

Canadian Drug Approval and Reimbursement System

Why you can't (usually) get what you need

Case Study

A patient is diagnosed with pNET.

He/she asks the doctor: “Is there a treatment I can take?”

The doctor replies “Yes and no. “

“What do you mean?” he/she asks with surprise. “I thought all drugs were available once they made it through clinical trials.”

The doctor shakes his/her head side to side with a sigh.

“ Not at all. Fortunately, a few for your disease have made it through the complex and lengthy approval steps.”

“ What holds up access to available drugs across Canada?” the patient asks

Choose the best answer:

- 1.The manufacturer has not applied to Health Canada to sell it
2. Health Canada has not approved it as safe and efficacious for Canadians.
3. The Health Technology Assessment (HTA) process has not found it to be of sufficient “value“ to recommend reimbursement by the provinces/ territories on public drug plans
- 4.The provinces have not negotiated a price with the manufacturer they find acceptable
5. Ontario decides it cannot afford to list it on the public reimbursement plan
6. Your private insurer does not cover it
7. You cannot afford the Trillium co-pay for the drug
- 8.Any or all of the above

Question : Why is Canada's drug approval and reimbursement process like a camel ?

Answer : Because it is a horse built by several committees over many years and by different governments.

Health Canada

- Considers clinical evidence from clinical trials to decide if a drug is safe and effective for sale
- If so, the manufacturer can sell
- Your role in this process: formally none
- Informally : support CNETS Canada's role in intervening through meeting with Health Canada and if necessary politicians

Coordinating Agency For Drugs and Technologies for Health (CADTH)

- Considers clinical evidence, economic impact and lastly patient evidence
- Decides if the drug is of “value” to the public and to the health care system
- If yes, recommends to the provinces/territories to list on public reimbursement plans, with or without conditions
- Note: Cancer drugs are reviewed by an organization, the pan-Canadian Oncology Drug Review (pCODR), that is being integrated into CADTH as one of its programmes by April 1, 2015

Warning:

This may mean :

- fewer oncology drugs will be recommended,
- the review process will be slower
- clinical reviews by site specific tumour experts may not continue and/or
- patient input will have less influence than it does now

Your role:

CNETS Canada puts in a submission with all patient information it receives when a new NET drug is under review by pCODR

You are asked to provide information about experience with the drug that CNETS Canada can use in its submission

CNETS Canada is also monitoring the PCODR transfer to CADTH and will seek your help if problems arise for oncology patients in the process

Pan-Canadian Pharmaceutical Alliance

- Provincial/territorial coalition
- Negotiates behind close doors with the manufacturers to find an acceptable price
- Problems: No one gets access to the drug while negotiations are ongoing
 - : there is no time limit for negotiations
 - : Provinces may still decide they cannot afford to pay for the drug through the drug budget

How To Get What You Need –At Least Sometimes

Your role:

- Support CNETS Canada's advocacy for:
- a formal framework for these negotiations with metrics for each step and for the whole process
- access to the drugs during negotiations for those in need paid for by the negotiating parties

Advocacy in Action

The Canadian system works on the squeaky wheel process

Advocacy is the tool for squeaking

Definition: The act of pleading for, supporting, or recommending a cause or course of action

It can be individual, group or systemic

Components of an Advocacy Campaign

1. Understand the issue and get all the facts
2. Understand for whom you are advocating and what they want eg yourself, another person, a group or an organization

NOTE :Principles are advocacy require that you ask for only what the individual/group wants, not what the advocate wants for them

Components (continued)

3(a). Identify:

- decision makers
- allies and potential allies
- detractors/opponents
- influencers

3(b) Understand their motives/reasoning are

4. Identify potential role of, and timing for, media involvement

Components (continued)

5. Develop strategies, public and private
eg. letters, meetings, public education

6. Implement these strategies

Components (continued)

7. Evaluate success of strategies eg.

- did you achieve your goals
- was the person/ group for whom you are advocating satisfied
- were the strategies right
- did you stick to the principles of advocacy

Components (continued)

8. Start again if need be
 - go back to 1 and work through the process again

This is a marathon, not a sprint

How To Get What You Need – At Least Sometimes

1. Support CNETS Canada
2. Meet politicians and bureaucrats
3. Tell others the problems with the system
4. Get support from others for your advocacy
5. Learn about your disease, treatments and become your own advocate
6. Don't give up - this is marathon, not a sprint