Intelligence MEMOS

From: Rosalie Wyonch and Åke Blomqvist

To: Canadian drug regulators

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Re: **Drug Price Regulation Update**

Yesterday, the federal government released revised rules for regulation of drug prices by the Patented Medicine Prices Review Board (PMPRB), whose mandate is to protect public and private payers from "excessive" prices for patented medicines. The changes are expected to result in 10-year savings of $8.8 billion (present value) for public, private and individual payers.

The new rules imply substantial changes in the way PMPRB will set maximum allowable prices.

One major change is the ejection of the US and Switzerland, two high-cost countries, from the roster of nations used for international price comparisons.

Estimates of a drug's cost-effectiveness, and its expected market size, will now be major factors in the process for some drugs. As well, the PMPRB will begin to regulate net prices, not just the list price. This means pharmaceutical companies will have to report for the first time on confidential rebates or any other price reductions in the form of free goods, free services, gifts or other benefits they pay.

While using market size and cost-effectiveness to regulate drug prices in Canada is new, it is widely used in regulation and pricing negotiations elsewhere. Value-based pricing is now a factor in pharmaceutical reimbursement and pricing decisions in most OECD countries, except for the US. In several countries, including Australia, the UK and Sweden, various versions can be said to be the main criterion, especially for new drugs in therapeutic classes where patients have few alternatives. Cost effectiveness assessments by government agencies are used by insurers in price negotiations and their listing decisions, but until now have not been used in PMPRB price setting.

The government trumpeted the changes yesterday as "the biggest step to lower drug prices in a generation," and we agree that the new rules will likely have a significant impact on drug costs for newly launched medicines.

However, in predicting how effective they will be ultimately, two things should be kept in mind.

First, a large share of drug costs in Canada are already being purchased by provincial and federal government plans that already are paying net prices that are substantially lower than the PMPRB's maximums. They are able to do so by virtue of being part of the pan-Canadian Pharmaceutical Alliance (pCPA), an agency with substantial bargaining power because it negotiates on behalf of all those plans together.

Until now, private insurance plans have not been eligible for the rebated or lower prices negotiated by the pCPA for patented drugs. If the new Canadian Drug Agency that was announced in the 2019 federal budget becomes the pCPA's successor and gets a mandate to negotiate drug prices on behalf of all payers, private as well as public, drug prices in Canada would likely fall even without new regulation. How the new regulatory role for the PMPRB will mesh with the proposed mandate for the new Canadian Drug Agency is yet to be determined.

The second issue to bear in mind is that pharmaceutical-pricing policies must balance two conflicting objectives: making efficient use of medicines and medical technologies that have already been developed, and providing incentives for pharmaceutical firms to develop new ones. This balancing must be done jointly with other countries because drug R&D can be undertaken anywhere in the world, even though the benefits will be shared globally.

The new drug price regulations take steps toward lowering the price of patented medicines in Canada while keeping them comparable to those in other wealthy nations.

However, if the regulatory tools are used too aggressively, they may result in Canadian drug prices that are so low that other countries begin to think of us as a free rider: A country unwilling to contribute its fair share to the profits that give pharmaceutical companies an incentive to undertake the R&D that results in valuable new drugs.

Elsewhere, we have argued that on this issue, Canada should pursue a two-track strategy. In the short run, we should use regulation and negotiation tools to aim for drug prices that make our contribution to global R&D acceptable to our peer countries and main trading partners. At the same time, we should work with other countries and international organizations toward an agreement on the principles that should be used in an equitable sharing of the cost of an optimal amount of global R&D to develop different kinds of new drugs.

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