IMDRF International Medical Device Regulators Forum

HSA Health Sciences Authority 25 YEARS AND BEYOND

30th IMDRF 2026

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Health Canada Regulatory and Policy Update

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Exploring the use of international reliance in premarket reviews

- In Fall 2025, Health Canada and the Public Health Agency of Canada published a Report on Red Tape Reduction, including a commitment to increase the use of international reliance
- Health Canada recently published a**Reliance Order for drugs**, providing the ability to rely on certain foreign regulatory authority documents or decisions in premarket reviews.


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Order Providing for Reliance on Decisions of, or Documents Produced by, Foreign Regulatory Authorities in Respect of Certain Drugs: SOR/2026-162

Canada Gazette, Part II, Volume 160, Number 14

Registration
SOR/2026-162 July 7, 2026

FOOD AND DRUGS ACT

Whereas the Minister of Health believes on reasonable grounds that the annexed Order is necessary for a safety purpose or is otherwise in the public interest;

And whereas the Minister of Health believes on reasonable grounds that, having regard to its benefits and the annexed Order is unlikely to result in unacceptable health, safety or, if applicable, environmental risks unacceptable degree of uncertainty respecting health, safety or, if applicable, environmental risks;

Therefore, the Minister of Health makes the annexed *Order Providing for Reliance on Decisions of, or Docume by, Foreign Regulatory Authorities in Respect of Certain Drugs* under section 30.06 of the *Food and Drugs A*

A similar Ministerial Order is being explored in the context of medical devices

Reliance Orders: Context, conditions, and scope

2024

***Food and Drugs Act* (FDA) Amendment**

Provides the authorityto createrelianceorders

A Reliance Order:

- Allows Health Canada to consider certain Canadian regulatory requirements as deemed based on a foreign regulator's decision or supporting information and documents.
- Can only be issued when the Minister determines that it serves a health and safety purpose or the public interest, and does not introduce unacceptable health or safety risks.
- Would be limited to specific categories of products identified in the order.

Reliance Order – proposed approach

- The Reliance Order would allow Health Canada to deem that certain regulatory requirements are met, based on the authorization of a foreign regulatory authority.
- **To use the Reliance Order, a manufacturer would need to:**
  - Submit a Canadian licence submission containing all required data and information
  - Meet the requirements of the Order and the applicable Medical Devices Regulations (MDR) requirements
  - Ensure that their medical device is within a device category that Health Canada has specified can use the Reliance Order
  - Ensure that the medical device has been authorized by a Regulatory Authority that Health Canada has determined it can rely on

Reliance Order – proposed approach

For each device category, Health Canada would have the authority tospecify:

- Foreign regulatory authorities that can be relied on
- Eligible medical devices
- Whichparts of the review can be deemed

Deeming:

Means specified Health Canada regulatory requirements are met on the basis of a decision or documents from a foreign regulatory authority that Health Canada has determined it can rely on

Reliance Order– key concepts

- The Reliance Order would not be a separate pathway, but rather a regulatory review tool within the existing Canadian licence application process.
- Class II, III and IV devices may be considered for inclusion in the scope of the Reliance Order (new licences and certain amendments).
- In order to be considered under the reliance order, there must be no substantial differences between the device in the Canadian submission and the foreign device (i.e. same device by the same manufacturer).

Only differences that do not affect safety or effectiveness would be permitted

Regulatory Requirements Continue to Apply

Requirements in the Regulations would continue to apply, such as:

- Manufacturer's licensing responsibilities (e.g. submitting amendments,annual renewal)
- Manufacturer's post-market responsibilities

The Health Minister would retain authorities such as:

- Imposing terms and conditions on the licence
- Suspending or cancelling licences

Next steps

- The policy for the medical device Reliance Order is currently under development
- A formal public consultation will be undertaken to solicit stakeholder feedback

Thank You!

Health Canada

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