Recognition of GMP extra-jurisdictional inspection outcomes (as of January 31, 2025)
Background

In 2000, the MRA between Canada and Switzerland on Medicinal Products: Drug GMP Compliance Certification (Sectoral Annex on GMP) became operational. The MRA allows Canada and Switzerland to maintain its efficiency and effectiveness of compliance and enforcement efforts, through a mutual recognition of certification for good manufacturing practices for pharmaceutical facilities located in their respective territories.

As of January 31, 2025, Health Canada and Swissmedic agreed to expand the existing approach of recognizing GMP inspection results to include inspections that are conducted in countries outside of the respective Parties' jurisdictions (i.e., extra-jurisdictional inspections) for products included in the indicative list of products of the Sectoral Annex on GMP.

Operationalization of stable medicinal products derived from human blood or human plasma, and active pharmaceutical ingredients (as of January 31, 2025)

As of January 31, 2025, Health Canada and Swissmedic recognized each other’s GMP compliance programme as equivalent for the GMP oversight of stable medicinal products derived from human blood or human plasma (SMP) and active pharmaceutical ingredients (API). Therefore, it was agreed to include SMP and API in the operational scope of the Sectoral Annex on GMP.

Benefits

Stakeholders will benefit from the exchange of certificates of GMP compliance between Canada and Switzerland for extra-jurisdictional inspections, SMP and API. This will contribute to reducing the regulatory burden for the importers to obtain information to demonstrate compliance to GMP for foreign buildings.

On-site evaluation and Pre-approval inspection (as of January 31, 2025)

As of January 31, 2025, prior to planning and conducting a product-specific on-site evaluation (OSE) in Switzerland related to the review decision for a submission under consideration by Health Canada, or a pre-approval inspection (PAI) by Swissmedic to confirm GMP compliance of the manufacturing of a product in a facility in Canada, Health Canada and Swissmedic will inform the other Party of the possible scope of the OSE or PAI and will request available information about the facility (including inspections reports). Any decision to carry out an OSE or a PAI should only be made after an assessment of all information. If at the conclusion of the assessment, a Party considers an OSE or a PAI necessary, it will propose to the other Party to conduct one on its behalf. Where there is still a need to proceed with either an OSE or a PAI in the other Party’s jurisdiction, each Party can conduct its own OSE or PAI, and the other Party will be invited to participate.