The Drug Approval Process in Canada

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Saturday, April 26, 2014

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Overview

- Process
- Drug approvals
- Pricing
- Common Drug Review
- Listings (QC)

Process

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- Public drug formularies are impacted by federal, provincial and national policies
- Manufacturer submits to Health Canada for approval
- Common Drug Review (CDR) reviews new drugs (non-oncology) and makes reimbursement **recommendations**
- Provinces also review new drugs and make reimbursement **decisions**

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Drug Approvals

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- Submissions for approval are to the Therapeutic Products Directorate of Health Canada
- Reviewed and assessed for safety, efficacy and quality
- Issued a Notice of Compliance (NOC) or Notice of Compliance with Conditions (NOCc)

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Pricing

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- In Canada, we have regulated prices for patented or brand name drugs
- Mission – contribute to Canadian health care by ensuring that prices of patented medicines are not excessive
- Also report on price trends of all medicines and R&D conducted by patentees
- Annual Report 2012 – Canadian prices were the fourth highest among the seven comparator countries, lower than prices in Switzerland, Germany and the US.

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Common Drug Review

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- Review process within The Canadian Agency for Drugs and Technologies in Health (CADTH)
- Quebec drug plan does not participate
- Recommendations are made by the Canadian Drug Expert Committee (CDEC) based on:
  - Clinical studies, which assess efficacy and safety
  - Therapeutic advantages vs. current therapies
  - Cost effectiveness vs. current therapies

Common Drug Review – 2013

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- 37 recommendations issued in 2013:
  - 10 – Do not list
  - 3 – Do not list at submitted price
  - 24 – List with criteria/conditions
  - 0 - List

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Common Drug Review – Patient Input

- New patient input process in place as of May 13, 2010
- Patient evidence submissions will be accepted from patient groups directly to the CDEC
- There had never before been a process to allow this kind of direct engagement between the members of the CDEC and the public
- Having said that, the process and guidelines around submissions are very narrow

Listings

- Provinces and territories have (and will continue to have) the final word on whether a medication is publicly funded
- Federal government does the same with their six public formularies (i.e. Non-Insured Health Benefit Program for Canadian First Nations and Inuit people, veterans, Canadian Forces members, designated migrants, RCMP and Correctional Service Canada)
- 19 different public formularies, each with their own review and decision-making processes

Listings - Quebec

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- Submission process to the Institut national d-excellence en sante et en services sociaux (INESSS) takes about six months to complete
- Drug manufacturer submits a registration application to INESSS within specified deadlines
- If in order, the drug product is added to INESSS's work plan and posted on their website
- During the 30-day posting period, professional and consumer groups are invited to send their feedback on the drug under review

Listings - Quebec

- Applications are then reviewed by INESSS and the scientific registration committee
- The committee issues a report to the INESSS Board of Directors, which ratifies the recommendations that are made to the Minister of Health
- The Minister then approves or rejects the recommendations of INESSS and the *List of Medications* are updated accordingly

Listings - Quebec

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- The *List of Medications* contains some exceptional medications for which coverage is provided under certain conditions:
  - When a drug product is considered effective for limited indications, since its effectiveness or the cost of treatment cannot justify its regular and continued use for other indications;
  - When a drug product does not provide a therapeutic advantage that would justify its higher cost compared to other products on the list that possess the same pharmacotherapeutic properties, but when those drugs are not tolerated, are contra-indicated or have been rendered ineffective for a patient's clinical condition.

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