

ada has also systematically assessed the strengths and weaknesses of and gaps in the current regulatory framework. In spring 2006, Health Canada opened the process and sought the early inclusion of decision-makers such as the provinces and territories, health care professionals, industry and patients by inviting them to participate in ongoing discussions and workshops.

A number of common themes have emerged from the research and consultations to date. There is agreement that the new framework should be focused on patients and that drug safety should remain a paramount concern at the federal level. There is also agreement that a drug's benefits and risks should be assessed throughout its life cycle. Furthermore, any changes to the system should eliminate duplication and inefficiency in data collection and in communication of information about drug benefits and risks.

Areas that will merit extensive exploration include the evidence required to initially license a drug for market, especially for those that meet a previously unmet medical need and are therefore desired quickly by patients, or for drugs that present challenges in the collection of initial data, such as a drug for a very small target population.

In developing the Progressive Licensing Framework, Health Canada will continue to include decision-makers such as the provinces and territories, industry, health care professionals and patients to ensure that the resulting system is one that will benefit all Canadians. Discussions are expected to narrow into a practical assessment of the proposed regulatory structure and will include legal authorities. This assessment will include an analysis of how these potential changes will affect the health care system. Feedback was sought through workshops held in May and June of 2007; other meetings will continue through

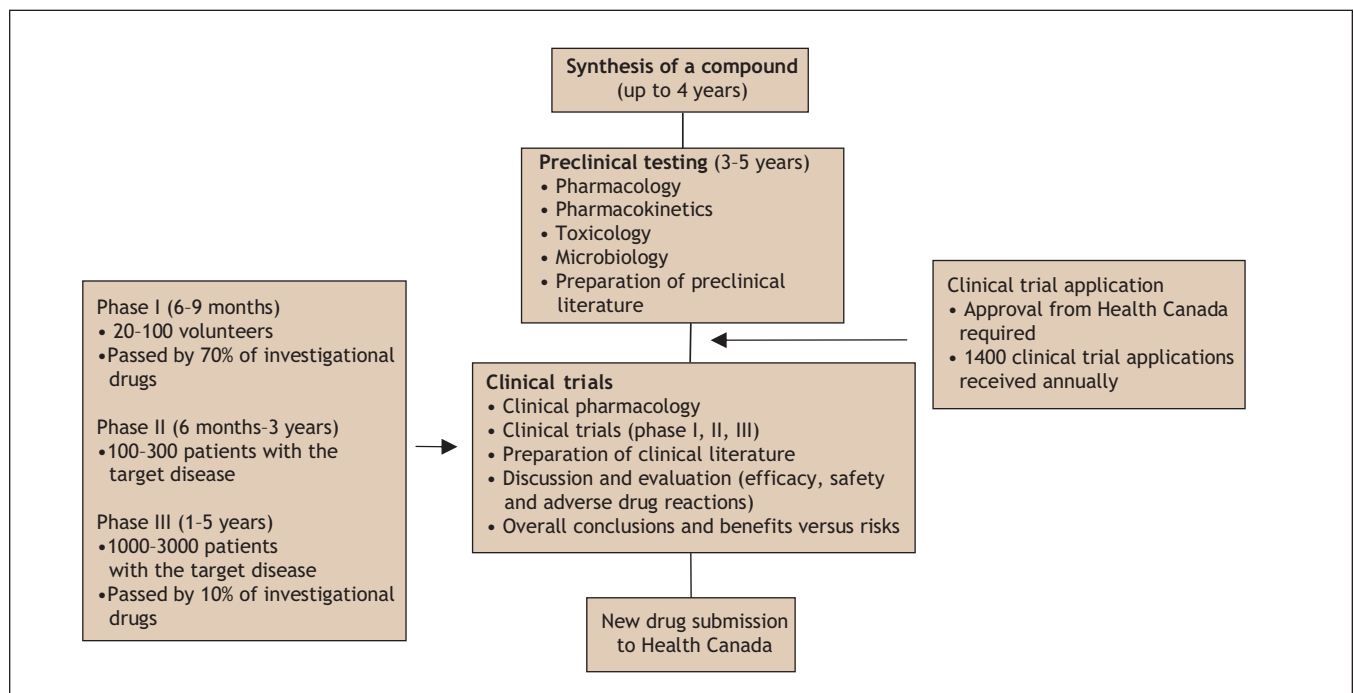


Fig. 2: The current drug development and regulatory process in Canada.

Table 1: Features of pre- and postmarket drug assessment in the United States and the European Union

Jurisdiction and agency	Premarket features	Postmarket features
United States • Food and Drug Administration (FDA)	<ul style="list-style-type: none"> Assesses drug safety and efficacy Fast-tracks the approval process for drugs that address an unmet medical need Accelerates approval on the basis of surrogate end points 	<ul style="list-style-type: none"> Provides guidance documents for industry about pharmacovigilance and risk management Encourages (but does not require) the use of plans for risk minimization for certain drugs Recent passage of the Enzi-Kennedy bill in the US Senate may result in new FDA authority over postmarket activities
European Union • European Medicines Agency	<ul style="list-style-type: none"> Bases drug approval on a favourable benefit-risk balance Has processes in place for accelerated approval Permits conditional market authorization for drugs that address an unmet medical need 	<ul style="list-style-type: none"> Requires risk management plans, including pharmacovigilance, for all new drugs Requires manufacturers to employ a person qualified in pharmacovigilance

fall 2007. Comments can also be submitted through the Progressive Licensing Web site until the end of August 2007. A formal consultation phase will be initiated after prepublication of the regulations, anticipated to occur in 2008.

The experience and views of physicians and other health care professionals are critical in helping create a framework that will support them in formulating benefit–risk assessments and in providing their patients with the best care possible. To ensure that the new system of drug regulation is patient-centred and supports the optimal use of drugs by maximizing the benefits and minimizing the risks, Health Canada welcomes your feedback. For more information about the Progressive Licensing Framework, please visit www.healthcanada.gc.ca/progressive_licensing.

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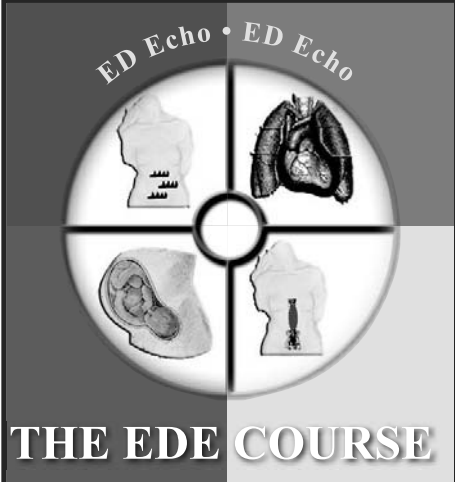
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