

EXPLAINING PUBLIC REIMBURSEMENT DELAYS FOR NEW MEDICINES FOR CANADIAN PATIENTS

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Canada maintains a high status globally for the approval & launch of new medicines.

It is time to modernize Canada's reimbursement system. Canadians have been waiting far too long.

Recommendation: All pharmaceutical policy reforms, including the PMPRB reforms, must seriously consider the impact to Canadian patients in terms of access to new medicines, especially with respect to drugs for rare diseases and drugs recognized by regulators as meeting unmet needs (i.e. special review status).

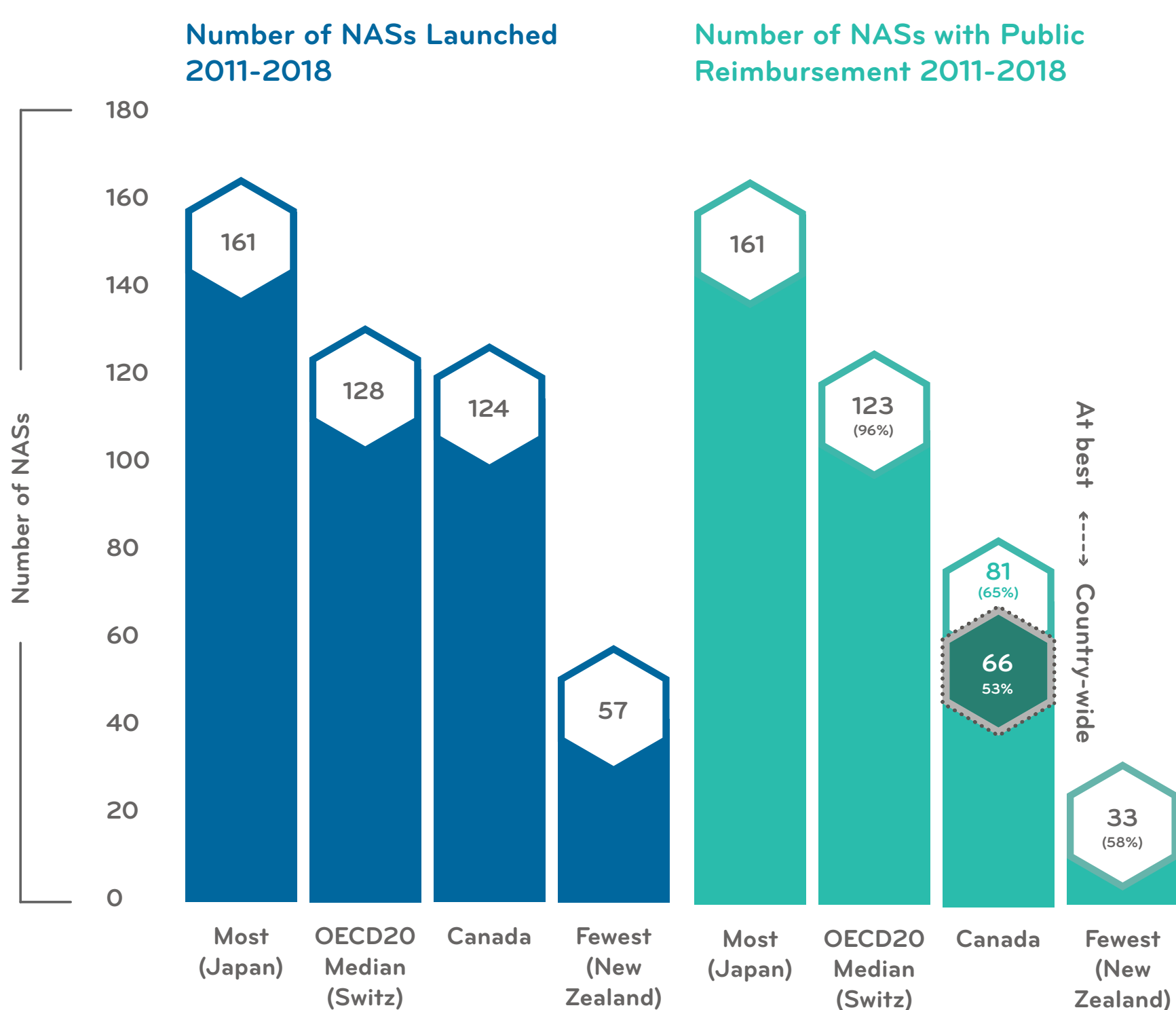
Recommendation: Canada's reimbursement system is slow due to its sequential nature and the growing pCPA process timelines. We need to remove barriers to existing streamlining opportunities and create additional opportunities in the public reimbursement process that encourages innovation and offers faster access to all Canadians.



Recommendation: Canada needs to adopt global best practices to speed up reimbursement for products that have been identified as priority medicines by Canadian and other global regulators and payers. This could be piloted with the creation of a Drugs for Rare Diseases framework.

1

CANADA IS SIMILAR TO THE OECD20 MEDIAN IN NUMBER OF LAUNCHES, BUT REIMBURSES 32%-45% FEWER NEW MEDICINES IN ITS PUBLIC PLANS.*



Canada's launch rate is similar to the OECD20 median; however, its reimbursement rate is significantly lower: 65% at best compared to 96% (32% fewer). When considering country-wide reimbursement, Canada's reimbursement rate falls to 53% (when allowing a minimum 2-year lag) (45% fewer), approaching the level of New Zealand, which has the fewest new drugs launched and publicly-reimbursed in the OECD20.

BACKGROUND

Canadian patients face sizable access delays for new medicines due to submission filing and regulatory decisions,¹ as well as from Canada's fragmented and sequential reimbursement process^{2,3}.

OBJECTIVE

Understand how Canadian reimbursement compares to our peer countries, to what extent Canadian reimbursement delays are due to regulatory vs reimbursement process timelines, and which drugs and patients are most impacted.

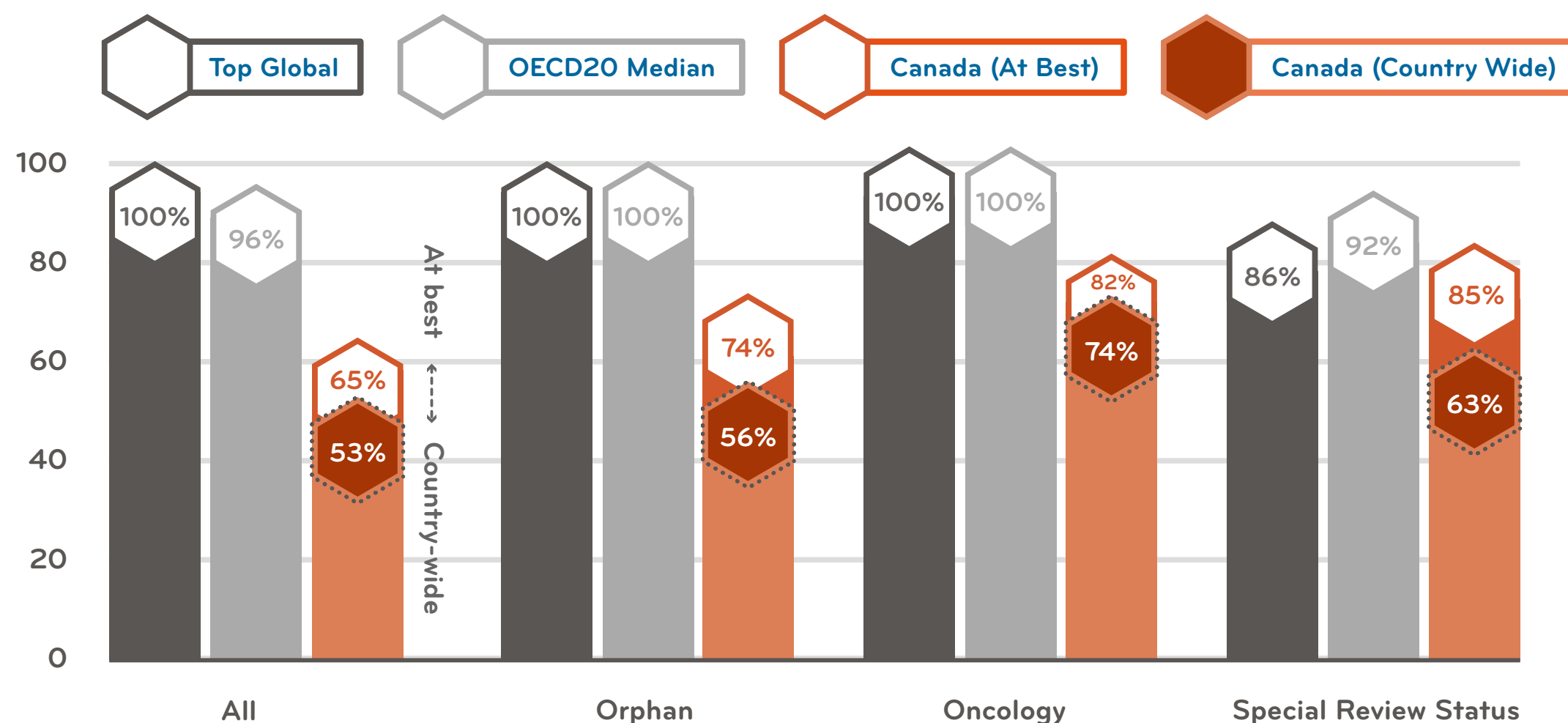
METHODS

Using data from IQVIA MIDAS & Pricing Insights and a local pan-Canadian database of reimbursement metrics, this study follows the global timeline sequence of regulatory approval, launch, and public reimbursement milestones for new medicines approved in 20 OECD countries, and specific milestones across Canada's public drug plans. Metrics include the number of new medicines and timelines starting from 1st global approval. Sub-analyses include therapeutic categories and priority status.

2

CANADA REIMBURSES FEWER LAUNCHED PRODUCTS THAN ITS GLOBAL COUNTERPARTS, REGARDLESS OF SPECIAL REVIEW STATUS, ONCOLOGY, OR ORPHAN DESIGNATIONS.*

% Share of Launched NASs with Public Reimbursement, by Type of Product

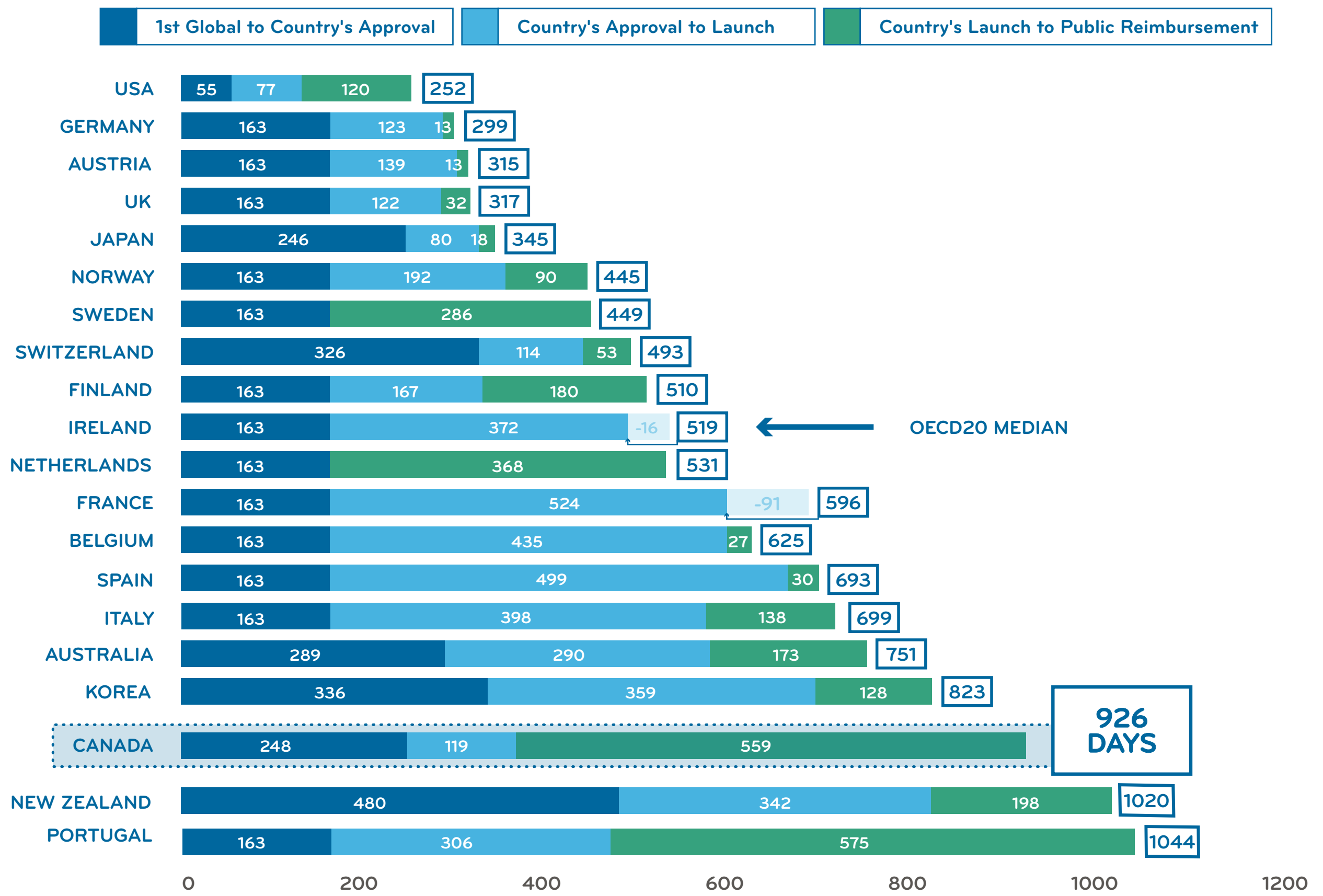


Canada also underperforms the OECD20 Top and Median countries in terms of reimbursement for drugs that treat unmet needs, as well as all medicines generally. In the case of orphan and oncology medicines, Canada reimburses at best 74% and 82% of launched medicines, respectively, and only 56% to 74% country-wide, respectively, compared to 100% in the OECD20 Top and Median countries. As for drugs obtaining local special review status by their regulatory authority, Canada does not do marginally better compared to the OECD20 Median country. This indicates that Canada does not seem to prioritize high-need medicines for its public reimbursement access.

3

CANADA IS RELATIVELY QUICK TO APPROVE AND LAUNCH NEW MEDICINES, BUT AMONG THE SLOWEST OF THE OECD20 TO REIMBURSE THEM THROUGH ITS PUBLIC PLANS.*

Total Time From 1st Global Approval, to Local Country Public Reimbursement, 2012-2018

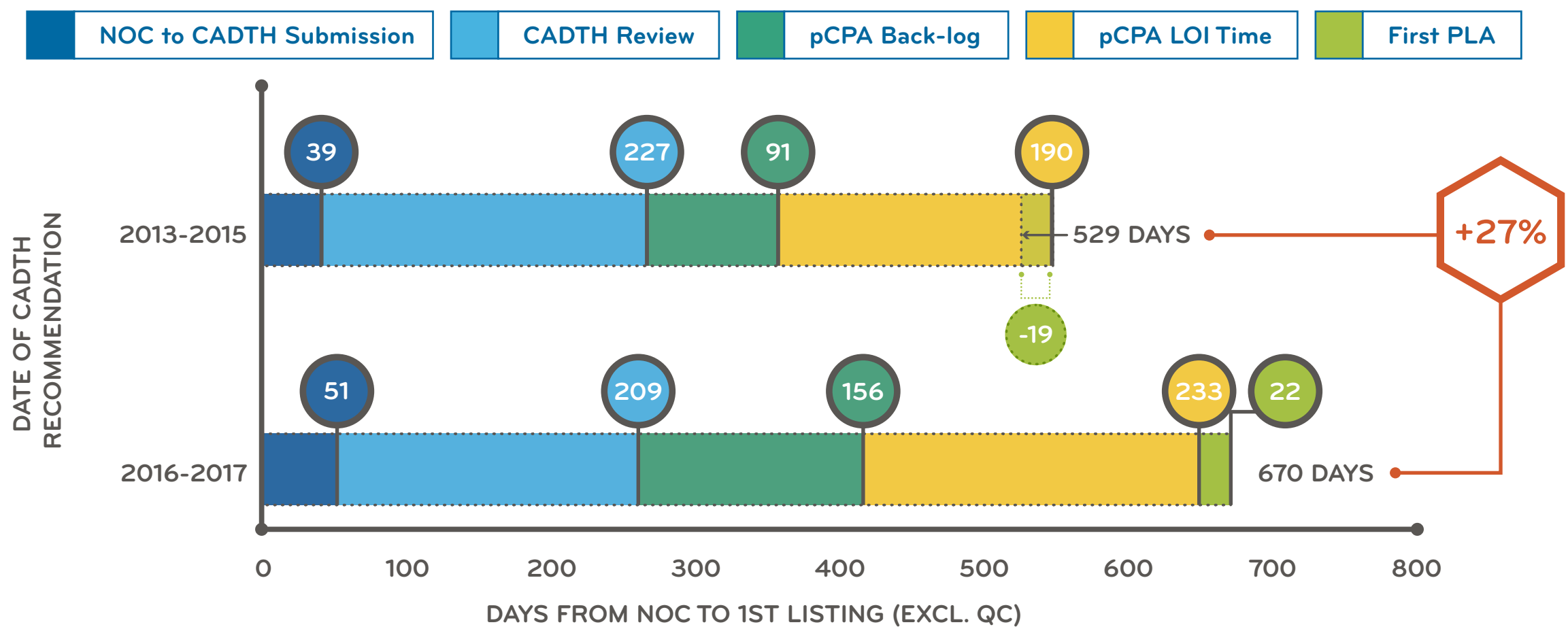


Canada ranks 18th out of 20 OECD countries from 1st global authorization to public reimbursement under the best-case scenario (20% of public plan beneficiaries). Compared to the 1st global authorization (in the OECD20), Canada takes on average 248 days to reach approval, 119 days to launch, and another 559 days to reach its best-case public reimbursement. Compared to the fastest, the OECD20 Median, and the slowest country to reach public reimbursement, Canada's authorization and launch timelines are comparable, but its reimbursement is nearly identical to Portugal, the slowest country in the OECD20. This indicates that Canada's slow public reimbursement process is responsible for Canada's long global access delay.

4

CANADA'S PUBLIC REIMBURSEMENT PROCESS IS SLOW DUE TO ITS SEQUENTIAL NATURE, AND IS GETTING SLOWER AS THE PCPA TIMELINES WORSEN.**

Days from Approval to First Provincial Listing, As of March 2019

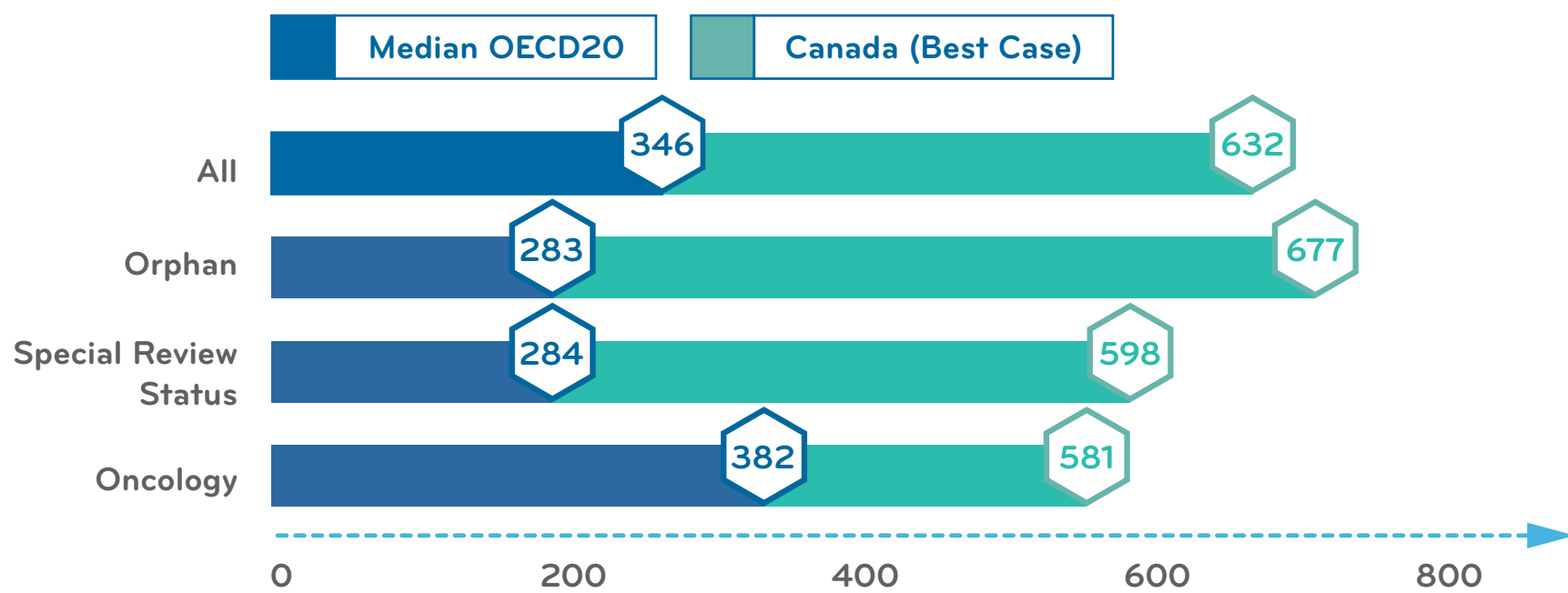


As of March 2019, time from NOC to reach first public listing (excluding Quebec) had increased from 529 days to 670 days. Although the timelines to reach CADTH recommendations in 2016-2017 fell compared to 2013-2015, the overall increase in delays from NOC to reach first public listing can be attributed to longer pCPA timelines. pCPA letters of intent and listings achieved following 2016-2017 CADTH recommendations continue to show a large discrepancy between oncology and non-oncology products, with non-oncology standing at 708 days from NOC, compared to 590 days for oncology products.

5

UNLIKE THE OECD MEDIAN, CANADA'S REIMBURSEMENT PROCESS DOES NOT APPEAR TO PRIORITIZE BASED ON PATIENT NEEDS.*

Time from Local Marketing Authorization to Public Reimbursement, by Category



The OECD20 Median country's reimbursement process appears to prioritize drugs for high unmet needs such as orphan drugs and drugs with special regulatory review status (such as an accelerated, breakthrough or priority review). This is not the case in Canada, which is the slowest to reimburse orphan drugs vs other drugs and takes more than twice as long to reimburse both orphan drugs and special review status drugs compared to the OECD20 median. Although there are some accelerated process opportunities such as the joint HTA-regulatory process, there remain barriers to their uptake which may include high uncertainty regarding the use of CADTH reviews as part of PMPRB's proposed Guidelines.

REFERENCES & NOTES

¹ Sarah Lussier Hoskyn. Factors Associated with Submission and Regulatory Timelines for New Medicines. Presented at DIA Annual Summit, October 2018.

² Salek Sam, Lussier Hoskyn Sarah, Johns Jeffrey Roy, Allen Nicola, Sehgal Chander. Factors Influencing Delays in Patient Access to New Medicines in Canada: A Retrospective Study of Reimbursement Processes in Public Drug Plans . *Frontiers in Pharmacology*, VOLUME 10, Mar 29, 2019. DOI 10.3389/fphar.2019.00196.

³ Salek Sam M., Lussier Hoskyn Sarah, Johns Jeffrey, Allen Nicola, Sehgal Chander. Pan-Canadian Pharmaceutical Alliance (pCPA): Timelines Analysis and Policy Implications . *Frontiers in Pharmacology*, VOLUME 9, February 18, 2019. DOI 10.3389/fphar.2018.01578

* Data from IQVIA, International Access to Medicines 2019. Analysis by Innovative Medicines Canada, February 2020. New Active Substances approved in individual countries between 2011-2016, and launched or publicly-reimbursed between 2011-2018. Measure of "Most", "Median", and "Fewest" country selected based on number of reimbursements for consistency (with their respective number of launches). NAS = new active substances. "At best" or Best-case = 20% of public plan beneficiaries. "Country-wide" = 80% of public plan beneficiaries. Special Review Status = expedited review pathway in respective country. Orphan = FDA or EMA designated.

** Data from Health Canada, CADTH, and provincial listing data (excl QC), collected by IQVIA. Analysis by Innovative Medicines Canada. Includes all CADTH recommendations (including new indications) made from a manufacturer submission. Excludes resubmissions.