

Health Canada New Drug Authorizations: 2015 Highlights

New Active Substances, Subsequent Entry
Biologics, and Generic Pharmaceuticals



Health Canada is responsible for helping Canadians maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks.

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Foreword

Health Canada is pleased to release *Health Canada New Drug Authorizations: 2015 Highlights*. It contains information on new active substances (NASs), subsequent entry biologics (SEBs) (biosimilars), and new generic pharmaceuticals authorized in 2015. This document identifies a subset of the drugs reviewed by Health Canada in 2015. This document focuses on authorized NASs, SEBs, and new generic pharmaceuticals only.

Prior to being given market authorization, a manufacturer must present substantive scientific evidence of a product's safety, efficacy and quality as required by the [Food and Drugs Act](#) and [Regulations](#). New drugs are authorized for sale in Canada once they have successfully gone through the drug review process. This process is the means by which a drug application is reviewed by Health Canada scientists to assess the safety, efficacy and quality of a drug.

Throughout the process, the safety and well-being of Canadians is the paramount concern. The drug review process helps provide access for Canadians to innovative new products as well as contributing to cost savings in the health care system through the authorization of lower cost generic and subsequent entry biologic (biosimilar) medications.

For more information on the drug review process, please see: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/fs-fi/reviewfs_examenfd-eng.php.

Health Canada New Drug Authorizations: 2015 Highlights will be published by Health Canada on an annual basis. This document is not meant to replace the Quarterly or Annual Submission Review Performance Reports, which provide detailed metrics about the timeliness of pre-market drug review processes against the performance service standard. Those reports will continue to be prepared and [made available to the general public](#).

For any questions on the content of this document please contact BGTD.OPIC@hc-sc.gc.ca.

Please note that the indications provided here are intended to be plain-language summaries of the specific indications for which the drugs were authorized. To see the specific indications for each drug, we encourage you to visit the links provided, or visit the Product Monograph of the drug, available on the [Drug Product Database](#).



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37 New Active Substances

7 New Active Substances Issued Marketing Authorization with Conditions

5 New Active Substances Authorized with a Priority Review

25 Other New Active Substances

130 Subsequent Entry Biologics (Biosimilars) & Generic Pharmaceuticals

New Active Substances

In 2015 Health Canada authorized **37** new active substances for the Canadian market. Of those **37**, **7** were issued marketing authorization with conditions and **5** were authorized with a priority review. The remaining **25** new active substances were authorized without a priority review nor were issued marketing authorization with conditions. A new active substance (NAS) is a drug 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.

Cardiovascular

[Entresto](#)
[Repatha](#)
[Varithena](#)

Dermatology

[Cosentyx](#)
[Rosiver](#)

Endocrinology

[Eperzan](#)
[Jardiance](#)
[Strensiq](#)
[Trulicity](#)

Gastroenterology

[Amitiza](#)
[Entyvio](#)
[Movantik](#)
[Revestive](#)

Infections

[Daklinza](#)
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[Zerbaxa](#)

Metabolic

[Carbaglu](#)
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Neurology

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Oncology/Hematology

[Blincyto](#)
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[Iclusig](#)
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Ophthalmology

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Psychopharmacology

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Pulmonary/Respiratory

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New Active Substances Issued Marketing Authorization with Conditions

In 2015, Health Canada issued marketing authorization with conditions to **7** new active substances as outlined in Health Canada's Notice of Compliance with Conditions (NOC/c) Guidance.

A Notice of Compliance with Conditions may be granted for a drug product with promising clinical benefit, providing that it possesses an acceptable safety profile based on a benefit/risk assessment, and is found to be of high quality. Submissions that are granted NOC/c status are subject to shorter review targets

Health Canada's NOC/c guidance can be found at: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/compli-conform/nocccg_accd-eng.php

Blincyto (blinatumomab) *Amgen Canada Inc.* – Blincyto is used to treat adult patients with Philadelphia chromosome –negative relapsed or refractory B precursor acute lymphoblastic leukemia (ALL)

Daklinza (daclatasvir) *Bristol-Myers Squibb Canada* – Daklinza is used to treat chronic (long-lasting) infection with the hepatitis C virus (HCV) genotypes 1, 2 and 3

Iclusig (ponatinib) *ARIAD Pharmaceuticals Inc.* – Iclusig is used to treat adults with chronic myeloid leukemia (CML) and Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) who are no longer benefitting from treatment with other medicines

Keytruda (pembrolizumab) *Merck Canada Inc.* – Keytruda is used to treat patients with unresectable or metastatic melanoma

Strensiq (asfotase alfa) *Alexion Pharma GHBH* – Strensiq is an enzyme replacement therapy for patients with confirmed diagnosis of paediatric-onset hypophosphatasia (first drug treatment authorized for this indication in Canada)

Zydelig (idelalisib) *Gilead Sciences Canada, Inc.* – Zydelig is used in adults to treat Chronic Lymphocytic Leukemia and follicular lymphoma who were previously treated for their cancer

Zykadia (ceritinib) *Novartis Pharmaceuticals Inc.* – Zykadia is used to treat patients with anaplastic lymphoma kinase (ALK)-positive locally advanced or non-small cell lung cancer (NSCLC) who have progressed on or who were intolerant to crizotinib



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New Active Substances Authorized with a Priority Review

In 2015, Health Canada authorized **5** new active substances with a priority review.

Priority review status may be granted to a drug submission for a serious, life-threatening or severely debilitating disease or condition. Submissions that are granted priority review status are subject to shorter review targets.

Health Canada's Priority Review guidance can be found at: <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/priorit/priordr-eng.php>

Carbaglu (carglumic acid) *Orphan Europe S.A.R.L.* – Carbaglu is used if you are missing a liver enzyme called N-acetylglutamate synthase (NAGS) to treat high ammonia in the blood and to maintain your blood ammonia at a normal level (first drug treatment authorized for this indication in Canada)

Entresto (sacubitril and valsartan as sacubitril valsartan sodium hydrate complex) *Novartis Pharmaceuticals Canada Inc.* – Entresto is used to treat heart failure in adults

Opdivo (nivolumab) *Bristol-Myers Squibb Canada* – Opdivo is used to treat patients with unresectable or metastatic BRAF V600 wild-type melanoma

Pheburane (sodium phenylbutyrate) *Médunik Canada* – Pheburane is used to treat patients of all ages with urea cycle disorders (UCD), involving deficiencies of liver enzymes (first drug treatment authorized for this indication in Canada).

Revestive (teduglutide) *NPS Pharma Holdings Ltd.* – Revestive is used to treat adult patients with Short Bowel Syndrome (SBS) who are dependent on parenteral support



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Other New Active Substances

In 2015, Health Canada authorized **25** new active substances without a priority review and with no conditions.

Drugs are authorized for sale in Canada once they have successfully gone through the drug review process. This process is the means by which a drug application is reviewed by Health Canada scientists to assess the safety, efficacy and quality of a drug.

Throughout the process, for all types of submissions, the safety and well-being of Canadians is the paramount concern. More information on how drugs are reviewed and authorized in Canada can be found at:

http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/fs-fi/reviewfs_examenfd-eng.php

Cardiovascular

[Repatha](#) (evolocumab) *Amgen Canada Inc.* – Repatha is used in adult patients with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (CVD) who require lowering of low density lipoprotein cholesterol (LDL-C) (first drug treatment authorized for this indication in Canada)

[Varithena](#) (polidocanol) *Provensis Ltd.* – Varithena (polidocanol injectable foam) is for the treatment of problems with the great saphenous vein and other saphenous veins and varicose veins of the great saphenous vein system. It is for the treatment of veins above and below the knee. It is only for use in adults with significant venous reflux that was diagnosed by a duplex ultrasound (first drug treatment authorized for this indication in Canada)

Dermatology

[Cosentyx](#) (secukinumab) *Novartis Pharmaceuticals Canada Inc.* – Cosentyx is used in the treatment of moderate to severe plaque psoriasis in adult patients

[Rosiver](#) (ivermectin) *Galderma Canada Inc.* – Rosiver is used for the topical treatment of bumps and pimples found with rosacea



Other New Active Substances (continued)

Endocrinology

[Eperzan](#) (albiglutide) *GlaxoSmithKline Inc.* – Eperzan is a once weekly administration for the treatment of adults with type 2 diabetes mellitus

[Jardiance](#) (empagliflozin) *Boehringer Ingelheim (Canada) Ltd.* – Jardiance is used along with diet and exercise to improve blood sugar levels in adults with type 2 diabetes

[Trulicity](#) (dulaglutide) *Eli Lilly Canada Inc.* – Trulicity is a once-weekly treatment of adult patients with type 2 diabetes mellitus to improve glycemic control

Gastroenterology

[Amitiza](#) (lubiprostone) *Sucampo Pharma Americas LLC* – Amitiza is used to treat chronic idiopathic constipation, in adults, 18 years and older

[Entyvio](#) (vedolizumab) *Takeda Canada Inc.* – Entyvio is used in the treatment of adult patients with moderately to severely active ulcerative colitis

[Movantik](#) (Naloxegol oxalate) *AstraZeneca Canada Inc.* – Movantik is indicated for the treatment of opioid-induced constipation in adult patients with non-cancer pain who have had an inadequate response to laxative(s)

Infections

[Genvoya](#) (emtricitabine, elvitegravir, cobicistat, tenofovir alafenamide as tenofovir alafenamide hemifumarate) *Gilead Sciences Canada Inc.* – Genvoya is used to treat people with HIV infection who do not have an HIV virus that is resistant to Genvoya

[Sivextro](#) (tedizolid phosphate) *Cubist Pharmaceuticals Canada, Inc.* – Sivextro is a medicine which is used to treat infections of the skin caused by certain bacteria, in adults 18 years of age and over

[Zerbaxa](#) (tazobactam sodium, ceftolozane sulfate) *Merck Canada Inc.* – Zerbaxa is used to treat complicated infections within the abdominal cavity and urinary tract infections in adults

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Other New Active Substances (continued)

Neurology

[Plegridy](#) (peginterferon beta – 1a) *Biogen Canada Inc.* – Plegridy is used in the treatment of relapsing remitting multiple sclerosis (RRMS) for adult patients

Oncology/Hematology

[Cyramza](#) (ramucirumab) *Eli Lilly Canada Inc.* – Cyramza is used in the treatment of patients with advanced or metastatic gastric cancer or gastro-esophageal junction adenocarcinoma (first drug treatment authorized for this indication in Canada)

[Ferriprox](#) (deferiprone) *ApoPharma Inc.* – Ferriprox is used to treat patients with thalassemia syndromes who have too much iron in their body from blood transfusions when other chelators do not work

[Lenvima](#) (lenvatinib mesylate) *Eisai Limited* – Lenvima is used to treat a type of thyroid cancer that can no longer be treated with radio-active iodine

[Obizur](#) (antihemophilic factor (recombinant) porcine sequence) *Baxalta Canada Corporation* – Obizur is used to treat bleeding episodes in patients with Acquired Hemophilia A (AHA)

Ophthalmology

[Prolensa](#) (bromfenac sodium sesquihydrate) *Bausch & Lomb Incorporated* – Prolensa is used for treatment of pain and inflammation following cataract eye surgery



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Other New Active Substances (continued)

Psychopharmacology

[Fetzima](#) (levomilnacipran as levomilnacipran hydrochloride) *Actavis Specialty Pharmaceuticals Co.* – Fetzima is used to relieve symptoms of depression which may include feeling sad, loss of interest in usual activities, significant change in weight or appetite, change in sleeping habits, difficulty concentrating, feeling tired or suicidal thoughts

[Viibryd](#) (vilazodone hydrochloride) *Forest Laboratories Canada Inc.* – Viibryd is used to relieve symptoms of depression which may include feeling sad, loss of interest in usual activities, significant change in weight or appetite, change in sleeping habits, difficulty concentrating, feeling tired or suicidal thoughts

Pulmonary/Respiratory

[Nucala](#) (mepolizumab) *GlaxoSmithKline Inc.* – Nucala is an add-on maintenance treatment of adult patients with severe eosinophilic asthma

[Ofev](#) (nintedanib) *Boehringer Ingelheim (Canada) Ltd.* – Ofev is used in the treatment of Idiopathic Pulmonary Fibrosis (IPF) in adults

Reproductive Health

[Mifegymiso](#) (mifepristone, misoprostol) *Linepharma International Limited* – Mifegymiso is used for the medical termination of a developing intra-uterine pregnancy with a gestational age up to 49 days as measured from the first day of the Last Menstrual Period (LMP) in a presumed 28-day cycle

Vaccine

[Gardasil 9](#) (human papillomavirus (HPV) 9 valent vaccine, recombinant) *Merck Canada Inc.* – Gardasil 9 is a vaccine that helps protect against some diseases caused by some types of Human Papillomavirus (HPV types 6, 11, 16, 18, 31, 33, 45, 52, 58)



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Subsequent Entry Biologics (Biosimilars)

In 2015, Health Canada authorized **2** subsequent entry biologics (SEBs) (biosimilars).

A SEB (biosimilar) is a biologic drug that enters the market subsequent to a previously authorized biologic drug in Canada with a demonstrated similarity to the previously authorized biologic drug.

Health Canada's SEB (biosimilar) guidance can be found at: <http://www.hc-sc.gc.ca/dhp-mps/consultation/biolog/submission-seb-exigences-pbu-eng.php>

Basaglar (insulin glargine) *Eli Lilly Canada Inc.* – Basaglar is indicated for once daily subcutaneous administration in the treatment of patients over 17 years of age with Type 1 or Type 2 diabetes mellitus who require basal insulin for the control of hyperglycemia

Grastofil (filgrastim) *Apotex Inc.* – Grastofil is indicated in cancer patients receiving Myelosuppressive chemotherapy, patients with Acute Myeloid Leukemia, cancer patients Receiving Myeloablative Chemotherapy Followed by bone marrow transplantation, cancer patients undergoing Peripheral Blood Progenitor Cell (PBPC) Collection and Therapy, Patients with Severe Chronic Neutropenia (SCN) and Patients with HIV Infection

Generic Pharmaceuticals

In 2015, Health Canada authorized **128** new generic pharmaceuticals.

A generic drug is a copy of a brand name product, known as the 'reference product.' Generic drugs contain the same medicinal ingredients as the brand name drug, and are considered bioequivalent to the reference product.

More information on how Health Canada handles generic pharmaceuticals can be found at: <http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/med/med-gen-eng.php>

