

## Pharma in brief - Canada

### Health Canada proposes regulations allowing importation of drugs not yet available in Canada for an urgent public health need

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Health Canada has proposed regulations that will amend the *Food and Drug Regulations* to allow for importation of drugs that have not yet received regulatory approval from Health Canada. The new regulations will provide access to drugs that address an urgent public health need provided they have been approved in the United States, the European Union, or Switzerland. "Urgent public health need" is not a defined term in the regulations, but Health Canada identified treatment of opioid use disorder as a current example of an urgent need.

This scheme does not replace existing programs that provide access to drugs that have not received regulatory approval, such as the Special Access Programme or a Clinical Trial Application. Unlike those programs, the new regulations will only allow importation after a public health official notifies the minister of an urgent public health need for the drug.

While importation and sale of these drugs will be exempt from many aspects of the *Food and Drug Regulations*, certain reporting and record-keeping obligations will be imposed. Further, healthcare institutions will be required to report serious adverse events to Health Canada. This is the first time regulations have required adverse event reporting by healthcare institutions. The authority to do so comes from not-yet-in-force provisions of the *Protecting Canadians from Unsafe Drugs Act [Vanessa's Law]*.

The proposed regulations will not come into force until the necessary provisions in *Vanessa's Law* are in force. In the meantime, Health Canada is taking preparatory steps, including developing guidance and canvassing public health officials to populate an initial list of drugs.

#### Link:

The proposed regulations and Regulatory Impact Analysis Statement can be found [here](#).

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For more information, please contact your IP/Life sciences or healthcare practice professional at Norton Rose Fulbright Canada LLP.

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