



Health  
Canada

Santé  
Canada

# Helping you maintain and improve your health

Drug and medical device highlights 2017



Canada 

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.

Également disponible en français sous le titre :  
Pour maintenir et améliorer votre santé : Faits saillants de 2017 sur les médicaments et les instruments médicaux

To obtain additional information, please contact:

Health Canada  
Address Locator 0900C2  
Ottawa, ON K1A 0K9  
Tel.: 613-957-2991  
Toll free: 1-866-225-0709  
Fax: 613-941-5366  
TTY: 1-800-465-7735  
E-mail: [publications@hc-sc.gc.ca](mailto:publications@hc-sc.gc.ca)

© Her Majesty the Queen in Right of Canada, as represented by the Minister of Health, 2018

Publication date: April 2018

This publication may be reproduced for personal or internal use only without permission provided the source is fully acknowledged.

Cat.: H169-9/2018E-PDF  
ISBN: 978-0-660-26074-7  
Pub.: 170572

# HELPING YOU MAINTAIN AND IMPROVE YOUR HEALTH

## DRUG AND MEDICAL DEVICE HIGHLIGHTS 2017

Learn about the new and innovative drugs and medical devices that have been approved for sale in Canada, risk communications that were published, and our other accomplishments in 2017.



# CONTENT

<b>INTRODUCTION</b>	<b>5</b>
<b>NEW DRUGS AND MEDICAL DEVICES APPROVED IN 2017</b>	<b>7</b>
<b>DRUG AND MEDICAL DEVICE APPROVAL OVERVIEW</b>	<b>14</b>
<b>DRUG AND MEDICAL DEVICE POST-MARKET SURVEILLANCE</b>	<b>18</b>
<b>2017 ACCOMPLISHMENTS</b>	<b>20</b>
<b>DRUGS AND MEDICAL DEVICES: MORE DETAILS</b>	<b>24</b>
<b>APPROVED DRUGS AND MEDICAL DEVICES 2017</b>	<b>26</b>
<b>HEALTHY CLICKS</b>	<b>65</b>

## INTRODUCTION

Welcome to our 2017 Highlights Report about the new and innovative drugs and medical devices approved for sale in Canada.

Health Canada is here to help you maintain and improve your health. New drugs and medical devices can mean new treatment and diagnostic options for patients and advances in health care available to you. Our job is to evaluate and monitor drugs and medical devices to ensure that the benefits of the products you have access to outweigh the risks in taking them, throughout the life cycle of the product.

It can take years, sometimes decades, to bring new drugs and medical devices from the lab to you. Part of our job is to ensure that the benefits of the products you have access to outweigh the risks in taking them. We have a role in approving clinical trials, providing scientific advice throughout the development process, and evaluating drugs and medical devices for approval for sale in Canada.

We also continue to monitor drugs and medical devices after they have been approved for sale in Canada, to watch for emerging safety problems. We take action when we determine there is a potential risk to your health and safety. We inform health professionals and the public about new risks, or other important information to assist with the safe use of a drug or medical device.

2017 was an important year for us. We carried out many initiatives this year aimed at improving the timely access to drugs and medical devices that meet health care system needs. This report highlights these initiatives and provides information on the new drugs and new medical devices with novel technology we have approved this year.

We could not do our work without your voice – the voice of the patient – along with the input and feedback we receive from all of our partners and stakeholders. We hope this report communicates the work we do in approving and monitoring new and innovative drugs and medical devices. While the number of products we approve is important, what is critical is that these drugs and medical devices contribute to the overall quality of health care for Canadians.

Click here to see a short [introductory video](#).



**Pierre Sabourin**

Assistant Deputy Minister  
Health Canada



**Kendal Weber**

Associate Assistant Deputy Minister  
Health Canada

# 1 | NEW DRUGS AND MEDICAL DEVICES APPROVED IN 2017

## AS A CANADIAN, YOU HAVE ACCESS TO A WIDE RANGE OF DRUGS AND MEDICAL DEVICES.

Every year, we approve new drugs and medical devices for sale in Canada, giving you newer and more innovative ways to help you maintain and improve your health.



**John Patrick Stewart**

Director General, Therapeutic  
Products Directorate  
Health Canada



**Cathy Parker**

Director General, Biologics and  
Genetic Therapies Directorate  
Health Canada

## 1.1 NEW DRUGS APPROVED

In 2017, Health Canada approved 67 new drugs, giving you new and innovative options for treatment, prevention and diagnosis of various health conditions. Twenty-four percent of these were approved through an expedited pathway, to address unmet medical needs.

### 36 NEW ACTIVE SUBSTANCES

Some new drug submissions introduce new active substances - medicinal ingredients that have never been approved for sale in Canada. Thirty-six percent of these were approved through an expedited pathway.

### 31 OTHER NEW DRUG SUBMISSIONS

Other new drug submissions use the same or similar substances already approved for sale in Canada. They may offer new dosages or treat different conditions, and include 3 new biosimilars.

We approved new generic drugs and biosimilars – bringing more choice and more affordable options.

### 138 NEW GENERIC DRUGS

Generic drugs contain the same medicinal ingredients as brand name drugs and cost less than their brand-name equivalents.

### 3 NEW BIOSIMILARS

Biosimilars are drugs that have been demonstrated to be highly similar to biologic drugs that were already approved for sale.





## 1.2 MEDICAL DEVICES APPROVED

Medical devices are products that are used for diagnostic and/or therapeutic purposes. Newly approved medical devices provide a broader range of options used to treat, manage, diagnose or prevent a disease or a physical condition.

### **6** MEDICAL DEVICES WITH NOVEL TECHNOLOGY

These medical devices introduce a new apparatus, appliance, software or material with novel technology never before approved for sale in Canada.

### **482** NEW CLASS III AND IV MEDICAL DEVICES

There are different classes of medical devices, ranging from Class I to IV. Class I devices are considered low-risk devices - for example, a tongue depressor. Class IV devices present the greatest potential risk - for example, a pacemaker.



## 1.3 CLINICAL TRIALS AND SPECIAL ACCESS PROGRAMS

We approve applications to allow companies and researchers to conduct clinical trials on drugs and medical devices in Canada. We also grant access to doctors for certain drugs and medical devices that have not yet been approved for sale in Canada through our Special Access Programs.

**1229**

**NEW CLINICAL TRIAL APPLICATIONS FOR DRUGS WERE APPROVED**

### CLINICAL TRIALS

New clinical trials mean more access to innovative choices.

**199**

**NEW INVESTIGATIONAL TESTING APPLICATIONS FOR MEDICAL DEVICES WERE APPROVED**

**12,887**

**REQUESTS FOR SPECIAL ACCESS TO DRUGS WERE AUTHORIZED**

### SPECIAL ACCESS PROGRAMS

Access to unapproved drugs and medical devices may be granted for emergency use or to patients with serious or life-threatening conditions. Our special access programs operate 24 hours a day, 365 days a year.

**2,401**

**REQUESTS FOR SPECIAL ACCESS TO MEDICAL DEVICES WERE AUTHORIZED**

## 1.4 MONITORING DRUGS AND MEDICAL DEVICES AFTER APPROVALS

It is not possible to know or predict all of the possible side effects of a drug, or the adverse events associated with a medical device, through clinical studies. Once drugs and medical devices are available in Canada, we monitor and evaluate reports of suspected adverse events.

**880,000**

**ADVERSE REACTIONS AND INCIDENT REPORTS**

### POST-MARKET ADVERSE DRUG REACTION AND MEDICAL DEVICE INCIDENT REPORTS

We received 880,000 post-market reports of adverse reactions to drugs, and medical device incidents, from domestic and international sources.

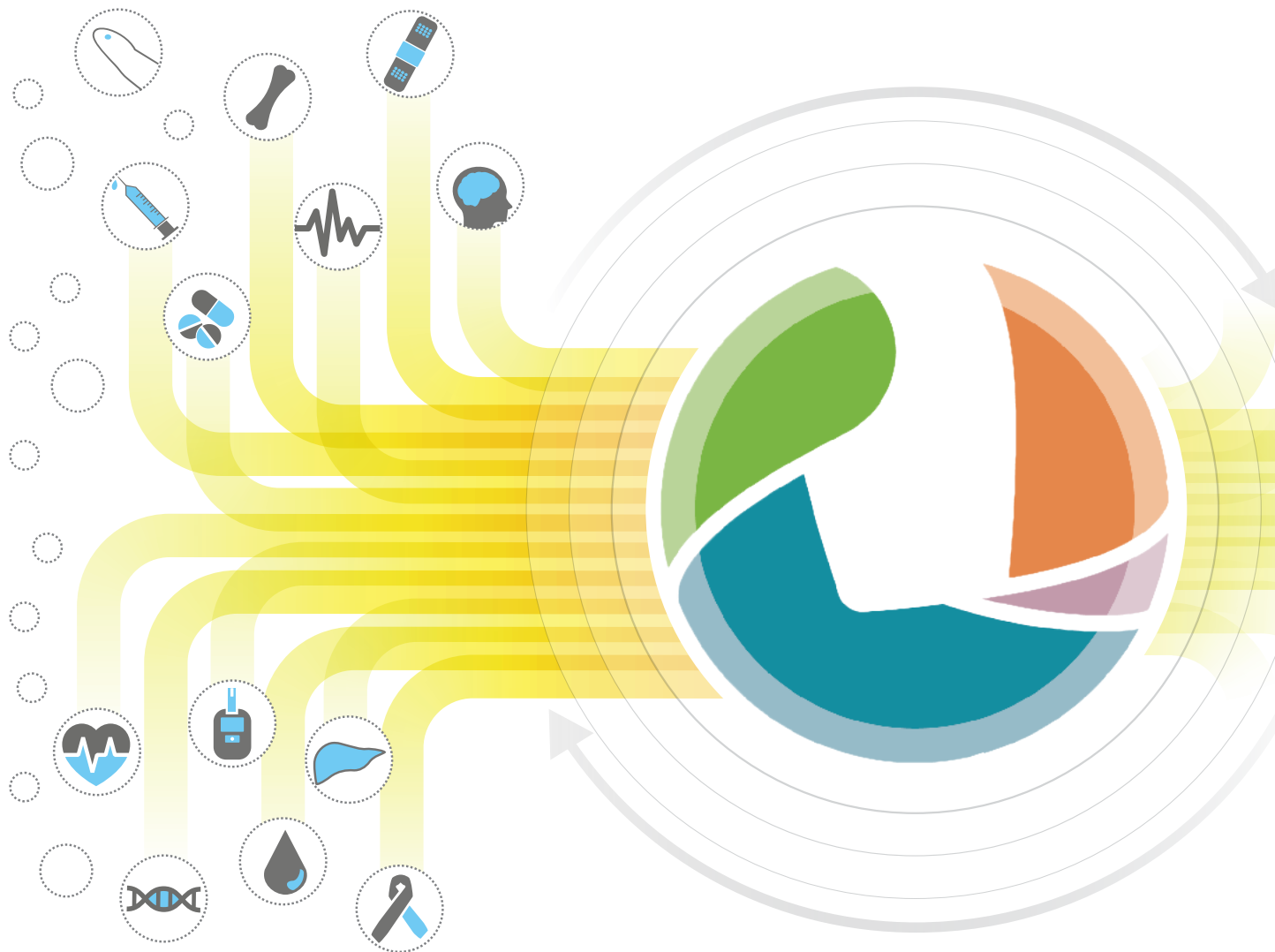
**987**

**POST MARKET ACTIONS**

### POST-MARKET ACTIONS

We initiated 987 post-market actions, including reviewing risk management plans and periodic safety update reports, completing safety reviews and their summaries, issuing risk communications, and reviewing health product advertising complaints.





## **The Broader System of New Drug and Medical Device Development & Approval**

Health Canada is here to help you maintain and improve your health. New drugs and medical devices can mean new treatment and diagnostic options for patients and advances in health care available to you.

It can take years, sometimes decades, to bring new products from the lab to you. Our job is to evaluate and monitor drugs and medical devices to ensure that the benefits of the products you have access to outweigh the risks in taking them.

We have a role in approving clinical trials, providing scientific advice throughout the development process, and evaluating drugs and medical devices for approval for sale in Canada.



### **Clinical Trials**

Clinical Trials for drugs and Investigational Testing for medical devices represent potential new health care therapies which may eventually address the needs of Canadians. Trial sponsors (including manufacturers and researchers) submit their applications to conduct a clinical trial with a drug or medical device in Canada.

### **Special Access Programs**

Drugs and medical devices that are not approved may also be available through our Special Access Programs. The Special Access Program for drugs provides access to drugs that cannot otherwise be sold or distributed in Canada, and the Special Access Program for medical devices provides access to custom-made or unlicensed devices. Access may be granted for emergency use or to patients with serious or life-threatening conditions when conventional therapies have failed, are unavailable or are unsuitable.

### **Product Submission and Review**

When a company decides that it would like to market a drug or medical device in Canada, it files an application to us for a new drug submission or new medical device licence. Reviewers evaluate the safety, effectiveness, and quality data to assess the potential benefits and risks of the products. They also review the information to be provided to healthcare practitioners and consumers about the drug or medical device.

### **Expedited Review Pathways**

We have various review processes that can provide an expedited path to a final decision for certain drugs and medical devices, including those that target specific health care needs. For example, in 2017 36% of the new drug submissions for new active substances were approved via an expedited pathway.

### **Approval of Drugs and Medical Devices**

When a new drug is approved, it is issued a Notice of Compliance (NOC). When a new medical device is approved, it is issued a medical device licence. This does not mean the drug or medical device will immediately be available to patients, as many other factors can influence that timeline.

### **Post Market Surveillance**

Part of our job is to collect and evaluate reports of suspected adverse reactions after products are approved for sale in Canada. These are undesirable effects potentially caused by health products.

We conduct risk assessments and recommend appropriate measures. These can include informing the public and health care professionals of new product safety information, recommending labelling changes, and removing a product from the market.

### **Risk Management and Intervention**

Health Canada uses Risk Management Plans (RMPs) to enhance the quality of our evaluation. The RMP includes measures to be taken by a company to identify, prevent or minimize known or potential risks to patients.

2

**DRUG AND MEDICAL DEVICE**  
APPROVAL OVERVIEW

## CLINICAL TRIALS

Clinical Trials for drugs and Investigational Testing for medical devices represent potential new health care therapies which may eventually address the needs of Canadians.

Trial sponsors (including manufacturers and researchers) submit their applications to conduct a clinical trial with a drug or medical device in Canada. We review these applications and, if acceptable, we issue approvals to allow the trial to be conducted in Canada.

In 2017, Health Canada authorized 1229 new clinical trial applications for drugs, and 199 new investigational testing applications for medical devices.

You can find out what clinical trial applications have been approved for drugs in Canada by searching [Health Canada's Clinical Trials Database](#).

Click here to see a short video about [clinical trials and special access programs](#).

## SPECIAL ACCESS PROGRAMS

Drugs and medical devices that are not approved may also be available through our Special Access Programs.

The [Special Access Program for drugs](#) provides access to drugs that cannot otherwise be sold or distributed in Canada.

The [Special Access Program for medical devices](#) provides access to custom-made or unlicensed devices.

In both programs, access is provided to the healthcare practitioner that is treating a patient. Access may be granted for emergency use or to patients with serious or life-threatening conditions when conventional therapies have failed, are unavailable or are unsuitable.

In 2017, Health Canada authorized 12,887 requests for special access to drugs, and 2,401 requests for special access to medical devices.

## DRUG AND MEDICAL DEVICE SUBMISSION AND REVIEW

When a company decides that it would like to [market a drug](#) or [medical device](#) in Canada, it files an application to us for a new drug submission or new medical device licence.

Submissions for drugs and higher-risk medical devices are reviewed by our scientists. They perform a thorough review of the submitted information, sometimes using external consultants and advisory committees.

Reviewers evaluate the safety, effectiveness, and quality data to assess the potential benefits and risks of the drugs and medical devices. They also review the information to be provided to healthcare practitioners and consumers about the drug or medical device.

We publish a [list of the new drug submissions](#) that are currently under review. The list is updated monthly and includes the outcome of submissions that have reached a conclusion.

## EXPEDITED REVIEW PATHWAYS

We have various review processes that can provide an expedited path to a final decision for certain drugs and medical devices, including those that target specific health care needs. For example, in 2017 36% of the new drug submissions for new active substances were approved via an expedited pathway.

### Priority review

Drug submissions and medical device applications that are granted priority review status are subject to an expedited review process. Drugs or medical devices for serious, life-threatening, or severely debilitating diseases or conditions can be given a priority review status.

### Notice of compliance with conditions

When a new drug is approved it is issued a Notice of Compliance (NOC). An NOC may be issued with conditions (NOC/c) to a drug with promising clinical benefit, for serious, life-threatening or severely debilitating diseases or conditions. The manufacturer must still demonstrate that the drug has an acceptable safety profile based on a benefit/risk assessment and is of high quality.

Submissions that are reviewed under this pathway are also subject to an expedited review process.



## **APPROVAL OF DRUGS AND MEDICAL DEVICES**

When a new drug is approved, it is issued a Notice of Compliance (NOC). When a new medical device is approved, it is issued a medical device licence.

This does not mean the drug or medical device will immediately be available to patients, as many other factors can influence that timeline.

In 2017, Health Canada approved 67 new drugs, including 36 new active substances. We approved 138 new generic drugs, and 3 biosimilars. We also approved 482 new Class III and IV medical devices, including 6 with novel technology.

Click here to see [the information we publish](#) about approved drugs and medical devices, and our regulatory decisions.

3

# DRUG AND MEDICAL DEVICE POST-MARKET SURVEILLANCE



**Rhonda Kropp**

Director General , Marketed  
Health Products Directorate  
Health Canada

Health Canada collects and evaluates reports of suspected adverse reactions after products are approved for sale in Canada. These are undesirable effects potentially caused by health products.

We conduct risk assessments and recommend appropriate measures. These can include informing the public and health care professionals of new product safety information, recommending labelling changes, and removing a product from the market.

## DETECTING AND ASSESSING SIGNALS

Health Canada collects post-market information from a variety of sources. We evaluate the data to detect new safety signals that warrant more investigation.

**In 2017, we received:**

- 860,000 Post-Market Adverse Reaction Reports (over 132,000 Domestic, and 727,000 Foreign)
- 22,000 Medical Devices Incident Reports (20,600 Domestic)

We publish Summary Safety Reviews (SSRs) to inform Canadians of any safety investigation that might affect the health products they use.

In 2017, Health Canada reviewed 166 [safety issues](#), resulting in 44 [Summary Safety Reviews](#).

You can report adverse reactions and medical device incidents to your medical professional, to a hospital, or to the company that made the product. You can also report them to Health Canada through [MedEffect Canada](#) or by phone at **1-866-234-2345**.

## **RISK MANAGEMENT AND INTERVENTION**

Health Canada uses Risk Management Plans (RMPs) to enhance the quality of our evaluation. The RMP includes measures to be taken by a company to identify, prevent or minimize known or potential risks to patients.

**In 2017, Health Canada reviewed 231 Risk Management Plans.**

Once risks have been identified, the risk information is communicated to health care professionals and the public.

In 2017, Health Canada issued 137 Risk Communications to healthcare practitioners and Canadians. These risk communications can be searched in the [Recalls and Safety Alerts Database](#).

[Health Product Infowatch](#) provides information about emerging health product safety risks to healthcare professionals, for use with their patients.

## **ADVERTISING COMPLAINTS FOR MARKETED HEALTH PRODUCTS**

Health Canada regulates the advertising of marketed health products in Canada to ensure that companies are not making false claims about their products.

**In 2017, Health Canada reviewed 67 [advertising complaints related to health products](#).**

After reviewing a complaint we take appropriate action, which may include asking a company to stop selling and advertising an unapproved product.

Click here to see a short video about our [post-market surveillance activities](#).

4

**DRUG AND MEDICAL DEVICE**

2017

ACCOMPLISHMENTS

Health Canada is recognized around the world as a highly respected regulatory authority.

**AGILE AND ADAPTIVE  
APPROVAL PROCESSES**

**COMMUNICATING THE RISKS  
ASSOCIATED WITH OPIOIDS**

**BETTER ENGAGEMENT:  
THE PATIENT VOICE**

**ANTICIPATING EVOLVING  
HEALTH NEEDS OF  
CANADIANS**

## **AGILE AND ADAPTIVE APPROVAL PROCESSES**

The Canadian health care system is changing rapidly. We need to be able to adapt to changes in health care delivery while giving Canadians faster access to the drugs and medical devices they need.

We must continue to make sure that all drugs and medical devices we approve are of high quality, and the benefits outweigh the risks.

In Budget 2017, the Government of Canada funded a [series of projects](#) to improve access to necessary prescription medications and medical devices.

## **COMMUNICATING THE RISKS ASSOCIATED WITH OPIOIDS**

Canada is facing a national opioid crisis. This is a complex health and social issue and we have [committed to taking action](#).

### **Implementing regulations**

Health Canada is responsible for implementing new regulations that give access to drugs that would help address an urgent public health need but are not yet authorized for sale in Canada. Drugs must have been approved in the United States, the European Union, or Switzerland.

### **Publishing draft regulations**

We published draft regulations that would require risk management plans for opioids, and would require a patient information handout and warning sticker for all prescription opioids at the time of sale. The sticker and handout would better inform Canadian patients about the safe use of opioids and their associated risks.

### **Updating opioid labelling requirements**

We are updating the labelling requirements for all prescription opioid drugs to add and clarify information that may help reduce risks to Canadians

### **Reviewing drug submissions**

We reviewed submissions for drugs, and combination drug/medical device products, indicated for the treatment of opioid use disorder and for safe pain management. Health Canada also wrote to industry to encourage them to pursue paths to market such products in Canada.

## **BETTER ENGAGEMENT: THE PATIENT VOICE**

We could not do our work without help from the public, our partners, and stakeholders. Our stakeholders include the drug and medical device industries, and communities of medical and healthcare professionals. Patient and consumer voices are critical components in our work.

We met with patient and patient advisory groups throughout 2017 to get feedback and direction on our priorities. We will continue to seek out patient opinions, and incorporate them into our activities.

We use the [Consultation and Stakeholder Information Management System \(CSIMS\)](#) to share information on health topics and to invite people to take part in consultations.

We invite you to register as a member of an organization or as an individual, and participate more actively in our work.

Click here to see a short video about the [patient perspective](#).

## ANTICIPATING EVOLVING HEALTH NEEDS OF CANADIANS

It is important for us to understand emerging health issues and new approaches that medical science has developed to secure health outcomes that respond to your needs.

Our goal is to identify and prioritize important and emerging health needs to ensure that future investments address the health challenges most likely to affect Canadians. We will identify high-impact health issues and undertake in-depth analysis to explore the implications for existing and new regulations and investment.

We are building networks to engage with stakeholders to inform and guide our work.

Click here to see a short video about [predicting future health needs](#).

### Planning for the Future

Our planning initiative focuses on four key activities:

- Monitor the changing scientific landscape to better understand new and emerging products, the challenges they pose, and evolving science
- Identify and prioritize future health needs to ensure that ongoing Health Canada activities help to address challenges likely to affect Canadians
- Study high-impact issues (e.g., advances in gene therapies, personalized medicine, machine learning, robotics) and their effects on existing laws, regulations, and Health Canada investments and activities
- Build opportunities to engage with multiple voices and perspectives in each of these activities

## DRUGS AND MEDICAL DEVICES

### 5

# MORE DETAILS

#### **Reviewing drugs and medical devices**

Find information about how Health Canada reviews drugs: [How Drugs are Reviewed in Canada](#) and medical devices: [Safe Medical Devices in Canada](#).

#### **Drug shortages**

Find information on actual and anticipated drug shortages: [Drug Shortages in Canada](#).

#### **New drugs approved**

Find information for consumers about drugs that are currently marketed in Canada: [Drug and Health Product Register](#).

Find a listing of all drugs approved for sale in Canada: [Drug Product Database](#). In the database, many drugs are accompanied by their Product Monographs, which describe the conditions of use of the product.

Find the lists of drug submissions currently under review: [Submissions Under Review Lists](#).

Find the approvals (Notices of Compliance, or NOCs) issued for new drugs: [Notice of Compliance database](#).

Find the purpose of a drug submission, and the reasons for our decision: [Regulatory Decision Summary](#).

Find the detailed regulatory, safety, effectiveness and quality considerations that factored into our decision to approve certain drug submissions: [Summary Basis of Decision](#).

#### **New medical devices approved**

Find the approvals (licences) issued for medical devices: [Medical Devices Active Licences](#).

Find the purpose of an application for a medical device licence, and the reasons for our decision: [Regulatory Decision Summary](#).

Find the detailed regulatory, safety, effectiveness and quality considerations that factored into our decision to approve certain medical devices: [Summary Basis of Decision](#).



### **Clinical trials for drugs**

Find out what clinical trial applications have been approved for drugs in Canada: [Health Canada's Clinical Trials Database](#).

### **Special access programs for drugs and medical devices**

Find out more information about the special access program for drugs: [Special Access to Drugs](#) and for medical devices: [Special Access to Medical Devices](#).

### **Post-market surveillance of drugs and medical devices**

Find out more information about Health Canada risk communications: [Recalls and Safety Alerts Database](#).

Report a drug adverse reaction, or a medical device incident: [MedEffect Canada](#).

Find information on safety reviews of drugs and medical devices: [New Safety Reviews](#).

Find summaries of our reviews of potential safety issues for drugs and medical devices: [Summary Safety Reviews](#).

Find the health product advertising complaints that have been filed with Health Canada, and our assessment: [Health Product Advertising Complaints](#).

# APPROVED 6 | DRUGS AND MEDICAL DEVICES 2017

Select a health category to see the new drugs, medical devices with novel technology, generic drugs, and biosimilars approved for sale in Canada in 2017, and the risk communications issued.

## HEALTH CATEGORIES

Anesthetics and surgery

Antibiotics

Arthritis

Blood health (non-cancer)

Cancer therapies

Diabetic health

Diagnostic agents

Digestive and bladder health

Extraordinary use

Eye health

The flu

Genetic disorders

Heart health

Hormone therapies

Immune system health

Kidney disease

Liver disease

Mental health

Neurological therapies

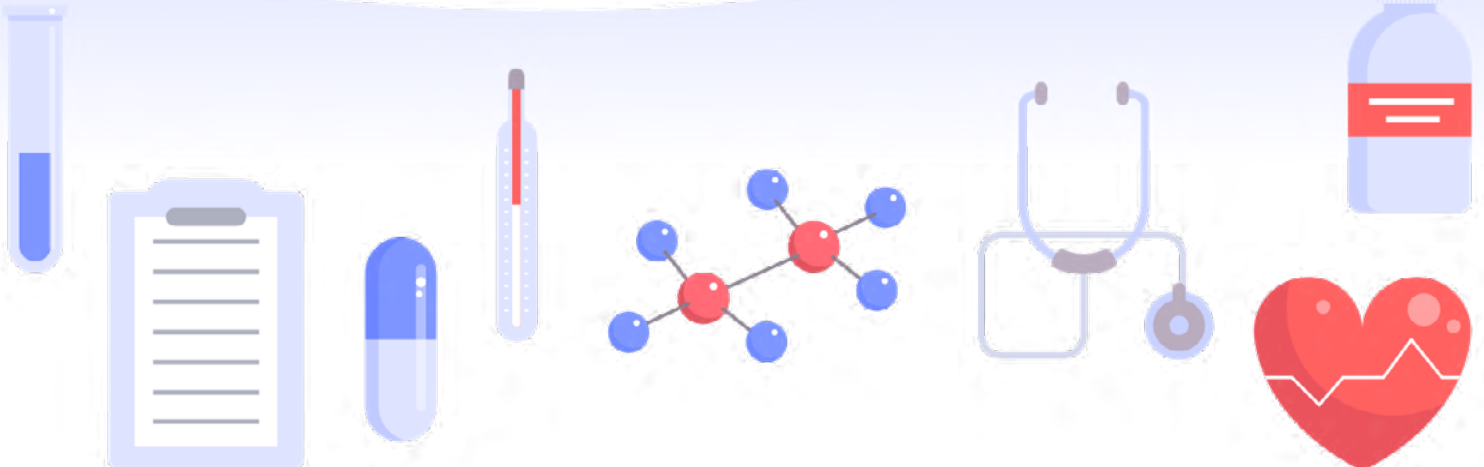
Reproductive health

Respiratory health

Skin health

Vaccines

“Other” risk communications



## PRODUCT CATEGORIES

Within each health category, we have identified products using the following icons

- B** Biologic drugs are biologically-derived products such as vaccines, blood-derived products, and products produced through biotechnology.
- O** Orphan drugs are used to treat rare diseases, and have received orphan designation in either the United States or the European Union.
- C** A Notice of Compliance may be issued with Conditions (NOC/c) to a drug with promising clinical benefit, for a serious, life-threatening, or severely debilitating disease or condition. The manufacturer must still demonstrate that the product has an acceptable safety profile based on a benefit/risk assessment, and is of high quality. Submissions that are reviewed under this pathway are subject to shorter review targets.
- P** Priority review status may be granted to a drug submission or medical device application for a product for a serious, life-threatening or severely debilitating disease or condition. Submissions that are granted priority review status are subject to shorter review targets.

## IMPORTANT DEFINITIONS

### **New Drugs**

New drugs give you new and innovative options for treatment, prevention and diagnosis of various health conditions.



### **New active substance (NAS)**

A new 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.

### **Biosimilar**

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.

### **Generic Drugs**

A copy of a brand name product. Generic drugs contain the same medicinal ingredients as the brand name drug, and are considered bioequivalent to the brand name drug. There may be many generic versions of one brand name drug. Generic drugs cost less, so approving generic drugs can mean considerable savings to the healthcare system.

### **Medical Devices**

Medical devices are products that are used for diagnostic and/or therapeutic purposes. Newly approved medical devices provide a broader range of products used to treat, manage, diagnose or prevent a disease or a physical condition.



### **Novel Technology**

Medical devices with novel technology introduce a new apparatus, appliance, software or material with novel technology never before approved for sale in Canada.

### **Risk Communications:**

Issued by Health Canada for a specific drug or medical device, or a group of related products, to inform healthcare professionals and the public of newly identified safety issues. Visit [Search recalls and safety alerts](#) for more details.

4

**NEW GENERIC DRUGS**

Health Canada approved four new generic drugs for anesthetics and surgery.

1

**NEW MEDICAL DEVICE**

**MAGEC SPINAL BRACING AND DISTRACTION SYSTEM**

*Indication:*

A magnetic driven, self-lengthening spinal rod that could reduce the number of surgeries in the correction of scoliosis in children.



1

**RISK COMMUNICATION**

Health Canada released one risk communication on anesthetics and surgery.

## 1 NEW DRUG

### AURO-CEFIXIME

[Decision Summary](#)

#### *Medical Ingredient*

Cefixime

#### *Indication:*

Auro-Cefixime is used for the treatment of the following infections:

- upper respiratory tract
- middle ear
- paranasal sinuses
- lower respiratory tract
- urinary tract
- uncomplicated gonorrhoea

## 14 NEW GENERIC DRUGS

Health Canada approved fourteen new generic drugs for antibiotics.

## 4 RISK COMMUNICATIONS

Health Canada released four risk communications on antibiotics.

## 2 NEW DRUGS

### KEYZARA

[Decision Summary](#)

#### *Medical Ingredient*

Sarilumab



NAS



BIOLOGIC DRUG

#### *Indication*

Kevzara is used to treat adult patients with moderately to severely active rheumatoid arthritis (RA).

### TRIAMCINOLONE HEXACETONIDE INJECTABLE SUSPENSION

[Decision Summary](#)

#### *Medical Ingredient*

Triamcinolone Hexacetonide

#### *Indication*

Triamcinolone Hexacetonide Injectable Suspension is used in adults and adolescents to treat the symptoms of subacute and chronic inflammatory joint diseases including:

- rheumatoid arthritis
- Juvenile Idiopathic Arthritis (JIA)
- osteoarthritis and post-traumatic arthritis
- inflammation of the membrane that lines the joint (synovitis)
- inflammation or irritation of the tendon, a thick cord that attaches bone to muscle (tendinitis)
- inflammation or irritation of the bursa, the fluid filled sac located between tissues such as bone, muscle, tendons and skin that decreases rubbing and irritation (bursitis)
- inflammation of the tendons around an epicondyle, the end of a bone, often in the elbow (epicondylitis)

## 2 NEW GENERIC DRUGS

Health Canada approved two new generic drugs for arthritis.



## 2 NEW BIOSIMILARS

### ERELZI

#### *Medical Ingredient*

Etanercept

#### *Indication*

Erelzi is a medicine for treating people with moderate to severe forms of rheumatoid arthritis (RA) or juvenile idiopathic arthritis (JIA). Erelzi is also for treating adults with a type of arthritis called ankylosing spondylitis (AS).

[Decision Summary](#)

- B** BIOLOGIC DRUG
- O** ORPHAN DRUG

### RENFLXIS

#### *Medical Ingredient*

Infliximab

#### *Indication*

Renflexis is a medicine that is used in people with moderate to severe rheumatoid arthritis (in combination with methotrexate) and ankylosing spondylitis. Renflexis is also used in people with moderate to severe plaque psoriasis. Renflexis is also used in people with active psoriatic arthritis. Renflexis is also used in adults, children and teenagers with moderate to severe Crohn's disease or with moderate to severe ulcerative colitis.

[Decision Summary](#)

- B** BIOLOGIC DRUG
- O** ORPHAN DRUG

## 1 RISK COMMUNICATION

Health Canada released one risk communication on arthritis.

### 3 NEW DRUGS

#### DEFITELIO

[Decision Summary](#)

*Medical Ingredient*

Defibrotide



NAS



BIOLOGIC DRUG



ORPHAN  
DRUG



PRIORITY  
REVIEW

*Indication*

Defitelio is used to treat a condition called hepatic venoocclusive disease, in which the blood vessels in the liver become damaged and obstructed by blood clots.

#### FIBRYGA (FORMERLY FIBRYNA)

[Decision Summary](#)

*Medical Ingredient*

Fibrinogen (human)



BIOLOGIC DRUG



ORPHAN  
DRUG

*Indication*

Fibryga is used for the treatment of acute bleeding episodes and perioperative prophylaxis in children and adults with congenital afibrinogenemia and hypofibrinogenemia.

#### REBINYN

[Decision Summary](#)

*Medical Ingredient*

Coagulation Factor IX (Recombinant), Pegylated



NAS



BIOLOGIC DRUG



ORPHAN  
DRUG

*Indication*

Rebinyn is used to treat and prevent bleeding in patients with hemophilia B (also called congenital factor IX deficiency).

**6**

## **NEW GENERIC DRUGS**

Health Canada approved six new generic drugs for blood health (non-cancer).

**3**

## **RISK COMMUNICATIONS**

Health Canada released three risk communications on blood health (non-cancer).

## 10 NEW DRUGS

### AKYNZEO

[Decision Summary](#)

*Medical Ingredient*

Palonosetron Hydrochloride, Netupitant



*Indication*

Prevention of nausea (feeling sick) and vomiting that may happen after taking certain anti-cancer medicines (chemotherapy).

### BAVENCIO

[Decision Summary](#)

*Medical Ingredient*

Avelumab



*Indication*

Bavencio is a medicine used to treat a rare type of skin cancer that has spread called metastatic Merkel cell carcinoma in previously treated adults.

### IMFINZI

[Decision Summary](#)

*Medical Ingredient*

Durvalumab



*Indication*

Imfinzi (durvalumab) is a medicine used to treat adults with a bladder cancer (called urothelial carcinoma) including cancer of the ureter, urethra or kidney pelvis.

### LARTRUVO

[Decision Summary](#)

*Medical Ingredient*

Olaratumab



*Indication*

Lartruvo is a cancer medicine used together with doxorubicin (another cancer medicine) to treat soft tissue sarcoma (a cancer of muscles, fat or other tissues) when treatment with radiation or surgery are not options.

**ONCASPAR***Medical Ingredient*

Pegaspargase

*Indication*

Oncaspar is used to treat acute lymphoblastic leukaemia (ALL).

[Decision Summary](#)



-  BIOLOGIC DRUG
-  ORPHAN DRUG

**ONIVYDE***Medical Ingredient*

Irinotecan hydrochloride trihydrate

*Indication*

Onivyde is used to treat adult patients with metastatic pancreatic cancer (cancer of the pancreas that has already spread elsewhere in the body).

-  ORPHAN DRUG
-  PRIORITY REVIEW

**PORTRAZZA***Medical Ingredient*

Necitumumab

*Indication*

Portrazza is a cancer medicine used in combination with gemcitabine and cisplatin (other anti-cancer medicines) for the treatment of patients with a type of advanced lung cancer (called squamous non-small cell lung cancer) who have not received prior chemotherapy for this condition.

[Decision Summary](#)

-  NAS
-  BIOLOGIC DRUG
-  ORPHAN DRUG

**RYDAPT***Medical Ingredient*

Midostaurin

*Indication*

Rydapt is used in combination with other chemotherapy treatments to treat acute myeloid leukemia (AML) in adults who have a new diagnosis of a defect in a gene called FLT3.

[Decision Summary](#)

-  NAS
-  ORPHAN DRUG
-  PRIORITY REVIEW

**TECENTRIQ***Medical Ingredient*

Atezolizumab

*Indication*

Tecentriq is used to treat a type of bladder cancer called urothelial carcinoma that cannot be removed by surgery or has spread to other parts of the body. Tecentriq is used after you have tried chemotherapy and it did not work or is no longer working.

[Decision Summary](#)

-  NAS
-  BIOLOGIC DRUG
-  NOC WITH CONDITIONS

## TEPADINA

[Decision Summary](#)

### *Medical Ingredient*

Thiotepa

### *Indication*

Tepadina is used to treat adult patients with central nervous system (CNS) lymphoma. It is used in combination with other anticancer medicines and is followed by stem cell transplantation.

-  ORPHAN DRUG
-  NOC WITH CONDITIONS

## 17

### NEW GENERIC DRUGS

Health Canada approved 17 new generic drugs for cancer.

## 2

### NEW MEDICAL DEVICES

#### MAMMOMAT INSPIRATION

[Decision Summary](#)

### *Indication:*

A medical device used for two-dimensional and three-dimensional mammograms to screen and diagnose breast cancer.

-  NOVEL TECHNOLOGY

#### MRIDIAN LINAC SYSTEM

[Decision Summary](#)

### *Indication:*

A combination MRI and linear accelerator system intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumours, and conditions anywhere in the body where radiation treatment is indicated.

-  NOVEL TECHNOLOGY

## 14

### RISK COMMUNICATIONS

Health Canada released 14 risk communications for cancer.

## 4 NEW DRUGS

### ADLYXINE

[Decision Summary](#)

*Medical Ingredient*

Lixisenatide



*Indication*

Adlyxine is used along with diet and exercise to improve control of blood sugar levels in adults with type 2 diabetes.

### ENTUZITY KWIKPEN

[Decision Summary](#)

*Medical Ingredient*

Insulin Injection Human Biosynthetic



*Indication*

Entuzity is a synthetic human insulin that is used to control high blood sugar in patients with diabetes mellitus who need more than 200 units of insulin in a day.

### FIASP

[Decision Summary](#)

*Medical Ingredient*

Insulin Aspart



*Indication*

Fiasp is used in the treatment of patients with diabetes mellitus who require insulin for the control of high blood sugar.

### TRESIBA (FLEXTOUCH), TRESIBA (PENFILL)

[Decision Summary](#)

*Medical Ingredient*

Insulin Degludec



*Indication*

Tresiba is a long-acting man-made insulin used to control high blood sugar in adults with diabetes mellitus.

## 2 NEW GENERIC DRUGS

Health Canada approved two new generic drugs for diabetic health.

## 1 NEW BIOSIMILAR

### ADMELOG

[Decision Summary](#)

#### *Medical Ingredient*

Insulin Lispro



#### *Indication*

Admelog (insulin lispro injection), is indicated for the treatment of patients with diabetes mellitus who require insulin for the maintenance of normal glucose homeostasis.

## 1 NEW MEDICAL DEVICE

### FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM

[Decision Summary](#)

#### *Indication:*

A medical device used for measuring interstitial fluid glucose levels in adults aged 18 years and older who have at least 2 years of experience in self-managing their diabetes, and is intended to replace blood glucose testing in certain cases.



## 3 RISK COMMUNICATIONS

Health Canada released three risk communications for diabetic health.



## 1 NEW DRUG

### LIPIODOL ULTRA FLUID

[Decision Summary](#)

#### *Medical Ingredient*

Iodine

#### *Indication*

Lipiodol Ultra Fluid is a drug used in X-ray tests.

## 5 NEW GENERIC DRUGS

Health Canada approved five new generic drugs for diagnostic agents.

## 4 RISK COMMUNICATIONS

Health Canada released four risk communications for diagnostic agents.

## 2 NEW DRUGS

### MICTORYL

[Decision Summary](#)

*Medical Ingredient*

Propiverine Hydrochloride



*Indication*

Mictoryl is used in adults who have difficulty in controlling their bladder due to bladder over activity.

### VIBERZI

[Decision Summary](#)

*Medical Ingredient*

Eluxadoline



*Indication*

Viberzi is used to treat adults with irritable bowel syndrome with diarrhea (IBS-D).

## 5 NEW GENERIC DRUGS

Health Canada approved five new generic drugs for digestive and bladder health.

## 3 RISK COMMUNICATIONS

Health Canada released three risk communications for digestive and bladder health.

Health Canada recognizes that there are circumstances in which manufacturers cannot reasonably provide substantial evidence demonstrating the safety and efficacy of a therapeutic product as there are logistical or ethical challenges in conducting the appropriate human clinical trials. For these types of products, which may be needed as part of emergency preparedness in Canada, the regulations for Extraordinary Use New Drugs (EUND) allow for the possibility of a market authorization based primarily on animal data.

Once a product has received market authorization as an EUND, the sale of the product for that indication is restricted to federal, provincial and territorial, and municipal government(s).

1

**NEW DRUG**

**ANTHRASIL**

[Decision Summary](#)

*Medical Ingredient*

Anthrax Immune Globulin (Human)

*Indication*

Anthraxil is used to treat inhalational anthrax, a bacterial infection.



NAS



BIOLOGIC DRUG



ORPHAN  
DRUG

## 1 NEW DRUG

### XIIDRA

[Decision Summary](#)

*Medical Ingredient*  
Lifitegrast



#### *Indication*

Xiidra is an eye drop used to treat the signs and symptoms of dry eyes.

## 1 NEW GENERIC DRUG

Health Canada approved one new generic drug for eye health.

1

NEW DRUG

**RAPIVAB**

[Decision Summary](#)

*Medical Ingredient*  
Peramivir



*Indication*

Rapivab is used to treat flu symptoms in patients 18 years of age and older.

## 7 NEW DRUGS

### CERDELGA

[Decision Summary](#)

*Medical Ingredient*

Eliglustat Tartrate



NAS



ORPHAN  
DRUG

*Indication*

Cerdelga is a medicine used for treating adult patients with Gaucher disease type 1.

### GALAFOLD

[Decision Summary](#)

*Medical Ingredient*

Migalastat Hydrochloride



NAS



ORPHAN  
DRUG

*Indication*

Galafold is used for the long-term treatment of Fabry disease in adults who have certain genetic mutations (changes) in an enzyme called alpha-galactosidase A ( $\alpha$ -Gal A).

### HAEGARDA

[Decision Summary](#)

*Medical Ingredient*

C1 Esterase Inhibitor (Human)



BIOLOGIC DRUG



ORPHAN  
DRUG

*Indication*

Haegarda is an injectable medicine used to prevent swelling and/or painful attacks in adults and adolescents with Hereditary Angioedema (HAE).

### KANUMA

[Decision Summary](#)

*Medical Ingredient*

Sebelipase Alfa



NAS



BIOLOGIC DRUG



ORPHAN  
DRUG



NOC WITH  
CONDITIONS

*Indication*

Kanuma is used to treat infants, children and adults with lysosomal acid lipase deficiency (LAL deficiency)- a condition that affects an individual's ability to breakdown and use fats and cholesterol. It is used to treat infants, children and adults with lysosomal acid lipase deficiency (LAL deficiency).

**PROCYSBI**[Decision Summary](#)*Medical Ingredient*

Cysteamine Bitartrate

*Indication*

Procysbi is used for treatment of nephropathic cystinosis, a rare metabolic disease.



NAS

ORPHAN  
DRUGPRIORITY  
REVIEW**REPLAGAL**[Decision Summary](#)*Medical Ingredient*

Agalsidase Alfa

*Indication*

Replagal is used to treat patients with a confirmed diagnosis of Fabry Disease.



BIOLOGIC DRUG

ORPHAN  
DRUGNOC WITH  
CONDITIONS**SPINRAZA**[Decision Summary](#)*Medical Ingredient*

Nusinersen Sodium

*Indication*

Spinraza is used to treat a genetic disease called 5q Spinal Muscular Atrophy (SMA). Spinal Muscular Atrophy- a disease of the nervous system that affects voluntary muscle movement.



NAS

ORPHAN  
DRUGNOC WITH  
CONDITIONS

1

## NEW DRUG

### BRINAVESS

[Decision Summary](#)

*Medical Ingredient*

Vernakalant Hydrochloride



*Indication*

Brinavess is for the treatment of a fast, irregular heart rate called atrial fibrillation.

33

## NEW GENERIC DRUGS

Health Canada approved 33 new generic drugs for heart health.



## 2 NEW MEDICAL DEVICES

### CARDIOMEMS HF SYSTEM

[Decision Summary](#)

*Indication:*

A medical device used for wirelessly measuring and monitoring pulmonary artery pressure in New York Heart Association Class III heart failure patients who have been hospitalized for heart failure in the previous year. Changes in pulmonary artery pressure can be an effective early predictive measure of worsening heart failure.



### IMPELLA RP CIRCULATORY SUPPORT SYSTEM

[Decision Summary](#)

*Indication:*

A medical device providing circulatory assistance for up to 14 days in adult patients who develop acute right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery.



## 3 RISK COMMUNICATIONS

Health Canada released three risk communications for heart health.

**3**

**NEW GENERIC DRUGS**

Health Canada approved three new generic drugs for hormone therapies.

## 4 NEW DRUGS

### FLEBOGAMMA 5%, FLEBOGAMMA 10%

[Decision Summary](#)

#### *Medical Ingredient*

Immune Globulin (Human)

**B** BIOLOGIC DRUG

#### *Indication*

Flebogamma is indicated for replacement therapy in adults, children and adolescents (2-18 years) in:

- patients with Primary Immunodeficiency (PID), an inborn lack of antibodies
- hypogammaglobulinaemia (a condition implying low immunoglobulin levels in your blood) and recurrent bacterial infections in patients with chronic lymphocytic leukaemia (cancer of the blood where too many white blood cells are produced), in whom prophylactic antibiotics have failed
- hypogammaglobulinaemia (a condition implying low immunoglobulin levels in your blood) and recurrent bacterial infections in myeloma (tumour composed of cells derived from the bone marrow) patients who failed to respond to pneumococcal immunisation
- hypogammaglobulinaemia (a condition implying low immunoglobulin levels in your blood) in patients after a stem cell transplantation (allogeneic haematopoietic stem cells transplantation), when you are given stem cells from another person
- children and adolescents with the Acquired Immune Deficiency Syndrome (AIDS), it can be used to prevent troublesome infections

Treatment of certain autoimmune disorders (immunomodulation) in adults, children and adolescents (2 – 18 years):

- primary immune thrombocytopenia (ITP), a condition where the number of platelets in the blood stream is greatly reduced. Platelets form an important part of the clotting process and a reduction in their numbers may cause unwanted bleeding and bruising. The product is also used in patients at high risk of bleeding or prior to surgery to correct the platelet count
- Guillain Barré syndrome, where the immune system damages the nerves and hinders them from working properly

**CUVITRU**

[Decision Summary](#)

*Medical Ingredient*

Immune Globulin (Human)

**B** BIOLOGIC DRUG

*Indication*

Cuvitru is a ready-to-use, liquid medicine that contains immunoglobulin G (IgG) antibodies, which protect the body against infection. Cuvitru is used to treat patients with primary immunodeficiency diseases (PI) and with secondary humoral immunodeficiency diseases (SI).

**ODEFSEY**

[Decision Summary](#)

*Medical Ingredient*

Emtricitabine, Rilpivirine Hydrochloride, Tenofovir Alafenamide Fumarate

*Indication*

Odefsey is used to treat people with Human Immunodeficiency Virus (HIV) infection. Odefsey is for adults.

**PREVMIS**

[Decision Summary](#)

*Medical Ingredient*

Letermovir

**NAS**

*Indication*

Prevymis is a medicine to help to keep adults 18 years of age and older from getting ill from CMV (cytomegalovirus).

**O** ORPHAN DRUG

**P** PRIORITY REVIEW

**21**

**NEW GENERIC DRUGS**

Health Canada approved 21 new generic drugs for immune system health.

**7**

**RISK COMMUNICATIONS**

Health Canada released seven risk communications on immune system health.

## 1 NEW DRUG

### ACCEL-SEVELAMER

[Decision Summary](#)

#### *Medical Ingredient*

Sevelamer Carbonate

#### *Indication*

ACCEL-Sevelamer is used for the control of high phosphorus levels in patients with end stage kidney disease undergoing dialysis (whether hemodialysis or peritoneal dialysis).

## 1 NEW GENERIC DRUG

Health Canada approved one new generic drug for kidney disease in 2017.

## 1 RISK COMMUNICATION

Health Canada released one risk communication on kidney disease.

## 4 NEW DRUGS

### MAVIRET

[Decision Summary](#)

*Medical Ingredient*

Glecaprevir, Pibrentasvir

*Indication*

Maviret treats people with chronic (long-lasting) hepatitis C in adults. Hepatitis C is caused by an infection with the Hepatitis C virus (HCV).



NAS



ORPHAN  
DRUG



PRIORITY  
REVIEW

### OCALIVA

[Decision Summary](#)

*Medical Ingredient*

Obeticholic Acid

*Indication*

Ocaliva is used to treat primary biliary cholangitis (PBC).



NAS



ORPHAN  
DRUG



PRIORITY  
REVIEW

### VEMLIDY

*Medical Ingredient*

Tenofovir Alafenamide Hemifumarate

*Indication*

Vemlidy is used to treat chronic (long-lasting) hepatitis B in adults. Hepatitis B is caused by an infection with the hepatitis B virus (HBV).

### VOSEVI

[Decision Summary](#)

*Medical Ingredient*

Sofosbuvir, Velpatasvir, Voxilaprevir

*Indication*

Vosevi is used to treat chronic (long-lasting) hepatitis C in adults who have:

- genotype 1, 2, 3, 4, 5, or 6 infection and have been previously treated with a type of medicine called an NS5A inhibitor
- genotype 1, 2, 3 or 4 infection and have been previously treated with sofosbuvir without another medicine called an NS5A inhibitor



NAS



ORPHAN  
DRUG



PRIORITY  
REVIEW

## 4 NEW DRUGS

### APO-DESVENLAFAXINE

---

*Medical Ingredient*

Desvenlafaxine

*Indication*

APO-Desvenlafaxine has been prescribed to you by your doctor to treat your depression.

### FOQUEST

---

*Medical Ingredient*

Methylphenidate Hydrochloride

*Indication*

Foquest is used in adults to treat Attention Deficit Hyperactivity Disorder (ADHD).

### PMS-FLUOXETINE

---

*Medical Ingredient*

Fluoxetine Hydrochloride

*Indication*

pms-Fluoxetine has been prescribed by your doctor to relieve your symptoms of:

- Depression (feeling sad, a change in appetite or weight, difficulty concentrating or sleeping, feeling tired, headaches, unexplained aches and pain)
- Bulimia (eating disorder, characterized by self-induced vomiting after eating)
- Obsessive-Compulsive disorder (recurrent and intrusive thought, feeling, idea, or sensation; recurrent pattern of behaviour, or unwanted thoughts or actions)

### REXULTI

---

*Medical Ingredient*

Brexpiprazole

*Indication*

Rexulti is used for the treatment of schizophrenia in adults.

[Decision Summary](#)



**3**  
**NEW GENERIC DRUGS**

Health Canada approved three new generic drugs for mental health.

**3**  
**RISK COMMUNICATIONS**

Health Canada released three risk communications for mental health.



## 7 NEW DRUGS

### BELBUCA

[Decision Summary](#)

#### *Medical Ingredient*

Buprenorphine Hydrochloride

#### *Indication*

Belbuca is used for the long-term management of pain, when:

- the pain is severe enough to require daily, around-the-clock pain medication
- the doctor determines that other treatment options are not able to effectively treat your pain

### CUVPOSA

[Decision Summary](#)

#### *Medical Ingredient*

Glycopyrrolate



ORPHAN  
DRUG

#### *Indication*

Cuvposa is used for reducing drooling caused by certain health problems. It is for patients that are 3-18 years old.

### DATSCAN

[Decision Summary](#)

#### *Medical Ingredient*

loflupane (123I)



NAS



BIOLOGIC DRUG

#### *Indication*

DaTscan is a radioactive diagnostic agent which is used with a special camera to take pictures of the brain. In adult patients who have symptoms of Parkinsonian Syndromes (such as Parkinson's disease), DaTscan is used along with other diagnostic tests to give the doctor more information about their condition.

### GLATECT

[Decision Summary](#)

#### *Medical Ingredient*

Glatiramer Acetate



ORPHAN  
DRUG

#### *Indication*

Glatect is used to treat patients with Relapsing Remitting Multiple Sclerosis (RRMS).

**MAVENCLAD**

[Decision Summary](#)

*Medical Ingredient*  
Cladribine



*Indication*

Mavenclad is used to treat adult patients with relapsing-remitting multiple sclerosis (RRMS). Multiple sclerosis (MS) is a disease that affects the brain and spinal cord.

**NEURACEQ**

[Decision Summary](#)

*Medical Ingredient*  
Florbetaben (18F)



*Indication*

NeuraCeq is given to people with memory problems so that doctors can perform a type of brain scan, called a PET scan (Positron Emission Tomography). A NeuraCeq PET scan, along with other brain function tests, can help your doctor determine whether or not you may have  $\beta$ -amyloid plaques in your brain.

**OCREVUS**

[Decision Summary](#)

*Medical Ingredient*  
Ocrelizumab



*Indication*

Ocrevus is a prescription medicine used to treat adults with active Relapsing Remitting Multiple Sclerosis (RRMS).

**14**  
**NEW GENERIC DRUGS**

Health Canada approved 14 new generic drugs for neurological therapies.

**9**  
**RISK COMMUNICATIONS**

Health Canada released nine risk communications for neurological therapies.

## 1 NEW DRUG

### UTROGESTAN

[Decision Summary](#)

*Medical Ingredient*  
Progesterone



*Indication*

Utrogestan is used in women undergoing treatment for in vitro fertilization (IVF).

## 3 NEW GENERIC DRUGS

Health Canada approved three new generic drugs for reproductive health.

## 5 RISK COMMUNICATIONS

Health Canada released five risk communications on reproductive health.

## 3 NEW DRUGS

### ACARIZAX

[Decision Summary](#)

#### *Medical Ingredient*

Dermatophagoides Pteronyssinus Extract, Dermatophagoides Farinae Extract

**B** BIOLOGIC DRUG

#### *Indication*

Acarizax is for adults aged 18 to 65 who are allergic to house dust mites and have allergic rhinitis (with or without conjunctivitis).

### AERMONY RESPICLICK

[Decision Summary](#)

#### *Medical Ingredient*

Fluticasone Propionate

#### *Indication*

Aermony Respiclick is used to treat and prevent asthma in people who are 12 years of age and older. It is used by people who need regular treatment for their asthma.

### BACA RESPICLICK

[Decision Summary](#)

#### *Medical Ingredient*

Salbutamol Sulfate

#### *Indication*

Baca Respiclick is used in adults and children of 4 years and older to:

- treat and/or prevent bronchospasm in patients who have narrowing of the airways
- prevent exercise-induced bronchospasm

## 1 NEW GENERIC DRUG

Health Canada approved one new generic drug for respiratory health.

## 2 RISK COMMUNICATIONS

Health Canada released two risk communications on respiratory health.

## 4 NEW DRUGS

### DUPIXENT

[Decision Summary](#)

*Medical Ingredient*

Dupilumab



NAS



BIOLOGIC DRUG

*Indication*

Dupilumab is an injectable prescription medicine used to treat adult patients with moderate-to-severe atopic dermatitis, also known as atopic eczema.

### OZANEX

[Decision Summary](#)

*Medical Ingredient*

Ozenoxacin



NAS

*Indication*

Ozanex is a medication which is applied on the skin to treat bacterial skin infections.

### SITAVIG

[Decision Summary](#)

*Medical Ingredient*

Acyclovir

*Indication*

Sitavig is a medication that is applied once to treat outbreaks of cold sores (herpes labialis) in adults.

### TREMFYA

[Decision Summary](#)

*Medical Ingredient*

Guselkumab



NAS



BIOLOGIC DRUG

*Indication*

Tremfya is a prescription medicine used to treat adults with moderate to severe “plaque psoriasis”, an inflammatory condition affecting the skin and nails.

**3**

**NEW GENERIC DRUGS**

Health Canada approved three new generic drugs for skin health.

**3**

**RISK COMMUNICATIONS**

Health Canada released three risk communications for skin health.

## 2 NEW DRUGS

### SHINGRIX

[Decision Summary](#)

*Medical Ingredient*

Varicella-Zoster Virus Glycoprotein E (Ge)

*Indication*

Shingrix is a vaccine that helps to protect adults against herpes zoster (also called shingles).



NAS



BIOLOGIC DRUG

### TRUMENBA

[Decision Summary](#)

*Medical Ingredient*

Neisseria Meningitidis Grp B Recombinant Lipoprotein 2086 Subfamily A, Neisseria Meningitidis Grp B Recombinant Lipoprotein 2086 Subfamily B

*Indication*

Trumenba is a vaccine to prevent invasive meningococcal disease, caused by Neisseria meningitidis serogroup B bacteria, for use in people aged 10 through 25 years.



NAS



BIOLOGIC DRUG

## **OTHER RISK COMMUNICATIONS**

Seven additional risk communications were issued in other categories, including three risk communications for medical devices, and one for bone health. The remaining two risk communications dealt with a product used in cases of poisoning, and a non-medicinal ingredient used in medications, such as tablets or capsules.





## 7 | HEALTHY CLICKS

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.



[Follow us on Facebook](https://facebook.com/HealthyCdns)  
(facebook.com/HealthyCdns)



[Follow us on Twitter](https://twitter.com/GovCanHealth)  
(twitter.com/GovCanHealth)



[Follow us on YouTube](https://youtube.com/user/HealthyCdns)  
(youtube.com/user/HealthyCdns)

See the latest news from Health Canada [on our website](https://canada.ca/en/health-canada.html) (canada.ca/en/health-canada.html)

Find other Health-related information on the [Government of Canada website](https://canada.ca/en/services/health.html) (canada.ca/en/services/health.html)