

Forced and Child Labour Report for 2023 Fiscal Year

Otsuka Canada Pharmaceutical Inc.



This Forced and Child Labour Report (the “Report”) addresses the period from January 1, 2023 to December 31, 2023 and has been prepared in compliance with the Fighting Against Forced Labour and Child Labour in Supply Chains Act (Canada) (the “Act”). This Report is made on behalf of Otsuka Canada Pharmaceutical Inc. (“OCPI”). Ce rapport est également disponible en français sur le site de [Sécurité publique Canada](#) et sur [notre site](#).

1. Introduction

Forced labour and child labour, each as defined in the Act, are crimes and serious violations of human rights. As a leading pharmaceutical business, and in keeping with the overarching corporate philosophy of “Otsuka – people creating new products for better health worldwide”, OCPI recognizes the important role that we have in ensuring that our operations and products, and the supply chains that support these, adhere to the highest ethical standards, including the prevention and identification of forced labour and child labour in our supply chain. This Report summarizes the activities during Fiscal Year 2023 to prevent and reduce the risk that forced labour or child labour is used in the production of goods in Canada or elsewhere by OCPI or of goods imported into Canada by OCPI.

2. Our Business

OCPI is a pharmaceutical company headquartered in Ville Saint-Laurent, Quebec, that commercializes central nervous system and nephrology prescription medicines for the Canadian market. OCPI is a subsidiary of Otsuka America Inc., itself a subsidiary of Japan-based Otsuka Pharmaceutical Co., Ltd., itself a subsidiary of Otsuka Holdings Co., Ltd. This report summarizes the activities of OCPI only (including OCPI’s participation to the Otsuka group of companies’ global initiatives).

OCPI’s prescription medicines supply chain includes businesses that supply goods and services to our organization, including:

- finished or semi-finished products
- packaging from semi-finished to finished products
- medical devices (syringes and needles) and sterile water vials accompanying injection prescription medicines
- testing services
- third party logistics (3PL) services (warehousing, shipping, distribution)

In total, we procure goods and services from a dozen direct suppliers to manufacture, package, import and distribute the prescription medicines we market in Canada.

The prescription medicines are sold under license from Otsuka Pharmaceutical Co., Ltd. (Japan) and Vifor Fresenius Medical Care Renal Pharma Ltd. (Switzerland). OCPI imports semi-finished products into Canada from Otsuka Pharmaceutical Co., Ltd. and finished products from Vifor Fresenius Medical Care Renal Pharma Ltd. For semi-finished products, OCPI also procures directly from third party suppliers medical devices components, sterile water vials and product packaging for the Canadian market. These direct suppliers are based in Canada, Denmark, France, Germany, Israel, Japan, the Philippines and the United States.

Furthermore, products marketed in Canada by OCPI must comply with Health Canada's Current Good Manufacturing Practice ("cGMP") regulations governing the methods, facilities, controls, and personnel qualifications necessary for the manufacturing, processing, and packing of a drug product. These regulations not only set high quality thresholds for the work environment, but also impose stringent training requirements for the individuals working in these facilities.

Further information about our business can be found on our corporate website (<https://otsukacanada.com/>).

3. Our Policies

Through our organizational and governance policies, we communicate our values and expectations, setting a high bar for ourselves, our suppliers, and our selling partners, and make it clear that any forms of forced labour or child labour are prohibited. We are committed to consistently evolving and improving our approach. We prohibit child, forced or bonded labour in any of our operations or by suppliers working for us. We want to ensure our activities do not have a negative impact on human rights. Here is an overview of our relevant policies:

Global Code of Business Ethics

As a member of the Otsuka group of companies, we are committed to conducting our business in a lawful and ethical manner. We adhere to the Otsuka Global Code of Business Ethics, which affirms our commitment to the highest standards of ethical conduct. As the foundation of the Otsuka group policies, it sets out guiding principles on professional conduct and establishes that in performing their job duties, OCPI's employees should always act lawfully, ethically and in the best interests of the company.

Global Business Partner Code of Ethics

We adhere to the Otsuka Business Partner Code of Ethics ("Partner Code"), which was developed throughout the course of 2023 and approved by Otsuka Holdings Co., Ltd.'s governing Board in the beginning of 2024. The Partner Code details the requirements and

expectations we have of how our business partners will conduct their business. We expect our business partners to comply with all applicable legal requirements in the jurisdictions in which they operate and consistently monitor and enforce our Partner Code or equivalent principles and standards in their own operations and supply chain. Our Partner Code also sets forth our principles related to human rights, labour and employment practices, ethical business practices, environmental management, privacy, confidentiality, quality and operational excellence. We seek to engage with business partners that are committed to these same principles.

Global Human Rights Policy

We recognize that respect for human rights in every aspect of our business activities must be the premise upon which we build to meet the expectations of our stakeholders, create new value, and contribute to the health and wellbeing of people all over the world as we continue to grow sustainably. We adhere to the Otsuka Global Human Rights Policy, which was established to guide our efforts to promote human rights initiatives, focusing on four key operating principles which are human rights due diligence, dialogue and consultation, education and awareness raising, and salient human rights issues.

Global Speak-Up Policy

OCPI is committed to high standards of business conduct. In line with this commitment, our employees and contractors have the right and the duty to raise, in good faith, concerns about improper business conduct without fear of retaliation in any form. Allegations of any breach of our policies or any non-compliant and unethical matters are taken seriously. OCPI has an Integrity Hotline where individuals can anonymously report concerns. In early 2024, OCPI's Integrity Hotline was also made available externally on OCPI's website to facilitate accessibility to external individuals, furthering OCPI's commitment to an ethical business culture. Retaliation against anyone speaking up in good faith is strictly prohibited as specified in our Global Code of Business Ethics and Global Business Partner Code of Ethics.

Due Diligence

We expect third parties with which we work to adhere to business principles and values similar to our own and to comply with all applicable laws and regulations.

We acknowledge that forced labour or child labour is a potential risk for any supply chain, including ours. To mitigate this risk, we perform the following due diligence activities.

While OCPI does not currently carry out specific due diligence on its suppliers for the risk of forced and child labour, we perform risk-based due diligence before entering into an agreement with a new supplier. This due diligence includes a review of the information found on a potential supplier from the databases of two leading providers of supplier financial, reputational, sanctions, legal and compliance risks screening/due diligence solutions, which we expect to make us aware of any publicly known forced or child labour issue involving this supplier.

To address issues identified as part of this screening, OCPI could for example decide to include additional contractual requirements, perform additional assessments or monitoring, require the adoption and completion of a corrective action plan, or forego contracting with the proposed supplier.

The sourcing, manufacturing, packaging, testing and distribution of all prescription medicines marketed in Canada by OCPI is governed by Health Canada’s cGMP regulations, which include specific personnel and workplace qualifications. OCPI verifies compliance of its manufacturing, packaging, testing and distribution direct suppliers (“cGMP Suppliers”) with Health Canada’s cGMP regulations through regular audits and site inspections.

OCPI conducts due diligence on cGMP Suppliers prior to their engagement, as well as throughout the period of their engagement. This includes initial screening and audits if appropriate, as well as regular audits and site inspections of cGMP Suppliers to ensure compliance with our quality agreements. OCPI cGMP Suppliers are also subject to potential audits and inspection by government agencies, including Health Canada.

While forced and child labour are not specific targets of these audits, OCPI personnel would be required to escalate any such observations or suspicions immediately.

Contractual arrangements between OCPI and our cGMP Suppliers require compliance with local laws, rules, and regulations, which would include those concerning labour and employment in the region where the supplier operates.

4. Assessing Our Risk

OCPI engages in various activities to identify, assess, and manage supplier risk. In assessing the risk of forced and child labour in our business and supply chains, we have completed mapping of our cGMP Suppliers in 2023. As part of our existing due diligence process for new direct suppliers, we verify the databases of two leading providers of supplier financial, reputational, sanctions, legal and compliance risks screening/due diligence solutions. We also include provisions requiring compliance to all applicable laws in our services agreements with direct suppliers. To identify the business activities with the greatest exposure to these risks, we may consider the following factors:

- Reliance on low skilled workforce
- Dangerous or undesirable work
- Presence of migrant workers
- Presence of labour intermediaries
- Offshore production
- Long, complex, or non-transparent supply chains
- Presence of child labour
- Jurisdictional risks, including poverty, conflict, and level of enforcement of international human rights standards

We initiated but did not complete the analysis of the risk of forced and child labour in our supply chain in 2023, but we would expect to find that we have a relatively low risk of forced or child labour in our cGMP supply chain, based on the combination of the following factors:

- Our cGMP Suppliers operate in a regulated industry, which requires high standards of compliance and regular audits by regulatory bodies
- We source most of our goods and services from suppliers based in Canada, Europe, Japan, and the United States, which have a low prevalence of modern slavery according to the Global Slavery Index

- We do have a fairly complex supply chain, and have not performed a supply chain mapping other than for our cGMP Suppliers. However, such mapping is expected to have been performed by our finished or semi-finished prescription drug suppliers as part of their own cGMP obligations

We have identified one supplier operating in a higher risk jurisdiction; we have requested and received information in 2023 on their efforts to comply with applicable laws, adhere to human and labour rights and prevent forced and child labour. Their response confirms that they have activities and policies governing adherence to human rights and preventing forced or child labour.

We are conscious that a low risk does not mean none, and remain committed to taking steps in 2024 to continue to decrease our vulnerability to the risk of relying on forced or child labour.

5. Our Commitments

Otsuka Holdings Co., Ltd. is a signatory to the United Nations Global Compact, a voluntary initiative that unites companies in their commitment to create a sustainable and inclusive global economy. By signing this compact, the Otsuka group of companies, including OCPI, have pledged to advance numerous human rights principles, including the elimination of all forms of forced and compulsory labour and the effective abolition of child labour. These principles are consistent with the Otsuka group of companies long-standing values and the expectations stipulated in the Global Code of Business Ethics that OCPI adheres to.

Activities to Prevent and Reduce Risks of Forced and Child Labour

As further detailed in this report:

- We have initiated a high-level risk and prioritization assessment of our exposure to the risk of forced or child labour in 2023. Our cGMP Suppliers were identified as our main priority
- We have completed mapping of our cGMP Suppliers in 2023
- We verify the databases of two leading providers of supplier financial, reputational, sanctions, legal and compliance risks screening/due diligence solutions as part of our contracted supplier due diligence process, and have a process to manage issues that may be identified as part of this due diligence
- We require compliance to all applicable laws in our contracts with our direct suppliers
- We have several policies addressing directly or indirectly forced and child labour
- We perform regular monitoring and auditing of our cGMP Suppliers

Remediation Measures

Our Global Speak-Up Policy require all employees of OCPI to report actual or possible misconduct. We also undertake due diligence efforts as further described in this Report that are not specific to forced and child labour but nevertheless help ensure that the risk of forced labour and child labour is mitigated in our business. If we were to discover any forced labour or child labour in our business and supply chains, the following measures could be taken to remediate such forced labour or child labour based on the severity of the issue:

- Ensure proper investigation of the issue

- Work with the concerned supplier to address the issue
- Impose additional contractual requirements
- Adopt capacity-building measures, ensure enhanced supervision and/or monitoring of supplier, sub-supplier or contractor
- Require implementation of a corrective action plan
- Suspend or terminate a supplier, sub-supplier or contractor
- Take actions to prevent forced labour or child labour and associated harms from reoccurring
- Take actions to support victims of forced labour or child labour
- Take actions to support victims of forced labour or child labour and/or their families such as workforce reintegration and psychosocial support
- Consider compensation for victims of forced labour or child labour and/or their families
- Engage with community and stakeholders and consider wider capacity-building measures

No forced or child labour remediation measures were required to be taken in 2023.

Training

Every year, OCPI employees at all levels are required to complete a mandatory training to ensure that our Code of Business Ethics is understood and properly applied to our daily activities. Every new employee of OCPI must complete mandatory online training on our values and policies, including our Global Code of Business Ethics and the Innovative Medicines Canada Code of Ethical Practices, and is informed of how to report wrongdoing under our Global Speak-Up Policy. We provide employees with ongoing and periodic training opportunities to ensure that all employees have current knowledge. In addition, in 2023, our employees completed Human Rights training that explained the concept of conducting business in adherence to Human Rights, the Global Human Rights Policy, and the UN Global Compact.

6. Our Progress and Effectiveness

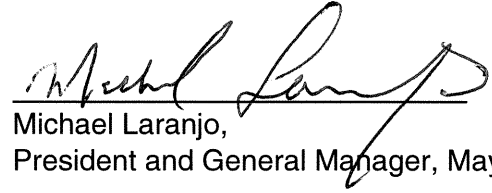
As part of our governance processes, we monitor compliance with our policies on an ongoing risk-level basis. We also review any concerns raised through our Global Speak Up Policy and other informal mechanisms of employee feedback. To date, no significant concerns or complaints have been identified.

OCPI is currently focusing its efforts on the assessment, mapping, policy and procedure development and implementation and engagement with suppliers' aspects of its forced and child labour risk prevention and reduction activities. Given this, a specific assessment of effectiveness at preventing or reducing these risks was not completed in 2023.

7. Approval and Signature

In accordance with paragraph 11(4)(a) of the Act, this Report was approved by Otsuka Canada Pharmaceutical Inc.'s Board of Directors on May 27, 2024, and has been submitted to the Minister of Public Safety and Emergency Preparedness in Canada. This Report is also available on our company website at www.otsukacanada.com/forced_child_labour_reporting.

In accordance with the requirements of the Act, and in particular section 11 thereof, I attest that I have reviewed the information contained in this Report for Otsuka Canada Pharmaceutical Inc. Based on my knowledge, and having exercised reasonable diligence, I attest that the information in this Report is true, accurate and complete in all material respects for the purposes of the Act, for the reporting year listed above.



Michael Laranjo,
President and General Manager, May 28, 2024

I have the authority to bind Otsuka Canada Pharmaceutical Inc.