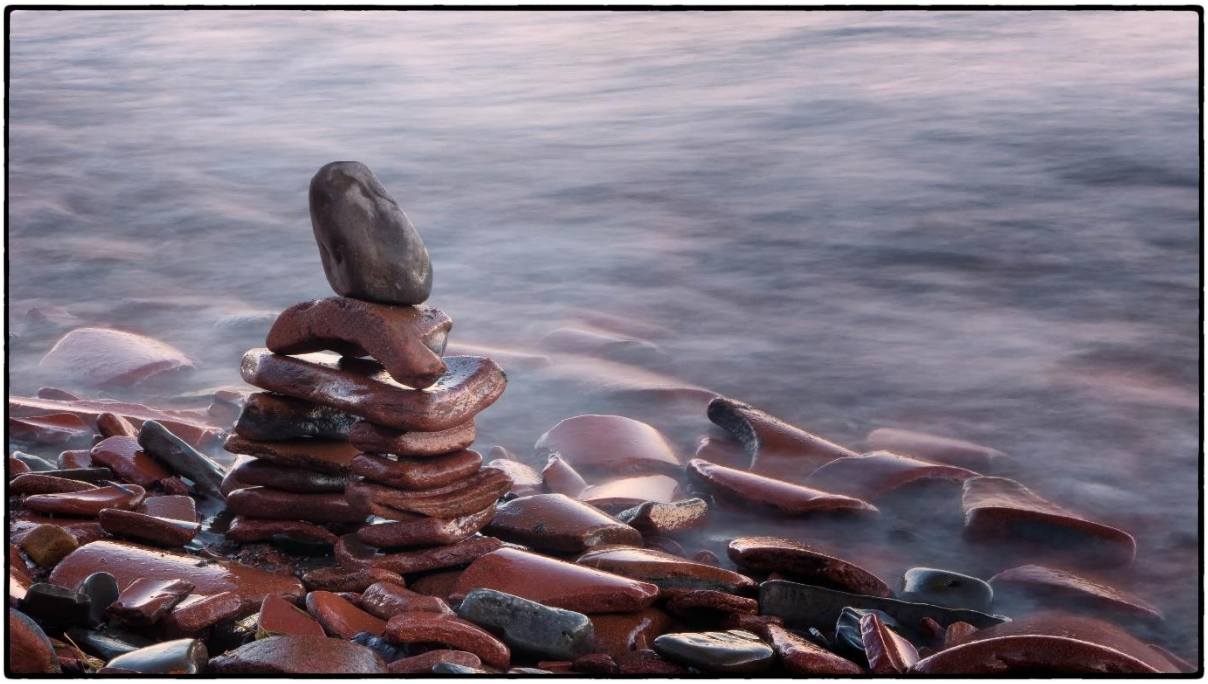
Canada Attempts Biosimilar Balancing Act



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Executive Summary:

Plans to make Canada's biologics market more competitive for biosimilars are advancing as payers are planning consultations on how price negotiations for biosimilars and biologics will proceed.

Biosimilars have so far had little penetration in Canada, but this could soon change. The pan-Canadian Pharmaceutical Alliance (pCPA), which negotiates medicine prices for public drug plans, wants to introduce a standardized approach to price negotiations for biosimilars and is planning a detailed consultation process.

Both originator and biosimilar companies will pay close attention to developments as any changes could impact the market share they can command, say Arvind Mani and Sherry O'Quinn from Morse Consulting. Mani and O'Quinn advise firms to positively engage with

the forthcoming consultations, which could lead to a coherent policy framework for developing the biosimilars market.

The consultations will follow the pCPA's First Principles published in 2016 that offered a "starting point" for building a policy framework for negotiating product listing agreements for biosimilars. Among other things, these First Principles laid down the expectation of transparent pricing. (Also see "Canada Ups Pricing Pressure on Biosimilars And Originators" - Scrip, 22 Apr, 2016.)

In a recent letter sent to trade associations, the pCPA says it recognizes that industry wants more clarification about how negotiations might be conducted. So, in the name of transparency and to eventually arrive at "a more predictable and standardized approach" to negotiations, the alliance wants further consultation "that results in an added level of detail and clarity regarding the pCPA's approach." According to Mani, 2017 and 2018 will see the arrival of multiple biosimilars for the same branded biologic in Canada and payers now need to lay out their expectations for these products.

Consultation

The pan-Canadian Pharmaceutical Alliance says that feedback on its "First Principles" showed that there are "varied positions which span the spectrum in terms of a place for biosimilars in the Canadian market."

There were a number of common themes to the feedback, which perhaps show the biggest areas of concern across industry. These included; switching and interchangeability; stability of biosimilar supply; expectations for transparent pricing; the pCPA's approach to second and third biosimilars; the clinical assessment of biosimilars compared to reference biologics; and the interplay of the pCPA's engagement with biosimilar and reference biologic manufacturers.

As such, the pCPA has picked six topics for consultation which include; expectations regarding price transparency; available options for formulary listing; switching and interchangeability; and consideration of proposals on reference biologics.

The approach that the pCPA eventually takes will likely have a big impact on how Canada's emerging biosimilar market develops. Biosimilars have so far failed to make a big splash in Canada. For example, one such product that has gone through pCPA negotiations, Pfizer Inc.'s Inflectra (biosimilar infliximab, Remicade), is not performing particularly well compared to the originator, with sales coming from new patients, not switches, says Mani. He believes the best outcome of the pCPA's endeavors is a biologics market that generates savings for the healthcare system and which allows biosimilars and originators to compete. However, he warns against any measures that might stifle uptake of biosimilars, "if you aren't able to have any kind of uptake for biosimilars and the innovator continues to have the lion's share of the market, there will be very little incentive for biosimilar manufacturers to launch in the Canadian market." He points to Ireland where biosimilars manufacturers have complained that price cuts affecting originators have impeded uptake of biosimilars.

(Also see "Biosimilar Firms Say Irish Price Deal Hinders Uptake, As Govt Plans New Policy Measures" - Pink Sheet, 10 Feb, 2017.)

Switching

Switching is one of the topics that the pCPA wants to explore following feedback from industry. According to O'Quinn, originator companies are nervous about "rumblings" that payers might start mandating switching. While this has not yet been proposed, there have been signs that this may eventually happen. For example, a recent HTA recommendation in Canada on filgrastim included comment that patients should discuss switching with their physicians. "This type of comment has been found in HTA recommendations for other biosimilars as well and is causing some uproar among originators," says O'Quinn. Mani adds that the landmark NOR-SWITCH study on switching from Johnson & Johnson's infliximab to the Celltrion rival has made waves in Canada. (Also see "Biosimilars Switching Debate Escalates After Remicade and Remsima Match In Landmark Study" - Pink Sheet, 20 Oct, 2016.)

Furthermore, he says the next round of biosimilars coming to Canada will be backed by switch data, which could strengthen the clinical rationale for switching.

"Originators want a chance to play in the entire space and think that the choice should be left between the physician and patient, they perhaps feel that there may be an unfair playing field," says O'Quinn. Indeed, the recent creation of a new organization, the Canadian Originator Biologics Coalition, underscores concern on the part of originators. Made up of AbbVie Inc., Janssen Inc., Hoffmann-La Roche Inc. and Takeda Canada Inc., the organization says in its guiding principles that it does not support switching for any "non-medical reason". It adds that: "Biosimilars and originator biologic products should co-exist and compete for the benefit of patients. Limiting the originators' ability to compete will result in an overall reduction in access to novel treatment options for Canadians."

From the editors of Scrip Regulatory Affairs.