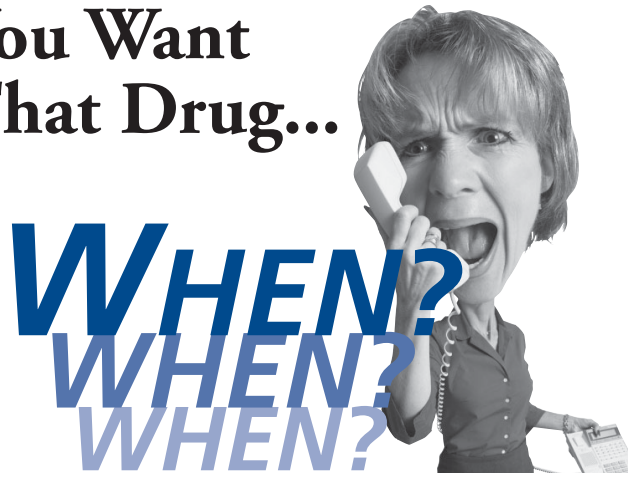
You Want That Drug...



by Brian Huskins

Mentoring, while sometimes a challenge in a country as geographically large as Canada, is a critical component of ensuring a vibrant advocates community within the HIV/AIDS movement

Over the years, knowing about the developmental progress and availability of new pharmaceutical drugs to treat HIV/AIDS has been a source of hope for many. Just back a few years during the difficult days, when so many people were dying, the news that a new drug was on its way was the only hope that many people had. In some ways, being involved and tracking the research, development and approval of new pharmaceuticals was the advocates' way of interpreting and sharing that hope with communities who were often paralyzed by grief.

This dynamic has led to the development of a culture within the HIV/AIDS movement that is unique and involves the mentoring and participation of those most impacted by the drug approval and accessibility process: people living with HIV/AIDS. This legacy continues today as people living with HIV/AIDS continue to be at the forefront in changing public policy to ensure that the barriers to approving and accessing new pharmaceuticals are removed.

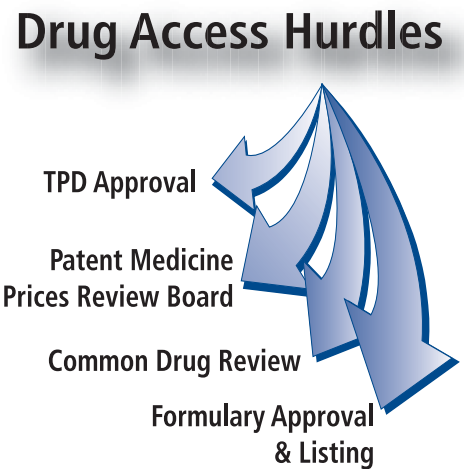
Mentoring, while sometimes a challenge in a country as geographically large as Canada, is a critical component of ensuring a vibrant advocates community within the HIV/AIDS movement. Louise Binder of CTAC and I presented a workshop at the CATIE Educational Conference held in Ottawa this past June. One of our goals was to mentor and assist participants in better understanding the process of how pharmaceutical drugs come to market in Canada.

In this workshop we reviewed the process of how drugs are approved and become available to people living with HIV/AIDS in Canada. By examining case studies that illustrated the complexity and delays within the system, individuals were encouraged to identify ways to become involved in advocating for improvements in our system. Those who attended the two-hour session were extremely pleased and felt that more people should know about these issues.

Hurdles

A number of hurdles must be overcome in the journey of a new pharmaceutical drug from clinical trial to being available to those who need them in Canada. One consistent part of much of the drug approval process is a Health Canada department called the Therapeutic Products Directorate (TPD).

Once a significant amount of background scientific work has been completed to compile data and the drug has shown promise in the test tubes and animals, a drug manufacturer submits an Investigational New Drug Submission for approval to run a clinical trial on people.



The clinical trials process serves a number of purposes, namely, to establish the efficacy, dosing, safety, quality and risk/benefit of the drug. These results must be reviewed by the TPD to ensure that the data submitted by the manufacturer supports the claims made about how the drug works. In Canada, this is a time-consuming and sometimes lengthy process.

Generally, the TPD targeted time for drug review has been 355 days. This target is still 30%-60% longer than other developed countries. In 2000, the Canadian average was over 700 days for approval! Most HIV/AIDS drugs have been granted Priority Review status. Priority Review is the process of fast-tracking the review of a

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new drug submission because it is intended for the treatment of a serious, life-threatening or severely debilitating disease or condition.

Once the hurdles of approval have been surmounted, it does not mean that you can automatically access a new drug. Someone has to pay for the drug. For those who have private insurance or can afford to personally pay for the drug, the approved drug is available to you once your doctor prescribes it.

Drug Plans

Approximately 35% of Canadians depend on drug coverage through provincial or federal drug plans. If your drugs are paid for by one of these plans, the regulator of the plan must agree to pay for the new drug and list it on what is referred to as the "formulary".

In Canada there are at least 18 different drug plans, each with its own formulary. It is important to know which one applies to you. This is the next hurdle to accessing a drug once approved.

Average Days to Listing
1995-2000 (Provinces Only)

Province	Days
British Columbia	330
Alberta	358
Saskatchewan	406
Manitoba	362
Ontario	480
Quebec	351
New Brunswick	540
Nova Scotia	395
PEI	783
Newfoundland & Labrador	504

Each plan has its own approval system and schedule. For some idea on the variance, see the list on the left; bear in mind this applies only to those drugs that were listed on the formulary. It says nothing about those that were not!

This means that a person in one province may not be able to access a drug available to someone with the same condition in another province because of different formularies. Or even that two people in the same province who are covered by different plans may not be able to access the same drug for the same condition!

Improvements... or more obstacles?

While there have been improvements to some of the timelines, they have not been significant and, indeed, have been made more complex by some attempts to improve the system!

One of the new improvements to the system is the Common Drug Review (CDR). However, it is also one of the new hurdles in the process. In an attempt to coordinate and expedite the process of listing a drug on the formulary, the Federal Government put in place the CDR. While a great idea on paper, some provinces are not a part of the CDR and this has only solved the issue for federally governed drug plans. Moreover, all provinces have kept their existing approval systems which do nothing to reduce timeframes. An approval for listing by the CDR does not mean a listing in a province; it means the province will look at the drug for formulary inclusion. A denial by CDR means that it won't be looked at by any province. (For more information on CDR, see the article in the October 2003 issue of the CTAC newsletter at http://www.ctac.ca/english/pdf/newsletter_1003.pdf.)

One other obstacle which can be faced at any point in this process is the Patented Medicine Prices Review Board (PMPRB). This is the group which approves the price for any patented drug which comes to market in Canada. While normally a process which happens behind the scene with impact only on the price of these drugs (hence, lower prices in Canada because of a central control), there have been circumstances recently where this has been a problem.

Conclusion

The issues of "You want that drug...When?" are complex and cannot all be explained in one article. Continuous education and information sessions are a critical component of building the skills and knowledge so that people living with HIV can become involved in advocating for changes in the current system. That certainly is one of CTAC's key goals and CATIE will continue to work with them in partnership to make this happen.

For a better understanding of these issues check out these documents on the CTAC Web site:

Timeliness and Transparency: Assessing the Review Process for HIV Drugs
http://www.ctac.ca/english/pdf/paper_timelines.pdf

Making Treatments Accessible: Determining Appropriate Pricing for Brand-Name Pharmaceutical Treatments for HIV/AIDS in Canada
http://www.ctac.ca/english/pdf/paper_drug_pricing.pdf ■