Interview: Imran Ali – Senior Manager, pan-Canadian Pharmaceutical Alliance (pCPA)

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Imran Ali, senior manager of the pan-Canadian Pharmaceutical Alliance (pCPA) Office, the body that provides dedicated centralized support to the national negotiating process for drug prices, representing all 14 public drug plan jurisdictions in Canada, discusses the mandate of the pCPA, the main achievements so far, as well as the organization's priorities over the next few years.

Imran, could you please introduce the genesis of the pan-Canadian Pharmaceutical Alliance (pCPA) to our international audience?

In Canada, while the Federal government oversees marketing authorization through Health Canada, pricing and reimbursement decisions for public funding are constitutionally the mandate of the individual provinces and territories, who historically have negotiated individual pricing agreements with industry to varying extents. In August 2010, the Premiers of the provinces and territories, excluding the province of Québec at the time, decided to come together to negotiate as one country, against a backdrop of pricing and healthcare budget sustainability issues as well as the increasing prevalence of confidential pricing agreements.

The goal was to promote greater consistency in drug prices as well as more effective use of resources. While there was endorsement from political leadership at the top, the actual work of the pCPA, including negotiations, were tasked to the public drug plans of each province and territory, and there was initially no incremental dedicated resourcing put in place to support this activity. In

this way, pCPA was more of a grassroots initiative that grew organically as provinces and territories explored and found ways to work together on negotiations.

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In 2015, IBM was contracted to produce an assessment of the efforts thus far. The resulting 70-page report, the Pan Canadian Drugs Negotiation Report, included a recommendation to create a centralized body that could support the provinces and territories in formalizing and standardizing these activities, and be a dedicated resource to pCPA negotiations. This led to the official launch of the pCPA Office as it exists today.

I, along with Senior Negotiator, Anchalee Srisombun, was hired two years ago, and we now have a small team here to support our work. Strictly speaking, the Office of the pCPA encompasses more than just this office – it really represents and supports the collective voice of the provinces and territories on the negotiation of pharmaceutical pricing.

What is the process by which pCPA negotiates branded drug prices with industry?

At the beginning, the pCPA initially selected from the drugs that had made it through the various HTA processes based on what made sense. Then it moved on to encompass non-oncology drugs, and only began to negotiate the prices for oncology drugs a few years ago, because there is quite a lot of variation in the public coverage and reimbursement of oncology drugs across provinces.

Having gone through that evolution, we no longer choose which drug to negotiate prices for. Once a drug receives the final recommendation from the Canadian Agency for Drugs and Technology in Health (CADTH – the HTA agency for all Canadian provinces and territories except Quebec) and/or INESSS (Quebec's HTA agency), it is brought to pCPA so that the various jurisdictions can discuss the evidence and comparators in more detail. Where there are relevant confidential product listing agreements (PLAs) already in place, we do not discuss them openly or in detail, but simply establish whether they exist and whether the proposed pricing and other objectives for the new product being considered are acceptable.

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If the pCPA decides to enter into pan-Canadian negotiations (or a sub-set), a lead (a specific jurisdiction) will be assigned based either on specific experience within that therapeutic space or a matter of administrative capacity. Ultimately, the lead is a central touch point and common representative of the jurisdictions, and its mandate for the specific negotiation has been agreed by all participating jurisdictions – so from a collective standpoint, it does not matter who the lead is.

A letter will then be sent to the manufacturer's office identifying the lead and the participating jurisdictions. If clinical and economics terms are agreed upon during negotiations, the lead signs a Letter of Intent (LOI) on behalf of pCPA, which is the end product of the collective negotiations process.

How does the LOI affect future pricing and reimbursement decisions by the provinces and territories?

As a result of the way the Canadian healthcare system is constitutionally defined, each individual participating jurisdiction must translate the terms of the LOI into a PLA which is the contractual or legal obligation to fund a product. In this respect, Canada differs from many other jurisdictions where the price negotiation entity is itself the sole funder.

Individual Canadian jurisdictions vary in a number of ways, including their particular fiscal circumstance at any given point. This will impact the length of time from collective pCPA LOI completion to individual jurisdictional PLA and product listing.

That said, some of the larger jurisdictions usually move from the LOI to the PLA well within three months. Where the LOI is signed into a PLA, all the terms are accepted as is. This process would not work if there was not a certain level of predictability in the movement from the LOI to the PLA.

In addition, there is nothing in the pCPA process that dictates that all jurisdictions must participate in all negotiations at all times. Jurisdictions can opt out of negotiations but the commitment is that they do not enter into a separate, individual negotiations or agreements with the manufacturer separately. The LOI does allow for a jurisdiction that has opted out initially to add themselves to the LOI subsequently through an amendment – and then move on to a PLA.

What would you highlight as some of the successes for pCPA so far?

Firstly, the 2014 agreement on generics pricing was a success as it was the first time any sort of generics pricing agreement was established at the pan-Canadian level. Recently, we have built upon this success and reached a next phase of the generics initiative with a new agreement to be effective April 2018.

Across all our negotiations on branded and generics products, the headline figure that has been quoted by key stakeholders including the Federal Minister of Health is that some CAD 1.2 billion in annual savings have been achieved in terms of cost-avoidance. There is some nuance to this figure but this is a broad indication of our impact.

As of December 2017, around 175 LOIs have been reached – and over half of that has been achieved over the last two years alone. A notable accomplishment in the brand negotiations space were the LOIs reached related to hepatitis C treatments as announced in early 2017. The negotiated arrangements have given public drug plans access to much improved hepatitis C drugs at a lower cost and are helping to rapidly increase access for most patients with hepatitis C and help reduce its prevalence in Canada.

We have really increased the pace of our activity as pCPA gains momentum. For instance, two years ago, the average number of active negotiations in any month was below 20. Today, it is more commonly over 40.

Fundamentally, one of our objectives is to increase equity of access to drugs across Canada, as well as lower pricing. There used to be a huge discrepancy in drug prices even when they were listed on public formularies. Some jurisdictions, in particular, are benefiting hugely from this initiative because they are able to receive drug prices that would never have been possible. We do enjoy significant buy-in from the various jurisdictions, which is another testament to the value of our work.

What do you see as some of the current challenges pCPA is facing?

I think the public drug plans that we support and represent would agree that prudent financial investment in pharmaceuticals are amongst our biggest challenges. Public drug plans across the country are feeling the burden of increasing drug prices. This applies particularly to oncology therapies, whose prices have increased dramatically over the past few years even as funding to cancer agencies or programs have changed to better align with more modest healthcare spending increases in general. Biologics and rare diseases therapies also represent great challenges, especially as these are areas in which usual measures of cost-effectiveness may not be as applicable. In the case of rare diseases, given the type of evidence available, it is also extremely difficult for us to know the value of these therapies.

Having the 14 different jurisdictions (including the Federally administered public drug plans, which oversee healthcare provision for a few defined groups) also presents challenges when it comes to coordination, because healthcare priorities, disease prevalence and funding differ across the country.

We do also reach out to our counterparts from other countries to share best practices, challenges and options, particularly with regard to really important drugs and those that have the potential to have a huge budgetary impact. We are also looking at more ways to generate value beyond

straightforward volume discounts, including looking at real world evidence.

A trending topic within the industry is the use of outcomes-based or more innovative pricing models. How open is pCPA to this?

Through our dialogue and best practice sharing with our counterparts from other countries, our impression is that Canada does have more than its share of innovative, outcomes-based pricing agreements. This may not be well-publicized as we do not list details of pricing agreements publicly the way the UK does, for instance, but they certainly exist within Canada.

Such models are not the panacea some may think they are, however. Firstly, Canada does not yet have a culture where patients, physicians and other healthcare stakeholders are used to de-listing or ceasing the funding for a product once it has been listed on the public formularies – as is a feature in some other international jurisdictions. From a public perception standpoint, it is extremely difficult to delist or stop funding a product, because a drug not working as well as expected does not mean that it has not benefited at least some patients. Beyond the negotiating table, for outcomes-based agreements to work, there needs to be some level of understanding between us, manufacturers, patients and clinicians in terms of the definition of an outcomes-based agreement, desired outcome levels and the conditionality attached to them, as well as some way to manage expectations.

Having the right data infrastructure is extremely important as well. With Canada's decentralized healthcare provision, not only is our data infrastructure very heterogeneous across the country, so is legislation regulating the sharing of patient data, even for research purposes. There is still a lot of work to be done before we have the means to collect, track and analyze patient data routinely.

The devil is also in the details when it comes to such pricing negotiations. Theoretically, everyone agrees that outcomes-based agreements are positive, but when it comes to actually designing a framework that works, it is very tricky. You have to pick the right drug, the right context, the right patient population … there have been studies done in the US that in some cases, it is less cost-effective to invest time and effort into designing such agreements than to simply negotiate a straightforward volume-discount agreement.

To begin wrapping up, with pCPA still in somewhat of a start-up phase, what are your main priorities for the organization over the next few years?

Our four objectives are to increase access to clinically effective and cost-effective drugs; increase consistency of decisions; promote consistent and lower drug costs; as well as reduce duplication

and improve the use of resources when it comes to price negotiations.

We are really still formalizing the governance of pCPA and building the organization. The pace of activity has been increasing and we are trying to increase our efficiency as well.

Another major priority moving forward would be to increase the transparency of our activities and organization. Thus far, we have not had a strong public-facing element, so we aim to move towards a more standardized, predictable and transparent mode of operation, as our organization develops.

We recognize the truly unique approach that pCPA represents in having multiple jurisdictions collaborate on pursuing common objectives and are committed to pushing the initiative forward as a successful example of cooperation between governments and industry for the benefit of patients and citizens.

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