The Drug Review & Approval Process in Canada

INFOGRAPHIC

How are drugs developed, reviewed and authorized to be sold in Canada?

Sponsors of drugs to be sold in Canada, need to be authorized by Health Canada. The average time of the full drug development and approval process is between 8 & 15 years. The stages presented below, navigated with the support of a regulatory expert, can turn a seemingly complex, intimidating & long journey into a more manageable and predictable one.

3 - 6 years

STAGE 1: RESEARCH & DISCOVERY

Research and testing of new drugs usually start in the laboratory where various compounds are developed and tested to identify those that show more promise for a new treatment. Exceptions apply.

What can a regulatory expert help with at this stage?

Ensures that the planned development of the drug follows international requirements.

STAGE 2: PRE-CLINICAL RESEARCH

Researchers administer compounds to selected species of animals (in vivo) or cells (in vitro). If results show acceptable safety levels and clear or potential efficacy, then the next step would be to submit a Clinical Trial Application to Health Canada for authorization to allow human participation in a Canadian clinical trial.

What can a regulatory expert help with at this stage?

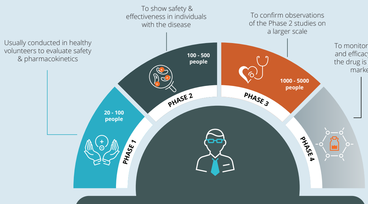
Ensures that the pre-clinical and the quality (CMC) development program meets local and international requirements prior to a first in man study

6 - 7 years

STAGE 3: CLINICAL TRIALS

A Clinical Trial Application (CTA) must be submitted to Health Canada by the sponsor for clinical trials to be conducted on Canadians. A "No Objection" decision by Health Canada is needed before a trial can begin. Other requirements also apply.

There are 4 phases to a Clinical Trial:



What can a regulatory expert help with at this stage?

Ensures that both local and international require-ments are met, coordinates Pre-CTA meetings with and CTA submissions to Health Authorities, medical and regulatory writings, QA & review submission documents for local and global compliance. Offers similar services for the EU and FDA clinical trial initiatives.

6 months - 2 years

STAGE 4: REGULATORY PROCESS & APPROVAL

Once all relevant development stages are completed, the scientific data is documented and a new Drug Submission (NDS) may be prepared and submitted by the sponsor to Health Canada for regular or fast-track review. If the benefit/risk profile of a drug is favoura-ble, Health Canada may authorize the drug to be sold in Canada. Other verifications include:

PRE-SUBMISSION MEETING
It may be relevant to schedule a meeting with Health Canada before submitting an NDS. There may be pending questions or concerns regarding the data or when seeking a fast-track review.

IDENTIFICATION OF A CANADIAN IMPORTER/DISTRIBUTOR
Health Canada oversees how a drug is manufactured as well as how it is imported and distributed. A Drug Establishment License identifying all manufacturing sites, including Canadian sites must be submitted to Health Canada prior to the NDS submission.

SOME LABELLING & MARKETING CONSIDERATIONS
A complete or partial brand name analysis may need to be performed for the proposed brand name. Also, Health Canada oversees the drug's labelling content to ensure proper and accurate communication to Health Care Professionals and to the Public.

HEALTH CANADA'S DECISION
Health Canada reviews all data sent to them, including if the drug complies to the Food and Drug Act and its Regulations. Questions may also be raised with as-signed standard delays given by Health Canada for receiving responses. The evaluation process typically takes 6 months to 2 years, rarely longer.
The possible outcomes are summarized as follows:

In general, there are 4 possible outcomes:

The Notice of Compliance is the ultimate goal. A unique Drug Identification Number (DIN) will also be assigned to the drug throughout its lifetime.

What can a regulatory expert help with at this stage?

Provides vital support and knowledge during each step of this stage. Assists sponsors in successfully navigating submission preparation, identifies potential concerns ahead of submission time & proactively finds solutions. Efficiently interfaces with health authorities and making the regulatory process more predictable until drug approval.

STAGE 5: COMPLIMENTARY INITIATIVES

Other initiatives to consider in parallel to the Stage 4 are provincial reimbursement initiatives, pricing, product launch with the related marketing tools and training events planning.

What can a regulatory expert help with at this stage?

Prepares provincial reimbursement submissions and supports sponsors with reimbursement negotiations with decision makers. Reviews marketing material and advertisement initiatives for compliance with the Food and Drug regulations and PAAB Code. Liaison between PAAB decision makers and sponsor.

Lifetime of Drug

STAGE 6: AFTER APPROVAL

Getting an approval and Notice of Compliance from Health Canada isn't the last step in the process of selling and marketing the drug in Canada. Sponsors have further processes and regulations to consider and follow to ensure its continued compliance. Including:

- Pharmacovigilance: Monitor ongoing drug safety and provide updates to health Canada
- Lifecycle management regulatory activities to support the continued drug development / improvements
- Lot release (biologics)
- Commitments to the NOC

Health Canada continues to monitor all drugs for safety once products are available to the public.

What can a regulatory expert help with at this stage?

Remains the point of contact with Health Canada, evaluates the reportability of pharmacovigilance activi-ties in compliance with Canadian regulations, evaluates the type of post-approval variations and documents required, prepares and coordinates all post approval submissions to Health Canada, coordinates telecoms or face to face meetings with Health Canada when needed.

A skilled regulatory expert will help sponsors navigate the drug approval process in Canada, facilitate compliance and timeliness, and advocate for their client in all phases of development.

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