Interview: Douglas Clark – Executive Director, Patented Medicines Price Review Board (PMPRB), Canada

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26.09.2017

Tags: Canada, PMPRB, Regulatory Reform, Regulator, Pricing

Douglas Clark, Executive Director of the Patented Medicine Prices Review Board (PMPRB), Canada's federal price regulator for patented medicines, highlights the PMPRB's mandate to protect consumers against excessive prices for patented drugs, the rationale behind the recent proposed changes to their guidelines, and the role PMPRB can play within Canada's regulatory landscape.

Doug, the Patented Medicine Prices Review Board (PMPRB) was established within a particular historical context to act as a sort of price regulator. Could you provide an introduction to PMPRB's mandate?

PMPRB was created in 1987 as part of a major overhaul of Canada's drug patent regime (Bill C-22), which culminated in the repeal of compulsory licensing for pharmaceuticals. The compulsory licensing regime, which had been in effect in Canada since 1969, enabled generic manufacturers to produce and sell generic versions of patented drugs on the payment of a relatively modest royalty to the patentee. It spawned a robust and homegrown generic pharmaceutical industry but was also a major irritant in the Conservative government's efforts to negotiate a free trade agreement with the US. The PMPRB was created as the consumer protection pillar of Bill C-22 as a concession to opponents of that legislation, who were concerned that repealing compulsory licensing would prompt pharmaceutical patentees to abuse their newfound rights by charging monopoly prices.

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This was within the broader context of what has been described as a pharma 'accord', with branded pharma companies granted patent rights in exchange for a commitment in terms of R&D investment as well as non-excessive pricing. Thirty years on, how well is this accord performing?

This is the big question today. There is a great deal of internal reflection going on at the federal level about how well a policy balance conceived 30 years ago can address the challenges of the modern-day pharmaceutical marketplace. Canada's regulatory landscape for patented pharmaceuticals has sometimes been critiqued as a relay race, with the market approval, price regulation and health technology assessment steps all taking place consecutively before reimbursement and meaningful market access can occur. Health Canada is currently spearheading a major overhaul of that process, in an effort to have the various steps operate more synergistically, with the ultimate goal being more timely market entry of truly innovative drugs that meet health system needs and are priced responsibly. Budget 2017 earmarked about CAD 140 million in new funding to advance these reforms.

On the specific question of how well the PMPRB is performing 30 years on, we have been quite outspoken in acknowledging that our regulatory framework has failed to keep pace with some important changes in our operating environment and we are in the midst of modernizing both our regulations and guidelines.

It is important to understand that Canada is a federation with a division of powers between federal and provincial authorities in the regulation and reimbursement of pharmaceuticals. We all do our best to optimize the policy tools at our disposal while recognizing our constitutional limitations.

PMPRB's mandate surrounds the concept of 'excessive pricing'. What does this mean, in practice?

Canada's Patent Act does not explicitly define the concept but rather provides factors that act as guideposts in our determination of what is an appropriate ceiling price. This allows for a flexible and contextually driven interpretation of excessive pricing that evolves with time and changing circumstances.

In practice, under the current framework, the PMPRB determines excessiveness mainly by benchmarking Canadian prices against prices of the same drug in other countries or prices of other drugs in the same class in Canada. However, the problem with that approach today is that public list prices do not reflect the true reimbursement rates negotiated confidentially between manufacturers and insurers. As a price regulator, the PMPRB is doubly handicapped in the sense that we are blind to the true price of drugs not only internationally but domestically. This is a pretty big problem when price benchmarking is the backbone of your regulatory regime.

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Another problem with our approach to price regulation is that it was conceived at a time when the average annual cost of most top-selling prescription drugs was in the hundreds of dollars, whereas today that figure is very often in excess of CAD 10,000.

Our ongoing efforts to reform and modernize our regulations and guidelines is driven by the realization that the current way we operationalize the factors has failed to keep pace with industry trends, and that we should potentially consider new factors, like cost-effectiveness and budget impact, in considering how to regulate some of these very high-cost drugs.

Every country in the world is struggling with how to spend sustainably on pharmaceuticals and Canada is no exception. In considering how best to ensure the sustainability of our own system, we are intent on adopting international best practices in pricing and reimbursement.

As you mentioned, Canada already has a very complex regulatory landscape. With PMPRB reforming its guidelines, how will it ensure that it does not overlap the functions of various existing regulatory, pricing and reimbursement bodies?

We are very mindful of the need to avoid duplicating the efforts of other players in the pharmaceutical ecosystem and have articulated that to stakeholders in various public documents. We understand that we cannot be all things to all people and that finding our niche means identifying where we can bring the most value to the system. For instance, we recognize the concern that having the PMPRB consider cost-effectiveness as factor in determining excessiveness means that we will be replicating the work of CADTH. However, our intent is to leverage CADTH’s work, not replicate it. Similarly, we are aware of the important role played by the pCPA in leveraging the collective purchasing power of public payers to negotiate deep discounts for their respective drug plans. We want to complement that role by providing regulatory relief in instances where the monopsony power of the pCPA is an insufficient countervailing force to the monopoly power of the patentee.

At the end of the day, we do not want to spend our limited time and resources regulating highly cost-effective drugs with multiple therapeutic competitors in the market. Our objective is to adopt a more risk-based approach to regulating that builds on the efficiencies in the system, not add a redundant step to the relay race.

With the regulatory environment in a state of flux, how is PMPRB collaborating and aligning with the other entities you have mentioned to ensure alignment and a smooth transition?

In terms of the PMPRB, strengthening strategic partnerships and building public awareness of our activities is one of our foremost priorities. Domestically, the immediate result of our efforts in this regard has been broad stakeholder interest and participation in both our consultation initiatives and our excessive price hearings recently. Internationally, we are much more engaged in the Pharmaceutical pricing and reimbursement information (PPRI) and other WHO-based pricing and reimbursement organizations and initiative,s and routinely speak on the phone with our counterparts in other countries on issues of shared concern. This is a source of invaluable intelligence for us, and hopefully for them.

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At a more macro level, the ‘behind the scenes’ success story of the last few years has really been the unprecedented level of cooperation and collaboration between and among federal, provincial and territorial participants in the pharmaceutical regulatory system in Canada. I think that the influx of very high cost drugs in recent years has made people realize that we cannot afford to operate in silos. We have already seen some concrete examples of this trend, with Quebec and the federal government joining the pCPA last year, but I believe it will yield even bigger dividends in the years to come, with the work that Health Canada is leading to address the federal government’s commitment to improve the affordability and accessibility of prescription drugs.

How much dialogue and communication exists between PMPRB and industry?

I like to think there has been quite a bit. We have been very open and transparent with our stakeholders and the public in terms of our reform agenda with the release of our strategic plan in 2015. The public consultations on guideline and regulatory reform which took place in 2016 and 2017, respectively, followed very naturally from our plan and resulted in a record number of submissions from a diverse array of stakeholders. All along, we have been very forthright with the public about our shortcomings and what we feel we need to change, which is a scary thing to do because failure can have potentially dire consequences for the organization.

I would characterize our relationship with industry as professional, cordial and mutually respectful. We almost never say no to a meeting request, even when we are constrained in what we can say about a pending policy or enforcement matter. We also attend a growing number of industry sponsored conferences, workshops seminars and the like.

The industry may not always agree with our policy direction or enforcement approach but few would accuse us of being arbitrary, heavy-handed or duplicitous in our dealings with them. Like any industry, they crave stability and predictability in their business and regulatory environment and so I suspect the biggest criticism of the PMPRB these days is that our reform agenda is having a disruptive effect on their ability to plan for the future. However, while every industry may want these things, in my experience, few ever get them, even less so in the more technology-intensive sectors of the economy.

On a separate note, during this period of transition and uncertainty, how do you motivate your staff to boost morale and support them?

I think the single greatest motivator for our staff is seeing the progress we are making in our efforts to have a more meaningful and relevant impact on sustainable pharmaceutical spending in Canada. One measure of that progress is the degree to which we are on the public radar. The last few years have seen a number of firsts for the PMPRB – our first mention in the electoral platform of a major governing party, the first time we have been earmarked new funding in a federal budget – which is fairly remarkable for an organization of our size. I like to think most people join the public service because the want to make a positive difference for the country and do right by their fellow citizens. Our employees recognize that the road ahead will be difficult but the potential payoff is what they signed up for.

That said, even positive change can be inherently destabilizing for some people so we have made a concerted effort to engage with our employees as the process unfolds. Just last month, we brought in a workplace psychologist to speak to us about how to develop healthy coping skills in times of change. Whatever we are doing appears to be working thus far, because our survey results show across the board improvement in staff feedback on issues of job satisfaction, wellness and work life balance. I am proud to say we score much higher in these critical areas than the public service as a whole and even other micro agencies – but we can always do better, and that is what we are striving for.

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