Outline

1. Overview: Pharmaceuticals
2. Global Pharmaceutical Market
3. Canadian Pharmaceutical Market
4. Market Access Challenges
5. Role Of Economists
6. Summary
7. Q&A
Overview

• Pharmaceutical:
  A chemical compound or biologic manufactured for use as a medicinal drug

• Uses:
  Medical Diagnosis, Cure, Treatment or Prevention of Disease

Total drug expenditure in Canada is forecast to have reached $33.0 billion in 2012
Overview: A Diverse Product Market

Pharmaceuticals

- Over the Counter Medications
- Prescription Drugs
- Generic Drugs
- Vaccines
- Biosimilars
- Biologics
Overview: Key Players in the Industry

- Pharmaceutical Manufacturers
- Regulatory Agencies
- Patients
- Pharmacists
- Payers
- Hospitals & Physicians
Global Pharmaceutical Market
The Global Pharmaceutical Market

The global pharmaceuticals market is worth US $300 billion a year, a figure expected to rise to US $400 billion within 3 years.


Source: PMPRB 2012 Annual Report citing IMS Health
Canada is an Important Market

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Appendix notes
Ranking in all years based on spending in constant US$ at Q4 2011 exchange rates. Index in each year based on ratio of country spending to U.S. spending (in constant US$) in the year.

Source: IMS Market Prognosis, May 2012

Canadian Pharmaceutical Market
• Health care system is government funded:
  • Universal, comprehensive, accessible, portable, publicly administered
  • Federal government funds health care and established general policies – provinces/territories responsible for administration & delivery of health care
  • “Comprehensive” coverage includes all physician and hospital costs but not cost of prescription drugs outside hospital
  • Provinces have established drug plans primarily for seniors (age > 65) and the poor
Expenditure on All Drugs in Millions in 2012

CIHI

The Big 4:
Quebec
Ontario
Alberta
British Columbia

Account for
~ 85% of all expenditure on drugs
How does a drug get on the market in Canada?

1. Patent Application
2. Phase I
3. Phase II
4. Phase III
5. R&D, Clinical Trials
6. Market Authorization
7. Regulatory Approval
8. HTA Review
9. Submit for Regulatory Approval
10. Gov’t Reimbursement
11. Market Access
12. Generic Entry
13. Patent Expiry
R&D and Clinical Trials: Brand Name Drugs

• Significant time to develop a drug: 10 – 15 years (Phrma, 2013)

• Significant risk: for every 5,000 – 10,000 compounds in the pipeline, only 1 is approved

• Significant cost to develop a drug (including the cost of failures): **Avg est. $1.2 billion** (Phrma, 2013)

• Brand name drugs are protected by a patent which means that the drug can be produced, sold or licensed only by the company holding the patent
Canadian Pharmaceutical Market

Regulatory Approval

Patent Application

Phase I

Phase II

Phase III

R&D, Clinical Trials

Market Authorization

Submit for Regulatory Approval

Gov’t Reimbursement

Regulatory Approval

HTA Review

Market Access

Generic Entry

Patent Expiry

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Regulatory Approval

• Drugs must receive regulatory approval from Health Canada which is given in the form of a Notice of Compliance (NOC)

• Health Canada will review:
  • The drug's safety, effectiveness and quality
  • Which includes evaluating
    • the results of the preclinical and clinical studies
    • details regarding the production of the drug
    • packaging and labelling details
    • information regarding therapeutic claims and side effects

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Pricing

• The manufacturer can set the launch price, but if the drug is **patented**, then it must be within the limits set by the Patented Medicine Prices Review Board (PMPRB)

• The PMPRB ensures that the prices of patented medicines sold in Canada are not excessive

• If a price is found to be excessive, the Board can hold public hearings and order price reductions and/or the offset of excess revenues
Canadian Pharmaceutical Market

Health Technology Assessment

- Patent Application
- Phase I
- Phase II
- Phase III
- R&D, Clinical Trials
- Market Authorization
- Regulatory Approval
- HTA Review
- Gov’t Reimbursement
- Market Access
- Submit for Regulatory Approval
- Patent Grant
- Generic Entry
- Patent Expiry

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Health Technology Assessments

- The Common Drug Review (CDR) evaluates the clinical and cost effectiveness of new drugs to recommend if a drug should be publicly funded
- The CDR Directorate oversees clinical and pharmacoeconomic reviews
- pCODR reviews cancer drugs

The majority of new drugs are not provided “List” recommendations by CDR

Those with a positive recommendation usually have restrictions – provincial plans generally follow CDR recommendations

CDR Recommendations as of January 2014 (n=278)

- List in a Similar Manner: 9%
- List with Conditions: 39%
- List: 3%
- Do not List at submitted price: 2%
- Do not list: 47%

The majority of new drugs are not provided “List” recommendations by CDR

Those with a positive recommendation usually have restrictions – provincial plans generally follow CDR recommendations
Reimbursement

• Each Federal, Provincial & Territorial government drug plan can make its own decisions about coverage
• All drug plans will assess their respective budget impact
• Each plan independently advises manufacturer of its listing decision and coverage status of the drug.

Affordability & budget impact are the key factors for the drug plans.
Who pays for these prescription drugs in Canada?

% Distribution of Rx Drug Expenditures Canada 2012

- Public Payers 44%
- Private Insurers 36%
- Out of Pocket 20%

Public
- Federal/ Provinicial Drug Plans
- Hospital in-patients
- Separate Cancer Agencies

Private Insurers
- Employer sponsored drug coverage for employees and their families

Out of Pocket
- No coverage / uninsured / underinsured
- Non-reimbursed drugs
- Deductibles / co-payments

Source: Canadian Institute for Health Information (CIHI), Drug Expenditure in Canada, 1985 – 2012 (Published 2013)
Canadian Pharmaceutical Market

Patent Expiry & Generic Entry

- Patent Application
- Phase I
- Phase II
- Phase III
- R&D, Clinical Trials
- Market Authorization
- Regulatory Approval
- HTA Review
- Gov’t Reimbursement
- Market Access
- Submit for Regulatory Approval
- Generic Entry
- Patent Expiry

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A generic drug contains the same active medicinal ingredients as the brand drug product and is comparable in dosage form, strength, route of administration, quality and performance characteristics and intended use.
Generic Drug Policies in Canada

• Substitution is mandated through provincial legislation/regulations; some jurisdictions have mandatory substitution
• Provinces and territories pay between 18 and 40 per cent of brand name prices
• Historically, Canadian generic prices higher than most other countries
• Strict policies on pharmacist “allowances”
Market Access Challenges
Market Access Challenges – Regulatory

- On average, Canadians may wait up to two years for access to new drugs due to the regulatory and reimbursement procedures.

Non-weighted consolidated average delay for regulatory and marketing approval of new drugs 2006–2010

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Market Access Challenges – Pricing

- PMPRB mandate to regulate maximum prices
- Lower prices in reference countries puts downward pressure on prices
- Appreciation of the Canadian dollar can impact price ceiling
- Canadian prices higher than most European prices
Market Access Challenges - HTA

- Provinces will rarely make a decision on reimbursement if CDR has not yet reviewed a product.
- If CDR is backlogged or establishes that a product should not be listed it can have a significant impact on the potential sales and patent life of a drug.
- pCODR can be delayed and can have similar effects except for oncology products.

Median Time-to-Listing for All Drugs in Days

Source: CMAJ November 22, 2011 vol. 183 no. 17 E1259-E1266
Role of Economists
Role of Economics in the Pharma Industry

Economics

Policy Based Analysis
- Government Relations Specialists
- Health Policy Analysts

Mathematical Analysis
- Health Economists
- Budget Impact Analysis Specialists

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Government Relations Specialists

- Political Science
- Law
- Discuss & implement the policy

Health Policy Analysts

- Evaluation & Analysis
- Examples;
- Health Expenditure
- Pharmaceutical Utilization
- Patent Issues

Policy Research
Health Economists

Pharmacoeconomic
Cost Effectiveness
Cost Minimization
Cost Utility
Cost Benefit
Cost Consequence

BIA Specialists

Sub-Group of HE Models estimating cost of reimbursing a new drug for drug plans

Cost Analysis
Summary

• The global pharmaceutical market is large and growing.
• Numerous stakeholders are involved in the regulation, pricing and reimbursement of pharmaceuticals.
• Health Canada, the Patented Medicine Prices Review Board, the Common Drug review and provincial/private payers are all key players in pharmaceutical reimbursement
• Economists can play an important role in the pharmaceutical sector:
  • Policy specialization
  • Mathematics and model building
Questions?
Thank You
Arvind Mani is the Director of Market Access and Policy Research at PDCI. Arvind leads a team of consultants on pharmaceutical reimbursement (budget impact analyses), policy, and patent litigation projects. Arvind has more than 15 years of experience working in industry, associations and consulting. He provides expert knowledge to companies, governments on pharmaceutical pricing, regulatory, market access, and patent issues and is also responsible for contributing to pricing and reimbursement policy and analysis projects. Before joining PDCI, Arvind spent several years as the Director of Corporate Affairs at the National Association of Pharmacy Regulatory Authorities (NAPRA) in Ottawa. Prior to NAPRA, he worked for 8 years at Canada’s Research-Based Pharmaceutical Companies (Rx&D), an association that represents the interests of innovative pharmaceutical companies in Canada. Arvind held various positions at Rx&D, including Research Analyst, Director of Regulatory Affairs, and Director of Policy Development. Prior to joining Rx&D, Arvind was a Market Analyst with Ciba Geigy (now Novartis Pharmaceuticals Canada Inc.).

PDCI Market Access (PDCI) is a leading pharmaceutical pricing and reimbursement (P&R) consultancy based in Ottawa and Toronto. Established in 1996, the firm features a senior team of multi-lingual market access professionals with extensive experience assisting clients navigate the complex P&R challenges facing Canadian pharmaceutical manufacturers. PDCI develops successful P&R strategies and prepares comprehensive submissions to CDR, pCODR, public & private payers and the PMPRB. The firm’s senior consultants facilitate meetings with CDR/payers/PMPRB, negotiate product listing agreements (PLAs) and resolve pricing compliance issues with the PMPRB. PDCI maintains databases of international pharmaceutical prices and provincial drug claims and costs.