The Drug Approval Process in Canada

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Overview

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

• 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
Drug Approvals

• 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)
Pricing

• 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.
Common Drug Review

• 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

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

• Submission process to the Institut national d'excellence en santé 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

• 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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