Launching a New Drug in Canada: Q&A for Entrant Companies

Ravi Deshpande
PharmD,
Vice-President
McKesson Specialty
Pharmaceutical
Solutions

Dale Weil
Vice-President and
General Manager,
Pharmaceutical
Solutions
McKesson Canada

Development of pharmaceuticals by small, research-based organizations is increasing. Unlike multi-national firms, such companies need to find a strategy to develop the infrastructure and resources needed to launch a drug in Canada. Specifically, smaller organizations have the following challenges:

- The company infrastructure and expertise is based on clinical knowledge and research rather than drug manufacturing, distribution and marketing
- If based outside Canada, the company may not have operations outside the home country
- Their product may be a specialized one, with a small target group of physicians and patients; it may have advanced reimbursement and economic data requirements to obtain coverage
- It may be the sole product for the company

While a detailed discussion of all the aspects of commercialization is beyond the scope of this article, a few relevant questions and answers are provided below.

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Licence to market

Who approves drugs in Canada?

Health Canada, an agency of the Canadian federal government reviews New Drug Submissions (NDSs) and provides, upon approval, a Notice of Compliance (NOC) to market the product. Different types of NOCs correspond to restrictions on marketing that may be imposed.

What factors should a new entrant into Canada consider when submitting an NDS?

Companies without infrastructure in Canada need to establish a Canadian entity in order to file an NDS. For some drugs, there may be pressure to make the drug available prior to approval—Health Canada provides two ways to accomplish this, the Special Access Program (SAP) or through filing of a Clinical Trial Application (CTA), similar to filing a US Investigational New Drug (IND).

Distribution

What are the requirements to distribute a pharmaceutical product in Canada?

A company must have:
- an "establishment license,"
- a licensing or distribution agreement with an existing manufacturer, or
- an "agency agreement" with a logistics provider who will carry out importation, quarantine and release on its behalf.

How will patients access the product?

If medication is to be used in an acute care setting, establishing a distribution network to hospitals is needed. If it is prescribed by physicians and requires general availability at retail pharmacies, it needs a broad distribution network. A more specialized medication with a very small patient population and/or control on patient use may necessitate a customized distribution approach through a small number of specialized pharmacies.

What are the various distribution models available?

A pharmaceutical manufacturer can deliver directly to either hospital or to retail pharmacies. In Canada, almost 90% of the market is consolidated through the wholesale channel, whereby pharmacies enjoy a "one stop shop" benefit. In either case, a third party logistics provider or the manufacturer's own logistics assets may be used to ship to wholesalers or directly to pharmacies. In the case of highly specialized, more restricted distribution models, a manufacturer may consider using an exclusive wholesaler and specialized pharmacy group.

How do I choose a distribution model?

A number of factors should be considered. Your own infrastructure or planned infrastructure in Canada or licensing agreements will determine your need for a logistics provider. The therapeutic area and number of target patients, as well as specific requirements of your molecule will direct the choice of the best distribution model. Regulatory and other requirements for the control of your product or its pricing are also important elements.

Reimbursement

Who pays for drugs in Canada?

Reimbursement of your product is perhaps the biggest single hurdle after you have received NOC. Canada has 10 provinces which individually make decisions on whether your drug will be funded. In addition, numerous private payers (*i.e.*, insurers, pharmacy benefit managers) will also individually decide whether to cover your drug. About 40% of all drug funding originates with provincial health ministries, while private drug plans cover about 40% of patients. Cash payers make up the rest.

How do I get my drug covered?

Canada has a highly developed system of review for products that seek public funding. The Common Drug Review is a federal agency which reviews many new drugs and makes recommendations on whether a drug should be covered, but does not pay for any drugs—individual decisions to reimburse are left to each province. Depending on the drug, provincial drug plans or special provincial disease agencies (*e.g.*, HIV, cancer) require reimbursement submissions to make final funding decisions.

Private plans are similar to US private payers, but in general, Canadian private payers are less developed in their policies and restrictions.

Submissions must be made to each of these payers. A complete dossier, which includes clinical, budget impact and economic data, about your drug is required.

How long will coverage take?

Generally, public payers will not be reimbursing your drug for a period that can last up to 24 months. A period of at least 12 months should be expected.

Pricing

Will my price be controlled in Canada?

If you are selling a drug which is patented, or a generic drug which is covered by a provincial formulary, the answer is yes. In the former

case, a pricing submission to the Patented Medicines Pricing Review Board is needed. The submission will contain, among other things, a description of the clinical characteristics of the drug and its likely comparators (whether indicated for the condition or not). The eventual maximum allowed price will depend on how the drug is classified and possibly the price in markets outside Canada.

Sales and marketing plan

Canada's > 50,000 physicians are comprised of fewer specialists and more family physicians than in the US. All physicians in Canada receive payments from their provincial government for providing services and cannot accept other payments for those services deemed medically necessary.

Marketing drugs, in particular specialty drugs, is a process of working with the small cohort of specialists who will influence and direct the use of your product. Physician practices have different incentives for performing procedures or providing infusions in comparison to the US. This may result in a different sales, marketing and distribution strategy for your product in Canada.

All the above questions highlight the complex nature of launching a new product in Canada. If you are launching in Canada for the first time, contact Ravi Deshpande at 1 (800) 811-9880 ext. 102 or rdeshpande@phase4health.com to discuss your strategy. CPM

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