Danish Ministry of Health and Prevention

Analysis of Hospital Pharmaceuticals

Country Report - Canada

March 2009

COWI

COWI

COWI A/S

Parallelvej 2
DK-2800 Kongens Lyngby
Denmark

Tel +45 45 97 22 11
Fax +45 45 97 22 12
www.cowi.com

Danish Ministry of Health and Prevention

Analysis of Hospital Pharmaceuticals

Country Report

March 2009

Table of Contents

1 Introduction

The Canadian hospitals are according to the constitution under the jurisdiction of the 13 provinces and territories. The hospital services including pharmaceuticals for inpatients are fully covered by the Medicare programme.

Regulation of prices for patented pharmaceuticals

There is free pricing of off-patent pharmaceuticals whereas prices of patented pharmaceuticals are regulated by the Patented Medicine Prices Review Board. The objective of the Board is to protect the citizens against excessive pricing on medicines. Prescription and non-prescription patented pharmaceuticals are subject to review.

Hospitals negotiate freely with manufacturers

Hospitals - sometimes joining hospital purchasing groups - negotiate directly with the pharmaceutical manufactures with regards to prices and terms of delivery for pharmaceuticals.

There is no definition of the term "hospitals drugs". "Hospital only drugs" were until recently a definition of pharmaceuticals only used in hospitals. These drugs were not part of the provinces drug plans setting reimbursement rates. The term is now becoming more blurred as some "hospital only drugs" are used in ambulatory and home settings.

This study is done mainly on basis of desk-research, however, a draft version of this report has been reviewed by Mr Paul Kasimatis of Health Canada.

2 Regulation and legislation

Legislation and rules

Canada has according to the Canada Health Act a system in which medical and hospital services as well as pharmaceuticals used in inpatient care are publicly and 100 % covered by the Medicare programme.

The federal responsibility within the pharmaceuticals sector is primarily focussed on two areas: drug approval based on safety and efficacy and pharmaceuticals management through federal price regulation of patented drugs (Patented Medicine Prices Review Board (PMPRB)) at the manufacturing price level and support of cost-effectiveness and best practice guidelines through various mechanisms such as the Common Drug Review.

The Patented Medicine Prices Review Board is mandated to protect consumers by ensuring the prices of patented pharmaceuticals sold in Canada are not excessive.

Prices of off-patent original products are not regulated in Canada.

Regulation of prices for patented pharmaceuticals

The PMPRB is responsible for regulating the prices that patentees charge, the "factory-gate" price, for prescription and non-prescription patented pharmaceuticals sold in Canada, to wholesalers, hospitals or pharmacies, for human and veterinary use to ensure that they are not excessive. The PMPRB regulates the price of each patented pharmaceutical product, including each dosage form of patented medicine sold in Canada.

Comparator countries

The Board compares a price proposed by a manufacturer either to prices of existing pharmaceuticals in Canada or to prices in France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States.

The "excessive price" criterion used in assessing the price of a new pharmaceutical depends on the degree of the innovation in the new products.

The manufacturers are requested to supply price levels for four classes of customers (hospitals, pharmacies, wholesalers and others) in all provinces as well as prices for the seven comparator countries mentioned above.

To determine if the price of a patented pharmaceutical sold in Canada is excessive, the PMPRB applies factors set out in the *Patent Act* and in its price guidelines.

In summary:

- Most new patented pharmaceutical prices are limited by the range of the cost of therapy for existing pharmaceuticals sold in Canada used to treat the same disease;
- Breakthrough pharmaceutical prices are limited to the median of the prices for the same pharmaceuticals charged in specified industrialized countries that are set out in the *Patented Medicines Regulations* (France, Germany, Italy, Sweden, Switzerland, U.K. and the U.S.).
- Existing patented pharmaceutical prices cannot increase by more than the Consumer Price Index (CPI);
- The Canadian prices of patented medicines can never be the highest in the world.

Public drug plans also play a role in pharmaceutical pricing through the listing of pharmaceuticals on formularies for purposes of reimbursement.

Excessive prices

If the Board considers a price to be excessive there are two alternatives: 1) The company agrees to cut its price and pay a compensation to the government of Canada 2) The company does not agree in which case the Board holds a public hearing to reconsider the conclusion of excessive price. If the hearing confirms that the price is excessive the company may appeal to the Federal Court.

In some cases the list price of the manufacturer is not altered, but the manufacturer guarantees that no customer in Canada will pay more than the maximum non-excessive price. The advantage is that the manufacturer can disregard implications of a relatively low Canadian list price on other countries' external reference price system. This renders that list prices are less attractive for potential USA purchasers.

The PMPRB also monitors and reports on non-patented drug prices.

Organisation and finance of hospitals

The jurisdiction over hospitals (and psychiatric institutions) is by the constitution assigned to the provinces. Each province prepares a health care insurance plan which covers all insured health services provided by hospitals.

Financing of hospital pharmaceuticals

The payments to hospitals are done by the provinces either directly or through global funding to regional health authorities.

Common Drug Review (CDR)

The Common Drug Review (CDR) process streamlines the reimbursement review process for provincial drug plans.

Each province has its own public plan formulary which list pharmaceuticals that are reimbursable by the public drug plan. Usually hospital only drugs (such as IV cancer drugs) are not included in these formularies.

However, many provincial drug plans cover cancer agents, so if a cancer pharmaceutical is not "hospital only" the manufacturer would prepare a submission

to the Common Drug Review (CDR). Pharmaceuticals that are administrated in hospital only would not be submitted to CDR.

Traditionally, pharmaceuticals administrated intravenously were considered hospital only drugs. However, this distinction cannot be uniformly applied as more of these agents are administrated in the non-hospital and home settings and are funded by the provincial plans.

Free pricing for pharmaceuticals for inpatients

There is free ex-factory pricing for pharmaceuticals for inpatients with exception of patented drugs subjected to the PMPRB procedure (see above).

Pharmaceuticals used in hospitals and other institutions are covered under the hospital coverage regulated by the Canada Health Act. Drugs used outside hospitals and other institutions are for the large majority of Canadians under provincial and territorial jurisdiction, with drug coverage varying across jurisdictions. Federal drug coverage is limited to special federal populations, three examples of which are First Nations and the Inuit, the armed forces, and veterans

The hospitals (or group of hospitals) request price quotes for the pharmaceutical industry for specific pharmaceuticals and the final price is an outcome of negotiation between the two parties.

3 Market place and purchasing

Initiatives for cost containment

Canadian Hospitals operate under fixed budgets and / or payments per case which the hospitals use to procure pharmaceuticals provided free to their patients. Global hospital budgets are set by the provincial governments through their Ministries of Health. Hospital purchases of medicines for inpatients use is under constraint of a defined drug budget.

The payment schemes for hospitals provide a strong incentive for cost-containment[1]. Once a generic version of a medicine is approved by Health Canada, hospital purchases concentrate on the generics and avoid using the original brand-name product.

Hospital group purchasing programmes

Hospitals typically use group purchasing programs to establish group contracts for set prices. The hospitals then buy directly from the manufacturer at the contract price.

The relatively high prices on generics (compared to other countries) are explained by the lack of competition due to high concentration of the market. Factors contributing to high generic drug prices are concentrated market structure, inelastic demand, and reimbursement system specifics (including price-control mechanisms).

Prices on patented pharmaceuticals are considered on level with prices in comparable countries. According to some sources the price level for the patented pharmaceuticals can be attributed to the PMPRB procedure described above. Prices of patented drugs are affected by various factors, including provincial buying power, PMPRB regulation, and incomes of Canadians.

[1] OECD:

4 Professional management / clinics

Hospitals are responsible for developing their own formularies through a Pharmaceutical and Therapeutics Committee. Formularies are adapted to the hospital's activities and patient profile.

5 Turnover and prices

Total drug expenditures were $23.3B in 2005 (82.9% of which was on prescribed drugs).

Expenditures for hospitals pharmaceuticals accounted for CAN $ 1.5 billion in 2003 representing 7.7 % of the prescription pharmaceutical expenditure The expenditure growth was slightly higher for prescribed drugs outside hospitals (11.1%) than for drugs inside hospitals (9.9%).[2]

[2] CIHI and personal communication with Paul Kasimatis of Health Canada.

References:

Marchildon GP. Health Systems in Transition: Canada. Copenhagen, WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies, 2005.

Ispor Global Health Care Systems Road Map. Reimbursement Processes Around the World. Canada. www.ispor.org/HTARoadMaps/Canada

OECD Directorate for Employment, Labour and Social Affairs: Health Working Papers. Pharmaceutical Pricing and Reimbursement Policies in Canada. 2007