CHPI Canadian Health Policy Institute

## Annual Report

# Access to new medicines in Canada 2016-2021

Federal-provincial public drug programs and private sector drug plans

# Access to new medicines in Canada 2016-2021

## Federal-provincial public drug programs and private sector drug plans

CONTRIBUTORS

(Alphabetical order)

Mark Rovere, PhD candidate, Canadian Health Policy Institute (CHPI)
Brett Skinner, PhD, Canadian Health Policy Institute (CHPI)

ATTRIBUTION

This paper is corporately authored and edited based on proprietary template models and methods that are intended to facilitate regular updates. The design and content are a cumulative reflection of the diverse contributions collectively attributable to the CHPI affiliated researchers who may have variously participated in updating each edition. Data sources, methods and editorial presentation may evolve from previous editions.

DISCLAIMER

This study uses data from IQVIA Inc. The analysis, conclusions and opinions expressed in this paper do not necessarily reflect the views of the data supplier.

CITATION

Canadian Health Policy Institute (CHPI) (2022). Access to new medicines in Canada 2016-2021 Federal-provincial public drug programs and private sector drug plans. *Canadian Health Policy*, APR 2022. ISSN 2562-9492 https://doi.org/10.54194/GCAP7754 canadianhealthpolicy.com.

COPYRIGHT ©

## Table of Contents

# Introduction

## What good is your drug plan if it doesn't cover new medicines?

Good drug insurance should provide financial protection from unexpected and unaffordable costs of accessing necessary medicines when you or your family experience serious health challenges. Most prescription drugs are priced low enough (relative to other household expenses) to be affordable as an out-of-pocket expense which does not require insurance. Older versions of widely used drug products tend to be the most affordably priced. Newer products – often the latest treatment advances, first-in-class therapies, or targeted therapies for rare diseases – can be expensive and unaffordable without insurance. Therefore, it is important to measure the quality of benefits provided under your drug insurance plan according to how good the coverage is for new medicines.

Since 2013, CHPI has regularly compared the quality of the benefits in private versus public drug plans, according to the scope of coverage for new medicines. Our analysis raises awareness about differences in the insurance benefits provided to patients and informs policy discussions about how best to achieve socio-economically optimal drug insurance systems in Canada.

The research is important because the federal government has proposed replacing Canada's private-public prescription drug insurance system with a single-payer national pharmacare program that would be modeled on existing public formularies. Public plans cover far fewer new drugs compared to private plans in Canada. Public plans also take much longer to cover new drugs compared to private plans. The limited scope of coverage in existing public drug plans is indicative of what Canadians can expect from national pharmacare. The results of this study forewarn that national pharmacare will reduce access to new medicines for Canadians currently covered under private plans.

## Objective

The study compares the percentage of available new medicines listed on the formularies of public sector and private sector drug plans; estimates how long Canadians waited for insured access to the available new medicines; identifies causes of limited availability and excessive waits, and recommends practical policy options.

# Data and Method

A new medicine (i.e. innovative or patented, drug or pharmaceutical) was defined as a patented prescription drug product (chemical or biologic), categorized as a new active substance (NAS) by Health Canada, and granted marketing authorization for human use in Canada during the calendar years 2016 to 2020. According to Health Canada, a new active substance is a new drug (pharmaceutical or biologic) that contains a medicinal ingredient not previously approved in a drug in Canada and that is not a variation of a previously approved medicinal ingredient.

The study uses the terminology “marketing authorization (MA)” interchangeably with “regulatory approval(s)”. Both terms mean that Health Canada has issued formal permission to sell a new drug. The terminology “formulary listings” is used interchangeably with “insurance coverage” or “reimbursement”.

Insured access to a new medicine was indicated by its inclusion on the formulary of a drug plan. Insurance coverage was deemed to be the only meaningful concept of access because the cost of many pharmaceuticals would be financially unaffordable for most people without the risk pooling associated with private insurance plans or the subsidy associated with publicly funded drug plans.

The availability status was verified, and wait times metrics were calculated, for the same drug across all jurisdictions. The number of formulary listings were calculated from counts of dates posted in the database. The insurance coverage delay was defined as the number of days lapsed between the date of marketing authorization, and the date that the medicine was included on an insurance formulary in the jurisdiction. The delays were calculated by subtracting earlier dates from later dates using the date value function of Microsoft Excel. The federal–provincial formulary data were aggregated at the national level by jurisdictional population weighted average observed across all listings, while the numbers for private drug plans were the first recorded experience with a paid claim in any plan. The difference in method was necessary due to the lack of perfectly comparable data.

The submission dates for new drug applications and the effective dates of regulatory approval were obtained by special request from Health Canada for all new active substances that were authorized for marketing from 1 January 2016 to 31 December 2020. Canadian formulary data were separately available for the 11 federal (Non-Insured Health Benefit NIHB) and provincial publicly funded drug plans, and were available collectively in aggregate across private sector drug plans from IQVIA Inc. **[**1**] [**2**]** The data were supplemented and cross-referenced by accessing the publicly available formulary lists from the federal and provincial drug plans and cancer care agencies. Formulary status was assessed current to 21 December 2021 to allow at least one year for formulary listings data to mature. The study excluded gene therapies and vaccines.

The data were compiled into CHPI's Canadian Access to Innovative Medicines Database (CA2IMD). The database includes the brand name, generic name, manufacturer, jurisdictional regulator, submission class (e.g. NAS), biologic/chemical identifier, new drug application date, marketing authorization date for drugs approved by Health Canada, and reimbursement data including first claim date across private sector drug plans, formulary listing dates for each federal and provincial drug plan, and the reimbursement status of each formulary listing. The database is updated annually.

## Formulary Listings

Health Canada reported 185 marketing authorizations for new active substances during 2016-2020. Three NAS were vaccines and were excluded from the data analysis, leaving 182 remaining. Multiplying the 182 NAS across 11 federal and provincial drug plans there were 2,002 total potential formulary listing opportunities from 2016 to 2021. The number of actual formulary listings across the 182 NAS and 11 jurisdictions totaled 424 (21% of 2,002). **[EXHIBIT 1]**

**EXHIBIT 2** shows the number of formulary listings in each of the federal and provincial drug plans, also stated as a percentage of the 182 new medicines authorized for marketing by Health Canada

from 2016-2020. Coverage for new drugs varied between the jurisdictions, ranging from 30% (54 of 182) in Ontario to 11% (20 of 182) in British Columbia.

**EXHIBIT 2** also shows the average number of formulary listings aggregated across public sector and private sector drug plan, stated as a percentage of the 182 new medicines authorized for marketing by Health Canada from 2016-2020. As a population weighted average, public drug plans covered only 43 (24%) of the 182 new drugs approved in Canada, compared to 116 (64%) in private drug plans.

EXHIBIT 1. Total formulary listings across 11 federal and provincial public drug plans 2016-2021 stated as a percentage of total potential.

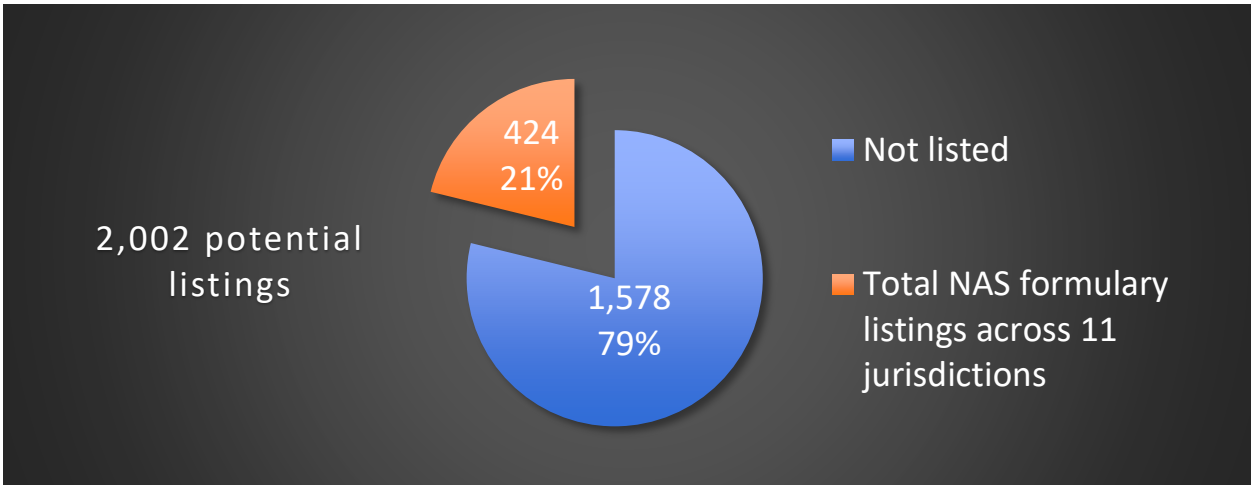
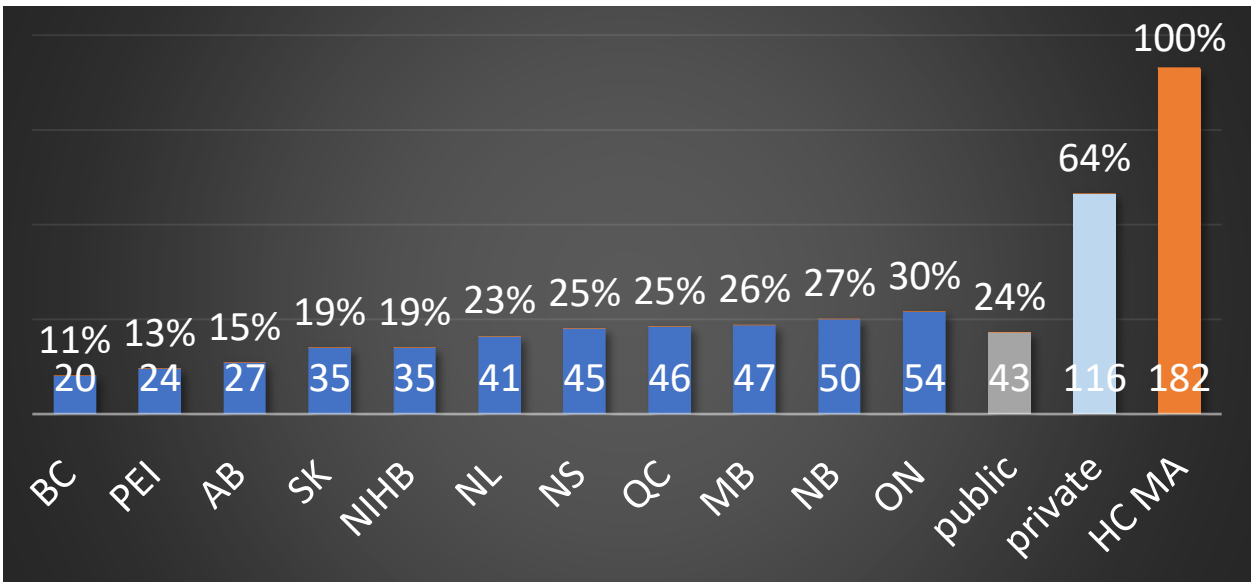



EXHIBIT 2. Formulary listings of 182 new drugs approved by Health Canada 2016-2020 in federal and provincial public sector and private sector drug plans as of December 21, 2021

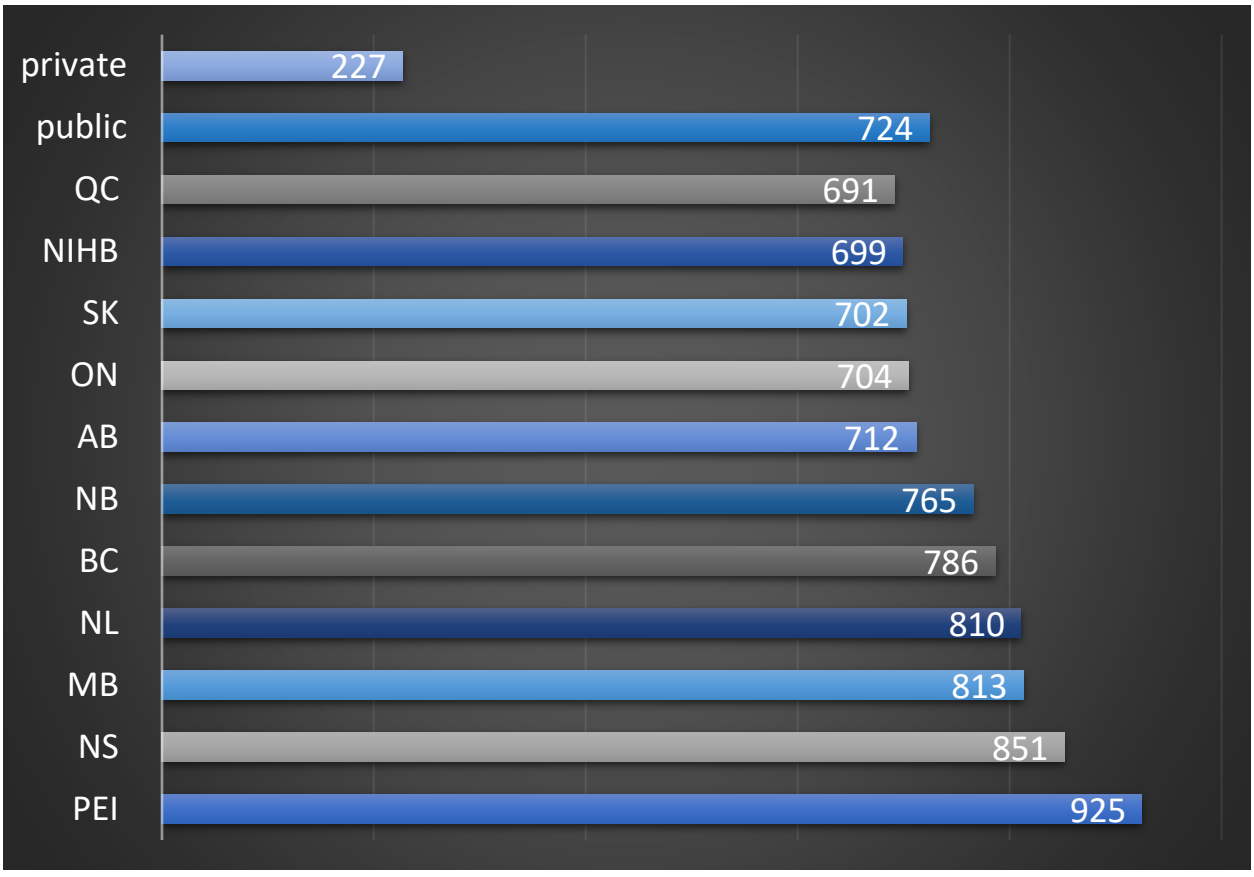


## Insurance coverage delay

The insurance coverage delay is represented by the time between the date of national marketing authorization and inclusion on a drug plan formulary. **EXHIBIT 3** shows the average number of days from national marketing authorization by Health Canada to first formulary listing in each of the federal and provincial drug plans. The data indicate that the insurance coverage delay, ranged from 691 days in Quebec, up to 925 days in Prince Edward Island.

**EXHIBIT 3** also presents the results from the analysis of public sector and private sector drug plans. Stated as a population weighted average, the insurance coverage delay to access new medicines under a public drug plan was 724 days compared to 227 days under private sector drug plans.

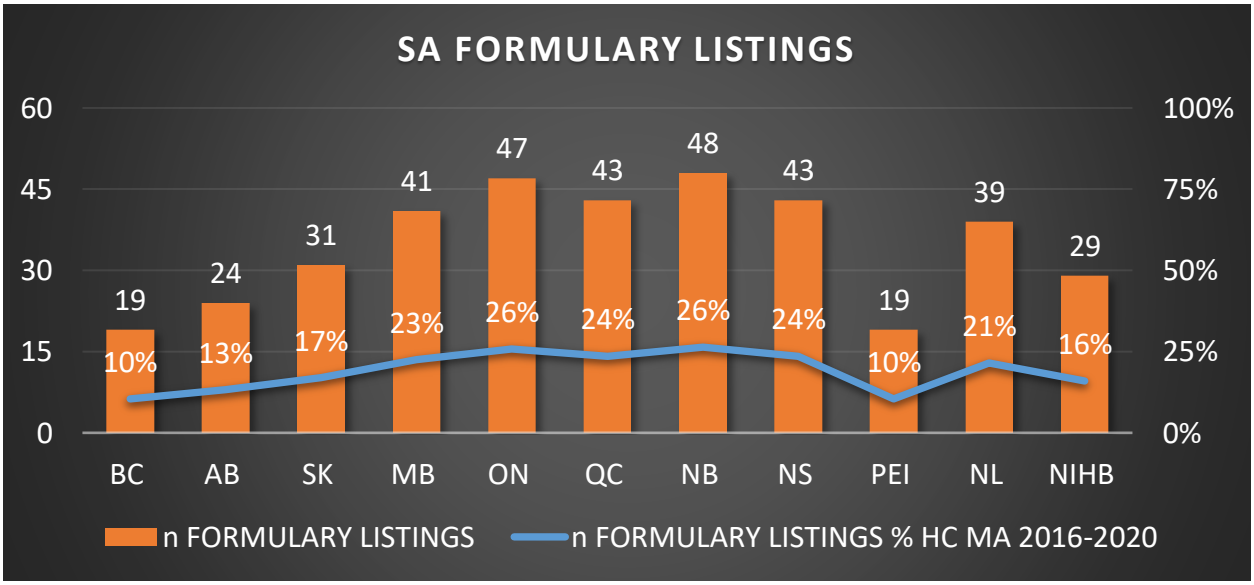
EXHIBIT 3. Average number of days between marketing authorization and formulary listing in federal and provincial, and public sector and private sector drug plans 2016-2021

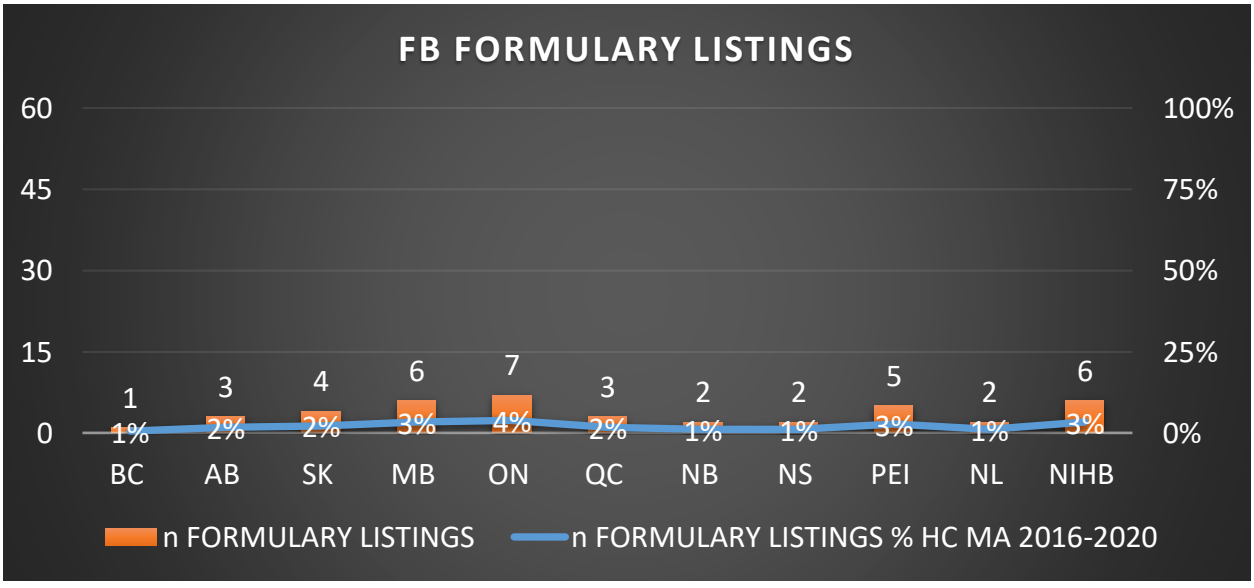


## Full benefit versus special authorization

When a new medicine is listed on a public formulary, federal and provincial drug plans make access conditional by listing the drug product either as an unrestricted full benefit (FB) or as a limited use benefit accessible only by special authorization (SA) from the ministry of health. **EXHIBIT 4** shows the number and percentage of SA and FB formulary listings in each federal and provincial drug plan, of the 182 marketing authorizations issued by HC from 2016–2020. The data indicate that even among the few drugs that are listed on a public formulary, access to most of them is restricted by special authorization status. Of the 424 cumulative public formulary listings across the 11 jurisdictions, access by SA (384) outnumbered FB (40).

EXHIBIT 4. Formulary listings by special authorization (SA) versus full benefit (FB)



# Policy Discussion

## National Pharmacare

The recent cooperation agreement between the federal Liberals and the NDP has revived proposals for a universal single-payer national pharmacare program. National pharmacare will entrench the scarcity and delays affecting access to new medicines in federal and provincial drug plans. Our analysis shows that public drug plans listed fewer than one-quarter of all new drugs approved by Health Canada, and the wait for coverage of these few drugs was almost 2 years on average. It is unlikely that National pharmacare will cover more new drugs than existing public drug plans. A universal single payer program could further reduce access because it would eliminate socially beneficial interprovincial policy competition, which creates at least some incentive for decision makers to add new drugs to public formularies. Moreover, Canadians covered under private plans will experience a significantly diminished drug insurance benefit under a universal single-payer system.

## pan-Canadian Pharmaceutical Alliance (pCPA)

The pan-Canadian Pharmaceutical Alliance (pCPA) negotiates prices and terms of coverage for new drugs under federal, provincial, and territorial public drug plans. The pCPA was initiated under the expectation that all jurisdictions would uniformly adopt its decisions and that it would improve access to new drugs. We examined whether the pCPA is achieving uniform adoption of new medicines across the country's public drug plans, and whether it facilitates or hinders coverage of new medicines. Our analysis suggests that the pCPA is failing on both counts. The data show significant variation in the coverage of new drugs across jurisdictions. Where commonality exists, it is mainly that all public drug plans cover few new medicines and take a long time to do so.

## Expedited formulary listing

Germany provides a real-world model for expediting insurance coverage for new medicines that could be useful to inform discussion of this issue in Canada. The German system for pharmaceutical pricing and reimbursement in its public drug plans is based on structured negotiation instead of regulation and is designed to allow immediate interim insurance coverage following marketing authorization, with permanent insurance coverage pending the outcome of negotiations. **[3]** Applying this model to Canada, the federal price regulations would be eliminated. New active substances would be listed on drug plan formularies immediately following the first market authorization issued by the EMA/FDA/Health Canada. The initial formulary list price would be the manufacturer's suggested price and would be used as a benchmark for rebates negotiated with the pCPA or directly with the drug plans. Negotiations would be informed, but not determined, by publicly available international reference prices and the HTA process. When negotiations were complete, the difference between the manufacturer's suggested price and the negotiated price would be retrospectively applied to sales that occurred in the interim period. Negotiations would be time limited and if agreement could not be reached, would progress to arbitration. The formulary listing would expire if either party rejected the arbiter's price and revenues earned under the interim price would be rebated according to the

arbiter's price. Manufacturers would have the option to request renegotiation in the future if new clinical or cost effectiveness data emerged, or any other circumstances changed the value proposition of the drug product. The pCPA would be obliged to accommodate a second round of negotiation. The proposed changes would expedite insured access to new drugs while leaving the bargaining leverage of the payer (formulary exclusion) and the seller (withholding product) ultimately intact. Adopting this policy change could reduce wait time by up to 724 days for publicly insured Canadians, equal to the current average time spent from Health Canada marketing authorization to formulary listing in a public drug plan. [**EXHIBIT 3**]

# Appendix

## EXHIBIT A. 182 drugs authorized for marketing by Health Canada 2016-2020

| Brand Name | Ingredient(s) |
|---|---|
| **ADDYI** | FLIBANSERIN |
| **ADLYXINE** | LIXISENATIDE |
| **ADYNOVATE** | ANTIHEMOPHILIC FACTOR (RECOMBINANT), PEGYLATED |
| **AFSTYLA** | LONOCTOCOG ALFA |
| **AIMOVIG** | ERENUMAB |
| **AJOVY** | FREMANEZUMAB |
| **AKLIEF** | TRIFAROTENE |
| **AKYNZEO** | PALONOSETRON HYDROCHLORIDE, NETUPITANT |
| **ALECENSARO** | ALECTINIB HYDROCHLORIDE |
| **ALUNBRIG** | BRIGATINIB |
| **ANTHIM** | OBILTOXAXIMAB |
| **ANTHRASIL** | ANTHRAX IMMUNE GLOBULIN (HUMAN) |
| **BALVERSA** | ERDAFITINIB |
| **BAT** | BOTULINUM ANTITOXIN SEROTYPE |
| **BAVENCIO** | AVELUMAB |
| **BELSOMRA** | SUVOREXANT |
| **BEOVU** | BROLUCIZUMAB |
| **BEPREVE** | BEPOTASTINE BESILATE |
| **BESPONSA** | INOTUZUMAB OZOGAMICIN |
| **BIKTARVY** | EMTRICITABINE, BICTEGRAVIR SODIUM, TENOFOVIR ALAFENAMIDE HEMIFUMARATE |
| **BLEXTEN** | BILASTINE |
| **BRIDION** | SUGAMMADEX |
| **BRINAVESS** | VERNAKALANT HYDROCHLORIDE |
| **BRINEURA** | CERLIPONASE ALFA |
| **BRIVLERA** | BRIVARACETAM |
| **CABLIVI** | CAPLACIZUMAB |
| **CABOMETYX** | CABOZANTINIB |
| **CALQUENCE** | ACALABRUTINIB |
| **CERDELGA** | ELIGLUSTAT TARTRATE |
| **CINQAIR** | RESLIZUMAB |
| **CORZYNA** | RANOLAZINE |
| **COTELLIC** | COBIMETINIB FUMARATE |
| **CRESEMBA** | ISAVUCONAZONIUM SULFATE |
| **CRYSVITA** | BUROSUMAB |
| **DACOGEN** | DECITABINE |
| **DARZALEX** | DARATUMUMAB |
| **DATSCAN** | IOFLUPANE (123I) |
| **DAURISMO** | GLASDEGIB |
| **DAYVIGO** | LEMBOREXANT |
| **DEFITELIO** | DEFIBROTIDE |
| **DEMYLOCAN** | DECITABINE |
| **DUPIXENT** | DUPILUMAB |
| **EMGALITY** | GALCANEZUMAB |
| **EMPLICITI** | ELOTUZUMAB |
| **ENSPRYNG** | SATRALIZUMAB |

| | |
|---|---|
| **EPCLUSA** | VELPATASVIR, SOFOSBUVIR |
| **ERLEADA** | APALUTAMIDE |
| **ESPEROCT** | ANTIHEMOPHILIC FACTOR VIII (RECOMBINANT, B-DOMAIN TRUNCATED), PEGYLATED |
| **EUCRISA** | CRISABOROLE |
| **EVENITY** | ROMOSOZUMAB |
| **FASENRA** | BENRALIZUMAB |
| **FIRDAPSE** | AMIFAMPRIDINE PHOSPHATE |
| **FOLOTYN** | PRALATREXATE |
| **GALAFOLD** | MIGALASTAT HYDROCHLORIDE |
| **GALLI EO** | GALLIUM (68GA) CHLORIDE |
| **GALLIAPHARM** | GERMANIUM (68GE) CHLORIDE, GALLIUM (68GA) CHLORIDE |
| **GIVLAARI** | GIVOSIRAN |
| **HEMLIBRA** | EMICIZUMAB |
| **IBRANCE** | PALBOCICLIB |
| **IBSRELA** | TENAPANOR |
| **IDELVION** | ALBUTREPENONACOG ALFA |
| **IDHIFA** | ENASIDENIB MESYLATE |
| **IMFINZI** | DURVALUMAB |
| **INCRELEX** | MECASERMIN |
| **INQOVI** | DECITABINE, CEDAZURIDINE |
| **INREBIC** | FEDRATINIB HYDROCHLORIDE |
| **INTRAROSA** | PRASTERONE |
| **JIVI** | ANTIHEMOPHILIC FACTOR (RECOMBINANT, B-DOMAIN DELETED, PEGYLATED) |
| **KANUMA** | SEBELIPASE ALFA |
| **KEVZARA** | SARILUMAB |
| **KISQALI** | RIBOCICLIB SUCCINATE |
| **KYMRIAH** | TISAGENLECLEUCEL |
| **KYPROLIS** | CARFILZOMIB |
| **LANCORA** | IVABRADINE HYDROCHLORIDE |
| **LARTRUVO** | OLARATUMAB |
| **LIBTAYO** | CEMIPLIMAB |
| **LIXIANA** | EDOXABAN |
| **LOKELMA** | SODIUM ZIRCONIUM CYCLOSILICATE |
| **LONSURF** | TIPIRACIL HYDROCHLORIDE, TRIFLURIDINE |
| **LORBRENA** | LORLATINIB |
| **LUTATHERA** | LUTETIUM (177LU) OXODOTREOTIDE |
| **LUXTURNA** | VORETIGENE NEPARVOVEC |
| **LYNPARZA** | OLAPARIB |
| **MAR-TRIENTINE** | TRIENTINE HYDROCHLORIDE |
| **MAVIRET** | PIBRENTASVIR, GLECAPREVIR |
| **MAYZENT** | SIPONIMOD |
| **MDK-NITISINONE** | NITISINONE |
| **MICTORYL, MICTORYL PEDIATRIC** | PROPIVERINE HYDROCHLORIDE |
| **MONOFERRIC** | IRON ISOMALTOSIDE 1000 |
| **MYLOTARG** | GEMTUZUMAB OZOGAMICIN |
| **NERLYNX** | NERATINIB MALEATE |
| **NETSPOT** | OXODOTREOTIDE |
| **NEURACEQ** | FLORBETABEN (18F) |
| **NINLARO** | IXAZOMIB CITRATE |
| **NITISINONE TABLETS** | NITISINONE |
| **NUBEQA** | DAROLUTAMIDE |
| **OCALIVA** | OBETICHOLIC ACID |
| **OCREVUS** | OCRELIZUMAB |
| **ODOMZO** | SONIDEGIB |
| **OLUMIANT** | BARICITINIB |
| **ONPATTRO** | PATISIRAN SODIUM |
| **ONSTRYV** | SAFINAMIDE |
| **ORFADIN** | NITISINONE |
| **ORILISSA** | ELAGOLIX |
| **ORKAMBI** | LUMACAFTOR, IVACAFTOR |
| **OXERVATE** | CENEGERMIN |
| **OZANEX** | OZENOXACIN |
| **OZEMPIC** | SEMAGLUTIDE |
| **PANHEMATIN** | HEMIN |

| | |
|---|---|
| **PIFELTRO** | DORAVIRINE |
| **PIQRAY** | ALPELISIB |
| **POLIVY** | POLATUZUMAB VEDOTIN |
| **PORTRAZZA** | NECITUMUMAB |
| **PRALUENT (PFP), PRALUENT (PFS)** | ALIROCUMAB |
| **PRAXBIND** | IDARUCIZUMAB |
| **PREVYMIS** | LETERMOVIR |
| **PROCYSBI** | CYSTEAMINE BITARTRATE |
| **QINLOCK** | RIPRETINIB |
| **RADICAVA** | EDARAVONE |
| **RAPIVAB** | PERAMIVIR |
| **RAVICTI** | GLYCEROL PHENYLBUTYRATE |
| **RAYALDEE** | CALCIFEDIOL |
| **REBINYN** | COAGULATION FACTOR IX (RECOMBINANT), PEGYLATED |
| **REBLOZYL** | LUSPATERCEPT |
| **REKOVELLE** | FOLLITROPIN DELTA |
| **REXULTI** | BREXPIPRAZOLE |
| **RINVOQ** | UPADACITINIB |
| **ROZLYTREK** | ENTRECTINIB |
| **RUPATADINE** | RUPATADINE FUMARATE |
| **RUZURGI** | AMIFAMPRIDINE |
| **RYDAPT** | MIDOSTAURIN |
| **SARCLISA** | ISATUXIMAB |
| **SILIQ** | BRODALUMAB |
| **SKYRIZI** | RISANKIZUMAB |
| **SPINRAZA** | NUSINERSEN SODIUM |
| **STEGLATRO** | ERTUGLIFLOZIN |
| **SUNVEPRA** | ASUNAPREVIR |
| **SYMDEKO** | TEZACAFTOR, IVACAFTOR |
| **TAGRISSO** | OSIMERTINIB, OSIMERTINIB MESYLATE |
| **TAKHZYRO** | LANADELUMAB |
| **TALTZ** | IXEKIZUMAB |
| **TALZENNA** | TALAZOPARIB |
| **TAVALISSE** | FOSTAMATINIB DISODIUM |
| **TECENTRIQ** | ATEZOLIZUMAB |
| **TEGSEDI** | INOTERSEN SODIUM |
| **TIBELLA** | TIBOLONE |
| **TOMVI** | ETOMIDATE |
| **TREMFYA** | GUSELKUMAB |
| **TRESIBA (FLEXTOUCH), TRESIBA (PENFILL)** | INSULIN DEGLUDEC |
| **TRULANCE** | PLECANATIDE |
| **TUKYSA** | TUCATINIB |
| **ULTOMIRIS** | RAVULIZUMAB |
| **UNITUXIN** | DINUTUXIMAB |
| **UPTRAVI** | SELEXIPAG |
| **VASCEPA** | ICOSAPENT ETHYL |
| **VEKLURY** | REMDESIVIR |
| **VELPHORO** | SUCROFERRIC OXYHYDROXIDE |
| **VELTASSA** | PATIROMER SORBITEX CALCIUM |
| **VENCLEXTA** | VENETOCLAX |
| **VERZENIO** | ABEMACICLIB |
| **VIBERZI** | ELUXADOLINE |
| **VITRAKVI** | LAROTRECTINIB |
| **VIZIMPRO** | DACOMITINIB |
| **VOCABRIA, CABENUVA** | RILPIVIRINE, CABOTEGRAVIR |
| **VONVENDI** | VON WILLEBRAND FACTOR (RECOMBINANT), VONICOG ALFA |
| **VOSEVI** | VOXILAPREVIR, VELPATASVIR, SOFOSBUVIR |
| **VYNDAQEL** | TAFAMIDIS MEGLUMINE |
| **VYZULTA** | LATANOPROSTENE BUNOD |
| **XENLETA** | LEFAMULIN ACETATE |
| **XERMELO** | TELOTRISTAT ETIPRATE |
| **XIIDRA** | LIFITEGRAST |
| **XOFLUZA** | BALOXAVIR MARBOXIL |
| **XOSPATA** | GILTERITINIB FUMARATE |

| | |
|---|---|
| **XTORO** | FINAFLOXACIN |
| **XYDALBA** | DALBAVANCIN |
| **YESCARTA** | AXICABTAGENE CILOLEUCEL |
| **ZEJULA** | NIRAPARIB |
| **ZEPATIER** | GRAZOPREVIR, ELBASVIR |
| **ZEPOSIA** | OZANIMOD HYDROCHLORIDE |
| **ZINBRYTA** | DACLIZUMAB BETA |
| **ZOLGENSMA** | ONASEMNOGENE ABEPARVOVEC |
| **ZONTIVITY** | VORAPAXAR SULFATE |

# References

**[1]** Health Canada. Biologics and Radiopharmaceutical Drugs Directorate Drug Submission Performance Annual Report, Fiscal Year 2020-2021, April 1 2020 - March 31 2021; Therapeutic Products Directorate Drug Submission Performance Annual Report, Fiscal Year 2020-2021, April 1 2020 - March 31 2021; Notice Of Compliance Database Extracts; Drug Products Database.

**[2]** IQVIA Inc. Integrated Market Access Console (IMAM) Database. 21 December 2021.

**[3]** OECD (2018). Pharmaceutical Reimbursement and Pricing in Germany. Organisation for Economic Cooperation and Development.