Weighing the Evidence

Canada

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Drugs in Canada

- Federal government has regulatory responsibilities, but delivery of health care largely provincial/territorial
- In-patient drugs covered by hospital global budget
- Out-patient drugs publicly reimbursed if they are on a formulary and patients are eligible (eg >65) – 46%
- Many patients not eligible for public reimbursement of drugs have private coverage – 34%
- Maximum price established nationally, based upon median price in seven other countries
- Very little price negotiation

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Reimbursement Committees

- A number of provincial committees, and one new national committee (Canadian Expert Drug Advisory Committee – www.ccohta.ca - CDR)
- All make recommendations based upon a review of the drug's cost-effectiveness
- Recommendations can be general listing, limited listing, or no listing
- Patients can obtain any drug not on the list if they pay for it

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Common Drug Review

- Common Drug Review (CDR) - "… a single process for reviewing new drugs and providing formulary listing recommendations to participating publicly funded federal, provincial and territorial drug benefit plans…."
- Funded by provincial, territorial and federal governments
- It consists of a systematic review of the available clinical evidence and a review of pharmacoeconomic data; and a listing recommendation made by the independent Canadian Expert Drug Advisory Committee (CEDAC)
- Drug programs may accept or reject recommendation

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CDR process

- Drug company submits information about effectiveness and cost-effectiveness
- Independent clinical and economic experts review the submission, with subsequent comments from company
- Canadian Expert Drug Assessment Committee (CEDAC) reviews material monthly and makes recommendation on the basis of cost-effectiveness (general benefit, limited listing, do no list)
- CEDAC – 11 members (8 MDs, 3 pharmacists)

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CDR Process - 2

- Drug companies may appeal - CEDAC considers appeal at next meeting. CEDAC decision is then final.
- Can resubmit if new information becomes available
- Average time from submission to “positive” decision – 5 months
- CEDAC recommendations publicly available (www.ccohta.ca)
- 9 “yes”, 13 “No”

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Perspectives - CEDAC

- In general, process has worked well
- Not easy to find methodologically sophisticated, clinically savvy, unbiased reviewers willing to work to tight timelines
- Concerns about possibility of unknown unpublished data, and not being allowed to comment on known unpublished data

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Perspectives – CEDAC 2

- Tension between making promising drugs available quickly and real-world cost-effectiveness (surrogate markers)
- Disappointment that some jurisdictions taking a long time to make a decision about recommendations
- Concerns about potential blurring between cost-effectiveness recommendation (CEDAC) and reimbursement decision which may incorporate other factors (Fabrys)
- No price negotiation

Perspectives – Patients and the Public

- Relatively little “public” interest, but great interest from patient groups
- Concern that public and patient voice not being heard – options being considered by Common Drug Review
- Concern that this process not appropriate for “Orphan” drugs
- General concern about “access” in Canadian health care system

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Perspectives – public formularies

- In general satisfied with CDR process
- Point to Vioxx story as justification for restrictive formularies
- To date, listing decisions follow CEDAC recommendations, although some deferred
- Still great pressure on drug budget
- Political pressure related to drugs for “Orphan” diseases, which will likely increase for anti-cancer drugs, and others in the future

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Perspectives - physicians

- Aware of problems with increasing drug costs
- However, desire to provide “the best” to their patients
- Frustration with the slowness of the restricted access system
- Formularies sometimes seem out-of-date

Perspectives - Industry

- Concerned about “restricted access” and time delays
- Emphasize apparent contradictions between regulator and those who reimburse
- Link lack of investment in Canada with restrictive drug policies

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Summary

- Long history in Canada of drug formularies based upon cost-effectiveness, with little price negotiation
- Landscape changing with switch from “blockbuster” modestly-priced drugs to smaller market extremely expensive drugs
- Drug policy is a mix of scientific evidence, judgment, altruism, self interest and politics; superimposed on a complex, semi-rational, constantly changing, over-burdened system
- Good luck

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