

S-211 2023 Annual Report for Halo Pharmaceutical Canada (Halo)

- Financial Year Reporting: January 1, 2023 through December 31, 2023
- Business number: 82902 5105 RC0004
- Entity Categorization: Corporation
- Sector/industry: Pharmaceuticals
- Location: Mirabel, Quebec

1. *What steps has the entity taken in the previous financial year to prevent and reduce the risk that forced labour or child labour is used at any step of the production of goods in Canada or elsewhere by the entity or of goods imported into Canada by the entity? Select all that apply. (Required)

- Mapping activities **Yes and updated in 2024**
- Mapping supply chains **Yes and updated in 2024**
- Conducting an internal assessment of risks of forced labour and/or child labour in the organization's activities and supply chains **Yes – low risk determined in current supply chain due to industry, regulatory framework, geographical distribution of vendors (see below)**
- Contracting an external assessment of risks of forced labour and/or child labour in the organization's activities and supply chains **Yes, updated in 2024 with this reporting requirement. Determined limited risk due to regulatory framework. Enhancing governance and risk framework within our Quality and Vendor management systems.**
- Developing and implementing an action plan for addressing forced labour and/or child labour **No, 2024 Initiative**
- Gathering information on worker recruitment and maintaining internal controls to ensure that all workers are recruited voluntarily **Yes – local workforce only**
- Addressing practices in the organization's activities and supply chains that increase the risk of forced labour and/or child labour **Determined current hiring and employment practices within existing facility would not result in any forced labour or especially child labour practices. Risk remains in the supply chain.**
- Developing and implementing due diligence policies and processes for identifying, addressing and prohibiting the use of forced labour and/or child labour in the organization's activities and supply chains **Limited 2023 activity, 2024 Initiative**
- Carrying out a prioritization exercise to focus due diligence efforts on the most severe risks of forced and child labour **No discernible 2023 activity. 2024 Initiative to review high-risk suppliers (China, India, etc.) in 2024 change**

supplier audit governance/practices and enhance internal training for awareness and identification

- Requiring suppliers to have in place policies and procedures for identifying and prohibiting the use of forced labour and/or child labour in their activities and supply chains labour **No**
- Developing and implementing child protection policies and processes **Canadian Labour laws protect and exist. Specific internal policies to be implemented in 2024**
- Developing and implementing anti-forced labour and/or -child labour contractual clauses labour **2024 Initiative**
- Developing and implementing anti-forced labour and/or -child labour standards, codes of conduct and/or compliance checklists **2024 Initiative to add supplier audits checklists.**
- Auditing suppliers - All **suppliers are audited to meet Customer, FDA and cGMP requirements as applicable. Independent site audits are conducted per Customer and regulatory compliance requirements. Future supplier audits to include additional scope related to anti-forced labor and/or child labor audit components.**
- Monitoring suppliers - **Vendors are continuously monitored for pharmaceutical compliance standards as part of the Halo vendor qualification process. Labour practices to be added as part of the risk assessment in 2024.**
- Enacting measures to provide for, or cooperate in, remediation of forced labour and/or child labour **Not practical**
- Developing and implementing grievance mechanisms **Not practical**
- Developing and implementing training and awareness materials on forced labour and/or child labour **To be implemented in 2024 as part of Supplier Selection Process and Employee On-Boarding for those associated with Vendor Management**
- Developing and implementing procedures to track performance in addressing forced labour and/or child labour **Not determinable if this is practical**
- Engaging with supply chain partners on the issue of addressing forced labour and/or child labour **2024 Initiative**
- Engaging with civil society groups, experts and other stakeholders on the issue of addressing forced labour and/or child labour **Not part of current scope**
- Engaging directly with workers and families potentially affected by forced labour and/or child labour to assess and address risks **Not part of current scope**

2. Please provide additional information describing the steps taken (if applicable) (1,500 character limit).

Halo operates in the highly regulated pharmaceutical environment overseen by both Health Canada and the FDA. As part of a rigorous vendor qualification process, all potential suppliers must undergo a thorough a GMP qualification audit either through our customers Quality Management System or a Halo Quality review (Refer to Halo SOP's and

questionnaire) and comply with all required Health Canada and FDA requirements, which may include on-site audits of the manufacturing facilities.

Halo requires all prospective suppliers to complete a site audit or if allowed a Halo Off-site Audit Questionnaire. In addition, the completion of “Supply Chain Material Information Request” form must be completed by all vendors the track the supply chain for all potential shipments. Our customers and our internal quality organization monitor Supplier performance. All supplies are required to stay compliant with Health Canada or US FDA regulations and are generally inspected every 3 years in order to maintain GMP compliance and therefore qualify as a supplier. Therefore, our internal quality management systems and the government body inspections provide us heightened assurance that the risk of child labour is reduced. At this time, it is impractical to provide assurances with respect to forced labour.

3. **Which of the following accurately describes the entity’s structure? (Required)*

Halo Pharmaceutical Canada Inc., a corporation organized under the laws of Canada, having offices at 17800 rue Lapointe Mirabel, QC, J7J 0W8 Canada.

4. **Which of the following accurately describes the entity’s activities? Select all that apply. (Required)*

- Halo is a contract manufacturer of drug products and does not produce goods outside of their Mirabel, Quebec facility.
- Halo is a contract manufacturer and does not support direct sales in or outside of Canada.
- Halo is not a Distributor of goods. All products are manufactured to specific Customer requirements and shipped directly to the Customer. Halo does not support direct distribution of any manufactured product within or outside of Canada.
- Halo Pharmaceuticals Canada imports direct and indirect materials produced outside Canada.

5. Please provide additional information on the entity's structure, activities and supply chains (1,500 character limit).

Halo Pharmaceutical Canada is a wholly owned subsidiary of the Noramco Group LLC and provides drug product contract manufacturing services to both Canadian and global pharmaceutical customers.

Based in Mirabel, Quebec, Halo operates a cGMP/Health Canada/FDA approved manufacturing site providing commercial and clinical scale capabilities to develop, manufacture, package and test a variety of drug product dosage forms including:

- Oral solids (tablets and capsules)
- Oral liquids
- Tubes (creams, ointments and gels)
- Suppositories

Halo utilizes direct materials supplied by our customers and purchases additional direct/indirect materials from qualified distributors and manufacturers meeting all supplier qualification criteria mandated by both the Halo Quality policy and all Regulatory Agencies

Manufacturers

The Halo manufacturing base provides a total of 1,928 active material numbers consisting of Packaging Components, Active Pharmaceutical Ingredients (API's), and Excipients:

- 82% of the manufacturing base resides in either Canada or the United States
- Less than 5% of materials are sourced from Low-Cost Regions (LCR's) including Brazil, China, Indonesia, India, Mexico, Malaysia, and Mexico
- Exposure to manufacturers located in higher risk countries for the use of forced/child labor would be mitigated via Regulatory oversight and reporting requirements within the pharmaceutical industry

Country	Material Count	Mfg. % by Country
Austria	7	0.36%
Belgium	2	0.10%
Brazil	3	0.16%
Canada	1087	56.38%
Switzerland	13	0.67%
China	32	1.66%
Czech Republ	3	0.16%
Germany	64	3.32%
Denmark	3	0.16%
Spain	26	1.35%
France	34	1.76%
Great Britain	6	0.31%
Hungary	3	0.16%
Indonesia	2	0.10%
Ireland	11	0.57%
Israel	2	0.10%
India	35	1.82%
Italy	23	1.19%
Japan	10	0.52%
Korea	6	0.31%
Mexico	10	0.52%
Malaysia	3	0.16%
Netherlands	17	0.88%
New Zealand	2	0.10%
Pakistan	1	0.05%
Poland	3	0.16%
Portugal	9	0.47%
Romania	1	0.05%
Sweden	5	0.26%
Slovakia	1	0.05%
Taiwan	9	0.47%
United States	495	25.67%
Total	1928	

Distributors

Halo is supported by over 100 approved distributors, with some manufacturers providing distribution services:

- 88% of all Distribution sites are in located in either Canada or the United States
- Less than 1% of materials are distributed by Low-Cost Regions (LCR's) including Barbados and India.
- Exposure to distributors located in higher risk countries regarding the use of forced/child labor would be mitigated via Regulatory oversight and reporting requirements within the pharmaceutical industry

Country	Material Count	Dist. % by Country
Austria	2	0.10%
Barbados	1	0.05%
Canada	1506	78.11%
Switzerland	12	0.62%
Czech Republic	1	0.05%
Denmark	3	0.16%
Spain	2	0.10%
Great Britain	2	0.10%
India	13	0.67%
Italy	6	0.31%
Japan	1	0.05%
Netherlands	1	0.05%
Portugal	1	0.05%
United States	377	19.55%
Total	1928	

Service Providers

Halo relies on their Service Providers to supply everything from contract services to lawn care to IT systems:

- 87% of all Service Providers are located within Canada or the United States
- Service Providers represent 48 individual countries
- Exposure to service providers located in higher risk countries regarding the use of forced/child labor would be mitigated via Regulatory oversight and reporting requirements within the pharmaceutical industry

Country	Vendor SAP # Count	Service Provider % by Country
Argentina	1	0.02%
Australia	1	0.02%
Austria	4	0.08%
Barbados	1	0.02%
Belgium	2	0.04%
Brazil	3	0.06%
Bulgaria	3	0.06%
Canada	3638	73.33%
Cayman Island	1	0.02%
Chile	1	0.02%
China	71	1.43%
Curacao	1	0.02%
Czech Republic	7	0.14%
Denmark	8	0.16%
Ecuador	1	0.02%
France	45	0.91%
Germany	90	1.81%
Great Britain	35	0.71%
Greece	2	0.04%
Hong Kong	1	0.02%
Hungary	12	0.24%
India	113	2.28%
Indonesia	4	0.08%
Ireland	7	0.14%
Israel	7	0.14%
Italy	44	0.89%
Japan	19	0.38%
Korea	5	0.10%
Malaysia	3	0.06%
Malta	2	0.04%
Mexico	5	0.10%
Netherlands	18	0.36%
New Zealand	5	0.10%
Norway	1	0.02%
Pakistan	1	0.02%
Phillipines	3	0.06%
Poland	2	0.04%
Portugal	3	0.06%
Puerto Rico	1	0.02%
Romania	1	0.02%
Singapore	1	0.02%
Slovakia	1	0.02%
Spain	28	0.56%
Sweden	3	0.06%
Switzerland	26	0.52%
Taiwan	10	0.20%
Turkey	2	0.04%
United States	718	14.47%
Grand Total	4961	

6. *Does the entity currently have policies and due diligence processes in place related to forced labour and/or child labour? (Required)

All direct and indirect materials used in the production of pharmaceuticals must be manufactured in facilities meeting Health Canada, FDA and cGMP certification requirements. Certification includes site audits which focus on all aspects of the quality and manufacturing systems.

6.1 *If yes, which of the following elements of the due diligence process has the entity implemented in relation to forced labour and/or child labour? Select all that apply. (Required)

While no specific due diligence is conducted solely focused on forced labour and/or child labour, any suspicious employment or labor practices would be observed, questioned, and documented as part of the audit processes identified above.

7. Please provide additional information on the entity's policies and due diligence processes in relation to forced labour and child labour (if applicable) (1,500 character limit).

Health Canada and FDA supplier auditing and certification requirements would mitigate the risk for exposure to forced or child labor violations.

8. *Has the entity identified parts of its activities and supply chains that carry a risk of forced labour or child labour being used? (Required)

Halo has identified the geographical locations of all their source manufactured goods used in the manufacturing process. The table above identifies the countries and territories where the products are manufactured. We have cross referenced those locations to identify high risk countries. Specifically, our current supplier list includes x suppliers from India and x suppliers from China. Areas identified as potential higher risk countries associated with lax employment laws relative to forced and child labour.

Our regulatory compliance environment reduces the risk and potential for these companies exploiting children and employing forced labour. Beyond our current framework it is impractical to reduce this risk to zero. However, we will in 2024, expand our

scope of the Supplier Audit to specifically include and request compliance over ethical employment practices including forced and child labour.

- Yes, we have identified risks to the best of our knowledge and will continue to strive to identify emerging risks.

8.1 *If yes, has the entity identified forced labour or child labour risks related to any of the following aspects of its activities and supply chains? Select all that apply. (Required)

- The sector or industry it operates in **Yes**
- The types of products it produces, purchases or distributes **Yes**
- The locations of its activities, operations or factories **Yes**
- The types of products it sources **Yes**
- The raw materials or commodities used in its supply chains **Yes**
- Tier one (direct) suppliers **Yes – utilized source manufacturing site data not distributors**
- Tier two suppliers **Yes – utilized source manufacturing site data not distributors**
- Tier three suppliers **Yes – utilized source manufacturing site data not distributors**
- Suppliers further down the supply chain than tier three **Yes – utilized source manufacturing site data not distributors**
- The use of outsourced, contracted or subcontracted labour
- The use of migrant labour **Yes – core supply chain in manufacturing facilities not traditionally associated with migrant labour. India and Chinese facilities difficult to collect more reliable data other than rely on on-site visits and/or government on-site inspections.**
- The use of forced labour **Adult forced labour is more challenging to discern through on-site GMP regulatory audits.**
- The use of child labour **Yes – India and Chinese facilities difficult to collect more reliable data other than rely on on-site visits and/or government on-site inspections.**

9. *Has the entity identified forced labour or child labour risks in its activities and supply chains related to any of the following sectors and industries? Select all that apply. (Required)

- Manufacturing - **Yes**
- Wholesale trade **Yes – our assessment and analysis primarily at source manufacturing sites.**
- Transportation and warehousing **Yes – to the extent we contract specifically with these organizations.**

- Professional, scientific and technical services **Yes – within our industry and scope. To the extent we contract specifically with these organizations.**

10. Please provide additional information on the parts of the entity's activities and supply chains that carry a risk of forced labour or child labour being used, as well as the steps that the entity has taken to assess and manage that risk (if applicable) (1,500 character limit).

Halo will initially focus on suppliers located in high-risk countries such as India and China.

11. *Has the entity taken any measures to remediate any forced labour or child labour in its activities and supply chains? (Required)

- Not applicable, we have not identified any forced labour or child labour in our activities and supply chains.

Halo has not taken any remediation steps at this time as specific company risk has not been identified as part of our current regulatory and audit outcomes. As indicated, we will continue to expand our existing audit framework to enhance the scope to consider specific forced and child labour practices. Additionally, internal awareness training will aid in potential issue identification.

11.1 *If yes, which remediation measures has the entity taken? Select all that apply. (Required)

Halo has not identified any forced labour or child labour concerns in our activities and supply chains to date.

12. Please provide additional information on any measures the entity has taken to remediate any forced labour or child labour (if applicable) (1,500 character limit).

Halo has not identified any forced labour or child labour concerns in our activities and supply chains to date.

13. *Has the entity taken any measures to remediate the loss of income to the most vulnerable families that results from any measure taken to eliminate the use of forced labour or child labour in its activities and supply chains? (Required)

- Not applicable, we have not identified any loss of income to vulnerable families resulting from measures taken to eliminate the use of forced labour or child labour in our activities and supply chains.

Halo has not identified any forced labour or child labour concerns in our activities and supply chains to date.

14. Please provide additional information on any measures the entity has taken to remediate the loss of income to the most vulnerable families that results from any measure taken to eliminate the use of forced labour or child labour in its activities and supply chains (if applicable) (1,500 character limit).

Halo has not identified any forced labour or child labour concerns in our activities and supply chains to date.

15. *Does the entity currently provide training to employees on forced labour and/or child labour? (Required)

Halo currently does not provide employee training on forced labour and/or child labour at this time but is in the process of evaluating options in 2024.

15.1 *If yes, is the training mandatory? (Required)

Halo currently does not provide employee training on forced labour and/or child labour at this time but is in the process of evaluating options in 2024.

16. Please provide additional information on the training the entity provides to employees on forced labour and child labour (if applicable). (1,500 character limit).

Halo currently does not provide employee training on forced labour and/or child labour at this time but are in the process of evaluating options in 2024.

17. *Does the entity currently have policies and procedures in place to assess its effectiveness in ensuring that forced labour and child labour are not being used in its activities and supply chains? (Required)

Halo currently does not have policies and procedures in place to assess its effectiveness in ensuring that forced labour and child labour are not being used in its activities and supply chains but are in the process of evaluating options in 2024.

17.1 *If yes, what method does the entity use to assess its effectiveness? Select all that apply. (Required)

Halo currently does not have policies and procedures in place to assess its effectiveness in ensuring that forced labour and child labour are not being used in its activities and supply chains but are in the process of evaluating options in 2024.

18. Please provide additional information on how the entity assesses its effectiveness in ensuring that forced labour and child labour are not being used in its activities and supply chains (if applicable). (1,500 character limit).

Halo operates in the highly regulated pharmaceutical environment overseen by both Health Canada and the FDA. As part of a rigorous vendor qualification process, all potential suppliers must undergo a thorough Halo Quality review and comply with all required Health Canada and FDA requirements, which may include on-site audits of the manufacturing facilities.

Halo requires all prospective suppliers to complete a site audit or if allowed a Halo Off-site Audit Questionnaire. In addition, the completion of "Supply Chain Material Information Request" form must be completed by all vendors the track the supply chain for all potential shipments.

Attestation

"In accordance with the requirements of the Act, and in particular section 11 thereof, I attest that I have reviewed the information contained in the report for the entity or entities listed above. Based on my knowledge, and having exercised reasonable diligence, I attest that the information in the report is true, accurate and complete in all material respects for the purposes of the Act, for the reporting year listed above."

x Adam Hopper

Adam Hopper, CPA, CF

President Halo Pharma

Date: May.31.2024

Signature:

"I have the authority to bind 'Halo Pharma.'"