Opella Africa, Middle East and Asia [AMEA]

Disclosure Report

Date Submitted: November 1st, 2024

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.

B Lab's Public Complaints Process

Any party may submit a complaint about a current B Corp through B Lab's Public Complaint Process. Grounds for complaint include:

1) Intentional misrepresentation of practices, policies, and/or claimed outcomes during the company's certification process
2) Breaches of the B Corp Community's core values as expressed in our Declaration of Interdependence

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

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	☑	☐
Fossil fuels 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 1 Litigation or Arbitration 2	☑	☐
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 - Chemical Intensive industries

Topic	Chemical Intensive industries
Summary of Issue	Opella AMEA operates in the pharmaceutical industry, which 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 a limited quantity of SVHC substance as a lab chemical 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***	The use of chemicals for quality control purposes at the manufacturing and R&D sites is below 1 ton/year. Therefore,

individuals affected)	these facilities would be exempted from restrictions 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: Environmentally Intensive Industry - Energy Intensive industries

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 their 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 comestics. Considering local contexts, each manufacturing site has its 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.
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 - Water Intensive Industry

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 municipality water for production and utilities, with some recovery efforts deployed at the site. The region is not water-stressed. 2. At Brisbane's facility, the company uses municipality water for production and utilities, with some rainwater recovery efforts deployed at the site for gardening needs. The region is not water-stressed. 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 comestics. Considering local contexts, each manufacturing site has its water intensity 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 use 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 manage properly 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: 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 before 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. 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 a 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 two years of self-reporting on the effectiveness of its enhanced internal controls, which ended in January 2021.

Management Practices	Opella shared that it abides by overarching Sanofi Group policies and procedures in relation to the 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 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 can use the revised advertisement.
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.
Releated Incidents (Yes/No)	No

Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Recalls

Issue Date	2019 - 2024
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 four (4) recalls across Thailand and India. (1) mandatory recall, and three (3) voluntary recalls. **Thailand** 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 Thai FDA. The quality defect is classified as class II. In April 2021, the manufacturing of this product ceased. The product is no longer sold by Opella Thailand.

	India 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 the 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 Sugarfree. Following a thorough investigation, the company took abundant precautionary measures 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.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	The four recalls represent approximately 1% of the company's overall production.
Impact on Stakeholders	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: 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 Inpection 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 into 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, and 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 was 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 improvement 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 a 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: 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 (eg, 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) 6. 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 has been performed in the last five years. Opella AMEA does not research and develop new drug molecules. They manufacture and sell over-the-counter (OTC) products that have already been proven to be safe and effective.
Size/Scope of Issue ***(e.g. $ financial implication, # of individuals affected)***	Opella AMEA has not conducted 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 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. When the execution of this study is mandatory for regulatory or safety reasons, the company will implement 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 is only conducted when the regulatory and scientific merit is established and under strict ethical oversight. 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 oversight. If animal testing is authorized, Sanofi monitors compliance by third parties (breeders, contract research organizations, and 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 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, use a program 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	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.