A Quick Trip To The Market

Ten Simple Steps to Hasten Approval Times For New Drugs in Canada

Anne Tomalin, president of the regulatory affairs consulting company, CanReg, summarizes ten simple ways to reduce your drug's time to market.

Gaining market access is key to the life of a pharmaceutical company. Knowing how to do it well, and get approvals quickly, is a strong competitive advantage. Faster approvals mean longer patent life and longer market access without competing with a generic product. How is it possible to improve the time to approval for new drug submissions in Canada?

It goes without saying that, unless the data is available, no matter how you strategize or prepare, the submission will not be successful. The best way to improve time to approval is to file complete submissions based on well-planned scientific studies with clear statistical evidence of efficacy and safety. Having said that, however, there are the other things that one can do to improve the time to approval for submissions.

1. File an IND

One of the first things a company should do for an important compound, is file an investigational new drug submission (IND) and conduct as many clinical trials in Canada as possible. This provides a number of advantages that can help the drug. First, you will meet with the Therapeutic Products Program (TPP) or the Bureau of Biologics and Radiopharmaceutics (BBR) to discuss your protocol in a pre-IND meeting. The probability is that the future reviewer of your submission will be there. You can begin to understand how the individuals who will be responsible for approving your compound view this therapeutic area in general and your compound in particular. For example, it is helpful to know that in order for an oncology drug to be approved, strong quality-of-life data will be looked for. At the same time, you can begin to inform them about your drug. You can begin to build relationships.

Filing an IND means that Canadian investigators are working with your drug. They may later be helpful in advising TPP/BBR or even the provincial governments. Having experience with your drug in Canada will be helpful in presenting the case that your drug has value for the Canadian market.

2. Consider a Priority Review

Anne Tomalin
Background

Anne Tomalin, BA, BSc, President of CanReg Inc., has practised exclusively in the area of regulatory affairs in Canada since 1971. In that time, she has worked with three international pharmaceutical companies to obtain registrations for prescription pharmaceuticals, OTCs and medical devices. Anne founded CanReg Inc., a regulatory affairs consulting company, in September 1996. Four years later, CanReg has 27 full time employees, and is one of the most successful regulatory consulting firms in Canada.

Prior to founding CanReg, Anne was employed for 20 years with Searle Canada, a unit of Monsanto Canada Inc., as a business unit Director. Responsibilities in the last several years at Searle included regulatory affairs, provincial government, reimbursement strategies, managed care, customer interface, legal and information services. Before joining Searle, Anne was employed by Hoffmann-LaRoche Limited for three years, and, prior to that, Anne was employed by Wyeth Ltd.

Anne has participated in the Regulatory Initiatives Advisory Committee for the Pharmaceutical Manufacturers Association of Canada, and also has chaired the Manitoba, Saskatchewan and Ontario committees for this association. Anne is a graduate of York University, and holds a BA in English and a BSc in Chemistry.

Anne has authored chapters in *Time To Market*, issued by IMS Health in 1997, and *New Product Launch* in 1999. She also has contributed to a number of other IMS publications over the past three years. In March 2000, she published an article on prescription-to-OTC switches in the RAPs Journal in Washington.

The target review time for a priority submission is 180 days as compared to 300 days for a non-priority submission. Performance data confirm that priority drugs are approved in about half the time of non-priority drugs. If you can achieve a priority status for your drug, do so. Priority status at TPP/BBR can be helpful later with provincial formularies.

3. File Simultaneously With Your Head Office

Submissions are frequently filed six or nine months later in Canada than they are in the United States. This is six or nine months of dead time that is completely in the hands of the company. If there are capacity problems to getting the job done faster, outsource it or hire contract personnel. Filing simultaneously with your head office will require that you have built strong and close relationships with these individuals so that you can develop the New Drug Submission (NDS) as they are developing their New Drug Application (NDA) in the United States or Marketing Application (MA) in Europe.

4. Consider a Computer-Assisted NDS

In some reviewing groups at TPP, more than 50% of the reviewers work off-site. They will not take the submission with them (all 350 volumes!). Instead, they will take the comprehensive summary and the summary volume and try to do the review with that. Having the submission on CD-ROM means that these reviewers can easily take the whole submission with them to review. Using a computer-assisted NDS means that you will need to meet with the reviewer to show him/her how to use it. You will need to interface with them when they have questions. This facilitates a closer working relationship with the reviewer than a paper NDS would.

5. Use International Reviews

Canada has a high degree of respect for reviews done by the United States., Sweden, and Australia. If you can get reviews from these countries, use them. If these countries have reviewed and approved your drug, using their review in Canada may save a significant amount of time.

6. Retain Outside Experts to Review Your

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Submission

Chemistry and manufacturing reviews and issues commonly delay the issuance of a notice of compliance (NOC). There are a number of strong chemistry and manufacturing reviewers who have left TPP/BBR recently and are working as consultants. Having your submission reviewed by one of these people, and providing the report to TPP, may help avoid problems in the submission itself, and reduce the review time at TPP.

Similarly, companies now frequently have an outside review of their submission done and submit the review with the submission. The review can be done in sections as the NDS is being compiled. Questions that are raised during these reviews can be answered. It is necessary to have TPP/BBR agreement to proceed in this manner, but it can save a great deal of time.

7. Answer Questions Quickly

If you receive a clarifax, you will have about 15 days to respond. For a Notice of Deficiency or Noncompliance, you will have 90 days to respond. If you are able to respond faster, it will help the submission move forward more quickly.

8. Improve Your Dialogue with TPP

Make use of pre-IND meetings and pre-NDS meetings to get to know the individuals and what they are expecting. Once you know who is reviewing your submission, find out about them. Do a Medline search and see what they have published. See if they are a practicing physician in Canada. Review the TPP Web site to see if there are guidelines or other documents that they have authored. Work with trade associations to build relationships with these individuals outside of the submission process. Always be honest and open. Don't let them find out about issues with your drug from trade journals or other companies.

9. Plan Ahead

State publicly and in writing when you will file. Have the staff in place. Have a working plan for how it will come together. Communicate vertically and horizontally. Take pride in making the date that is targeted. Put bonuses in place for making target, and bigger bonuses for exceeding target. Have a communication plan for after the submission has been accepted for review. Follow through with it. Keep everyone informed of what is happening. Challenge conventional thinking. Listen to alternative ideas about how to move forward.

10. Celebrate

When the NOC comes through, celebrate. Involve your regulatory affairs department – don't let them stand aside at a distance and celebrate on their own. Involve the company in the submission process and the regulatory affairs group in the launch of the drug when it occurs.

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For more information on CanReg and its services, please contact Anne Tomalin at (905) 689-3980 ext. 221 or atomalin@canreg.on.ca.