Generic Drug Pricing Discussion Paper
Fact Sheet

What is the relevance of generic drugs to Canadian health policy?
Prescription drugs account for an increasing proportion of Canada's growing health care system with rising costs that governments in this country are seeking ways to restrain. Canada's relatively high generic drug prices contribute to increased health care costs, put a strain on provincial drug program budgets, and can have a negative impact on Canadians' access to medicines and health care. There are potential options for governments to consider in order to institute reforms, reduce costs, and increase the transparency of generic drug transactions.

What are Generic Drugs?
Generic drugs use the same active ingredients as the original brand name products, and are generally available in the same strengths and dosage forms as the original. Relative to the brand name drug, a generic drug must have the same route of administration, be bioequivalent*, and meet the same quality standards. The generic may differ in colour, shape, taste, inactive ingredients, preservatives and packaging.

*Note: * To indicate bioequivalency, the generic must dissolve (in a beaker) at the same rate and to the same extent as the original brand name drug. If the two products dissolve in a virtually identical manner, it is believed they should behave the same way in the body.*

How does a drug manufacturer protect its products?
The developer of a new brand name drug or new compound may decide to apply for a patent, which if granted, will typically last for twenty years. The drug developer - the originator of the drug – then has the sole right to obtain regulatory approval to manufacture and market the drug, or license others to do so, during the life of the patent. The brand name drug is often protected as a trade mark and cannot be used by any other party. Developers often secure additional and ancillary patents after the initial patent is issued, in order to prolong their period of market exclusivity.

What happens when the patent on a brand name drug expires?
Once the patent on a brand name drug expires, the drug may be manufactured and sold by other companies under a different brand name, or under its generic name, once regulatory approval is obtained. When the drug is to be sold under its generic name it is referred to as a generic drug. All manufacturing and marketing of the generic drug must be conducted in strict compliance with the guidelines established by Health Canada.

Does every brand name drug have a generic counterpart?
No. If a generic version of a drug is not developed, even after expiration of the patent on a brand name drug, the latter would still remain the only approved product available. With the growing emphasis on generics, it's rare that a generic version or more than one generic version

of a drug is not developed around about the time that its brand name counterpart comes "off patent".

What are the manufacturing standards for generic drugs?

The manufacturing facilities and processes of all pharmaceutical companies, whether they are makers of brand name or generic drugs, must adhere to strict quality control procedures and standards, and are subject to stringent inspections by Health Canada. The approval process is complex for both brand name and generic manufacturing facilities. Many pharmaceutical companies that make brand name drugs also make drugs sold under generic labels.

What is the quality of generic drugs?

To be considered bioequivalent to its brand name counterpart, a generic drug must not only have the same active pharmaceutical ingredient, but the rate and extent of absorption of its active ingredient into the bloodstream must also be the same or similar, within ranges designated and approved by the Health Canada. If Health Canada is satisfied with the tests submitted by the manufacturers for its review, the authority rates the generic drug as bioequivalent to the brand, which means that the generic version is acknowledged as having the same therapeutic effect as the brand name drug.

Even when a generic substitute is available a patient's doctor might still prescribe the brand name drug if the doctor believes the patient will better tolerate the brand name formulation because of anticipated side effects from the generic formulation. Drug plans attempt to limit this degree of substitution.

Are generic drugs as safe and effective as brand name drugs?

The approval of a generic version of a drug means that it has been tested for bioequivalence, which ensures that the safety and efficacy standards of generic drugs are the same as brand name drugs. The manufacturing process of generic drugs is strictly regulated according to standards on par with the manufacturing process for original brand name drugs.

Why are generic drugs dispensed?

The time required to develop a generic drug is shorter and the costs much lower than that of a brand name medicine. Therefore, generic drug manufacturers can typically afford to sell their medications for a lower price than their brand name counterparts. By passing this cost benefit on to the consumer, the generic drug industry helps make medications accessible at more affordable costs to government and private health plans and to individual consumers who do not have coverage. Generic drugs thus help make the health system more sustainable.

How are drug prices set?

Many factors affect the final price of a drug. Brand name companies set prices for new drugs in each country that are intended to recoup the cost of research and innovation on the new compound and a portion of overall costs as well as a profit margin. These prices are calculated based on the expected patent life of the drug and estimates of potential clinical use, (number of prescriptions, incidence of disease etc).

When a new brand name drug is allowed onto the market in Canada, the Patented Medicines Prices Review Board (PMRB) analyses the prices for the new drug in 7 OECD comparator countries and publishes a median price and establishes this median as a ceiling price for Canada. Provinces may negotiate better prices or adopt this ceiling as their price.

Some provinces then layer on other policies and practices designed to get a better price. Ontario will negotiate with a drug company what is essentially a package cost for all that company's drugs currently on the provincial plan. The details of these negotiations are not generally made public and have been said to include additional non price incentives that resemble rebates used in other channels. Other provinces use open tendering (SK) or reference based pricing (BC) to lower costs. Most provinces also have a requirement that manufacturers have to provide a brand name (or generic) at the lowest price they offer in any other province (Quebec and Newfoundland/Labrador).

Generic prices are also set through a number of approaches that resemble those used in setting brand name prices with the exception that there is no equivalent to the PMPRB. Another common vehicle is to set generic price maximums as a percentage of the brand name equivalent. This is done in three of Canada's largest drug markets – Alberta, Quebec and Ontario. Although this process is straightforward, it does not relate price to the actual costs of the generic drug, time in market, acceptable margin or costs in different parts of the distribution and retail channels. Not surprisingly Ontario has grown dissatisfied with the "results" achieved. But rather than adopt new approaches, the province has simply ratcheted down the regulated percentage.

The patchwork of regulations that "set" prices do not come close to replicating normal market mechanisms nor do they compare well against other regulated price approaches that have been used in other sectors of the economy (electricity, pipelines, transport, telephone).

Private plan pricing is highly variable. This variability exists among private plans in different provinces and among different private plans in the same province. In fact, two patients on the same private plan may encounter different prices at different pharmacies within the same city.

What is the purpose of the commissioned paper by the Health Council of Canada on generic drugs?

The Health Council of Canada commissioned the independent discussion paper entitled, *Generic Drug Pricing and Access in Canada: What are the Implications?,* in order to provide Canadians with further insight into the generic drug sector and potential options to reduce generic drug prices. In recent years some provincial governments have launched initiatives to bring generic drug costs down. Yet for most Canadians, the issues concerning generic drug pricing are not well understood. The discussion paper is meant to encourage broader public discussion.

What is the National Pharmaceutical Strategy (NPS)?

The National Pharmaceuticals Strategy was part of the 2004 health accord, the *10-Year Plan to Strengthen Health Care,* in which participating provinces and territories agreed to take on a variety of improvements to their health care systems, accompanied by substantial new money from the federal government flowing into healthcare.

Growing concerns about the increasing costs and use of pharmaceuticals in all jurisdictions and significant differences in provincial and employer drug programs prompted governments to identify nine key areas for improvement and termed the package the National Pharmaceuticals Strategy. In 2004, there was recognition that there are limits to what individual provinces and territories could accomplish through their own programs to improve the safety and affordability of prescription medications, and that it was time to supplement and coordinate their efforts through a national strategy.

What did First Ministers ask for?

In the accord, the First Ministers (the prime minister and premiers) gave the provincial, territorial, and federal Ministers of Health the job of collectively addressing a number of priority areas in pharmaceutical reform. The First Ministers directed that the strategy include the following actions:

- Develop, assess and cost options for catastrophic pharmaceutical coverage;
- Establish a common National Drug Formulary for participating jurisdictions based on safety and cost effectiveness;
- Accelerate access to breakthrough drugs for unmet health needs through improvements to the drug approval process;
- Strengthen evaluation of real-world drug safety and effectiveness;
- Pursue purchasing strategies to obtain best prices for Canadians for drugs and vaccines;
- Enhance action to influence the prescribing behaviour of health care professionals so that drugs are used only when needed and the right drug is used for the right problem;
- Broaden the practice of e-prescribing through accelerated development and deployment of the Electronic Health Record;
- Accelerate access to non-patented drugs and achieve international parity on prices of non-patented drugs; and
- Enhance analysis of cost drivers and cost-effectiveness, including best practices in drug plan policies.

Why is the NPS important?

The First Ministers agreed no Canadian should undergo serious financial hardship to access medically necessary drug therapies and that equitable health outcomes for all Canadians are based on affordable access to drugs. With the current economic climate, the National Pharmaceuticals Strategy is more important than ever, with more Canadians likely to need help with the costs of their medications, as they lose jobs and employment-based health benefits. It has become even more critical to find ways to reduce the costs of medications, and to ensure that vulnerable Canadians will be covered for medically necessary medications, without their health status being further compromised.