MEDS ENTRY WATCH
NEW MEDICINES APPROVED IN 2016

The following table provides supplementary information on the manufacturer and approved indication(s) for each medicine that received first-time market authorization by the US Food and Drug Administration (FDA), the European Medicines Agency (EMA), and/or Health Canada in 2016.

Indications for new medicines approved by the FDA, the EMA, and/or Health Canada in 2016

Medicine (trade name)*	Approved indications	Manufacturer
Albutrepenonacog alfa (Idelvion)[B,O]	An antihemophilic factor indicated in patients with hemophilia B (congenital FIX deficiency, or Christmas disease) for: routine prophylaxis to prevent or reduce the frequency of bleeding episodes; control and prevention of bleeding episodes; and control and prevention of bleeding in the perioperative setting	CSL Behring
Asunaprevir (Sunvepra)	For use in combination with other agents for the treatment of chronic hepatitis C (CHC) in adult patients with hepatitis C virus (HCV) genotypes 1 or 4 and compensated liver disease, including cirrhosis	Bristol-Myers Squibb
Atezolizumab (Tecentriq)[B,C]	Indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who: have disease progression during or following platinum-containing chemotherapy; have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy	Genentech
Autologous cultured chondrocytes on a porcine collagen membrane (MACI)[B]	Indicated for the repair of symptomatic, single or multiple full-thickness cartilage defects of the knee with or without bone involvement in adults	Vercicel
Betulae cortex dry extract (Episalvan)	Indicated for the treatment of partial thickness wounds in adults	Amryt Pharma plc
Bezlotoxumab (Zinplava)[B]	Indicated to reduce recurrence of clostridium difficile infection (CDI) in patients 18 years of age or older who are receiving antibacterial drug treatment of CDI and are at a high risk for CDI recurrence	Merck & Co.
Brivaracetam (Brivlera)	Indicated as adjunctive therapy in the management of partial-onset seizures in adult patients with epilepsy who are not satisfactorily controlled with conventional therapy	UCB
Crisaborole (Eucrisa)	For topical treatment of mild to moderate atopic dermatitis in patients 2 years of age and older	Pfizer
Etelcalcetide (Parsabiv)	Used in patients on haemodialysis to reduce the levels of parathyroid hormone in adults	Amgen
Eteplirsen (Exondys 51)[B,O]	For the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping	Sarepta Therapeutics
Fluciclovine F 18 (Axumin)	Use for injection for positron emission tomography (PET) imaging in men with suspected prostate cancer recurrence based on elevated blood prostate specific antigen (PSA) levels following prior treatment	Blue Earth Diagnostics
Gallium Ga 68 dotatate (Netspot)[O]	For use with positron emission tomography (PET) for localization of somatostatin receptor positive neuroendocrine tumors (NETs) in adult and pediatric patients	Advanced Accelerator Applications
Grazoprevir, elbasvir (Zepatier)	Indicated for the treatment of chronic hepatitis C (CHC) genotypes 1, 3, or 4 infection in adults as follows: Without ribavirin: in genotype (GT) 1 or 4 treatment-naïve (TN) and peginterferon alfa + ribavirin (PR) treatment-experienced (TE) relapsers (12 weeks); in GT1 protease inhibitor (PI)/PR-TE relapsers (12 weeks); in GT1b TN, non-cirrhotic patients (8 weeks); in GT1b PR- or PI/PR-TE on-treatment virologic failures (12 weeks) With ribavirin: in GT1a PR- or PI/PR-TE on-treatment virologic failures (16 weeks); in GT4 PR-TE on-treatment virologic failures (16 weeks) With sofosbuvir: in GT3 TN patients (12 weeks)	Merck
Ixekizumab (Taltz)[B]	Indicated for the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy	Eli Lilly
Lifitegrast (Xiidra)	For the treatment of the signs and symptoms of dry eye disease (DED)	Shire
Lonoctocog alfa (Afstyla)[B]	A recombinant DNA-derived, antihemophilic factor indicated in adults and children with hemophilia A (congenital Factor VIII deficiency) for: control and prevention of bleeding episodes; routine prophylaxis to prevent or reduce the frequency of bleeding episodes; and perioperative management of bleeding (surgical prophylaxis)	CSL Behring

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Indications for new medicines approved by the FDA, the EMA, and/or Health Canada in 2016 *(continued)*

Medicine (trade name)*	Approved indications	Manufacturer
Migalastat (Galafold)[O]	Used to treat patients aged 16 years or over with Fabry disease	Amicus Therapeutics
Nalotimagene carmaleucel (Zalmoxis)[B,C,O,G]	Used as an add-on treatment in adults who have received a haematopoietic stem cell transplant (HSCT, a transplant of cells that can develop into different types of blood cells) from a partially matched donor (a so-called haploidentical transplant)	MolMed S.p.A.
Nusinersen sodium (Spinraza)[O]	Indicated for the treatment of 5q spinal muscular atrophy (SMA)	Biogen
Obeticholic acid (Ocaliva)[O]	Indicated for the treatment of primary biliary cholangitis1 (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA	Intercept Pharmaceuticals
Obiltoxaximab (Anthim)[B,O]	Indicated for the treatment of adult and pediatric patients with inhalational anthrax due to Bacillus anthracis in combination with appropriate antibacterial drugs and for prophylaxis of inhalational anthrax when alternative therapies are not available or are not appropriate	Elusys Therapeutics
Olaratumab (Lartruvo)[B,C,O]	Indicated, in combination with doxorubicin, for the treatment of adult patients with soft tissue sarcoma (STS) with a histologic subtype for which an anthracycline-containing regimen is appropriate and which is not amenable to curative treatment with radiotherapy or surgery	Eli Lilly
Opicapone (Ongentys)	Used to treat adults with Parkinson's disease as an add-on to levodopa/DOPA decarboxylase inhibitors (DDCI) in patients who are having fluctuations in the control of their condition	Bial
Pimavanserin (Nuplazid)	For the treatment of hallucinations and delusions associated with Parkinson's disease psychosis	Acadia Pharmaceuticals
Pitolisant (Wakix)[O]	Used to treat adults with narcolepsy	Bioprojet Pharma
Reslizumab (Cinqair)[B]	Indicated as an add-on maintenance treatment of adult patients with severe eosinophilic asthma who: are inadequately controlled with medium-to-high-dose inhaled corticosteroids and an additional asthma controller(s) (e.g., LABA); and have a blood eosinophil count of ^{3}400 cells μL at initiation of the treatment	Teva
Rucaparib (Rubraca)[C,O]	For use as monotherapy for the treatment of patients with deleterious BRCA mutation (germline and/or somatic) associated advanced ovarian cancer who have been treated with two or more chemotherapies	Clovis Oncology
Strimvelis (gene therapy product)[B,O,G]	Used to treat severe combined immunodeficiency due to adenosine deaminase deficiency (ADA-SCID) in patients who cannot be treated by a bone-marrow transplant because they do not have a suitable, matched, related donor	GlaxoSmithKline
Vaccine, pandemic influenza H5N1 (AstraZeneca)[B]	Indicated for prophylaxis of influenza in an officially declared pandemic situation in children and adolescents from 12 months to less than 18 years of age	AstraZeneca
Velpatasvir (Epclusa)	For the treatment of chronic hepatitis C virus (HCV) infection in adults without cirrhosis or with compensated cirrhosis; in combination with ribavirin for the treatment of chronic hepatitis C virus (HCV) infection in adults with decompensated cirrhosis	Gilead Sciences
Venetoclax (Venclexta)[C,O]	Indicated as monotherapy for the treatment of patients with chronic lymphocytic leukemia (CLL) with 17p deletion who have received at least one prior therapy, or patients with CLL without 17p deletion who have received at least one prior therapy and for whom there are no other available treatment options	AbbVie

Indications from Health Canada (HC); US Food and Drug Administration (FDA); European Medicines Agency (EMA).

* B: biologic; C: cancer; O: orphan medicines; G: gene therapies.
Data source: US Food and Drug Administration Novel Drugs 2016; European Medicines Agency Human Medicines Highlights 2016; Health Canada New Drug Authorizations: 2016 Highlights.