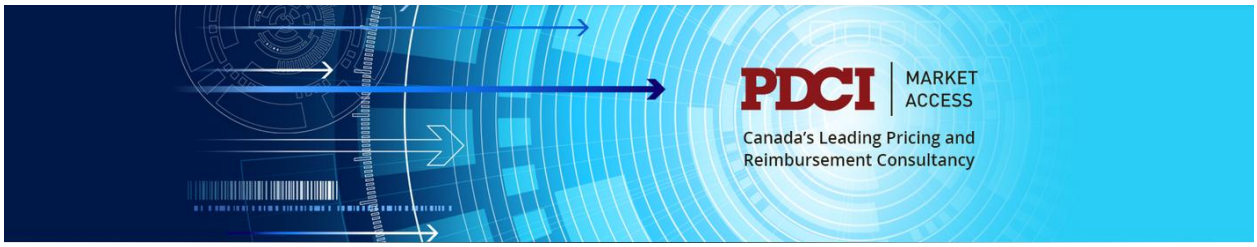

INTERNATIONAL TRENDS SERIES

Issue 3: Downgrading of Benefits

May 19, 2015

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1 Background

Earlier this year, France's health technology assessment body, *La Haute authorité de santé* (HAS), downgraded the *Service Médical Rendu* (SMR) or medical benefit rating, of Boehringer Ingelheim's anticoagulant Pradaxa® (dabigatran etexilate) from "important" to "moderate".

Until now, Pradaxa® and its two competitors, Eliquis® (apixaban; Bristol-Myers Squibb) and Xarelto® (rivaroxaban; Bayer Healthcare), were all rated as "important" in preventing stroke and systemic embolism. However, after reviewing the novel oral anticoagulants and new data from clinical trials, observational studies, and meta-analyses, the transparency committee concluded that Pradaxa® should be downgraded to a "moderate" rating, while the "important" rating assigned to Eliquis® and Xarelto® remained unchanged.

In France, the SMR rating has important implications for reimbursement; a drug with an "important" ranking is reimbursed at 65% of the cost, whereas a "moderate" ranking merits a reimbursement level of 30%. Thomas Borel, a spokesman of Boegringer Ingelhiem, stated that the company had the option of presenting new data to the committee and requesting re-evaluation of the product.[1] However, even if Pradexa regained its "important" rating following a re-evaluation, these reassessments are going to continue. The committee is planning to review these products again in a year's time, to ensure that any new studies or modifications to therapeutic practice are taken into consideration.

France's approach to reassessment and revaluation of coverage status for certain drugs could have important implications for both manufacturers and payers, raising some key questions for the industry. Specifically, what is the likelihood of this mechanism becoming more commonplace in the reimbursement landscape for all therapeutic areas, and will it set the precedent for international payers to follow suit?

2 Objective

PDCI surveyed of a group of pharmaceutical stakeholders in Canada and Europe to gauge whether public and private payers in other markets, such as Canada, will reasssess currently covered therapeutic areas to change their reimbursement criteria.

3 Methodology

PDCI Market Access conducted an on-line survey to obtain the perspective of industry and payers (public and private) on downgrading of benefits. Participants were individuals in Europe and Canada who responded to the on-line survey between March 19, 2015 and March 25, 2015. 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

The survey consisted of four questions regarding reassessments of currently covered products:

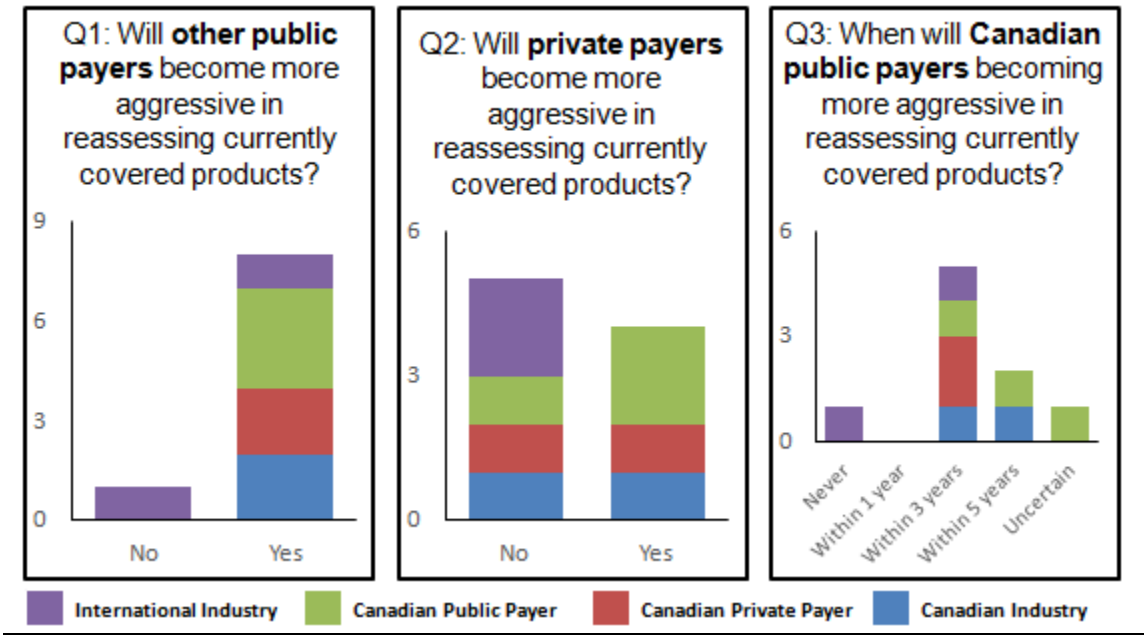
[1] Schofield, I. (2015, January 28). Boehringer attacks French HTA body's downgrading of Pradaxa. *SCRIP Intelligence.* Retrieved from: http://www.scripintelligence.com/policyregulation/Boehringer-attacks-French-HTA-bodys-downgrading-of-Pradaxa-356421

1) Do you believe that other public payers in different countries will become more aggressive in reassessing currently covered products to change their coverage status/criteria?
2) Do you believe that private payers will become more aggressive in reassessing currently covered products to change their coverage status/criteria?
3) When do you believe public payers will become more aggressive in reassessing currently covered products to change their coverage status/criteria?
4) How do you think industry will respond to aggressive reassessments of currently covered products?

4 Survey Results

Summarized in Figure 1 are stakeholders' opinions on whether payers in other markets, including Canada, may start reassessing currently covered products to change their coverage status/criteria.

Figure 1



Two of the nine respondents provided answers to how they think the industry will respond to aggressive reassessments of currently covered products to change their coverage status; responses are summarized in Table 1 below.

Table 1

Public Payer

By more aggressive marketing to physicians.

Private Payer

Concede on original pricing to re-establish the relative value of their products relative to competitors.

5 Summary

Eight of the nine survey respondents, including both Canadian public payers, believed that public payers in other markets will become more aggressive with reassessing currently covered products to change their coverage status. In comparison, only four of the nine thought that private payers will utilize the same mechanisms, including both Canadian public payers. With regards to the timing of reassessments, six of the nine respondents believed Canada will become more aggressive with respect to reassessments within the next three to five years.

This issue is pertinent in Canada as the Canadian Agency for Drugs and Technologies in Health (CADTH) continues to develop therapeutic reviews for a variety of disease conditions. For example, in 2013, CADTH released its therapeutic review for drug therapies to treat multiple sclerosis (MS). The entry of new oral and injectable agents for the treatment of relapsing-remitting multiple sclerosis (RRMS) has had a significant impact on the treatment strategies for patients with RRMS. Although the CADTH review generated significant interest among market access stakeholders, it does not appear to have resulted in any meaningful changes to the listing status of current MS treatments. It remains to be seen whether cost-containment pressures in Canada may change payer perspective on listing status as more therapeutic reviews are released 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.