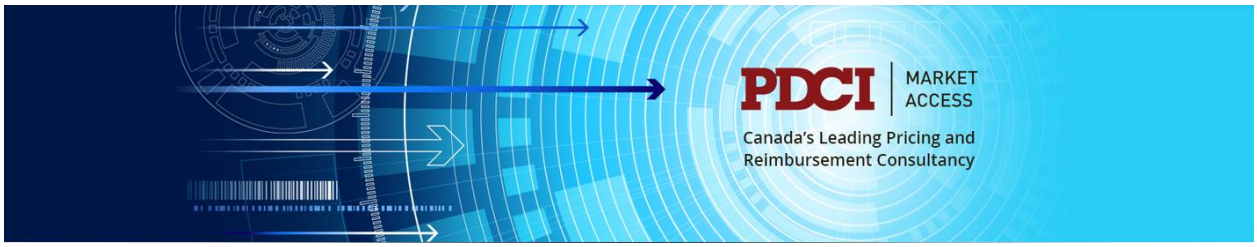


INTERNATIONAL TRENDS SERIES

Issue 1: Delisting of Oncology Treatments

May 4, 2015

1 Background

In November 2014, England's National Health Service (NHS) announced that a number of drugs being funded from the government's Cancer Drugs Fund (CDF) would be reassessed to determine if they were cost-effective.[1] Of the 31 drugs reassessed by the CDF in December 2014, more than half were deemed as not cost-effective – a number of which were new treatments introduced in the last 2 or 3 years. As a result of this assessment, manufacturers were notified that the CDF was withdrawing funding of these products.[2] In addition, funding was not granted for six more new therapies (for seven indications) due to the CDF's evaluation. The British research based pharmaceutical industry association issued the following response to these developments:

> *"We deplore any decision to restrict or remove patient access to cancer medicines. We reiterate that we are very disappointed that NHS England did not address concerns about the flawed process they are following, raised by the ABPI [Association of British Pharmaceutical Industry] and pharmaceutical companies, before proceeding to re-evaluate CDF medicines. Such a re-evaluation process would not be necessary if NICE quickly evolves the way it evaluates cancer medicines as part of more fundamental reforms."*[3]

The activities of the CDF are unprecedented and may auger how public payers in other international markets may deal with funding oncology treatments which are not deemed to be cost-effective.

2 Objective

PDCI surveyed of a select group of pharmaceutical stakeholders in Canada and Europe to gauge whether public and private payers in other markets, such as Canada, will adopt similar cost containment mechanisms to those found in the European Union and the United States.

3 Methodology

PDCI Market Access conducted an on-line survey focused on the perspective from industry and payers (public and private) from March 19, 2015 to March 25, 2015. We contacted individuals in Europe and Canada. Respondents preserved their anonymity in the survey by only indicating their location and which stakeholder group they represented. In total, nine individuals responded to the survey:

- Three public payers, including former and current, from Canada
- Two private payers from Canada
- Two industry members from Canada
- Two industry members from Europe

[1] http://www.theguardian.com/society/2014/nov/12/cancer-drugs-fund-drugs-reassessed-kadcyla-avastin
[2] "Cancer Drugs Fund table: 12 drugs delisted, six refused entry", 13 January 2015, Gemma Collier, Scrip Intelligence
[3] http://www.abpi.org.uk/media-centre/newsreleases/2015/Pages/090115.aspx

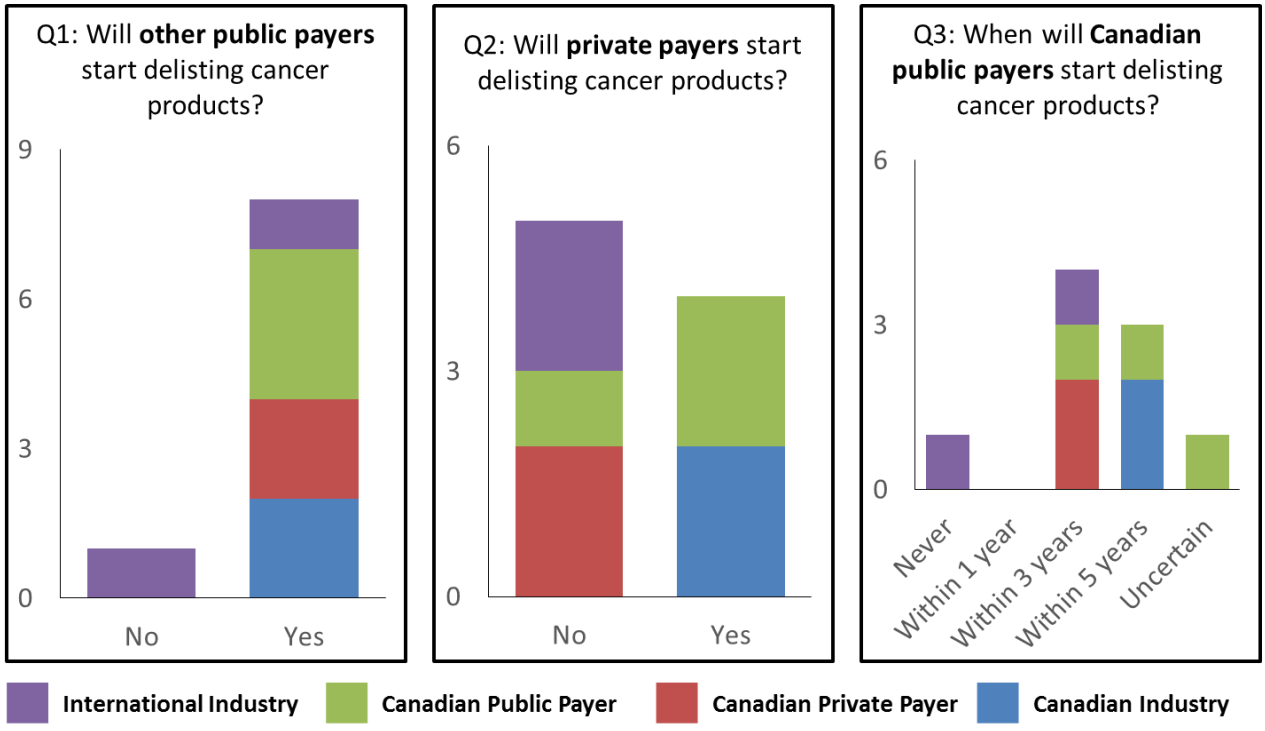
The respondents were asked four questions regarding the delisting of cancer products:

1) Do you believe that other public payers in different countries will start delisting cancer products more liberally as a means for controlling drug costs (particularly when cost-effectiveness has not been demonstrated)?
2) Do you believe that private payers will start delisting cancer products more liberally as a means for controlling drug costs (particularly when cost-effectiveness has not been demonstrated)?
3) When do you think public payers are likely to start delisting cancer products as a means of controlling drug costs in Canada?
4) How do you think industry will address delisting of their products (e.g., price decreases, PLA negotiations, coverage with evidence)?

4 Survey Results

Summarized in Figure 1 are stakeholders' opinions on whether payers in other markets, including Canada, may delist cancer products as a means of cost control.

Figure 1



Seven of the nine respondents provided answers to how they think industry will address the delisting of their oncology products. Their responses are summarized in Table 1 below.

Table 1

Industry

"Indication based pricing, if the countries can set up data base systems to support it."

"PLA negotiations, more real-world evidence to support effectiveness"

"PLAs, coverage with evidence, stakeholder advocacy"

Public Payer

"It is unlikely a price decrease will overcome a lack of clinical evidence so proposals for PLAs may focus more on evidence sharing and/or risk-sharing."

"As cancer is mainly protocol driven, a change in protocol is consistent with delisting. A protocol could be displaced from use, without delisting."

"All of the above." (i.e., price decreases, PLA negotiations, coverage with evidence)

Private Payer

"I hope pharma reconsiders their pricing models. Assuming quality and efficacy are comparable, then public payers are absolutely right to insist on price reduction or other added value as a condition of listing. Governments are stewards of taxpayer money for which there is no shortage of alternative uses."

5 Summary

Eight of the nine survey respondents, including all three Canadian public payer representatives, reported their belief that public payers in other markets, including Canada, may start to delist cancer products if cost effectiveness is not demonstrated. With regard to private payers delisting oncology treatments, stakeholder responses were more mixed: five representatives noted that they did not believe that private payers in Canada would follow down this path. From a timing perspective, seven of the nine respondents reported their belief that Canadian public payers could start to delist certain cancer products in the next three to five years. In terms of how industry may respond to such cost containment initiatives, a number of respondents noted the role that product listing agreements could play in addressing this issue. Although the results of the survey are based on a small sample, it should still give pause to oncology treatment manufacturers in Canada that delisting of products that are not cost effective may be seen as a viable cost containment solution for payers in the future.

About the Author

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Arvind provides strategic solutions to clients on market access-related issues throughout the entire product lifecycle. He leads the development of reimbursement submission dossiers that help clients effectively communicate the value proposition of new technologies to payers/ health technology assessment agencies. Arvind offers clients advice to help negotiate product listing agreements with the pan-Canadian Pharmaceutical Alliance (pCPA) and public drug plans and executes direct payer research projects through primary research interviews with current and former payers across Canada.