

Appendix 3. Rationale for a two-year launch window

The findings from the following studies have suggested a median time to launch longer than one year, or a low proportion of domestic launches among new patented medicines launched globally especially within one year, in most of our study countries including Canada. To balance the sample size to avoid a low number of launches in a specific study country in a time period, we chose using a 2-year launch window in our main analysis. We also used a 1-year launch window as a sensitivity analysis. However, we could not further conduct sub-group analyses using the 1-year launch window because of the (expected) low number of launches. We have presented the sample size by launching status (yes vs. no), country, and policy period for both 2-year launch window and 1-year launch window in Appendix Table S1 below. When using December 2017 as the effective date for our main analysis, the number of launches within one year during the uncertain period was smaller than 10 in Australia, Belgium, Italy, the Netherlands, Norway, Spain, and Switzerland.

1. Varol N, Costa-Font J, McGuire A. Does Adoption of Pharmaceutical Innovation Respond to Changes in the Regulatory Environment? Applied Economic Perspectives and Policy. 2012;34(3):531–53.

Varol et al. measured the median time to launch relative to the first global launch for multiple countries including all our study countries except Norway. Among new molecules launched globally as well as in the US or UK in 1995-2008, the median time to launch were less than one year among the US, Germany, Sweden, the UK, and the Netherlands. For the remaining countries, the median time to launch ranged from 1.136 years in Canada and then 1.413 years in Switzerland, to 2.667 years in Spain and 6.582 years in Japan.

2. Innovative Medicines Canada. An assessment of Canada's current and potential future attractiveness as a launch destination for innovative medicines [Internet]. 2019 [cited 2020 Oct 9]. Available from: http://innovativemedicines.ca/wp-content/uploads/2019/02/2019_01_29_-_IMC_PhRMA_LaunchSequencing_vFINAL3.pdf#page13.

This more recent report analyzed the 243 new active substances (NASs) launched from January 2011 to June 2018 and calculated the proportion of domestic launches, and the median launch lags (between the global first launch date and the domestic launch date) among those that were launched in a given country. About 49% of these 243 NASs were launched in Canada and their median launch lag was 11 months. Although the median launch lags were less than 1 year among the US, the Netherlands, Sweden, Germany, the UK, Japan, and Norway, their proportion of domestic launches ranged from 35% for the Netherlands to 88% for the US. The median launch lags were more than 1 year among Switzerland, Australia, Italy, Belgium, France, and Spain, and the proportion of domestic launches ranged from 31% for Australia to 52% for Switzerland.

3. Patented Medicine Prices Review Board. Meds Entry Watch, 2016 [Internet]. 2018 [cited 2024 Jan 24]. Available from: <https://www.pmprb-cepmb.gc.ca/view.asp?ccid=1374>.

4. Patented Medicine Prices Review Board. Meds Entry Watch 7th Edition [Internet]. 2023 [cited 2024 Jan 15]. Available from: <https://www.canada.ca/en/patented->

medicine-prices-review/services/npduis/analytical-studies/meds-entry-watch-7th-edition.html

The PMPRB’s Meds Entry Watch reports presented the sale status of new patented medicines for all our study countries. For example, among the new medicines that were approved by the US Food and Drug Administration, the European Medicines Agency, or Health Canada from 2016 to 2020, the share of new medicines with available sales by Q4 2021 ranged from 78% in the US and 57% in Germany, to 23% in Australia and 13% in the Netherlands. The share for Canada was 33%. Among 50 new medicines in 2020, 38 (76%) had sales in the US, 10 (20%) had sales in Canada, Sweden and Switzerland, 9 (18%) in Norway and Italy, 4 (8%) in Australia, 3 (6%) in the Netherlands and Belgium, and 2 (4%) in Spain by Q4 2021. Among 41 new medicines in 2015, 14 (34%) had sales in Canada, 12 (29%) in Italy, 11 (27%) in Spain, and 9 (22%) in Australia, Belgium and the Netherlands by Q4 2016.

Table S1. Number of launches by country, launch window and policy period

Country	Launch window	Before uncertain period 2012-2017 (N=242)	Uncertain period after 2017 (N=107)	Before uncertain period 2012-2015 (N=162)	Uncertain period after 2015 (N=187)
CANADA	one-year	60 (25%)	19 (18%)	39 (24%)	40 (21%)
CANADA	two-year	109 (45%)	33 (31%)	72 (44%)	70 (37%)
US	one-year	185 (76%)	88 (82%)	122 (75%)	151 (81%)
US	two-year	197 (81%)	88 (82%)	131 (81%)	154 (82%)
OTHERS	one-year	176 (73%)	63 (59%)	121 (75%)	118 (63%)
OTHERS	two-year	203 (84%)	75 (70%)	140 (86%)	138 (74%)
AUSTRALIA	one-year	31 (13%)	6 (6%)	23 (14%)	14 (7%)
AUSTRALIA	two-year	78 (32%)	19 (18%)	53 (33%)	44 (24%)
BELGIUM	one-year	23 (10%)	3 (3%)	14 (9%)	12 (6%)
BELGIUM	two-year	87 (36%)	17 (16%)	57 (35%)	47 (25%)
FRANCE	one-year	44 (18%)	12 (11%)	28 (17%)	28 (15%)
FRANCE	two-year	90 (37%)	36 (34%)	60 (37%)	66 (35%)
GERMANY	one-year	123 (51%)	36 (34%)	83 (51%)	76 (41%)
GERMANY	two-year	154 (64%)	57 (53%)	105 (65%)	106 (57%)
ITALY	one-year	25 (10%)	6 (6%)	17 (10%)	14 (7%)
ITALY	two-year	108 (45%)	33 (31%)	69 (43%)	72 (39%)
JAPAN	one-year	81 (33%)	33 (31%)	56 (35%)	58 (31%)
JAPAN	two-year	106 (44%)	41 (38%)	73 (45%)	74 (40%)
NETHERLANDS	one-year	45 (19%)	5 (5%)	34 (21%)	16 (9%)
NETHERLANDS	two-year	70 (29%)	11 (10%)	49 (30%)	32 (17%)
NORWAY	one-year	68 (28%)	6 (6%)	49 (30%)	25 (13%)
NORWAY	two-year	124 (51%)	26 (24%)	85 (52%)	65 (35%)

SPAIN	one-year	29 (12%)	4 (4%)	19 (12%)	14 (7%)
SPAIN	two-year	91 (38%)	20 (19%)	60 (37%)	51 (27%)
SWEDEN	one-year	86 (36%)	18 (17%)	60 (37%)	44 (24%)
SWEDEN	two-year	138 (57%)	33 (31%)	94 (58%)	77 (41%)
SWITZERLAND	one-year	61 (25%)	8 (7%)	46 (28%)	23 (12%)
SWITZERLAND	two-year	108 (45%)	27 (25%)	75 (46%)	60 (32%)
UK	one-year	104 (43%)	26 (24%)	71 (44%)	59 (32%)
UK	two-year	146 (60%)	50 (47%)	99 (61%)	97 (52%)