structured, and concise way so that the risk assessment and associated mitigation plan is shared at the appropriate management level and subsequently managed with the adequate level of priority.

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Facilities located in sensitive ecosystems

Topic	The company has a manufacturing facility at Origgio, in Lombardy region, Northern Italy.
Summary of Issue	The company's biotechnological plant is located adjacent to the following sensitive ecosystems in Origgio. ZSC IT2050001 Pineta di Cesate (part of Natura 2000) ZSC IT2050002 Boschi delle Groane (part of Natura 200) ZSC IT2050006 Bosco di Vanzago (managed by WWF)
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	Sanofi CHC Italy has only one manufacturing facility at Origgio. Therefore, 100% of the company's area and production are located adjacent to sensitive ecosystems.
Impact on Stakeholders	Having facilities & operations near protected/sensitive ecosystems can potentially impact the quality of the ecosystem (flora, fauna and the natural dynamics of these natural systems) Potential impacts derived from the company 's operations are noise & light pollution, potential spills, air / soil / water pollution.
Implemented Management Practices	A biodiversity assessment was conducted by a 3rd party expert (Ramboll) in 2022 based on the methodology “BIODIVERSITY INDICATORS FOR SITE-BASED IMPACTS” developed by UNEP-WCMC, Conservation International and Fauna & Flora International. In sum, the Biodiversity Risk Mapping Report shows that Origgio has: - A Moderate (22%) exposure rating - A high (55%) Vulnerability risks - A High Biodiversity risks The company's standard operation has low risk of impacting the adjacent protected/sensitive ecosystems

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Other - Mandatory Animal Testing

Issue Date	Ongoing
Topic	Sanofi CHC Italy is a subsidiary of Sanofi CHC and sells consumer healthcare products. Sanofi CHC Italy manufactures and sells but does not develop new drugs (e.g. new drug molecules), therefore Sanofi CHC Italy does not require the use of animal testing.
Summary of Issue	As a company that manufactures pharmaceutical products, Sanofi CHC is legally obligated to ensure the quality, safety, and efficacy of its medicines and other consumer healthcare products, for which animal testing is required in research and production. As a subsidiary of Sanofi CHC, Sanofi CHC Italy can market over the counter (OTC) products because they have already been proven to be safe and effective. Sanofi CHC does not engage in the regular practice of animal testing: It is only conducted when specifically required by regulatory authorities and no alternative methods can be applied.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	Sanofi CHC Italy has not conducted any animal testing on the products in the Opella Healthcare Italy portfolio over the past 5 years. However, the company currently sells medicines that had to go through animal testing previously.
Impact on Stakeholders	Sanofi CHC Italy does not develop new drug molecules and as stated above would only perform animal testing in rare situations when required by Regulatory Authorities due to safety concerns. Animal testing and experimentation is widely used to develop and test the safety of new drug molecules. When the execution of this study is mandatory for regulatory or safety reasons the company implements practices to promote animal welfare and prevent animal pain and distress in housing and procedure conditions.
Implemented Management Practices	Opella Healthcare Italy does not carry out animal testing at a local level. Sanofi at a group level has a policy for the protection of animals that includes a 3R principle towards animal testing; seeking to exceed regulation and standards. The company tests products on animals only: - when a non-animal method is unsuited for the required use or

	not accepted by the authorities (replacement) - with the smallest number of animals necessary for quality science (reduction) - with the implementation of state-of-the-art practices to promote animal welfare and prevent animal pain and distress in housing and procedure conditions (refinement). Sanofi has animal ethics committees with principles to ensure impartiality and independence of the ethical review. Sanofi CHC rarely authorizes animal testing and only when the regulatory and scientific merit is established and under strict ethical over-sight. If animal testing is authorized, Sanofi monitors compliance by third parties (breeders, contract research organizations, not-for-profit collaborations). External partners are expected to comply with animal welfare laws and commit to the spirit of the Sanofi policy on the protection of animals. Sanofi professionals will evaluate animal care and use program of external partners on a regular basis and approve those that comply with Sanofi standards. In addition to the legal obligations, Sanofi has set internal standards to align requirements across the world and to ensure high welfare considerations. All Sanofi sites maintain or seek independent accreditation of their animal care and use programs through recognized expert organizations such as AAALAC International. Sanofi applies the same principles to subcontractors and breeders; their animal welfare program is assessed by Sanofi professionals to ensure the consistency of the animal care. Further information can be found in the Sanofi Animal Protection Factsheet and Animal Protection Policy (links below). Sanofi is also a signatory of the pharmaceutical industry declaration on animal housing and use, Marseille Declaration (see link below) External stakeholders can raise concerns in relation to animal testing directly to the Chief Veterinary Officer through Sanofi.com.
Report	Sanofi Animal Protection Factsheet Sanofi Policy on Animal Protection Signed Marseille Declaration

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Litigation , Arbitration and Penalties

Issue Date	2020-2023
Topic	Penalties related to the late notification of shortage of medicinal product to the Health Authority.
Summary of Issue	In the last five years, Sanofi CHC Italy had 19 penalties related to late notification of a shortage of medicinal products to the Health Authority. The shortage of medicinal products was communicated beyond the terms outlined in Art. 34, paragraph 6, of Legislative Decree no. 219/2006, as amended by Decree n. 35/2019 which resulted in penalties by the Italian Medicine Agency (AIFA). This issue is common across the pharmaceutical industry.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	The total penalties represent less than 1% of the company's revenues.
Impact on Stakeholders	This is a regulatory requirement. Therefore, the main stakeholders affected are the Health Regulatory Agency (AIFA) and final consumers.
Resolution	All penalties were paid by the company.
Implemented Management Practices	Sanofi CHC Italy is trying to improve internal ways of working to increase compliance with local regulatory requirements on shortages notifications.
Related Incidents	No related incidents

Sanofi CHC Germany

Disclosure Report

Date Submitted: October, 2023

Disclosure Questionnaire

Industries and Products

	Yes	No
Please indicate if the company is involved in production of or trade in any of the following. Select Yes for all options that apply.		
Animal Products or Services	☐	☑
Biodiversity Impacts	☐	☑
Chemicals	☑	☐
Disclosure Alcohol	☐	☑
Disclosure Firearms Weapons	☐	☑
Disclosure Mining	☐	☑
Disclosure Pornography	☐	☑
Disclosure Tobacco	☐	☑
Energy and Emissions Intensive Industries	☐	☑
Gambling	☐	☑
Genetically Modified Organisms	☐	☑
Illegal Products or Subject to Phase Out	☐	☑
Industries at Risk of Human Rights Violations	☐	☑
Monoculture Agriculture	☐	☑
Nuclear Power or Hazardous Materials	☐	☑
Payday, Short Term, or High Interest Lending	☐	☑
Water Intensive Industries	☑	☐
Tax Advisory Services	☐	☑

Outcomes & Penalties

	Yes	No
Please indicate if the company has had any formal complaint to a regulatory agency or been assessed any fine or sanction in the past five years for any of the following practices or policies. Check all that apply.		
Anti-Competitive Behavior	☐	☑
Breaches of Confidential Information	☐	☑
Bribery, Fraud, or Corruption	☐	☑
Company has filed for bankruptcy	☐	☑
Consumer Protection	☐	☑
Financial Reporting, Taxes, Investments, or Loans	☐	☑
Hazardous Discharges Into Air/Land/Water (Past 5 Yrs)	☐	☑
Labor Issues	☐	☑
Large Scale Land Conversion, Acquisition, or Relocation	☐	☑
Litigation or Arbitration	☐	☑
On-Site Fatality	☐	☑
Penalties Assessed For Environmental Issues	☐	☑
Political Contributions or International Affairs	☐	☑
Recalls	☐	☑
Significant Layoffs	☐	☑
Violation of Indigenous Peoples Rights	☐	☑
Other	☐	☑

Practices

	Yes	No
Please indicate if the following statements are true regarding whether or not the company engages in the following practices. Check all that apply. If the statement is true, select "Yes." If false, select "No."		
Animal Testing	☑	☐
Company/Suppliers Employ Under Age 15 (Or Other ILO Minimum Age)	☐	☑
Company prohibits freedom of association/collective bargaining	☐	☑
Company workers are prisoners	☐	☑
Conduct Business in Conflict Zones	☐	☑
Confirmation of Right to Work	☐	☑
Does not transparently report corporate financials to government	☐	☑
Employs Individuals on Zero-Hour Contracts	☐	☑
Facilities located in sensitive ecosystems	☐	☑
ID Cards Withheld or Penalties for Resignation	☐	☑
No formal Registration Under Domestic Regulations	☐	☑
No signed employment contracts for all workers	☐	☑
Overtime For Hourly Workers Is Compulsory	☐	☑
Payslips not provided to show wage calculation and deductions	☐	☑
Sale of Data	☐	☑
Tax Reduction Through Corporate Shells	☐	☑
Workers cannot leave site during non-working hours	☐	☑
Workers not Provided Clean Drinking Water or Toilets	☐	☑
Workers paid below minimum wage	☐	☑
Workers Under Bond	☐	☑
Other	☐	☑

Supply Chain Disclosures

	Yes	No
Please indicate if any of the following statements are true regarding your company's significant suppliers.		
Business in Conflict Zones	☐	☑
Child or Forced Labor	☐	☑
Negative Environmental Impact	☐	☑
Negative Social Impact	☐	☑
Other	☐	☑

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Other - Mandatory Animal Testing

Issue Date	Ongoing
Topic	Sanofi CHC Germany is a subsidiary of Sanofi CHC that manufactures and sells consumer healthcare products. Sanofi CHC Germany does not perform research and development activities (e.g. new drug molecules) that require the use of animal testing. Due to the nature of the portfolio of established products, animal testing is only performed in rare situations when required by Regulatory Authorities due to safety concerns and no alternative methods can be applied.
Summary of Issue	As a company that manufactures, and sells pharmaceutical products, the company is legally obligated to ensure the quality, safety, and efficacy of its medicines and other consumer healthcare products. As a subsidiary of Sanofi CHC, Sanofi CHC Germany sells consumer healthcare products which have already been proven to be safe and effective and therefore do not require the generation of new animal safety data for their registration procedure. In sum, Sanofi CHC Germany would only perform animal studies in rare situations when required by Regulatory Authorities to evaluate and assess major safety concerns and if no alternatives are available including if literature/data was unavailable for the study endpoints needed, and if performing human testing was unethical.
Size/Scope of Issue **(e.g. $ financial implication, # of individuals affected)**	Sanofi CHC Germany has not conducted any animal testing on the products in the Sanofi CHC Germany portfolio over the past 5 years. However, the company sells healthcare products that rely on animal data generated previously to demonstrate the efficacy and safety of the treatment and/or to satisfy Regulatory Authorities requests.
Impact on Stakeholder(s)	Animal testing is a regulatory requirement to develop and test the safety of new drug molecules. Many of these experiments can cause pain to the animals involved or reduce their quality of life in other ways. Therefore, the extent of animal safety testing is reduced to a minimum during the development of new molecules. Aforementioned, Sanofi CHC Germany does not

	develop new drug molecules and would only perform animal testing in rare situations when required by Regulatory Authorities e.g. due to safety.
Implemented Management Practices	Sanofi CHC Germany does not carry out animal testing at a local level. Sanofi at a group level has a policy for the protection of animals that includes a 3R principle towards animal testing; seeking to exceed regulation and standards. The company tests products on animals only: - when a non-animal method is unsuited for the required use or not accepted by the authorities (replacement) - with the smallest number of animals necessary for quality science (reduction) - with the implementation of state-of-the-art practices to promote animal welfare and prevent animal pain and distress in housing and procedure conditions (refinement). Sanofi has animal ethics committees with principles to ensure impartiality and independence of the ethical review. Sanofi CHC rarely authorizes animal testing and only when the regulatory repectively scientific merit is established and under strict ethical over-sight. If animal testing is authorized, Sanofi CHC monitors compliance by third parties (breeders, contract research organizations, not-for-profit collaborations). External partners are expected to comply with animal welfare laws and commit to the spirit of the Sanofi policy on the protection of animals. Sanofi professionals will evaluate animal care and use program of external partners on a regular basis and approve those that comply with Sanofi standards. In addition to the legal obligations, Sanofi has set internal standards to align requirements across the world and to ensure high welfare considerations. All Sanofi sites maintain or seek independent accreditation of their animal care and use programs through recognized expert organizations such as AAALAC International. Sanofi applies the same principles to subcontractors and breeders; their animal welfare program is assessed by Sanofi professionals to ensure the consistency of the animal care. Further information can be found in the Sanofi Animal Protection Factsheet and Animal Protection Policy (links

	below). Sanofi is also a signatory of the pharmaceutical industry declaration on animal housing and use, Marseille Declaration (see link below) External stakeholders can raise concerns in relation to animal testing directly to the Chief Veterinary Officer through Sanofi.com.
Report	Sanofi Animal Protection Factsheet Sanofi Policy on Animal Protection Signed Marseille Declaration

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Environmentally Intensive Industries

Issue Date	Ongoing
Topic	Chemical Intensive Industries
Summary of Issue	Sanofi CHC Germany operates in the pharmaceutical industry which has been recognized as a chemical-intensive industry. The company is not involved in the production, operation, trade, or sale of chemicals that meet the European Union's list of Substances of Very High Concern (SVHC) under REACH. At Cologne site, the company uses SVHC lab chemicals for quality control purposes. While the company does not use SVHC, in the laboratory, the company tries to reduce the amount/potency of chemicals by always looking for alternative methods first. This is in line with German best practices in safety management, called STOP: S - Substitution T - Technical protective measures O - Organizational protective measures P - Personal protective measures
Size/Scope of Issue **(e.g. $ financial implication, # of individuals affected)**	The use of chemicals for quality control purposes at the Cologne site is approximately 1 ton/year and does not include any SVHC.
Impact on Stakeholder(s)	The primary potential impacts of chemical use in pharmaceutical products are potential negative effects on the environment and potential negative health impacts on workers exposed to chemical ingredients. Risks to workers exposed to chemical ingredients are mitigated through appropriate controls such as engineering controls and respiratory protection. In the last five years, Sanofi CHC Germany has not experienced any incidents and/or fines related to environmental or worker health impacts for chemical use.
Implemented Management Practices	All chemicals used are handled, stored, disposed of, and transported following corporate standards, local legal requirements, Standard Operating Procedures, and local Permits. Furthermore, wastewater is managed by complying with all local legal requirements, Standard Operating Procedures and Permits, assuring all wastewater parameters are within the defined local regulation limits. The company regularly tests the wastewater and shares result

	reports with authorities periodically, in line with German regulation and permits. At the global level, the company has implemented a program to identify substances of potential future concern in the company's formula and plan their substitution or removal whenever possible from a technical or regulatory standpoint. The program includes a list of materials or substances to be banned, avoided, or restricted in Sanofi CHC products. Moreover, Sanofi CHC Germany has documented HSE requirements to minimize the use of Carcinogens, Mutagens, Reprotoxic and volatile organic compounds. All product formulas are approved under the relevant health authorities' requirements, go through quality control and quality assurance, and are subject to monitoring in terms of quality, safety & efficacy. Given the restricted regulation of the sector, the level of ingredients in the finished products remains adequate for the safe and intended use of consumers. At the local level, the company does not conduct an assessment and comparison with other companies regarding chemical use.

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Environmentally Intensive Industries

Issue Date	Ongoing
Topic	Water Intensive Industries
Summary of Issue	Sanofi CHC Germany operates in the pharmaceutical industry which is recognised as a water-intensive industry due to manufacturing and cleaning processes. The company's manufacturing site is in Cologne, Germany. Although the region is not a water stressed area, the company is working on a water use reduction plan. The company's manufacturing plant sources 100% of its water from the municipal water network.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	In the previous fiscal year, 100% of Sanofi CHC Germany was derived from the production of self-medication medicines/drugs, food/dietary supplements, and cosmetics Sanofi CHC Germany has a water intensity of 0.80 liter per unit of product produced for its standard manufacturing processes.
Impact on Stakeholders	As a water intensive industry, the manufacturing of pharmaceutical products poses risks such as water stress or depletion of local water sources if water use is not appropriately managed. The company sources 100% of its water from the municipal water network. The main stakeholders affected are other water users in the region, such as local water authorities & regulators, residents, other industrial plants, farmers, and the local biodiversity.
Implemented Management Practices	The company does not carry out an assessment of how it compares to other peers in the industry regarding water use and management. Globally, Sanofi CHC has the target of reducing water consumption by 20% by 2030, with 2019 levels as a benchmark. Sanofi CHC's sustainability strategy is based on water stewardship principles: increasing water efficiency, assessing risks in each local watershed and defining a strategy aligned with local communities to properly manage the watershed the company relies on.

Sanofi CHC NA

Disclosure Report

Date Submitted: July, 2023

Disclosure Questionnaire

Industries and Products

	Yes	No
Please indicate if the company is involved in production of or trade in any of the following. Select Yes for all options that apply.		
Animal Products or Services	☐	☑
Biodiversity Impacts	☐	☑
Chemicals	☑	☐
Disclosure Alcohol	☐	☑
Disclosure Firearms Weapons	☐	☑
Disclosure Mining	☐	☑
Disclosure Pornography	☐	☑
Disclosure Tobacco	☐	☑
Energy and Emissions Intensive Industries	☐	☑
Gambling	☐	☑
Genetically Modified Organisms	☐	☑
Illegal Products or Subject to Phase Out	☐	☑
Industries at Risk of Human Rights Violations	☐	☑
Monoculture Agriculture	☐	☑
Nuclear Power or Hazardous Materials	☐	☑
Payday, Short Term, or High Interest Lending	☐	☑
Water Intensive Industries	☑	☐
Tax Advisory Services	☐	☑

Outcomes & Penalties

	Yes	No
Please indicate if the company has had any formal complaint to a regulatory agency or been assessed any fine or sanction in the past five years for any of the following practices or policies. Check all that apply.		
Anti-Competitive Behavior	☐	☑
Breaches of Confidential Information	☐	☑
Bribery, Fraud, or Corruption	☐	☑
Company has filed for bankruptcy	☐	☑
Consumer Protection	☐	☑
Financial Reporting, Taxes, Investments, or Loans	☐	☑
Hazardous Discharges Into Air/Land/Water (Past 5 Yrs)	☐	☑
Labor Issues	☐	☑
Large Scale Land Conversion, Acquisition, or Relocation	☐	☑
Litigation or Arbitration Case A Case B	☑	☐
On-Site Fatality	☐	☑
Penalties Assessed For Environmental Issues	☐	☑
Political Contributions or International Affairs	☐	☑
Recalls	☑	☐
Significant Layoffs	☐	☑
Violation of Indigenous Peoples Rights	☐	☑
Other	☐	☑

Practices

	Yes	No
Please indicate if the following statements are true regarding whether or not the company engages in the following practices. Check all that apply. If the statement is true, select "Yes." If false, select "No."		
Animal Testing	☑	☐
Company/Suppliers Employ Under Age 15 (Or Other ILO Minimum Age)	☐	☑
Company prohibits freedom of association/collective bargaining	☐	☑
Company workers are prisoners	☐	☑
Conduct Business in Conflict Zones	☐	☑
Confirmation of Right to Work	☐	☑
Does not transparently report corporate financials to government	☐	☑
Employs Individuals on Zero-Hour Contracts	☐	☑
Facilities located in sensitive ecosystems	☐	☑
ID Cards Withheld or Penalties for Resignation	☐	☑
No formal Registration Under Domestic Regulations	☐	☑
No signed employment contracts for all workers	☐	☑
Overtime For Hourly Workers Is Compulsory	☐	☑
Payslips not provided to show wage calculation and deductions	☐	☑
Sale of Data	☐	☑
Tax Reduction Through Corporate Shells	☐	☑
Workers cannot leave site during non-working hours	☐	☑
Workers not Provided Clean Drinking Water or Toilets	☐	☑
Workers paid below minimum wage	☐	☑
Workers Under Bond	☐	☑
Other	☐	☑

Supply Chain Disclosures

	Yes	No
Please indicate if any of the following statements are true regarding your company's significant suppliers.		
Business in Conflict Zones	☐	☑
Child or Forced Labor	☐	☑
Negative Environmental Impact	☐	☑
Negative Social Impact	☐	☑
Other	☐	☑

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Litigation and Arbitration Topic

Issue Date	2020-2024 (Updated in April 2025)
Topic	Mass Tort Litigation and Class Action lawsuits related to consumer protection topics.
Summary of Issue	The company has Mass Tort litigations and Class Action Litigations related to Consumer Protection in three (3) different topics. 1. Historical Product Personal Injury Summary: Gold Bond Co. LLC, which is no longer part of Opella as of April 30th 2025, has several product liability litigations (Mass Tort) filed throughout the United States in multiple state and federal court districts. These litigations are related to a brand that was previously part of Opella's portfolio which plaintiffs allege are related to personal health injuries such as cancers. These litigations are part of lawsuits that a number of consumer health companies that sold similar talc-based products are facing. 2. Misrepresentation of product quality or safety. Summary: Opella NA is one company involved in a handful of related Class Action lawsuits that center around children' s mouthrinses. Plaintiffs allege that the mouthrinses are being improperly marketed to children based on current guidelines from health organizations. Opella disputes these allegations. 3. False advertisement Summary: Opella NA was previously involved in a Class Action lawsuit regarding its Unisom Simple Slumbers product, where plaintiffs alleged that Opella was making false claims about the "natural" characteristics of the product. Opella disputed these allegations and the case is now dismissed.
Size/Scope of Issue **(e.g. $ financial implication, # of individuals affected)**	1. These cases are ongoing, with multiple cases being filed and dismissed on a weekly basis, and it is not possible, at this stage, to assess their potential financial impact on Opella. So far there are no verdicts against the company. 2. The case is on-going, and it is not possible, at this stage, to assess reliably their potential financial impact on Opella.

	3. The case was settled for a de minimis amount without admission of liability.
Impact on Stakeholder(s)	1. The primary allegation of these talc-based products' litigations refers to allegedly personal health injuries such as cancers. 2. The primary allegation of the case refers to allegedly health and economic impact on consumers of this product. 3. The primary allegation of the case refers to allegedly health and economic impact on consumers of this product.
Resolution	1- No verdict against the company and a dismissed rate of 61% of all cases filed. 2. On-going. 3. Settled for a de minimis amount without admission of liability.
Implemented Management Practices	1. These cases are ongoing and subject to dispute, and it is not possible, at this stage, to assess and implement suitable management practices or internal controls. 2.These cases are ongoing and subject to dispute, and it is not possible, at this stage, to assess and implement suitable management practices or internal controls. 3. Settled for a de minimis amount without admission of liability.

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Environmentally Intensive Industries

Issue Date	Ongoing
Topic	Water Intensive Industries
Summary of Issue	Sanofi CHC NA does not consider itself to be a water intensive industry. Sanofi CHC NA operates in the pharmaceutical industry which has been recognised as water intensive due to their manufacturing and cleaning processes.
Size/Scope of Issue **(e.g. $ financial implication, # of individuals affected)**	In the previous fiscal year, 100% of CHCNA at Sanofi's revenue was earned from the sale of over the counter medicines/drugs, food/dietary supplements and cosmetics. NA CHC's water intensity was calculated in 2022 as 0.30 M3 per manufacturing unit.
Impact on Stakeholder(s)	As a water intensive industry, the manufacturing of pharmaceutical products poses risks such as water stress or depletion of local water sources if water use is not appropriately managed. The company has a plant in Chattanooga, Tennessee which sources its water from the public water supply, not considered a water stressed area.
Implemented Management Practices	Although the company does not carry out an assessment of how it compares to others in the industry on a local level in relation to water use as there are no comparable consumer healthcare producers, benchmarks are performed on a global pharmaceutical producer level. Sanofi CHC NA does not have R&D, Bio-technology plants nor chemical plants to manufacture active pharmaceutical ingredients or excipients, nor manage biological products within its portfolio, activities generally recognized in the pharmaceutical industry as water-intensive. Globally Sanofi CHC has the target of reducing water consumption by 20% by 2030, with 2019 levels as a benchmark. All of Sanofi CHC's production sites will contribute to this global reduction, including the Chattanooga manufacturing facility, which is due to conduct a Gap Assessment in 2023 to establish a Water Efficiency Management Plan for NA CHC.

	Sanofi CHC’s sustainability strategy is based on water stewardship principles: increasing water efficiency, assessing risks in each local watershed and defining a strategy aligned with local communities to properly manage the watershed the company relies on.

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Other - Mandatory Animal Testing

Issue Date	Ongoing
Topic	Sanofi CHC North America develops consumer healthcare products which do not require the use of animal testing during research. Animal testing is only performed in rare situations when required by Regulatory Authorities due to safety concerns.
Summary of Issue	As a company that creates and manufactures pharmaceutical products, the company is legally obligated to ensure the quality, safety, and efficacy of its medicines and other consumer healthcare products. As a subsidiary of Sanofi, Sanofi CHC North America does not research and develop new drugs e.g., new drug molecules. Over the counter (OTC) products are on the market because they have already been proven to be safe and effective. Therefore, CHC would only perform animal studies in rare situations to evaluate and assess major safety concerns. Animal studies would therefore only be conducted as a final resort if no alternatives are available including if literature/data was unavailable for the study endpoints needed, and if performing human testing was unethical.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	CHC North America at Sanofi has not conducted any animal testing in the past 5 years.
Impact on Stakeholders	CHC NA does not develop new drug molecules and as stated above would only perform animal testing in rare situations when required by Regulatory Authorities due to safety concerns. Animal testing and experimentation is widely used to develop and test the safety of new drug molecules. Many of these experiments can cause pain to the animals involved or reduce their quality of life in other ways.
Implemented Management Practices	In the limited circumstance that Sanofi CHC NA is required to conduct aminmal testing due to regulatory requirements, Sanofi CHC NA has a policy for the protection of animals that includes a 3R principle towards animal testing; seeking to exceed regulation and standards. The company tests products on animals only: - when a non-animal method is unsuited for the required use or not accepted by the authorities (replacement)

	- with the smallest number of animals necessary for quality science (reduction) - with the implementation of state-of-the-art practices to promote animal welfare and prevent animal pain and distress in housing and procedure conditions (refinement). Sanofi has animal ethics committees with principles to ensure impartiality and independence of the ethical review. Sanofi CHC NA rarely authorizes animal use and only when the regulatory and scientific merit is established and under strict ethical over-sight. If animal testing is authorized, Sanofi CHC NA monitors compliance by third parties (breeders, contract research organizations, not-for-profit collaborations). External stakeholders can raise concerns in relation to animal testing directly to the Chief Veterinary Officer through Sanofi.com.
Report	Sanofi Animal Protection Factsheet: https://www.sanofi.com/assets/dotcom/content-app/documents/Animal-Protection.pdf Signed Marseille Declaration: https://www.sanofi.com/assets/dotcom/content-app/documents/Marseille-Declaration-2022-signed.pdf

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Litigation and Class Actions

Issue Date	2019-2020
Topic	Complaints, Multidistrict Litigation and Class Action lawsuits related to product content with potentially harmful long term effects.
Summary of Issue	The Company has various litigations across the US and Canada: 1. Sanofi CHC NA has various product liability litigations filed throughout the United States in multiple state and federal court districts (including multidistrict litigations). These various litigations allege claims of personal health injuries based on consumption or use of product ingredients, as well as economic loss claims, etc. 2. Litigation involving multiple plaintiffs across the USA and Canada, claiming personal injury and economic loss from a Sanofi CHC NA medication no longer on the market referred to as Zantac with ranitidine allegedly containing the chemical N-Nitrosodimethylamine (""NDMA""). Legacy Zantac with ranitidine was launched in the United States as a prescription medication by GSK in 1983 (GSK continued to market the Rx version until 2017). In 1995, GSK launched an OTC version of its Zantac with ranitidine 75mg formula. In 1997, generic ranitidine entered the market. In 1998, Pfizer acquired the OTC rights and in 2004 it launched a 150mg version of the product as well. In 2006, Boehringer Ingelheim acquired the U.S. OTC rights for Zantac, and in January 2017 Sanofi acquired those OTC rights. On September 13, 2019, FDA issued a statement alerting the public that some ranitidine medicines, including over-the-counter Zantac, contained a nitrosamine impurity called N-nitrosodimethylamine (NDMA) at low levels. NDMA is a known environmental contaminant found in drinking water, soil, and common foods, including meats, dairy products, and vegetables. People are routinely exposed to small amounts of NDMA every day. In October 2019, Sanofi issued a voluntary recall of all ranitidine Zantac OTC products in the U.S. and Canada.

	Since that time, the medical, scientific, and regulatory communities have extensively evaluated the safety of legacy Zantac's active ingredient ranitidine, and the data show there is no evidence of consumer harm from real-world use of legacy Zantac with ranitidine. Within days of FDA's September 2019 announcement, class actions and personal injury lawsuits were filed in U.S. courts, alleging that legacy Zantac with ranitidine caused various injuries.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	1. These cases are ongoing, and it is not possible, at this stage, to assess reliably their potential financial impact on Sanofi CHC NA and/or stakeholders. 2. As of May 2023, there are approximately 90,000 Zantac cases filed in various U.S. state courts. Given that the litigation is ongoing, it is not possible, at this stage, to reliably assess the potential financial impact on Sanofi CHC.
Impact on Stakeholders	1. The primary allegation in US product liability cases typically is that plaintiffs/consumers allegedly suffered injury or economic loss based on their consumption or use of product ingredients. 2. The medical, scientific, and regulatory communities have extensively evaluated the safety of legacy Zantac's active ingredient ranitidine, and the data show there is no evidence of consumer harm from real-world use of legacy Zantac with ranitidine. Over time, both FDA and the European Medicines Agency have evaluated the available data and have also found no evidence that ranitidine causes cancer. There is no potential impact on current consumers as the product has been off the market since 2019. The potential impact on consumers would relate to those consumers who purchased the legacy product and are now claiming economic, financial, or alleged long-term health impacts as purported in the litigation.
Resolution	US litigations remain ongoing.
Implemented Management Practices	1. These cases are ongoing and subject to dispute, and it is not possible, at this stage, to therefore assess their potential impact on Sanofi CHC NA management practices or internal controls. 2. Ranitidine, the active pharmaceutical ingredient at issue, is not presently sold on the market.

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Environmentally Intensive Industries

Issue Date	Ongoing
Topic	Chemical Intensive Industries
Summary of Issue	Sanofi CHC NA operates in the pharmaceutical industry which has been recognized as a chemical intensive. The company is not involved in the production, operation, trade or sale of chemicals that meet the European Union's list of Substances of Very High Concern (SVHC). The company does use SVHC lab chemicals for quality control purposes on its Chattanooga site. All product formulas are approved by US and Canadian Health Authorities, go through qualityThe primary potential impacts of chemical use in pharmaceutical products are potential negative effects to the environment and potential negative health impacts to workers exposed to chemical ingredients. Risks to workers exposed to chemical ingredients are mitigated through appropriate controls such as engineering controls and respiratory protection. Risks to the environment have been assessed as per the company “Pharmaceuticals in the Environment” program and are considered to be low. In the last five years, Sanofi CHC NA has not experienced any significant incidents and/or fines related to environmental or worker impacts of its chemical use. control and quality assurance, and are subject to monitoring in terms of quality, safety & efficacy. The level of the ingredients in the finished products remain adequate for the safe and intended use of consumers.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	The use of chemicals for quality control purposes in the Chattanooga site is approximately 1 ton/year. All finished products are safe for their intended use.
Impact on Stakeholders	The primary potential impacts of chemical use in pharmaceutical products are potential negative effects to the environment and potential negative health impacts to workers exposed to chemical ingredients. Risks to workers exposed to chemical ingredients are mitigated through appropriate controls such as engineering controls and respiratory protection. Risks to the environment have been assessed as per the company “Pharmaceuticals in the Environment” program and are considered to be low.

	In the last five years, Sanofi CHC NA has not experienced any significant incidents and/or fines related to environmental or worker impacts of its chemical use.
Implemented Management Practices	All of the chemicals used are handled, stored, disposed of, and transported following corporate standards, local legal standards, Standard Operating Procedures, and Permits including wastewater management. The company ensures that wastewater parameters are within the defined legal limits. Sanofi CHC NA has documented HSE requirements to minimize the use of Carcinogens, Mutagens, Reprotoxic, and volatile organic compounds. The company also proactively monitors the scientific literature and publications of health authorities worldwide to ensure state-of-the-art formulation and production. All of Sanofi's formulas are approved by Health Authorities, go through quality control and quality assurance, and are subject to monitoring in terms of quality, safety & efficacy.

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Recalls

Issue Date	2018, 2019, 2020
Topic	Recalls due to potential presence of elemental impurities
Summary of Issue	Sanofi CHC NA had one significant voluntary recall over the last 5 years, a Voluntary Class I recall of over-the-counter products containing ranitidine. Ranitidine, the active pharmaceutical ingredient at issue, is not presently sold on the market.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	The recalled product represented 6.9% of total 2019 Sanofi CHC NA Net Sales in 2019.
Impact on Stakeholders	NDMA is a known environmental contaminant found in drinking water, soil, and common foods, including meats, dairy products, and vegetables. People are routinely exposed to small amounts of NDMA every day. NDMA is classified as a probable human carcinogen. The medical, scientific, and regulatory communities have extensively evaluated the safety of Zantac's active ingredient ranitidine, and the data show there is no evidence of consumer harm from real-world use of Zantac. Over time, both FDA and the European Medicines Agency have evaluated the available data and have also found no evidence that ranitidine causes cancer.
Implemented Management Practices	In October 2019, Sanofi CHC NA issued a voluntary recall of all ranitidine Zantac OTC products in the U.S. and Canada. Ranitidine is not presently sold on the market.
Unrelated Recall Incidents	Sanof CHC NA had 3 unrelated voluntary product recalls involving separate products over the last 5 years. Each was classified by Health Canada as a "Voluntary Type III Recall".