pCPA CHANGES AND IMPACT TO MARKET ACCESS IN CANADA: RESULTS FROM AN OBSERVATIONAL CROSS-SECTIONAL STUDY

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BACKGROUND

- Over the last decade, one of the most significant changes in the market access environment was the establishment of the pan-Canadian Pharmaceutical Alliance (pCPA) in August 2010
- The purpose of pCPA is to conduct joint provincial/territorial negotiations for brand name and generic drugs to increase access to drug treatment options, improve consistency of coverage criteria across Canada, and achieve lower drug costs and consistent pricing[1]
- While research has been conducted to understand the impact of pCPA on drug funding and market access[2], results were preliminary and there is a paucity of longer term data on the impact of pCPA on public access to medicines
- Further, a growing number of new drugs submitted to the Common Drug Review (CDR) are taking advantage of the pre-NOC submission process, which allows for the submission for Health Technology Assessment (HTA) up to 90-days before issuance of the Health Canada Notice of Compliance (NOC)

OBJECTIVES

- To understand how market access is evolving in Canada by observing the time required for newly approved drugs/ indications to obtain public reimbursement as the relative success rates of public reimbursement
- Specifically, the study seeks to examine the evolving impact of the pCPA and the CADTH pre-NOC review mechanism on public listing of new drugs

METHODS

Approach:

- The IQVIA Market Access Metrics database was used to track and analyze the time and outcome of CDR reviews, pCPA negotiations, and provincial listing decisions
- All drugs with a notice of compliance between 2010-2017 and subsequent CDR recommendation were selected for the analysis (n=293)

I. Time-to-List (TTL):

- TTL measures the total time from NOC to first provincial listing, excluding Quebec's Régie de l'assurance maladie due Québec (RAMQ), which did not participate in the CDR or pCPA process for the majority of the analysis period
- 154 reviews qualified for this analysis

II. Decision Metrics:

- All reviews that were considered for and/or had completed pCPA negotations (n=186), were included and the outcomes of those decisions were tracked
- In addition, the number of drugs with a CDR recommendation but no pCPA decision were also monitored

Data Comparisons:

I. Time to List:

- Compared TTL for reviews that received documented pCPA decisions to reviews that received provincial listing without pCPA negotiations
- Compared reviews that were submitted to CDR pre-NOC with post-NOC CDR reviews

II. Decision Outcomes:

- Tracked the annual volume of pCPA negotiation decisions (2014-2017) by decision type (n=186) including the appearance of re-negotiations (n=19)
- Tracked the proportion of CDR reviews that were negotiated by pCPA (2011-2017, n=110/154)
- Calculated time from CDR recommendation to pCPA decision date (2014-2017) for all negotiation types, excluding active negotiations (n=166)

RESULTS

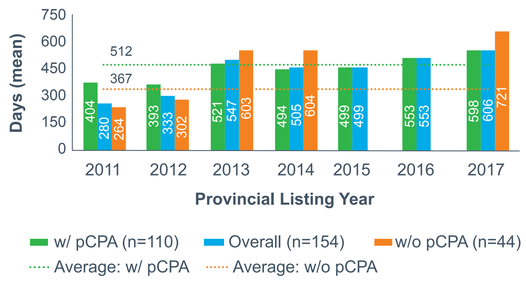
Overall, we found that new drugs that achieved listing in this time frame took, on average, 471 days to achieve public listing. (n=154)

Part I: *TTL Metrics – Time from NOC to First Provincial Listing for CDR reviews*

a) pCPA Impact

The average TTL for reviews that were listed without pCPA decisions was 367 days (n=44), ~3 ½ months (104 days) faster than the overall average. Reviews with pCPA decisions achieved provincial listing in ~17 months (512 days, n=110), which is 40% longer than reviews without pCPA decisions.

Figure 1: Average Time-to-List per CDR Review by Year: with pCPA versus without pCPA

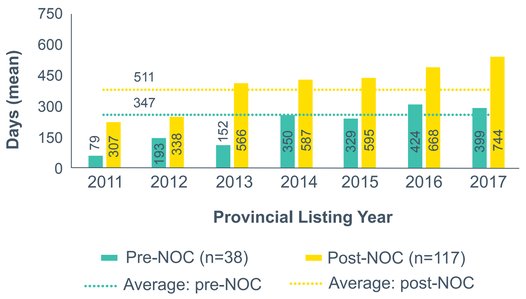


# OF REVIEWS	2011	2012	2013	2014	2015	2016	2017
With pCPA	2	9	15	26	25	19	14
Without pCPA	15	18	7	3	0	0	1
Total	17	27	22	29	25	19	15

b) Pre-NOC Impact

- The average TTL for pre-NOC and post-NOC reviews was 347 days (n=38) and 511 days (n=116), respectively
- Pre-NOC reviewed drugs were submitted to CDR 75 days (average) prior to NOC issuance, and achieved provincial listing ~5 1/2 months faster (average) than post-NOC reviews, which submitted to CDR ~199 days (average) after NOC issuance

Figure 2: Average Time-to-List per CDR Review by Year: Pre-NOC versus Post-NOC CDR Submissions



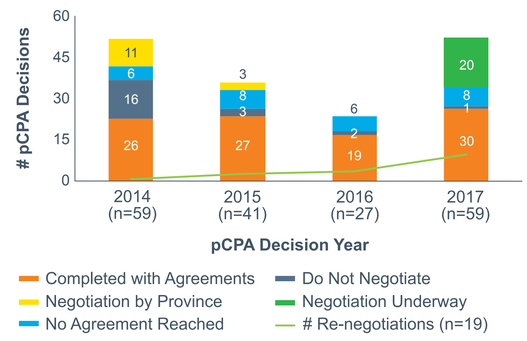
# OF REVIEWS	2011	2012	2013	2014	2015	2016	2017
Pre-NOC	2	1	1	10	9	9	6
Post-NOC	15	26	21	19	17	10	9
Total	17	27	22	29	26	19	15

Part II: *Decision Metrics – pCPA Analysis*

a) pCPA Decision Types

- The volume of pCPA negotiations experienced a downward trend during 2014-2016 until 2017
- The number of re-negotiations (n=19) increased 2014-2017, with the following decision types:
  - 11 completed with agreements
  - 1 negotiation by province
  - 2 closed with no agreement
  - 5 actively undergoing negotiation

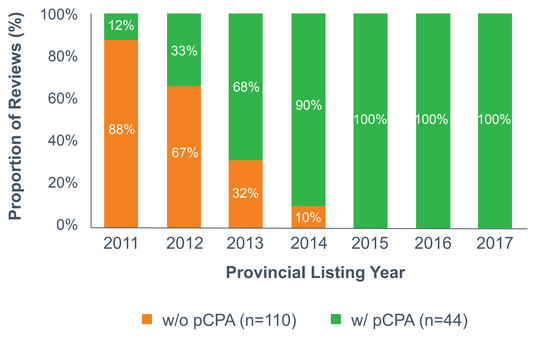
Figure 3: pCPA Negotiations by Decision Type and Volume by Year



b) pCPA Decision Types

- The proportion of CDR reviews considered for pCPA has increased each year to reach 100% in 2015

Figure 4: Proportion of CDR Reviews with pCPA Decisions by Year

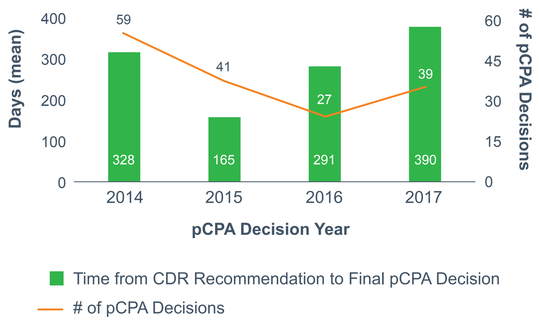


# OF REVIEWS	2011	2012	2013	2014	2015	2016	2017
With pCPA	2	9	15	26	25	19	15
Total CDR	17	27	22	29	25	19	15

c) Time Through pCPA

- Average time from CDR recommendation to pCPA decision decreased in 2015; however, an increase to 13 months was observed in 2017 (n=166)

Figure 5: Time from CDR Recommendation to pCPA Final Decision by Year



CONCLUSION

Summary of Findings:

- Overall, between 2010 and 2017, the average time to first public listing for new drugs was 1 year and 4 months (n=154)
- The proportion of CDR reviews with pCPA decisions increased to 100%, indicating that all drugs listed by provinces in 2015 onwards required pCPA negotiation decisions first
- Drugs that used the pre-NOC CDR review had a 274-day (75 + 199) head start compared to post-NOC drugs; the pre-NOC process saved an average of 164 days from time to first public listing when compared to the TTL for post-NOC drugs
- As the pCPA has ramped up to apply to all new drugs, the time through negotiation seems to have increased

Future Directions:

- To observe the evolution of TTL and decision metrics in:
  - Quebec, assessing the impact after INESSS joined pCPA
  - pCODR, comparing trends in oncology therapies to CDR
  - pCPA re-negotiations, to continue tracking the observed trend of re-negotiations as pCPA calls manufacturers back for discussions or as manufacturers file for second letters of intent
  - CDR, assessing the impact that the recently doubled pre-NOC threshold will have on public access, moving to 180-days effective April 2018
  - Overall access, looking at the proportion of new drugs listed across each province and identifying the characteristics of new products that lead to public reimbursement

Limitations:

- The CDR, pCPA, and provincial formulary data used in this study is based on publicly accessible information:
- pCPA negotiations actual start and completion dates are not disclosed
- The time spent in pCPA negotiations is impacted by both the pCPA and the drug manufacturer. Results may vary.

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