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# Health Canadaâ€™s Ministerial Reliance Order: A New Era in Canadian Drug Regulation

Health Canada has introduced a new Ministerial Reliance Order (MRO) that represents a significant development in Canada’s drug regulatory framework. The MRO creates a new mechanism allowing Health Canada, in defined circumstances, to rely on decisions or documents produced by comparable foreign regulatory authorities (FRAs) when reviewing certain drug submissions. The initiative aims to improve the efficiency of regulatory review while maintaining Canada’s standards for safety, efficacy, and quality.

The MRO forms part of a broader package of initiatives Health Canada announced in a news release published on July 15, 2026.

According to Health Canada, the MRO (or Order Providing for Reliance on Decisions of, or Documents produced by, Foreign Regulatory Authorities in Respect of Certain Drugs) aims to bring more medications and treatments to Canada sooner by reducing unnecessary duplication in regulatory review. Through the MRO, Health Canada may accelerate review of certain portions of a drug submission by relying on decisions or documents produced by select FRAs. Health Canada maintains that the approach preserves Canada’s requirements for safety, efficacy, and quality while making the review process more efficient and encouraging manufacturers to launch products in Canada.

## Reducing Red Tape

Health Canada describes the MRO as part of its broader commitment to reducing regulatory burden. It notes that drug submissions have become increasingly complex, submission volumes have increased, and expectations for faster access to new therapies continue to grow.

Health Canada also emphasizes its participation in international regulatory initiatives that reduce duplication and promote harmonized regulatory processes. The MRO builds on those collaborative relationships by giving Health Canada clear authority to rely on decisions and documents from comparable foreign regulators where appropriate. The result is a more efficient review process that preserves Canadian regulatory

oversight.

**Drug Approval Under the MRO**

The MRO allows Health Canada to “deem” certain parts of a drug submission complete if the submission meets the MRO’s requirements. In practical terms, this means Health Canada may treat specified components of the Canadian review as satisfied based on a comparable FRA’s decision or review documents.

The parts of a drug submission eligible for deeming under the MRO include:

- Non-clinical information
- Clinical information
- Chemistry and manufacturing information

Health Canada may deem those parts complete where a comparable FRA has either approved the foreign drug or produced a document based on its review of a portion of the foreign drug submission. Health Canada has published draft guidance on the MRO and is consulting with manufacturers and other stakeholders until September 12, 2026.

Manufacturers must request deeming when filing their Canadian submission and must continue to file a complete regulatory submission that complies with Canada’s *Food and Drug Regulations*, including requirements to demonstrate that the drug is safe, effective, and of high quality.

Manufacturers may request deeming through one of three pathways:

1. **General deeming** applies where a comparable FRA has already authorized the drug, but the product or indication has not yet been approved in Canada. This pathway aims to encourage manufacturers to bring additional products to the Canadian market.

2. **120-day filing** applies where a manufacturer files with Health Canada within 120 days of filing with a comparable FRA. Because the foreign review is still underway, deeming can occur only after the FRA authorizes the drug. This pathway aims to reduce delays between foreign and Canadian filings.

3. **Joint review** allows Health Canada to review a submission alongside one or more comparable FRAs and rely on portions of their review. This pathway aims to reduce duplicative work across regulators.

Deeming is available only where the submission meets the MRO's specific requirements. Among other things, the manufacturer must demonstrate that the Canadian product has the same medicinal ingredient(s), strength, dosage form, and route of administration as the foreign comparator, and that the proposed conditions of use fall within those reviewed by the FRA. The MRO permits deeming even where certain differences exist between the Canadian and foreign products, provided those differences do not negatively affect safety, efficacy, or quality.

The eligible classes of human and veterinary drugs, together with the corresponding FRAs, are set out in the list of classes of drugs and foreign regulatory authorities for the purposes of reliance on decisions or documents (the IbR List): Human Drugs under the MRO.

For new drug submissions (NDSs), Health Canada has listed 11 different drug classes that qualify for "general deeming" and a broad list of 14 drug classes that qualify for "joint review." The listed corresponding FRAs include regulators from the US, the EU, Singapore, Switzerland, Australia, and the UK. Health Canada maintains the IbR List and may update it where necessary for health or safety reasons or where it otherwise considers an update to be in the public interest.

**Prioritizing Review of Certain Generic Drug Submissions**

Alongside the MRO, Health Canada announced it is seeking feedback on a proposal to prioritize review of certain generic drug submissions involving Canadian manufacturing. According to Health Canada, strengthening Canada's generic pharmaceutical and life sciences sector will improve the resilience of the domestic drug supply and help reduce the risk of shortages.

Together, these initiatives reflect Health Canada's broader effort to modernize Canada's regulatory system and support faster access to drugs without compromising safety, efficacy, or quality. We previously discussed Canada's shift toward a modernized regulatory landscape here and the regulations Health Canada proposed to address drug and medical device shortages here.

**Implications**

These initiatives follow closely on the release of Health Canada's updated biosimilars guidance, published in May

2026. The revised biosimilar guidance, which is the first comprehensive review since 2016, reflects scientific advances, international regulatory developments, and Health Canada's experience reviewing biosimilar drug submissions over the past decade.

The MRO reflects a broader shift by Health Canada toward greater reliance on trusted foreign regulatory decisions and increased international regulatory alignment. Rather than duplicating every aspect of a scientific review that comparable regulators have already completed, Health Canada is seeking to create a framework that allows it to leverage those reviews while retaining responsibility for the final Canadian authorization decision.

For innovative pharmaceutical companies, the MRO may create opportunities to:

- Reduce regulatory duplication
- Better align global filing strategies
- Shorten Canadian review timelines where the eligibility criteria are met
- Obtain notices of compliance (its formal approval of a drug manufacturer's submission) more quickly in appropriate cases

Sponsors may increasingly consider coordinating filing strategies with designated foreign regulators to maximize the benefits of the new pathways.

At the same time, sponsors should be mindful that the MRO introduces new strategic considerations. Eligibility for deeming will depend on meeting prescribed criteria, including demonstrating sufficient alignment between the Canadian product and the foreign comparator. And, because manufacturers must still submit a complete application under the *Food and Drug Regulations*, the practical efficiencies realized under the new framework may vary by product, submission type, and reliance pathway.

As Health Canada gains experience with the MRO, the industry should expect administrative practices and expectations to continue evolving. Pharmaceutical companies should assess early whether a product may qualify for deeming and consider how the MRO may affect Canadian launch planning, global regulatory sequencing, and submission strategy.