



DRUG AND MEDICAL DEVICE HIGHLIGHTS 2018

Helping you maintain and improve your health



Health Canada
Santé Canada

Canada

DRUG AND MEDICAL DEVICE HIGHLIGHTS

2018

Helping you maintain
and improve your health

Learn about the new and innovative drugs and medical devices that Health Canada approved for sale in Canada, the information we published about potential safety issues, and our other accomplishments in 2018.

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. Health Canada is committed to improving the lives of all of Canada's people and to making this country's population among the healthiest in the world as measured by longevity, lifestyle and effective use of the public health care system.

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Préserver et améliorer votre santé : *Faits saillants de 2017 sur les médicaments et les instruments médicaux*

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WELCOME TO HEALTH CANADA'S ANNUAL HIGHLIGHTS REPORT

The report gives information about new drugs and medical devices that Health Canada approved for sale in Canada, the information we published about potential safety issues, and our other accomplishments in 2018.

This year, the report includes an expanded section on medical devices and a new section about veterinary drugs. We have also added non-prescription drugs, more commonly known as over-the-counter products. The report this year is divided into sections on drugs for human use, medical devices, and drugs for veterinary use to best portray information about these therapeutic products.

When Health Canada approves new products we continue to monitor their use in the real world, and take action when there are identified problems. This year's report provides information about how to report an adverse drug reaction or medical device incident. We also provide more detailed information about the risk communications we have issued for products on the Canadian market, that is, the information we have published to inform healthcare professionals and the public of newly identified safety issues.

Health Canada has a wealth of information available online for those seeking current, up-to-date information about drugs and medical devices. Based on feedback from last year's report, we have expanded the "Healthy Clicks" sections, where you will find the most up-to-date information on our activities. We also invite you to follow @GovCanHealth on Twitter for updates on newly approved drugs and medical devices.

We trust that the 2018 Highlights Report provides you with important information about the work that we do, and how the new drugs and medical devices we approved in 2018 make significant contributions to improved healthcare outcomes for Canadians.



Pierre Sabourin
Assistant Deputy Minister,
Health Canada

A blue ink signature of Pierre Sabourin.



Kendal Weber
Associate Assistant
Deputy Minister,
Health Canada

A blue ink signature of Kendal Weber.

MESSAGE FROM THE CHIEF MEDICAL ADVISOR

Health Canada plays a key part in enabling access to needed therapies. Because of our unique role in regulating the safety, effectiveness and quality of new drugs and medical devices, we also have a responsibility to provide credible information about those products to Canadians.

Now more than ever, people are looking to more sources, especially online, to help inform the decisions they make about their healthcare and that of their families. Helping patients and their healthcare teams have access to credible information on the health and safety of therapeutic products is a role we take very seriously.

In 2018, Health Canada furthered its plans to make more information available to Canadians regarding drugs and medical devices.

For example, we published:

- the reasons for our decisions about new drugs and medical devices
- summaries of our safety reviews of therapies being used in Canada
- information on drug shortages and other factors that impact access
- lists of drug submissions under review, including a list of submissions for generic drugs currently with Health Canada

This information will help patients, caregivers and healthcare providers to have more informed conversations about the benefits and possible risks of drugs and medical devices.

Accessing drugs and medical devices in Canada is a complex process: there are many partners in the healthcare continuum. There are also many factors that are involved throughout the life cycle of a product, from its development to approval, and then its use in the healthcare system. In 2018, Health Canada made significant progress in working with our partners, both within Canada and internationally, to make those processes faster and therefore bring more products to Canada, more quickly.

For example, we aligned our review processes for human drugs so that funding recommendations can come earlier, and drugs can reach patients more quickly. We also continued to work with international partners to help make drugs for human and veterinary use and medical devices available more quickly and efficiently.

Our priority is to protect and promote the health and safety of Canadians. Improving access to drugs and medical devices, and providing meaningful information about these products are both important parts of this work, and will continue to be our focus in the coming years.



Supriya Sharma
Chief Medical Advisor,
Health Canada

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MESSAGE FROM THE CHIEF REGULATORY OFFICER

Health Canada works to protect and promote the health and safety of Canadians. Our work is underpinned by Canadian laws and regulations. We are responsible for the regulations that bring important drugs, both for human and for veterinary use, and medical devices to you.

We need regulatory tools that are consolidated, modern, and flexible so that we can:

- make our science-based decisions in a timely manner and in a way that reflects the highest quality of decision making among regulators
- regulate advanced technologies appropriately
- maintain appropriate safety oversight over drugs and medical devices in Canada

In 2018, Health Canada made significant progress to modernize the regulations that support our work. For example, we continue to implement key regulations under Vanessa's Law, a comprehensive safety update to the Food and Drugs Act, including:

- finalized regulations to require a manufacturer to conduct tests, studies, and reassessments, and to require manufacturers to provide us with risk communications that were issued in other countries
- proposed regulations to improve the reporting of serious adverse drug reactions (also known as side effects) and medical device incidents by hospitals
- proposed regulations to make clinical information about the safety and effectiveness of drugs and medical devices available to the public

In 2018, we expanded our regulations to create a new pathway for low risk veterinary health products. We also finalized regulations to restrict marketing and advertising of opioids as part of the Government of Canada's response to the opioid crisis.

We will continue to make sure that our regulations are up to date and forward-looking. We are moving forward with a comprehensive modernization of our regulations for therapeutic products. We have analyzed coming trends, technology, and innovation, and we are consulting on those results in the areas of artificial intelligence, 3-D printing, cell therapies, and more.

This work, along with other projects underway in the Department, will lead to improved health outcomes for patients, including special populations such as children, seniors, and pregnant or nursing women.



David K. Lee
Chief Regulatory Officer,
Health Canada

A handwritten signature in blue ink, appearing to read 'D. Lee', written in a cursive style.



DRUGS FOR HUMAN USE

2018 IN BRIEF

Drugs for human use, including prescription pharmaceuticals and biologic drugs, vaccines, and over-the-counter (non-prescription) drugs, play an important role in helping Canadians lead healthy lives. We evaluate and monitor drugs to ensure that their benefits outweigh their potential risks, throughout their entire life cycle.

We regulate a vast spectrum of drugs, from over-the-counter pain relievers to personalized medicines administered in intensive care units in hospitals. Our scientific reviews form the basis of our regulatory work for all the drugs we regulate.

In 2018, we hired additional scientific staff to increase our ability to:

- review new drugs
- review cost-effective generics and biosimilars
- monitor the safety of drugs after they have reached the Canadian market
- implement new plain language requirements for non-prescription drugs

In addition to these new capacities, we enhanced our scientific knowledge through our partnerships with trusted regulators in other countries. These interactions help increase our knowledge of certain complex products, and help us to make decisions that will improve the safety of drugs on the Canadian market.

Making safe and effective drugs available in a timely manner is the core of our work. Using our resources efficiently helps give Canadians faster access to the drugs they need. In 2018, we met and exceeded our performance targets for drug review.

NEW DRUGS APPROVED

In 2018, we approved 78 new drugs, giving you new and innovative options for the treatment, prevention and diagnosis of various health conditions.

Forty of the new drugs approved in 2018 introduced new active substances: medicinal ingredients that have never been approved for sale in Canada. Thirty-five percent of these were approved through an expedited pathway, to address unmet medical needs, including the first gene therapy approved in Canada (Kymriah) and a novel treatment for some cystic fibrosis patients (Symdeko).

We also approved 135 new generic drugs and 4 new biosimilars in 2018, bringing more choice and more affordable options to Canadians.

For a list and description of the new drugs we approved in 2018, go to [“Drugs for Human Use: Approved in 2018”](#).

CLINICAL TRIALS AND SPECIAL ACCESS PROGRAMME

As part of our role in enabling access to key therapies, we approve applications to allow companies and researchers to conduct clinical trials on drugs in Canada. New clinical trials mean access to more innovative choices. In 2018, 1209 new clinical trial applications for drugs were approved, including several for advanced cell and gene therapies and targeted therapies for oncology.

There are also ways we provide access to drugs that are not available in Canada, through our Special Access Programme. The Programme provides a pathway for doctors to request treatments for their patients that are otherwise unavailable. Access to unapproved drugs may be granted for emergency use or for the treatment of serious or life-threatening conditions. In 2018, 13,125 requests for special access to drugs were authorized, including access to triamcinolone for juvenile arthritis.

POST-MARKET SURVEILLANCE

Once drugs are available in Canada, Health Canada continues to monitor and evaluate reports of suspected adverse drug reactions. We call this ‘post-market surveillance’. It is not possible to know or predict all of the possible adverse reactions to a drug through clinical studies at the time of market approval.

In 2018, we received 1,091,696 post-market reports of adverse reactions to drugs for human use from domestic and international sources. We undertook 620 post-market actions related to drugs for human use. These actions can include informing the public and healthcare professionals of new safety information, recommending labelling changes, and even removing a drug from the market in the most serious situations.

This “Drugs for Human Use” section of the report provides more information about our activities in 2018. You’ll find an overview of the progress we made in 2018 on our key priorities. You will learn about the product life cycle of a drug, and our role in ensuring the benefits of a drug continue to outweigh the potential risks. You will also find details about the new drugs we approved in 2018, as well as the actions we took to address safety issues for products already on the Canadian market. Please also take a look at the new “Healthy clicks” section, to follow up-to-date information on our activities.



John Patrick Stewart

Director General,
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Health Canada

A blue ink signature of John Patrick Stewart.



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A blue ink signature of Celia Lourenco.



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A blue ink signature of Rhonda Kropp.



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Director General,
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Health Canada

A blue ink signature of Manon Bombardier.



DRUGS FOR HUMAN USE

2018 ACCOMPLISHMENTS

REGULATORY REVIEW

The Canadian healthcare system is changing rapidly. We need a regulatory system that is able to continue to adapt to changes in healthcare delivery and that also gives people faster access to the drugs they need. We must also continue to make sure that all drugs we approve are safe, effective, and of good quality.

Health Canada developed the 'Regulatory Review of Drugs and Devices' initiative in 2017 to provide more timely access to drugs and medical devices to patients. Other goals include increasing our work with partners in the healthcare system in Canada and with other countries, and to make better use of real-world evidence (data collected outside of clinical trials) across a product's life cycle.

In 2018, we made significant progress in support of drug access. For example, we:

- reinforced our international partnerships to help bring critical drugs to patients sooner
- worked with healthcare system partners within Canada to align our review work, speeding up access to drugs
- made more information available to patients, caregivers, and healthcare professionals about drug submissions and our decisions about the approval of drugs

We also hired additional scientific staff to increase our ability to review innovative drugs as well as cost-saving generic drugs and biosimilars, and to monitor the safety and effectiveness of drugs after they are approved for sale in Canada.

This section of the report will provide you with more detailed information about these important projects, as well as some of our other priorities in 2018.

BUILDING INTERNATIONAL PARTNERSHIPS

Health Canada participates actively in several initiatives with other international regulators. These range from ad-hoc meetings to deal with global drug safety issues to regularly scheduled exchanges of information on topics related to drug safety, efficacy, and quality. Health Canada's collaboration with trusted international partners allows us to share scientific knowledge, find greater efficiencies in our processes, and reduce unnecessary regulatory burden. We come together to pool our expertise, develop policies, and set standards.

Some examples of our collaborations with other international regulators in 2018 included:

- **International Coalition of Medicines Regulatory Authorities (ICMRA)** – Health Canada is a founding member of ICMRA, which involves 30 regulatory authorities from around the world. This organization focuses on developing strategies to address issues that impact global health, for example, adapting to innovative health technologies that do not fit well within current regulatory frameworks. In 2018, The ICMRA ‘Increasing Adverse Event Reporting Working Group’ completed a survey and published a report on increasing the reporting of suspected adverse drug reactions, and improving the quality of adverse event reports. Eleven ICMRA members took part in this survey and the report was published on the **ICMRA public website**.
- **International Council for Harmonisation (ICH)** – Health Canada is also a member of ICH. Through this organization, scientific experts from around the world work together to develop harmonized guidelines that help regulators ensure that drugs are safe, effective, and of high quality. In 2018, work began on three new guidelines, including M11: Clinical Electronic Structured Harmonized Protocol (CeSHarP). M11 will provide a standardized template for the clinical trial protocol, which describes the processes and procedures directing the conduct and analysis of a clinical trial.
- **Australia-Canada-Singapore-Switzerland (ACSS) Consortium** – Through the ACSS Consortium, we work with trusted partners to review new drugs together, to get them to market quickly and efficiently. In 2018, Health Canada, together with Australia, approved the first drug (Erleada) to be evaluated through this work-sharing trial, or ‘joint review’. For more information about Erleada, go to **“Drugs for Human Use: Approved in 2018”**.

ALIGNING WITH PARTNERS IN THE CANADIAN HEALTHCARE SYSTEM

Getting drugs to patients is a complex process. After Health Canada decides to approve a product for sale in Canada, the following organizations may be involved before the drug is available to patients:

- Health technology assessment organizations (Canadian Agency for Drugs and Technologies in Health [CADTH], and Institut national d’excellence en santé et services sociaux [INESSS]), which look at whether the benefits of a drug outweigh its cost. They make recommendations to public healthcare plans about whether a drug should be funded, that is, whether it should be covered by public healthcare plans.
- The pan-Canadian Pharmaceutical Alliance acts on behalf of the federal, provincial and territorial governments to negotiate with drug companies about the prices governments will pay for certain drugs.
- The federal, provincial and territorial governments make decisions about whether their government will pay for drugs through their public healthcare plans.

As part of its Regulatory Review of Drugs and Devices initiative, in 2018 Health Canada continued to align its review processes with those of the health technology assessment organizations. This alignment helps drugs reach patients more quickly. We approved 8 new drugs with this ‘aligned review’ process in 2018. For more information, go to **“Drugs for Human Use: Approved in 2018”**.

USING REAL WORLD EVIDENCE

During drug development, sponsors (researchers and manufacturers) conduct clinical trials to demonstrate that a drug is safe and effective. In some cases, it can be harder to gather evidence through clinical trials. For example, there may be very few patients who can participate in a clinical trial for a rare disease.

In these cases, information about how drugs are being used in real-world settings (that is, outside of a clinical trial) can help us understand how to use the drugs safely and effectively. This in turn can lead to more treatment options.

Health Canada already considers the evidence gathered from real-world settings to inform our decisions throughout the life cycle of a drug. This evidence is used in the review of drug submissions, and to monitor the safety and effectiveness of drugs once they are available for sale in Canada.

We are expanding how we use evidence from real-world settings. This will help increase treatment options and will make our regulatory system even more responsive to the needs of Canadians. In 2018, we held discussions with our partners in the healthcare system about how to enhance the use of real-world evidence across the drug life cycle. These discussions will form the basis for joint approaches to better leverage evidence gathered from real-world settings. They will also inform the guidance we provide to drug companies on the quality of real-world evidence that they need to submit to Health Canada.

COMMUNICATING THE RISKS OF OPIOID USE

Health Canada is committed to addressing the national opioid crisis and took a number of measures in 2018. The growing number of overdoses and deaths caused by opioids, including fentanyl, is a public health emergency. This is a complex health and social issue that needs a response that is comprehensive, collaborative, compassionate and evidence-based.

New regulations to give you better information

Opioids are now required to be dispensed with a warning sticker and patient information handout. Together, these provide clear information to patients about the safe use and risks of these products.



We also require drug companies to develop and implement risk management plans for monitoring, preventing and mitigating risks associated with the use of their opioid products in Canada.

For more information go to [Opioid Warning Sticker and Patient Information in Handouts and Risk Management Plans](#).

Improving access to new treatments

In 2018, we approved two additional drugs for use in Canada to treat opioid use disorder, Probuphine and Sublocade. For more information on these products, go to [“Drugs for Human Use: Approved in 2018”](#).

We also provide access to drugs to address urgent public health needs. These are drugs that have been approved by the United States, European Union, or Switzerland but are not approved for sale in Canada, as posted on our [List of Drugs for an Urgent Public Health Need](#). Through this system, we provided access to Diaphin and Suboxone film to help federal, provincial and territorial public health officials address the opioid crisis.

Restricting and enforcing marketing and advertising for opioids

In June 2018, the Minister of Health called for pharmaceutical companies to volunteer to stop opioid marketing and advertising. [Industry’s responses are available to the public](#).

At the same time, Health Canada published a [Notice of Intent](#) to further restrict the marketing and advertising of opioids. [Feedback from this consultation](#) is informing how to proceed with further restrictions on opioid advertising and marketing.

In 2018, we launched a dedicated marketing compliance and enforcement team to monitor opioid marketing, and enforce existing rules about improper marketing.

REGULATING NON-PRESCRIPTION DRUGS

Every year Health Canada reviews hundreds of non-prescription drugs, also known as over-the-counter products, which can be bought without a doctor’s prescription. These products can make an important contribution to keeping Canadians healthy. They include:

- antiseptics
- pain relievers
- sunscreens
- cough and cold medicines

Health Canada regulates non-prescription drugs to make sure they are safe, effective, and of high quality. The Drug Identification Number (DIN) on the product label shows that the drug has met our requirements. As with all drugs, Health Canada monitors non-prescription drugs that are on the market, and will take corrective action if a problem is identified.

Information to help you make an informed choice

We have introduced new requirements for labels so that information about your drugs is easier to read, understand, and easier to locate on the package. In 2018, Health Canada approved 400 revised labels on non-prescription drugs.

For more information about the new labelling requirements, go to [Non-prescription drug labels](#).

ADDRESSING ANTIMICROBIAL RESISTANCE

Why is antimicrobial resistance a serious concern?

Bacteria, viruses, fungi and parasites can resist antimicrobials, such as antibiotics and antivirals, that are used to treat people who are sick. This is known as antimicrobial resistance (AMR). Since antimicrobials have been misused and over-used, AMR has spread in Canada and around the world.

AMR is a serious public health threat. When standard antimicrobials used to treat infections do not work as well as they should, we are less effective at treating common infectious diseases. The risks of persistent infections include prolonged illness, disability, and even death.

Health Canada continues to take important steps to safeguard the use of antimicrobial drugs for human use, and encourage the development of new and innovative therapeutic products. Health Canada contributes to the **Federal Action Plan on Antimicrobial Resistance and Use in Canada** and the **Pan-Canadian Framework for Action on Tackling Antimicrobial Resistance and Antimicrobial Use**. We work closely with leading experts and international partners.

Manufacturers of all antibiotics must now include information about the appropriate use of a drug on the label. This helps to increase awareness and encourages prudent use.

As well, we are looking at how we can make the review process for new drugs and diagnostic devices faster. **We will inform companies about products that we need urgently in Canada to address AMR**. We will also work with companies and the research community to set up clinical trials that will improve access to new therapies that target bacteria that are resistant to other available treatments.

To learn about antimicrobial resistance related to animals and veterinary drugs, go to **“Drugs for Veterinary Use: 2018 Accomplishments”**.





DRUGS FOR HUMAN USE: DRUG LIFE CYCLE

As part of Health Canada's mission to help Canadians maintain and improve their health, we evaluate drugs before and after they reach the Canadian market. Health Canada is involved throughout the life cycle of a drug for human use, including during clinical trials and testing of the drug, through the assessment for authorization, and once the drug has been marketed and made available to Canadians. For example, we:

- evaluate applications for clinical trials
- evaluate applications for special access
- review submissions to sell the drug in Canada
- monitor the safety and effectiveness of drugs in the real world, after they are available for sale in Canada

CLINICAL TRIALS

Clinical trials are conducted by sponsors (manufacturers or researchers) to gather information on a drug's safety and effectiveness in humans. Clinical trials for drugs represent potential new healthcare therapies which may eventually address the needs of Canadians. Companies may file the results of these trials to Health Canada as part of a drug submission. We then review these results to decide whether to approve a drug for sale in Canada.

Sponsors of clinical trials submit their applications to conduct a clinical trial with a drug in Canada. We review these applications and decide whether to allow the trial to be conducted in Canada. The [Clinical Trials Applications guidance document](#) provides detailed information about the timelines and processes for the review of clinical trial applications.

In 2018, Health Canada authorized 1209 new clinical trial applications for drugs.

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

DRUG SUBMISSION AND REVIEW

When a company decides that it would like to market a drug in Canada, it files an application to us for a new drug submission. A new drug submission contains scientific information about the years of testing of the drug in laboratories and animals, and clinical trials in humans.

Our scientists and medical professionals perform a thorough review of the information submitted, sometimes using external consultants and advisory committees. Reviewers evaluate the safety, effectiveness, and quality data to assess the benefits and potential risks of the drugs. They also review the information to be provided to healthcare practitioners and consumers about the drug.

We publish **lists of the new drug submissions** that are currently under review at Health Canada. The lists are updated monthly and include the outcome of submissions that have reached a conclusion. In 2018, we also began publishing a **list of generic drug submissions** that are currently under review. The lists will help Canadians know what has been accepted for review in Canada, and therefore what treatment options may be available in the future.

Different types of drug submissions have different target times for Health Canada to complete its review. It is important that we complete our reviews during our target times, so that everyone (patients, healthcare professionals, and drug companies) can predict when a decision will be made. The **Management of Drug Submissions guidance document** provides detailed information about the timelines and processes for the review of drug submissions.

EXPEDITED REVIEW PATHWAYS

We have several review processes that can provide an expedited path to a final decision for certain drugs, including those that target specific healthcare needs. That is, there are several review pathways that have shorter review targets for human drugs. Products approved through expedited review pathways can be available to patients sooner.

In 2018, 35% of the new drug submissions for new active substances were approved via an expedited pathway. Two examples of expedited pathways are Priority review and Notice of Compliance with conditions.

Priority review

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

The **Priority Review of Drug Submissions guidance document** provides detailed information about the timelines and processes for the review of drug submissions under this expedited process.

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 that showed 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 and is of high quality.

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

The **Notice of Compliance with Conditions guidance document** provides detailed information about the timelines and processes for the review of drug submissions under this expedited process.

APPROVAL OF DRUGS

After its review of a drug submission, Health Canada may conclude that the benefits of the product outweigh the potential risks and approve the drug for sale in Canada. When a new drug is approved, it is issued a Notice of Compliance (NOC) and a Drug Identification Number (DIN).

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

In 2018, Health Canada approved 78 new drugs, including 40 new active substances. We approved 135 new generic drugs, and 4 biosimilars.

For a list of what was approved in 2018, go to “**Drugs for Human Use: Approved in 2018**”. You can also reference the Update on New Drug and Medical Device Authorizations, published quarterly.

To request Quarterly and Annual Drug Submission Performance Reports, go to **Reports and Publications – Drug Products**.

SPECIAL ACCESS PROGRAMME

Drugs that are not approved in Canada may be available through our Special Access Programme. The **Special Access Programme for drugs** provides access to drugs that cannot otherwise be sold or distributed in Canada, if certain criteria are met.

In this program, access is provided to an individual healthcare practitioner who is treating a specific 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. Our Special Access Programme operates 24 hours a day, 365 days a year.

In 2018, Health Canada authorized 13,125 requests for special access to drugs.

POST-MARKET SURVEILLANCE

It is not possible to know or predict all of the possible adverse reactions to a drug through clinical studies. After a product is available for sale in Canada, we continue to monitor its use in the real world, that is, in a broader population that may be taking other medications. We call this ‘post-market surveillance’. We evaluate potential safety and effectiveness issues, and take action when there are identified problems.

Health Canada often reviews documents called Risk Management Plans (RMPs) submitted by drug manufacturers as part of their drug submissions. An RMP includes information on a drug’s safety

profile and how its risks will be prevented or minimized. It also contains plans for studies and other activities to learn more about the safety and efficacy of the drug. The RMPS are used to enhance the quality of the evaluation of safety risks.

In 2018, Health Canada reviewed 166 Risk Management Plans related to drugs for human use.

COLLECTING INFORMATION

Health Canada collects post-market information (that is, information collected about a product after it is approved) from a variety of sources.

One source of information for Health Canada is suspected adverse reactions that are reported after products are approved for sale. Adverse reactions are undesirable effects potentially caused by drugs.

In 2018, we received 1,091,696 post-market adverse reaction reports related to drugs for human use (177,153 in Canada and 914,543 from around the world).

You can report adverse drug 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**.

You can find information about the annual numbers and trends of adverse drug reaction case reports and medical device incident reports to Health Canada between 2008 and 2017 in the **Annual trends for the adverse reaction case reports of health products and medical device problem incidents to Health Canada (2008-2017)**.

EVALUATING SAFETY SIGNALS

We evaluate the data we collect to detect new safety signals, which we then investigate more closely. A 'safety signal' can be defined as information on a new or known adverse event that may be associated with a drug. These investigations are called signal assessments and they may result in recommendations for actions to be taken by the company, by Health Canada, or both. These actions can include informing the public and healthcare professionals of new safety information, recommending labelling changes, and even removing a drug from the market in the most serious situations.

For example, in 2018 we conducted a signal assessment for Fibrystal, a drug used to treat uterine fibroids, and the risk of liver injury. The signal assessment included an in-depth review of scientific literature, information from foreign regulatory agencies, and an assessment of adverse event reports. Following the review, the Canadian label for Fibrystal was updated regarding the risk management for liver injury, and risk communications were issued to inform the public and healthcare professionals about how to manage the risk.

We publish Summary Safety Reviews (SSRs) to inform Canadians about the outcomes of any safety investigation that might affect the therapeutic products they use. In 2018, Health Canada reviewed

102 **safety and effectiveness issues** related to drugs for human use. These reviews resulted in 22 Health Canada **Summary Safety Reviews** and requests to companies for 308 safety updates.

In 2018, Health Canada issued 65 Risk Communications to healthcare practitioners and Canadians related to drugs for human use. You can find these risk communications in the **Recalls and Safety Alerts Database**. We also publish monthly editions of the **Health Product InfoWatch**. This publication provides information about emerging health product safety risks to healthcare professionals, for use with their patients.

RISK MANAGEMENT PLANS

In addition to the Risk Management Plans (RMPs) associated with a drug submission, Health Canada also reviews RMPs that are submitted by companies after a drug is available for sale in Canada.

For example, as part of Health Canada's Opioid Action Plan, drug companies were required to develop and implement RMPs for opioid products in order to monitor, prevent and mitigate the risk associated with the use of opioids. We have received these plans and are in the process of reviewing them and providing feedback to the drug companies. Approximately 120 RMPs were received from various companies with opioid products on the market.

ADVERTISING COMPLAINTS

As part of its post-market work, Health Canada also regulates the advertising of drugs sold in Canada to ensure that companies are not making false claims about their products. We review advertising complaints to determine if a company is complying with our requirements.

In 2018, Health Canada reviewed 131 **advertising complaints** related to drugs for human use. For example, in 2018, Health Canada became aware of a guide for Trelegy Ellipta that contained numerous statements and claims that were misleading and could pose health risks to Canadian patients. Although there was no evidence that these claims were promoted to healthcare professionals, as a precaution Health Canada immediately requested that the drug company stop using misleading health claims in the document. Health Canada also published an article in the Health Product InfoWatch to remind healthcare professionals of the approved indication for the product.

After reviewing a complaint, we take appropriate action when non-compliance is identified. This may include requesting a company to stop disseminating non-compliant advertising and taking steps towards avoiding any future issues.

In addition to reviewing complaints, Health Canada recently put in place a dedicated team to identify advertising issues even before a complaint is made. This team will enforce the existing advertising rules and will take action where necessary, including recommending criminal charges where appropriate. Health Canada will post all non-compliant advertising on its website.

This initiative enhances the Department's ability to detect trends and issues which may become, or contribute to, serious public health crises.



DRUGS FOR HUMAN USE APPROVED IN 2018

This section outlines the new drugs, generic drugs, and biosimilars approved for sale in Canada in 2018, and the safety updates issued.

You can report adverse drug 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**.

HEALTH CATEGORIES

The drugs listed have been divided into categories according to the **Anatomical Therapeutic Chemical Classification (ATC) System**, a system of codes developed by the World Health Organization. ATC codes are often assigned according to the mechanism of action (that is, how the drug works) rather than the disease or condition to be treated.

We have included the indication of each new drug to give you some additional information. In addition, each new drug has a hyperlink to the Decision Summary (when available). These documents provide a brief overview of the rationale for our decision to approve the drug.

The categories are:

- | **Alimentary tract and metabolism** – for example, drugs for the gastrointestinal tract, anti-obesity drugs, drugs for diabetes, and vitamins
- | **Antiinfectives for systemic use** – for example, antibacterials, antifungals, antivirals, and vaccines
- | **Antineoplastic and immunomodulating agents** – for example, drugs for the treatment of cancer and drugs that stimulate or suppress the immune system
- | **Antiparasitic products, insecticides and repellents** – for example, drugs to treat infestations of parasites
- | **Blood and blood forming organs** – for example, drugs such as blood thinners and antihemorrhagics
- | **Cardiovascular system** – for example, drugs for high blood pressure and cholesterol reducers

- | **Dermatologicals** – for example, drugs for the skin such as drugs to treat psoriasis
- | **Genito-urinary system and sex hormones** – for example, hormonal contraception, fertility agents, and sex hormones
- | **Musculo-skeletal system** – for example, drugs affecting the muscles, bones, and joints including anti-inflammatories and muscle relaxants
- | **Nervous system** – for example, drugs that affect the brain and the nervous system, including anesthetics for surgery, drugs to treat addiction, antidepressants, and anti-seizure drugs
- | **Respiratory system** – for example, drugs that affect the respiratory system, including bronchodilators and cough medicines
- | **Sensory organs** – for example, drugs for the eyes and ears
- | **Systemic hormonal preparations, excluding sex hormones and insulins** – for example, drugs that affect the endocrine system, including corticosteroids and thyroid hormones
- | **Various** – for example, drugs unable to be classified into the other categories, such as diagnostic agents and drugs to treat high levels of potassium or phosphate in the blood

IMPORTANT DEFINITIONS

Aligned review

An aligned review is one where the drug company allowed information to be shared between Health Canada and health technology assessment organizations. For more information, go to “**Drugs for Human Use: 2018 Accomplishments**”.

Biologic drugs

Biologic drugs are biologically-derived products such as vaccines, blood-derived products, and products produced through biotechnology.

Biosimilars

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.

Extraordinary use new drug

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).

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.



Joint review

A joint review is one where Health Canada worked with other trusted partners to share the work of drug reviews. For more information, go to [“Drugs for Human Use: 2018 Accomplishments”](#).

New drugs

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



New active substance

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.



Notice of Compliance with conditions

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.



Orphan drugs

Orphan drugs are used to treat rare diseases, and have received orphan designation in either the United States or the European Union.



Over-the-counter (non-prescription) drug

Non-prescription drugs, also called over-the-counter (OTC) drugs, are products that can be bought without a doctor's prescription.



Priority review

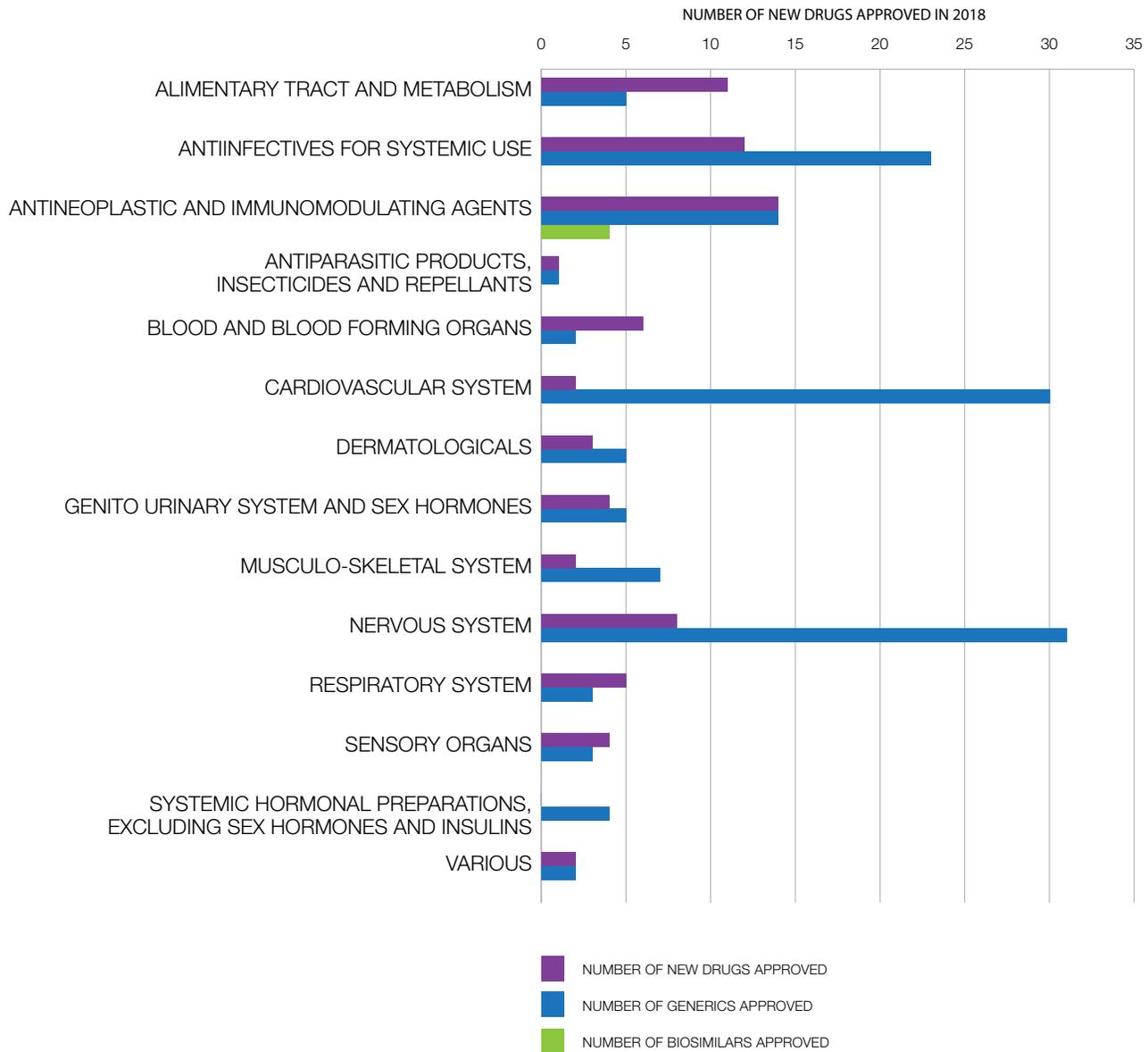
Priority review status may be granted to a drug submission for a product for a serious, life-threatening or severely debilitating disease or condition. Submissions that are granted priority review status are subject to shorter review targets.

Safety updates

Safety updates are designed to communicate information about potential health risks, so that patients and healthcare professionals can make informed decisions about their health.

For more information about the types of risk communications that can be found on the Government of Canada's website, go to [“Healthy Clicks – Drugs for Human Use At a Glance”](#).

NEW DRUGS, NEW GENERIC DRUGS, AND NEW BIOSIMILARS APPROVED IN 2018





ALIGNED REVIEW



BIOLOGIC DRUGS



EXTRAORDINARY USE NEW DRUG



JOINT REVIEW



NEW ACTIVE SUBSTANCE



NOTICE OF COMPLIANCE WITH CONDITIONS



ORPHAN DRUGS



OVER THE COUNTER



PRIORITY REVIEW

ALIMENTARY TRACT AND METABOLISM

For example, drugs for the gastrointestinal tract, anti-obesity drugs, drugs for diabetes, and vitamins.

11 NEW DRUGS

BRINEURA



▶ [Decision Summary](#)

Medicinal Ingredient

Cerliponase alfa

Indication

Brineura contains the active substance cerliponase alfa, which belongs to a group of medicines known as enzyme replacement therapies. It is used to treat patients with neuronal ceroid lipofuscinosis type 2 (CLN2) disease, also known as tripeptidyl peptidase-1 (TPP1) deficiency.

CONTRAVE

▶ [Decision Summary](#)

Medicinal Ingredient

Bupropion hydrochloride, naltrexone hydrochloride

Indication

Contrave should be taken with a reduced-calorie diet and increased physical activity. It is for weight management in:

- obese patients
- overweight patients who have at least one weight-related condition, such as:
 - high blood pressure that is controlled by medicine
 - type 2 diabetes
 - a high amount of lipids (cholesterol or other types of fat) in the blood

MEZERA

▶ [Decision Summary](#)

Medicinal Ingredient

Mesalazine

Indication

Treatment of active mild to moderate ulcerative proctitis.

OZEMPIC



▶ [Decision Summary](#)

Medicinal Ingredient

Semaglutide

Indication

Ozempic contains the active substance semaglutide. It is used to lower blood sugar (glucose) in adults with type 2 diabetes. Ozempic is used on its own if your blood sugar level is not properly controlled by diet and exercise alone and you cannot use metformin. Ozempic is used in combination with one or more other medicines for diabetes when they are not enough to control your blood sugar levels. These other medicines may include: oral antidiabetics (such as metformin, sulfonylurea medicines) or insulin.

RAYALDEE



▶ [Decision Summary](#)

Medicinal Ingredient

Calcifediol

Indication

Rayaldee is used to treat Secondary Hyperparathyroidism (SHPT) in adults with Stage 3 or 4 chronic kidney disease, who do not have enough Vitamin D.

SEGLUROMET

▶ [Decision Summary](#)

Medicinal Ingredient

Ertugliflozin pidolate, metformin hydrochloride

Indication

Segluromet is used with diet and exercise. It is used to improve blood sugar levels in adults with type 2 diabetes.

SOLIQUA

▶ [Decision Summary](#)

Medicinal Ingredient

Insulin glargine, lixisenatide

Indication

Soliqua is used along with diet and exercise to improve blood sugar levels in adults with type 2 diabetes. It is usually prescribed when insulin with or without metformin is not enough to control your blood sugar levels.

STEGLATRO



▶ [Decision Summary](#)

Medicinal Ingredient

Ertugliflozin

Indication

Steglatro is used along with diet and exercise to improve blood sugar levels in adults with type 2 diabetes in cases where prescribing metformin is not an option (due to contraindications or intolerance).

STEGLUJAN

▶ [Decision Summary](#)

Medicinal Ingredient

Ertugliflozin pidolate, sitagliptin phosphate monohydrate

Indication

Steglujan is used with metformin, diet and exercise. It is used to improve blood sugar levels in adults with type 2 diabetes.

XERMELO



▶ [Decision Summary](#)

Medicinal Ingredient

Tellotristat etiprate

Indication

This medicine is used in adults to treat diarrhea caused by a condition called 'carcinoid syndrome'.

Xermelo is used if your diarrhea is not well controlled with injections of other medicines called 'somatostatin analogues' (lanreotide or octreotide). You should keep having injections of these other medicines when taking Xermelo.

XULTOPHY



▶ [Decision Summary](#)

Medicinal Ingredient

Insulin degludec, liraglutide

Indication

Xultophy is used in combination with metformin, with or without sulfonylurea, to improve blood glucose (sugar) levels in adult patients with type 2 diabetes mellitus.

5 NEW GENERIC DRUGS

Health Canada approved 5 new generic drugs in this category:

- ▶ 1 product containing esomeprazole magnesium trihydrate
- ▶ 1 product containing glycopyrrolate
- ▶ 1 product containing granisetron hydrochloride
- ▶ 1 product containing odansetron hydrochloride dihydrate
- ▶ 1 product containing ursodiol

SAFETY UPDATES

Dipeptidylpeptidase-4 (DPP-4) Inhibitors: **Summary Safety Review: Assessing the potential risk of a skin reaction (bullous pemphigoid)**

Ocaliva (obeticholic acid): **Health Product InfoWatch: Liver issues (including liver failure) related to dose prescribing errors**

SGLT2 inhibitors (canagliflozin, dapagliflozin, empagliflozin): **Summary Safety Review: Assessing the potential risk of a rare brain condition (posterior reversible encephalopathy syndrome) in patients who have developed high levels of acids in the blood (diabetic ketoacidosis) and Summary Safety Review: Assessing the potential risk of inflammation of the pancreas (acute and chronic pancreatitis)**

ANTIINFECTIVES FOR SYSTEMIC USE

For example, antibacterials, antifungals, antivirals, and vaccines.

12 NEW DRUGS

AFLURIA TETRA



▶ [Decision Summary](#)

Medicinal Ingredient

Haemagglutinin-strain A(H1N1), haemagglutinin-strain A(H3N2), haemagglutinin-strain B(Victoria), haemagglutinin-strain B(Yamagata)

Indication

Afluria Tetra is indicated for active immunization of persons aged 5 years and older against influenza disease caused by the influenza virus types A and B contained in the vaccine.



ALIGNED REVIEW



BIOLOGIC DRUGS



EXTRAORDINARY USE NEW DRUG



JOINT REVIEW



NEW ACTIVE SUBSTANCE



NOTICE OF COMPLIANCE WITH CONDITIONS



ORPHAN DRUGS



OVER THE COUNTER



PRIORITY REVIEW

BIKTARVY



▶ [Decision Summary](#)

Medicinal Ingredient

Bictegravir sodium, emtricitabine, tenofovir alafenamide hemifumarate

Indication

Biktarvy is a single tablet for the treatment of human immunodeficiency virus 1 (HIV-1) infection in adults. Biktarvy is for people who do not have an HIV virus that is resistant to the components in Biktarvy.

BIOTHRAX



▶ [Decision Summary](#)

Medicinal Ingredient

Anthrax antigen filtrate

Indication

BioThrax Anthrax Vaccine Adsorbed is a vaccine used to prevent infection due to Bacillus anthracis.

CRESEMBA



▶ [Decision Summary](#)

Medicinal Ingredient

Isavuconazonium sulfate

Indication

Cresemba is used in adults to treat:

- aspergillosis
- mucormycosis (also called zygomycosis)

These are fungal infections that can be found in your blood or body tissue.

CUTAQUIG



▶ [Decision Summary](#)

Medicinal Ingredient

Immunoglobulin G (human)

Indication

Cutaquig is used to treat primary immunodeficiency (PID) and secondary immunodeficiency (SID) in people who need immune globulin replacement therapy.

DELSTRIGO

▶ [Decision Summary](#)

Medicinal Ingredient

Doravirine, lamivudine, tenofovir disoproxil fumarate

Indication

Delstrigo is used to treat Human Immunodeficiency Virus-1 (HIV-1) infection in adults. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome). Delstrigo is for people who do not have HIV virus that is resistant to doravirine, lamivudine or tenofovir.

JULUCA

▶ [Decision Summary](#)

Medicinal Ingredient

Dolutegravir sodium, rilpivirine hydrochloride

Indication

Juluca is used to treat HIV (human immunodeficiency virus) infection in adults.

KAMRAB



▶ [Decision Summary](#)

Medicinal Ingredient

Rabies immune globulin human

Indication

Kamrab is used to treat rabies infection. It is a single dose treatment used along with a full course of rabies vaccine.

MAR-CIDOFOVIR

▶ [Decision Summary](#)

Medicinal Ingredient

Cidofovir

Indication

Mar-Cidofovir is used to treat an eye infection called CMV (cytomegalovirus) retinitis in patients with AIDS (Acquired Immunodeficiency Syndrome).

PIFELTRO



▶ [Decision Summary](#)

Medicinal Ingredient

Doravirine

Indication

Pifeltro is used to treat Human Immunodeficiency Virus-1 (HIV-1) infection in adults. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome). Pifeltro is used along with other medicines to treat HIV infection. Pifeltro is for people who do not have HIV virus that is resistant to doravirine.

SYMTUZA

▶ [Decision Summary](#)

Medicinal Ingredient

Cobistat, darunavir ethanolate, emtricitabine, tenofovir alafenamide hemifumarate

Indication

Symtuza is a single tablet regimen containing antiretroviral medicine used to treat human immunodeficiency virus (HIV) infection. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

XYDALBA



▶ [Decision Summary](#)

Medicinal Ingredient

Dalbavancin

Indication

Xydalba is used to treat adults with infections of the skin or in the layers of flesh below the skin.

23 NEW GENERIC DRUGS

Health Canada approved 23 new generic drugs in this category:

- ▶ 1 product containing abacavir sulfate
- ▶ 1 product containing amikacin sulfate
- ▶ 1 product containing amoxicillin and clavulanic acid
- ▶ 1 product containing amoxicillin trihydrate
- ▶ 1 product containing amoxicillin trihydrate and clavulanate potassium
- ▶ 1 product containing atazanavir sulfate
- ▶ 2 products containing azithromycin dihydrate
- ▶ 1 product containing clarithromycin
- ▶ 1 product containing efavirenz, emtricitabine and tenofovir disoproxil fumarate
- ▶ 1 product containing fosfomycin tromethamine
- ▶ 1 product containing ganciclovir
- ▶ 1 product containing ganciclovir sodium
- ▶ 1 product containing itraconazole
- ▶ 1 product containing lamivudine
- ▶ 1 product containing linezolid
- ▶ 1 product containing oseltamivir phosphate
- ▶ 2 products containing tenofovir disoproxil fumarate
- ▶ 1 product containing vancomycin hydrochloride
- ▶ 3 products containing voriconazole

SAFETY UPDATES

Azithromycin: **Information Update: Potential risk of cancer relapse**

Beta-lactam antibiotics: **Summary Safety Review: Assessing the potential risk of severe skin side effects (severe cutaneous adverse reactions – SCAR)**

Isoniazid: **Summary Safety Review: Assessing the potential risk of inflammation of the pancreas (pancreatitis)**

Prezcobix (darunavir and cobicistat) and Symtuza (darunavir, cobicistat, emtricitabine, and tenofovir alafenamide): **Health Product InfoWatch: Risk of lower exposures of darunavir and cobicistat during pregnancy**

Rifadin (rifampin): **Health Product InfoWatch: Risk of vitamin K-dependent blood clotting disorder**

Tivicay, Triumeq and Juluca (dolutegravir): **Dear Healthcare Professional Letter: Risk of birth defects of the brain, spine, and spinal cord**

Vaccines from GlaxoSmithKline Inc.: **Dear Healthcare Professional Letter: Potential risk of underdosing**



ALIGNED REVIEW



BIOLOGIC DRUGS



EXTRAORDINARY USE NEW DRUG



JOINT REVIEW



NEW ACTIVE SUBSTANCE



NOTICE OF COMPLIANCE WITH CONDITIONS



ORPHAN DRUGS



OVER THE COUNTER



PRIORITY REVIEW

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

For example, drugs for the treatment of cancer and drugs that stimulate or suppress the immune system.

14 NEW DRUGS

ALUNBRIG



▶ [Decision Summary](#)

Medicinal Ingredient

Brigatinib

Indication

Alunbrig is used to treat a type of lung cancer called non-small cell lung cancer (NSCLC). It is used when this cancer has spread to other parts of the body (metastatic). It is only used in patients whose cancer has gotten worse after taking crizotinib or in patients who are unable to take crizotinib.

BAVENCIO



▶ [Decision Summary](#)

Medicinal 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. Bavencio is also used to treat bladder cancer that cannot be removed by surgery or has spread and has already been treated with a certain type of chemotherapy, which did not work or is no longer working.

BESPONSA



▶ [Decision Summary](#)

Medicinal Ingredient

Inotuzumab ozogamicin

Indication

Besponsa is used to treat a certain type of leukemia called acute lymphoblastic leukemia (ALL). ALL is a cancer of the blood where you have too many white blood cells. Besponsa is intended for the treatment of ALL in adult patients whose ALL has come back after a previous treatment (relapse) or if the ALL has not responded to the first treatment (refractory).

CABOMETYX



▶ [Decision Summary](#)

Medicinal Ingredient

Cabozantinib

Indication

Cabometyx is used to treat adults with a type of advanced kidney cancer called renal cell carcinoma who have had previous treatment with a specific type of cancer medication.

ERLEADA



▶ [Decision Summary](#)

Medicinal Ingredient

Apalutamide

Indication

Erleada is used to treat prostate cancer that:

- has not spread to other parts of the body, and
- no longer responds to a medicine or surgery that lowers testosterone

FOLOTYN



▶ [Decision Summary](#)

Medicinal Ingredient

Pralatrexate

Indication

Folotyn treats a type of cancer called Peripheral T-cell Lymphoma (PTCL). It is used when the cancer does not go away, gets worse, or comes back after use of another cancer treatment.

IMFINZI



▶ [Decision Summary](#)

Medicinal 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. It is used when:

- your cancer has spread and cannot be removed by surgery and

- you have received chemotherapy, and it did not work or is no longer working

Imfinzi is also used to treat adults with a type of lung cancer called non-small cell lung cancer. It is used when:

- your cancer has grown within your lung and cannot be removed by surgery and
- your cancer has responded or stabilized after treatment with chemotherapy and radiation therapy

KISQALI



- ▶ [Decision Summary](#)

Medicinal Ingredient

Ribociclib succinate

Indication

Kisqali is used for the treatment of postmenopausal women with a certain type of breast cancer that is advanced and may not be able to be removed by surgery or has spread to other parts of the body. Kisqali is to be used in combination with another medicine for breast cancer, called letrozole.

KYMRIAH



- ▶ [Decision Summary](#) and [Decision Summary](#)

Medicinal Ingredient

Tisagenlecleucel

Indication

Kymriah is used to treat:

- B-cell Acute lymphoblastic leukaemia (B-cell ALL) – a form of cancer composed of some types of white blood cells that have become malignant. It can be used in children and young adults from 3 to 25 years of age with this cancer.
- Diffuse large B-cell lymphoma (DLBCL) – a form of cancer composed of some types of white blood cells that have become malignant, mostly in the lymph nodes. Kymriah can be used in adults (18 years of age or older) for whom DLBCL has returned after other treatments or when other treatments did not work.

LONSURF



- ▶ [Decision Summary](#)

Medicinal Ingredient

Tipiracil hydrochloride, trifluridine

Indication

Lonsurf is used to treat adults with colon cancer or rectal cancer - sometimes called 'colorectal' cancer. It is used when the cancer has spread to other parts of the body. It is used when other treatments have not worked or when other treatments are not suitable for you.

OCREVUS



- ▶ [Decision Summary](#)

Medicinal Ingredient

Ocrelizumab

Indication

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

OLUMIANT



- ▶ [Decision Summary](#)

Medicinal Ingredient

Baricitinib

Indication

Olumiant, in combination with methotrexate, is indicated for reducing the signs and symptoms of rheumatoid arthritis (RA), in adult patients with moderately to severely active RA who have not responded well to one or more other medicines called disease modifying anti-rheumatic drugs (DMARDs).



ALIGNED REVIEW



BIOLOGIC DRUGS



EXTRAORDINARY USE NEW DRUG



JOINT REVIEW



NEW ACTIVE SUBSTANCE



NOTICE OF COMPLIANCE WITH CONDITIONS



ORPHAN DRUGS



OVER THE COUNTER



PRIORITY REVIEW

SILIQ



▶ [Decision Summary](#)

Medicinal Ingredient

Brodalumab

Indication

Siliq is used to treat a skin condition called 'plaque psoriasis', which causes inflammation and scaly plaque formation on the skin. Siliq reduces the inflammation and other symptoms of the disease. Siliq is used in adults with moderate to severe plaque psoriasis that involves large areas of the body, who may benefit from taking injections, pills, or phototherapy.

UNITUXIN



▶ [Decision Summary](#)

Medicinal Ingredient

Dinutuximab

Indication

Unituxin is used to treat high-risk neuroblastoma in babies, children and adolescents. Neuroblastomas are cancers that start in early nerve cells in the body.

4 NEW BIOSIMILARS

FULPHILA



Medicinal Ingredient

Pegfilgrastim

Indication

Fulphila is used to treat neutropenia. Neutropenia is a condition where the body makes too few white blood cells and which may be caused by drugs used to treat cancer. Neutropenia is the most serious common side-effect of chemotherapy. Neutropenia predisposes your body to infections and prevents you from fighting them. Fulphila increases the number of neutrophils, which fight infections.

HADLIMA, HADLIMA PUSHTOUCH



▶ [Decision Summary](#)

Medicinal Ingredient

Adalimumab

Indication

Hadlima (or Hadlima PushTouch) is a medicine that is used in:

- Adults with rheumatoid arthritis, which is an inflammatory disease of the joints.
- Adults with psoriatic arthritis, which is an inflammatory disease of the joints and skin.
- Adults with ankylosing spondylitis, which is a form of arthritis.
- Adults with Crohn's disease, which is an inflammatory disease of the digestive tract.
- Pediatrics with polyarticular juvenile idiopathic arthritis who are 4 years of age and older and require a full 40 mg dose based on body weight and height.
- Adults with ulcerative colitis, which is an inflammatory disease of the bowel (colon).
- Adults with moderate to severe hidradenitis suppurativa (HS) who have not responded to antibiotics. HS is a painful, progressive, chronic inflammatory skin disease that causes nodules, abscesses, sinus tracts and fistulas under the breasts, underarms, buttocks and groin.
- Adults with psoriasis, which is an inflammatory disease of the skin. The doctor prescribed Hadlima (or Hadlima PushTouch) to reduce the signs and symptoms of your plaque psoriasis.
- Adults with uveitis, which is an inflammatory disease of the eye.

LAPELGA



▶ [Decision Summary](#)

Medicinal Ingredient

Pegfilgrastim

Indication

Lapelga is used to treat neutropenia. Neutropenia is a condition where the body makes too few white blood cells and which may be caused by drugs used to treat cancer. Neutropenia is the most serious common side-effect of chemotherapy. Neutropenia predisposes your body to infections and prevents you from fighting them. Your doctor has decided to prescribe Lapelga for you to increase the number of neutrophils, which will fight infections.

MVASI



▶ [Decision Summary](#)

Medicinal Ingredient

Bevacizumab

Indication

Mvasi is used in combination with a specific type of chemotherapy (intravenous 5-fluorouracil [5-FU]-based chemotherapy) for treatment of patients diagnosed with metastatic colorectal cancer for the first time. Mvasi is also used with another type of chemotherapy (carboplatin and paclitaxel) for treatment of metastatic non-small cell lung cancer.

14 NEW GENERIC DRUGS

Health Canada approved 14 new generic drugs in this category:

- ▶ 1 product containing azacitidine
- ▶ 2 products containing buffer solution and melphalan hydrochloride
- ▶ 3 products containing busulfan
- ▶ 1 product containing erlotinib hydrochloride
- ▶ 2 products containing fluorouracil
- ▶ 1 product containing leflunomide
- ▶ 1 product containing mycophenolate mofetil
- ▶ 2 products containing pemetrexed disodium hemipentahydrate
- ▶ 1 product containing tacrolimus

SAFETY UPDATES

Avonex (interferon beta-1a): **Summary Safety Review: Assessing the potential risk of an inflammatory disease that affects one or more organs (sarcoidosis)**

Blinicyto (blinatumomab): **Dear Healthcare Professional Letter: Risk of benzyl alcohol toxicity for pediatric patients**

Erwinase (L- Asparaginase): **Dear Healthcare Professional Letter: Vials containing particulate matter made available to address ongoing shortage**

Gilenya (fingolimod): **Health Product InfoWatch: Risk of severe adverse events in patients with pre-existing heart conditions**

Gleevec and generics (imatinib mesylate): **Summary Safety Review: Assessing the potential risk of tendon disorders**

Halaven (eribulin mesylate): **Summary Safety Review: Assessing the potential risk of severe skin side effects (severe cutaneous adverse reactions – SCAR)**

Imbruvica (ibrutinib): **Summary Safety Review: Assessing the potential risk of a serious and life-threatening abnormal heart rhythm (ventricular tachyarrhythmia)**

Imuran (azathioprine): **Health Product InfoWatch: Risk of excessive activation of white blood cells mainly in people with arthritis**

Jakavi (ruxolitinib): **Summary Safety Review: Assessing the potential risk of drug interactions with P-glycoprotein (P-gp) substrates (including rosuvastatin)**

Lenvima (lenvatinib): **Health Product InfoWatch: Risk of a collapsed lung**

Ofev (nintedanib): **Dear Healthcare Professional Letter: Risk of drug-induced liver injury** and **Health Product InfoWatch: Risk of developing ruptures in the digestive system**

Remicade (infliximab): **Summary Safety Review: Assessing the potential risk of a blistering skin condition known as linear IgA bullous dermatosis**

Revlimid (lenalidomide): **Health Product InfoWatch: Risk of solid organ transplant rejection**

Ruxolitinib: **Summary Safety Review: Assessing the potential risk of liver injury**

Tecentriq (atezolizumab): **Dear Healthcare Professional Letter: Risk of inflammation of the kidney caused by immune system disorders** and **Dear Healthcare Professional Letter: Risk of inflammation of the heart muscle**

Vascular endothelial growth factor receptor tyrosine kinase inhibitors (VEGFR TKIs): **Summary Safety Review: Assessing the potential risk of abnormal structural changes of the artery walls, including rupture (artery dissections and artery aneurysms)**

Zinbryta (daclizumab): **Dear Healthcare Professional Letter: Voluntary withdrawal in Canada due to risk of inflammation of the brain**

Zydelig (idelalisib): **Health Product InfoWatch: Risk of a serious brain infection**



ALIGNED
REVIEW



BIOLOGIC
DRUGS



EXTRAORDINARY
USE NEW DRUG



JOINT
REVIEW



NEW ACTIVE
SUBSTANCE



NOTICE OF COMPLIANCE
WITH CONDITIONS



ORPHAN
DRUGS



OVER THE
COUNTER



PRIORITY
REVIEW

ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLANTS

For example, drugs to treat infestations of parasites.

1 NEW DRUG

STROMEKTOL

► [Decision Summary](#)

Medicinal Ingredient

Ivermectin

Indication

Stromectol is used to treat infections caused by some parasites (worms).

1 NEW GENERIC DRUG

Health Canada approved 1 new generic drug in this category:

- 1 product containing atovaquone

BLOOD AND BLOOD FORMING ORGANS

For example, drugs such as blood thinners and antihemorrhagics.

6 NEW DRUGS

ALPHANATE

► [Decision Summary](#)

Medicinal Ingredient

Antihemophilic factor (human), Von Willebrand factor (human)

Indication

Alphanate is used for prevention and treatment of mild and/or non-life-threatening bleeding episodes or surgical bleeding in adult and pediatric patients with von Willebrand Disease, when certain other medications are either not effective or cannot be used.

HEMLIBRA

► [Decision Summary](#)

Medicinal Ingredient

Emicizumab

Indication

Hemlibra is a medicine that can be used by all age groups. It is used to treat people:

- who have haemophilia A (a bleeding condition people can be born with or develop), which is caused by a missing or faulty protein (factor VIII) that prevents blood from clotting normally, and
- who have also developed 'factor VIII inhibitors' that prevent replacement factor VIII from working properly

JIVI

► [Decision Summary](#)

Medicinal Ingredient

Antihemophilic factor (recombinant, B-domain deleted, pegylated)

Indication

Jivi is for the treatment of hemophilia A in previously treated patients (PTPs) 12 years of age and older. Jivi can be used to:

- prevent bleeding before it happens
 - stop a bleeding episode that has already began

MONOFERRIC

► [Decision Summary](#)

Medicinal Ingredient

Iron isomaltoside 1000

Indication

Monoferric is used to raise your level of iron (sometimes called 'iron deficiency anaemia') when:

- you cannot tolerate oral iron or
- oral iron therapies do not work for you

PANHEMATIN



- ▶ [Decision Summary](#)

Medicinal Ingredient

Hemin

Indication

Panhematin is a hemin for injection prescription medication used to relieve repeated attacks of acute intermittent porphyria (AIP) related to the menstrual cycle in affected women, after initial carbohydrate therapy is known or suspected to be inadequate. Panhematin should not be used for preventing attacks of porphyria.

TAKHZYRO



- ▶ [Decision Summary](#)

Medicinal Ingredient

Lanadelumab

Indication

Takhzyro is a medicine that is used to prevent attacks of hereditary angioedema (HAE) in adults and adolescents (12 years and older). Takhzyro should not be used to treat an acute HAE attack. In the event of an acute attack, seek medical attention.

2 NEW GENERIC DRUGS

Health Canada approved 2 new generic drugs in this category:

- ▶ 1 product containing dabigatran etexilate
- ▶ 1 product containing dabigatran etexilate mesilate

SAFETY UPDATES

Dianeal peritoneal dialysis solution: **Advisory: Potential presence of particulate matter**

Pradaxa (dabigatran etexilate): **Summary Safety Review: Assessing the potential risk of liver injury**

CARDIOVASCULAR SYSTEM

For example, drugs for high blood pressure and anticholesterol agents.

2 NEW DRUGS

APO-PERINDOPRIL ARGININE

- ▶ [Decision Summary](#)

Medicinal Ingredient

Perindopril arginine

Indication

Your doctor can prescribe Apo-Perindopril Arginine to:

- treat mild to moderate high blood pressure
- treat mild to moderate congestive heart failure along with other medications
- reduce cardiovascular risk in patients with high blood pressure and/or those who have suffered a heart attack and have stable coronary artery disease

MYLAN-PERINDOPRIL ARGININE

Medicinal Ingredient

Perindopril arginine

Indication

Mylan-Perindopril Arginine is used in adults to:

- treat mild to moderate high blood pressure
- treat mild to moderate congestive heart failure along with other medications
- reduce cardiovascular risk in patients with high blood pressure and/or those who have suffered a heart attack and have stable coronary artery disease

30 NEW GENERIC DRUGS

Health Canada approved 30 new generic drugs in this category:

- ▶ 1 product containing ambrisentan
- ▶ 1 product containing amlodipine besylate and telmisartan
- ▶ 2 products containing atorvastatin calcium
- ▶ 1 product containing bosentan monohydrate
- ▶ 1 product containing cholestyramine resin



ALIGNED REVIEW



BIOLOGIC DRUGS



EXTRAORDINARY USE NEW DRUG



JOINT REVIEW



NEW ACTIVE SUBSTANCE



NOTICE OF COMPLIANCE WITH CONDITIONS



ORPHAN DRUGS



OVER THE COUNTER



PRIORITY REVIEW

- ▶ 1 product containing diltiazem hydrochloride
- ▶ 1 product containing eplerenone
- ▶ 1 product containing ethacrynate sodium
- ▶ 1 product containing flecainide acetate
- ▶ 1 product containing furosemide
- ▶ 2 products containing hydrochlorothiazide and olmesartan medoxomil
- ▶ 3 products containing indapamide and perindopril erbumine
- ▶ 2 products containing metoprolol tartrate
- ▶ 1 product containing midodrine hydrochloride
- ▶ 5 products containing perindopril erbumine
- ▶ 1 product containing sildenafil citrate
- ▶ 1 product containing sodium nitroprusside
- ▶ 4 products containing trandolapril

SAFETY UPDATES

Avapro (irbesartan) and Avalide (irbesartan and hydrochlorothiazide): **Health Product InfoWatch: Risk of worsening of an autoimmune skin condition characterized by red and scaly patches (psoriasis)**

Cardizem CD (diltiazem hydrochloride): **Health Product InfoWatch: Risk of spasms in lung airways, including asthma aggravation**

EpiPens:

Information Update: Shortage of EpiPen (0.3 mg) auto-injector in Canada

Information Update: Shortage of EpiPen (0.3 mg) and EpiPen Jr (0.15 mg) auto-injectors in Canada

Information Update: Update on shortage situation involving EpiPen (0.3 mg) auto-injectors

Dear Healthcare Professional Letter: Interim Order allowing the importation of AUVI-Q in response to shortages of EpiPen and EpiPen Jr

Advisory: EpiPen and EpiPen Jr auto-injectors may stick in their carrier tube

Tromboject 1% and 3% (sodium tetradecyl sulfate): **Dear Healthcare Professional Letter: Vials may contain visible and insoluble particles** and **Dear Healthcare Professional Letter: Update on the use of medical grade filters**

Several drugs containing valsartan:

Advisory: Recalled due to contamination with a potential carcinogen

Information Update: Expanded recall of valsartan drugs to include additional lot

Information Update: A second impurity linked to recalled valsartan drugs

Information Update: Health Canada updates Canadians on estimates of health risks for recalled valsartan drugs containing NDMA

Information Update: Mylan-Valsartan medications voluntarily recalled as a precaution due to an impurity

Information Update: Health Canada finds Zhejiang Huahai Pharmaceuticals (manufacturer of valsartan active pharmaceutical ingredient) site non-compliant with requirements for the manufacture of drug ingredients

DERMATOLOGICALS

For example, drugs for the skin such as drugs to treat psoriasis.

3 NEW DRUGS

EUCRISA



- ▶ [Decision Summary](#)

Medicinal Ingredient

Crisaborole

Indication

Eucrisa is a non-steroid prescription medicine used on the skin to treat mild to moderate eczema (atopic dermatitis).

FUCIBET

- ▶ [Decision Summary](#)

Medicinal Ingredient

Betamethasone, fusidic acid

Indication

Fucibet is used to treat eczema that is infected with bacteria or appears to be infected.

STRAMUCIN



Medicinal Ingredient

Mupirocin

Indication

Stramucin is used for the topical treatment of minor bacterial skin infections and minor infection in small cuts, wounds or abrasions.

5 NEW GENERIC DRUGS

Health Canada approved 5 new generic drugs in this category:

- ▶ 1 product containing acyclovir
- ▶ 1 product containing alitretinoin
- ▶ 1 product containing clindamycin phosphate
- ▶ 1 product containing clobetasol propionate
- ▶ 1 product containing imiquimod

SAFETY UPDATES

Hydroquinone: **Information Update: Health Canada reminds Canadians to consult a health professional before using high-concentration hydroquinone products**

Option+ and Personelle sunscreens: **Advisory: Recalled because of bacterial contamination**

Propecia (finasteride): **Health Product InfoWatch: Risk of muscle-related disorders**

Sunscreen products in Canada: **Information Update: Important sunscreen safety tips** and **Information Update: Health Canada's testing did not identify any serious concerns with the quality of the tested products** and **Summary Safety Review: Assessing the potential risk of skin reactions**

Tactupump and Tactupump Forte (adapalene and benzoyl peroxide): **Health Product InfoWatch: The risk of birth defects in pregnant women and in women planning a pregnancy**

GENITO-URINARY SYSTEM AND SEX HORMONES

For example, hormonal contraception, fertility agents, and sex hormones.

4 NEW DRUGS

ADDYI



- ▶ [Decision Summary](#)

Medicinal Ingredient

Flibanserin

Indication

Addyi is used to treat a condition called hypoactive sexual desire disorder (HSDD) in women. This means that you have had low sexual desire for a minimum of 6 months that happens 75-100% of the time and this causes you distress or difficulty in your relationships.

ORLISSA



- ▶ [Decision Summary](#)

Medicinal Ingredient

Elagolix

Indication

Orilissa is used to treat the painful symptoms of endometriosis.

PMS-PROGESTERONE

- ▶ [Decision Summary](#)

Medicinal Ingredient

Progesterone

Indication

pms-Progesterone is approved for use in women with an intact uterus (have not had surgery to remove the uterus) who are using estrogen replacement therapy for menopause.



ALIGNED REVIEW



BIOLOGIC DRUGS



EXTRAORDINARY USE NEW DRUG



JOINT REVIEW



NEW ACTIVE SUBSTANCE



NOTICE OF COMPLIANCE WITH CONDITIONS



ORPHAN DRUGS



OVER THE COUNTER



PRIORITY REVIEW

REKOVELLE



▶ [Decision Summary](#)

Medicinal Ingredient

Follitropin delta

Indication

Rekovele is used to treat female infertility and is used in women undergoing assisted reproduction programmes such as in vitro fertilisation (IVF) and intracytoplasmic sperm injection (ICSI).

5 NEW GENERIC DRUGS

Health Canada approved 5 new generic drugs in this category:

- ▶ 1 product containing progesterone
- ▶ 1 product containing sildenafil citrate
- ▶ 3 products containing vardenafil hydrochloride

SAFETY UPDATES

Alysena 28 birth control pill: **Advisory: One lot recalled due to chipped pills, which may reduce effectiveness in preventing pregnancy**

Alysena (levonorgestrel and ethinyl estradiol tablets) 28 and 21: **Advisory: Additional lots with broken/chipped pills discovered**

Birth control pills: **Advisory: Women taking birth control pills reminded to return any packages for replacement if the pills are missing or look unusual**

Demulen 30 birth control pills: **Advisory: Packages containing broken or chipped pills**

Fibristal (ulipristal acetate): **Information Update: Canadian and European reports of serious adverse events affecting the liver and Summary Safety Review: Assessing the potential risk of rare but serious liver injury**

Marvelon 28 birth control pills: **Advisory: Packages do not contain day-of-the-week stickers**

Proscar (finasteride): **Health Product InfoWatch: Risk of muscle-related disorders**

MUSCULO-SKELETAL SYSTEM

For example, drugs affecting the muscles, bones, and joints including anti-inflammatories and muscle relaxants.

2 NEW DRUGS

CRYSVITA



▶ [Decision Summary](#)

Medicinal Ingredient

Burosumab

Indication

Crysvita contains the active substance burosumab. This is a type of medicine called a human monoclonal antibody. Crysvita is used to treat X-linked hypophosphataemia (XLH). It is used in children one year of age and older and adults. XLH is a genetic disease. People with XLH have higher levels of a hormone called fibroblast growth factor 23 (FGF23). FGF23 lowers the amount of phosphate in the blood. The low level of phosphate may lead to bones that cannot grow and harden properly.

NUCEIVA



▶ [Decision Summary](#)

Medicinal Ingredient

PrabotulinumtoxinA

Indication

Nuceiva is indicated for the temporary improvement in the appearance of moderate to severe frown lines (glabellar lines) in adult patients < 65 years of age.

7 NEW GENERIC DRUGS

Health Canada approved 7 new generic drugs in this category:

- ▶ 1 product containing allopurinol
- ▶ 1 product containing calcium carbonate and risedronate sodium
- ▶ 1 product containing celecoxib
- ▶ 1 product containing diclofenac sodium
- ▶ 1 product containing naproxen sodium
- ▶ 2 products containing zoledronic acid

NERVOUS SYSTEM

For example, drugs that affect the brain and the nervous system, including anesthetics for surgery, drugs to treat addiction, antidepressants, and anti-seizure medications.

8 NEW DRUGS

ACETAMINOPHEN INJECTION

Medicinal Ingredient

Acetaminophen

Indication

It relieves pain and fever.

AIMOVIG



▶ [Decision Summary](#)

Medicinal Ingredient

Erenumab

Indication

Aimovig is a medicine used to prevent migraines in adults who have at least 4 migraine days per month.

BELSOMRA



▶ [Decision Summary](#)

Medicinal Ingredient

Suvorexant

Indication

Belsomra (suvorexant) is a sleep medication used for the treatment of insomnia in adults who have trouble:

- falling asleep and / or
- staying asleep (waking up too often or for too long during the night or waking up too early, and then not being able to fall back asleep)

PENTHROX

▶ [Decision Summary](#)

Medicinal Ingredient

Methoxyflurane

Indication

Penthrox is used for short-term relief of moderate to severe pain following trauma or during medical procedures.

PROBUPHINE

▶ [Decision Summary](#)

Medicinal Ingredient

Buprenorphine hydrochloride

Indication

Probuphine is:

- used to treat adults (18 years and older) who are dependent on opioid drugs
- for adults who are currently taking no more than 8 mg of sublingual buprenorphine
- a drug program used along with counseling and psychosocial support

RADICAVA



▶ [Decision Summary](#)

Medicinal Ingredient

Ederavone

Indication

Radicava is a prescription medicine used to treat Amyotrophic Lateral Sclerosis (ALS).

SUBLOCADE



▶ [Decision Summary](#)

Medicinal Ingredient

Buprenorphine

Indication

Sublocade is used to treat patients (18 years of age and older) who have moderate to severe opioid use disorder.



ALIGNED
REVIEW



BIOLOGIC
DRUGS



EXTRAORDINARY
USE NEW DRUG



JOINT
REVIEW



NEW ACTIVE
SUBSTANCE



NOTICE OF COMPLIANCE
WITH CONDITIONS



ORPHAN
DRUGS



OVER THE
COUNTER



PRIORITY
REVIEW

TEGSEDI



▶ [Decision Summary](#)

Medicinal Ingredient

Inotersen sodium

Indication

Tegsedi is used for treatment of stage 1 or stage 2 polyneuropathy in adult patients with hereditary transthyretin amyloidosis (hATTR).

31 NEW GENERIC DRUGS

Health Canada approved 31 new generic drugs in this category:

- ▶ 6 products containing aripiprazole
- ▶ 1 product containing atomoxetine
- ▶ 1 product containing bupropion hydrochloride
- ▶ 1 product containing dextroamphetamine sulfate
- ▶ 1 product containing eletriptan hydrobromide
- ▶ 1 product containing hydromorphone hydrochloride
- ▶ 5 products containing lacosamide
- ▶ 1 product containing levetiracetam
- ▶ 1 product containing modafinil
- ▶ 1 product containing pregabalin
- ▶ 1 product containing rivastigmine
- ▶ 1 product containing rizatriptan benzoate
- ▶ 1 product containing sufentanil citrate
- ▶ 2 products containing tramadol hydrochloride
- ▶ 3 products containing varenicline tartrate
- ▶ 2 products containing ziprasidone hydrochloride
- ▶ 1 product containing ziprasidone hydrochloride monohydrate
- ▶ 1 product containing zolmitriptan

SAFETY UPDATES

Atypical antipsychotics: **Summary Safety Review: Assessing the potential risk of drug reaction with eosinophilia and systemic symptoms (DRESS)**

Biomedic, Option+, Laboratoires Trianon Inc. strawberry-flavoured acetaminophen syrups: **Advisory: Several lots recalled because of defective child-resistant safety caps on the bottles and Advisory: Recall has been expanded to include all lots**

Clozapine: **Summary Safety Review: Assessing the effectiveness of monitoring for low numbers of white blood cells (agranulocytosis)**

Concerta (methylphenidate hydrochloride): **Health Product InfoWatch: Risk of brain blood vessel disorders, e.g., stroke**

Elavil (amitriptyline hydrochloride): **Health Product InfoWatch: Risk of heart rhythm disorders**

Imitrex injection (sumatriptan succinate): **Health Product InfoWatch: Risk of allergic reactions in latex sensitive individuals**

Lamotrigine (lamictal and generic products): **Health Product InfoWatch: International reports of blood disorder involving increased number of white blood cells**

Methadose and Metadol-D (methadone hydrochloride): **Summary Safety Review: Assessing the potential risk of serious harm in children exposed to methadone through breast milk**

Primidone: **Advisory: Recall due to elevated levels of lead**

Sevoflurane: **Summary Safety Review: Re-assessing the potential risk of slow heartbeat (bradycardia) in children with down syndrome**

Strawberry-flavoured acetaminophen infant oral drops: **Advisory: Recalled because of defective child-resistant safety caps**

Vimpat (lacosamide): **Health Product InfoWatch: Risk of abnormal heart rhythm**

Vita Health Products: **Advisory: Recalled because consumers may be unable to access important safety information on labels**

Zoloft (sertraline hydrochloride): **Health Product InfoWatch: Risk of heart rhythm disorders**

RESPIRATORY SYSTEM

For example, drugs that affect the respiratory system, including bronchodilators and cough medicines.

5 NEW DRUGS

ARBESDA RESPICLICK

▶ [Decision Summary](#) ↗

Medicinal Ingredient

Fluticasone propionate, salmeterol xinafoate

Indication

Arbesda Respiclick is used for the treatment of asthma. It is used in people who are 12 years of age and older.

BEVESPI AEROSPHERE

▶ [Decision Summary](#) ↗

Medicinal Ingredient

Formoterol fumarate dehydrate, glycopyrronium bromide

Indication

Bevespi Aerosphere is used in adult patients who have a hard time breathing because of a lung disease called chronic obstructive pulmonary disease (COPD). This includes chronic bronchitis and emphysema.

FASENRA



▶ [Decision Summary](#) ↗

Medicinal Ingredient

Benralizumab

Indication

Fasenra is a prescription medicine used in addition to other asthma medicines for maintenance treatment of adult patients with severe eosinophilic asthma, whose asthma is not controlled with their current asthma medicines. Severe eosinophilic asthma is a type of asthma where patients have increased eosinophils in the blood or lungs. Eosinophils are a type of white blood cell that are associated with inflammation of the airways that can cause your asthma to get worse or can increase the number of asthma attacks.

SYMDEKO



▶ [Decision Summary](#) ↗

Medicinal Ingredient

Ivacaftor, tezacaftor

Indication

Symdeko is used for the treatment of cystic fibrosis (CF) in patients 12 years of age and older who:

- are homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or
- are heterozygous for the F508del mutation and have one of the following mutations in the CFTR gene: P67L, D110H, R117C, L206W, R352Q, A455E, D579G, 711+3A→G, S945L, S977F, R1070W, D1152H, 2789+5G→A, 3272-26A→G, and 3849+10kbC→T

TRELEGY ELLIPTA

▶ [Decision Summary](#) ↗

Medicinal Ingredient

Fluticasone furoate, umeclidinium bromide, vilanterol trifenate

Indication

Trelegy Ellipta is used in adults for the long-term treatment of a lung disease called Chronic Obstructive Pulmonary Disease or COPD. This includes chronic bronchitis and emphysema. Trelegy Ellipta is used in patients whose COPD is not adequately treated by another combination medication (ICS/LABA).

3 NEW GENERIC DRUGS

Health Canada approved 3 new generic drugs in this category:

- 1 product containing cetirizine hydrochloride
- 1 product containing ipratropium bromide, salbutamol
- 1 product containing mometasone furoate

SAFETY UPDATES

Ventolin Diskus: **Advisory: One lot recalled as inhalers may not deliver the intended dose**



ALIGNED REVIEW



BIOLOGIC DRUGS



EXTRAORDINARY USE NEW DRUG



JOINT REVIEW



NEW ACTIVE SUBSTANCE



NOTICE OF COMPLIANCE WITH CONDITIONS



ORPHAN DRUGS



OVER THE COUNTER



PRIORITY REVIEW

SENSORY ORGANS

For example, drugs for the eyes and ears.

4 NEW DRUGS

ILUVIEN

- ▶ [Decision Summary](#)

Medicinal Ingredient

Fluocinolone acetonide

Indication

Iluvien is used to treat vision loss due to diabetic macular oedema. Iluvien is suitable for diabetic macular oedema patients who were treated with prior corticosteroids.

RESTASIS MULTIDOSE

- ▶ [Decision Summary](#)

Medicinal Ingredient

Cyclosporin

Indication

Restasis MultiDose is used to treat certain patients who have a condition called aqueous deficient dry eye disease.

VERKAZIA



- ▶ [Decision Summary](#)

Medicinal Ingredient

Cyclosporin

Indication

Verkazia is used in children [4 years through adolescents (12 to 18 years of age)] to treat a severe form of eye allergy called 'vernal keratoconjunctivitis'.

VYZULTA



- ▶ [Decision Summary](#)

Medicinal Ingredient

Latanoprostene bunod

Indication

Vyzulta is used to reduce the high pressure in the eye in patients with open-angle glaucoma or ocular hypertension.

3 NEW GENERIC DRUGS

Health Canada approved 3 new generic drugs in this category:

- ▶ 2 products containing diclofenac sodium
- ▶ 1 product containing moxifloxacin hydrochloride

SAFETY UPDATES

Alcaine (proparacaine hydrochloride): **Health Product InfoWatch: Risk of eye damage due to abuse or misuse**

Flarex (fluorometholone acetate ophthalmic suspension): **Health Product InfoWatch: Risk of corticosteroid toxicity**

SYSTEMIC HORMONAL PREPARATIONS, EXCLUDING SEX HORMONES AND INSULINS

For example, drugs that affect the endocrine system, including corticosteroids and thyroid hormones.

4 NEW GENERIC DRUGS

Health Canada approved 4 new generic drugs in this category:

- ▶ 3 products containing cinacalcet hydrochloride
- ▶ 1 product containing thiamazole

SAFETY UPDATES

Orgalutran (ganirelix acetate injection): **Health Product InfoWatch: Risk of allergic reactions in latex sensitive individuals**

Prednisone and prednisolone (glucocorticoids): **Summary Safety Review: Assessing the potential risk of a serious complication called scleroderma renal crisis in patients with systemic sclerosis**

VARIOUS

For example, drugs unable to be classified into the other categories, such as diagnostic agents and drugs to treat high levels of potassium or phosphate in the blood.

2 NEW DRUGS

VELPHORO



- ▶ [Decision Summary](#)

Medicinal Ingredient

Sucroferric oxyhydroxide

Indication

To control high phosphorus levels in adult patients who have end stage kidney disease and are on dialysis.

VELTASSA



- ▶ [Decision Summary](#)

Medicinal Ingredient

Patiomer sorbitex calcium

Indication

Veltassa is used to treat high amounts of potassium in the blood. Veltassa is only for use in patients with chronic kidney disease, except for end stage kidney disease.

2 NEW GENERIC DRUGS

Health Canada approved 2 new generic drugs in this category:

- ▶ 1 product containing deferasirox
- ▶ 1 product containing leucovorin calcium

SAFETY UPDATES

Gadolinium-Based Contrast Agents: **Summary Safety Review: Assessing the risk of gadolinium build-up in the brain and potential brain and nervous system (neurological) side effects**

Jamp-Glucose 50 and Jamp-Glucose 75: **Dear Healthcare Professional Letter: Risk of inaccurate oral glucose challenge or tolerance test results**

Kayexalate (sodium polystyrene sulfonate) and Resonium Calcium (calcium polystyrene sulfonate): **Health Product InfoWatch: Risk of decreased efficacy of other oral medications**

Xofigo (radium Ra 223 dichloride solution for injection): **Dear Healthcare Professional Letter: Risk of fractures and increased deaths**



HEALTHY CLICKS DRUGS FOR HUMAN USE AT A GLANCE

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the **Government of Canada website**
canada.ca/en/services/health.html

NEW DRUGS APPROVED

Health Canada **regularly tweets**
about new drugs approved.



NEW

It also publishes a **quarterly update** listing the
drugs and medical devices that have been
authorized during the previous three months.

Twitter #Drugandmeddevice 
twitter.com/GovCanHealth

The **Drug and Health Product Register**
provides information for consumers
about drugs that are currently marketed
in Canada.

Drug and Health Product Register 
hpr-rps.hres.ca/index.php

The **Drug Product Database** is a listing of
all drugs approved for sale in Canada. In the
database, many drugs are accompanied by
their Product Monographs, which describe the
conditions of use of the product.

Drug Product Database 
health-products.canada.ca/dpd-bdpp/

NEW DRUGS APPROVED (cont.)

The **Submissions Under Review Lists** show the drugs that are currently being reviewed by Health Canada.

Submissions Under Review Lists [↗](https://canada.ca/en/health-canada/services/drug-health-product-review-approval/submissions-under-review.html)
canada.ca/en/health-canada/services/drug-health-product-review-approval/submissions-under-review.html

The **Notice of Compliance database** lists the approvals (Notices of Compliance or NOCs) issued for new drugs.

Notice of Compliance database [↗](https://health-products.canada.ca/noc-ac/index-eng.jsp)
health-products.canada.ca/noc-ac/index-eng.jsp

Regulatory Decision Summaries include the purpose of a drug submission and the reasons for Health Canada's decision to approve or reject it.

Regulatory Decision Summary [↗](https://canada.ca/en/health-canada/services/drugs-health-products/drug-products/regulatory-decision-summary.html)
canada.ca/en/health-canada/services/drugs-health-products/drug-products/regulatory-decision-summary.html

NEW The **Generic Submissions Under Review List** shows the generic drugs that are currently being reviewed by Health Canada.

Generic Submissions Under Review List [↗](https://canada.ca/en/health-canada/services/drug-health-product-review-approval/generic-submissions-under-review.html)
canada.ca/en/health-canada/services/drug-health-product-review-approval/generic-submissions-under-review.html

Summary Basis of Decision documents give the detailed regulatory, safety, effectiveness and quality considerations that factored into Health Canada's decision to approve certain drug submissions.

Summary Basis of Decision [↗](https://health-products.canada.ca/noc-ac/index-eng.jsp)
<https://health-products.canada.ca/noc-ac/index-eng.jsp>

DRUG SHORTAGES

The **Drug Shortages in Canada website** gives information on actual and anticipated drug shortages.

Drug Shortages in Canada [↗](https://canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-shortages.html)
canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-shortages.html

CLINICAL TRIALS FOR DRUGS

The **Clinical Trials Database** lists the clinical trial applications that have been approved for drugs in Canada.

Health Canada's Clinical Trials Database [↗](https://canada.ca/en/health-canada/services/drugs-health-products/drug-products/health-canada-clinical-trials-database.html)
canada.ca/en/health-canada/services/drugs-health-products/drug-products/health-canada-clinical-trials-database.html

POST-MARKET SURVEILLANCE OF DRUGS

REPORT AN ADVERSE DRUG REACTION OR A MEDICAL DEVICE INCIDENT.

You can report adverse drug 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**.

The **Recalls and Safety Alerts Database** includes the recalls, advisories, safety alerts and other publications issued by Health Canada.

Recalls and Safety Alerts Database [↗](#)
healthycanadians.gc.ca/recall-alert-rappel-avis

New Safety and Effectiveness Reviews are tables listing reviews that are currently ongoing in Health Canada.

New Safety Reviews [↗](#)
canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/safety-reviews/new.html

The **Canada Vigilance Adverse Reaction Online Database** includes information about suspected adverse reactions to health products and about medical device incidents. These reports have been submitted by consumers and health professionals as well as drug manufacturers and distributors.

Canada Vigilance Adverse Reaction Online Database [↗](#)
canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-database.html

Summary Safety Reviews summarize our completed reviews of potential safety issues for drugs.

Summary Safety Reviews [↗](#)
hpr-rps.hres.ca/reg-content/summary-safety-review.php

Health Product InfoWatch is a monthly publication intended primarily for healthcare professionals. The Health Product InfoWatch provides clinically relevant information about health products and their safety.

Health Product InfoWatch [↗](#)
canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/health-product-infowatch.html

The **summary tables of advertising complaints** list the complaints about health product advertising that have been filed with Health Canada, and the action we have taken.

Health Product Advertising Complaints [↗](#)
hpr-rps.hres.ca/reg-content/summary-safety-review.php



MEDICAL DEVICES

2018 IN BRIEF

Canadians rely on medical devices to maintain and improve their health and well-being. We take a risk-based approach to the regulation of medical devices. That is, our level of review before approval depends on the risks that might be associated with using the medical device.

In Canada, we categorize medical devices into four classes based on potential risk. These range from Class I, which have the lowest potential risk (e.g. a tongue depressor) to Class IV, which have the highest potential risk (e.g. a pacemaker).

In 2018, we published the **Action Plan on Medical Devices**, which describes a three-part strategy to improve the safety and effectiveness of medical devices and optimize health outcomes for patients:

- improving how devices get on the market in Canada
- strengthening monitoring and follow-up of devices once they are being used by Canadians
- providing more information to Canadians about the medical devices they use

The products we regulate are very diverse and encompass a wide variety of scientific and technical expertise. The pace of change is ever-increasing and one area of particular growth is that of digital health technologies. We want to meet growing technology demands from patients, healthcare partners and industry. However it is critical that we ensure that medical devices using this technology are safe and effective.

In 2018, we created a new division to review medical devices involving digital health technologies. This division will focus on addressing safety issues related to digital health technologies such as securing private health information and preventing hacking and cyber security threats.

Making safe and effective medical devices available in a timely manner is the core of our work. Using our resources efficiently helps give Canadians faster access to the health products they need. In 2018, we met and exceeded our performance targets for medical device reviews.

NEW MEDICAL DEVICES APPROVED

In 2018, we approved 355 new Class III medical devices and 80 new Class IV medical devices.

These provide a broader range of options used to treat, manage, diagnose or prevent a disease or a physical condition.

Four of the new Class IV medical devices included ‘novel technology’: a new apparatus, appliance, software or material with novel technology never before approved for sale in Canada.

For a list and description of the new medical devices we approved in 2018, go to **“Medical Devices: Approved in 2018”**.

CLINICAL TRIALS AND SPECIAL ACCESS PROGRAMME

As part of our role in enabling access to key therapies, we approve applications to allow companies and researchers to conduct clinical trials (called investigational testing) on medical devices in Canada. New clinical trials mean access to more innovative choices. In 2018, 199 new investigational testing applications for medical devices were approved.

There are also ways we provide access to medical devices that have not yet been approved for sale in Canada, through our Special Access Programme. The Programme provides a pathway for doctors to request treatments for their patients that are otherwise unavailable. Access to unapproved medical devices may be granted for emergency use or to patients with serious or life-threatening conditions. In 2018, 2,619 requests for special access to medical devices were authorized.

POST-MARKET SURVEILLANCE

Once medical devices are available in Canada, Health Canada continues to monitor and evaluate reports of suspected medical device incidents. We call this ‘post-market surveillance’. It is not possible to know or predict all of the possible adverse events or incidents associated with a medical device through clinical studies at the time of market approval.

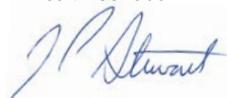
In 2018, we received 28,176 post-market reports of medical device incidents from domestic and international sources. We undertook 54 post-market actions related to medical devices. These actions can include informing the public and healthcare professionals of new safety information, recommending labelling changes, and even removing a medical device from the market in the most serious situations.

This “Medical Devices” section of the report provides more information about our activities in 2018. You’ll find an overview of the progress we made in 2018 on our key priorities. You will learn about the product life cycle of a medical device, and our role in ensuring the benefits of a device continue to outweigh the potential risks. You will also find details about the new medical devices we approved in 2018, as well as the actions we took to address safety issues for products already on the Canadian market. Please also take a look at the new “Healthy clicks” section to follow up-to-date information on our activities.



John Patrick Stewart

Director General,
Therapeutic Products,
Health Canada



Rhonda Kropp

Director General, Marketed
Health Products,
Health Canada





MEDICAL DEVICES

2018 ACCOMPLISHMENTS

REGULATORY REVIEW

The Canadian healthcare system is changing rapidly. We need a regulatory system that is able to continue to adapt to changes in healthcare delivery and that also gives people faster access to the medical devices they need. We must also continue to make sure that all devices we approve are safe, effective, and of good quality.

Health Canada developed the 'Regulatory Review of Drugs and Devices' initiative in 2017 to provide more timely access to drugs and devices to patients. Other goals include increasing our work with partners in the healthcare system in Canada and with other countries, and to make better use of real-world evidence (data collected outside of clinical trials) across a product's life cycle.

In 2018, we made significant progress in support of access to medical devices. For example, we:

- Worked with healthcare system partners within Canada to align our review work, speeding up access to medical devices.
- Created a digital health technology review unit, which will focus on technologies such as wireless medical devices, telemedicine, and artificial intelligence.
- Made more information available to patients, caregivers, and healthcare professionals about medical devices. For example, Health Canada regularly tweets about new medical devices approved.

We also hired additional scientific staff to increase our ability to review innovative medical devices and help monitor the safety and effectiveness of devices after they are approved for sale in Canada.

This section of the report will provide you with more detailed information about these important projects, as well as some of our other priorities in 2018.

ACTION PLAN ON MEDICAL DEVICES

Health Canada's Action Plan on Medical Devices is a strategy to strengthen the regulatory system for medical devices in Canada. The strategy is focused on Canadian patients, and will continuously improve the safety, effectiveness and quality of devices in Canada and optimize health outcomes for patients.

In working with our partners, the three-part Action Plan will accelerate work to:

- Improve how devices get on the market by increasing research by medical professionals, reviewing evidence requirements for medical device approvals, and expanding the use of outside experts and patient perspectives while building our internal expertise.
- Strengthen monitoring and follow-up by expanding and improving the reporting of incidents by healthcare institutions, implementing regulatory levers to identify and respond to safety issues, and increasing inspections to ensure quality medical devices.
- Provide more information to Canadians by improving access to clinical data, publishing review decisions on higher risk medical devices, publishing information on medical device incidents, and improving access to inspection results.

By promoting open communication and engagement with Canadians throughout this action plan, Health Canada is ensuring that all perspectives are taken into account when developing policies and regulations. The plan will also keep Canadians up to date with progress on the action plan so that they know what Health Canada is doing to enhance the safety and effectiveness of the devices they use.

For more information, go to [Health Canada's Action Plan on Medical Devices: Continuously Improving Safety, Effectiveness and Quality](#).

DIGITAL HEALTH TECHNOLOGIES

Digital health technologies will be key in the delivery of future patient care. Adopting and using them will likely make the delivery of healthcare more accessible, convenient and cost-effective. We want to meet growing technology demands from patients, healthcare systems and industry. However, we must also ensure that medical devices remain safe and effective for Canadians.

In 2018, we created a new Digital Health Division. This group of scientists and engineers review medical device applications with digital health technologies. They also focus on addressing safety issues such as securing private health information, and preventing hacking and cyber security threats.

Health Canada is also seeking expert advice on digital health technologies, to help inform our decisions related to these medical device applications. In 2018, we established a Scientific Advisory Committee on Digital Health Technologies (SAC-DHT). This committee will help increase and diversify our knowledge of the benefits and potential risks of these products. For more information, go to [Scientific/Expert Advisory Committees – Digital Health Technologies](#).

SAFETY, EFFECTIVENESS AND QUALITY OF MEDICAL DEVICES

In 2018, Health Canada made significant progress on work that will continue to ensure our high standards for safety, effectiveness, and quality of medical devices are met.

For example, we posted two draft guidance documents for industry that will help clarify our standards related to cyber security and 3-D printing. New technologies have the potential to benefit Canadians. However, they pose unique challenges for Health Canada and manufacturers. Our guidance documents will ensure that medical devices with novel technologies continue to meet our standards for safety and effectiveness and take into account potential cyber security risks.

The high quality of a medical device helps ensure that it functions as it is intended. This is particularly important for devices with long lifetimes and those that are implanted within the body. In 2018, we continued our transition to an audit system called the Medical Device Single Audit Program, or MDSAP. This program aligns with our partners in other countries and continues to ensure the quality of the medical devices sold in Canada.





MEDICAL DEVICES

MEDICAL DEVICE LIFE CYCLE

As part of Health Canada's mission to help Canadians maintain and improve their health, we evaluate medical devices before and after they reach the Canadian market. Health Canada is involved throughout the life cycle of a medical device, including during investigational testing of the device, through the assessment for authorization, and once the device has been marketed and made available to Canadians. For example, we:

- evaluate applications for investigational testing (clinical trials)
- evaluate applications for special access
- review applications to sell the device in Canada
- monitor the safety and effectiveness of medical devices in the real world, after they are available for sale in Canada

CLINICAL TRIALS (INVESTIGATIONAL TESTING)

Clinical trials are conducted by sponsors (manufacturers or researchers) to gather information on a medical device's safety and effectiveness in humans. Clinical trials (investigational testing) for medical devices represent potential new healthcare therapies which may eventually address the needs of Canadians.

Sponsors of investigational tests submit their applications to conduct a clinical trial with a medical device in Canada. We review these applications and decide whether to allow the trial to be conducted in Canada. The guidance document on [Applications for Medical Devices Investigational Testing Authorizations - Summary](#) provides detailed information about the timelines and processes for the review of applications for investigational testing.

In 2018, Health Canada authorized 199 new investigational testing applications for medical devices.

SPECIAL ACCESS PROGRAMME

Medical devices that are not approved in Canada may be available through our Special Access Programme. The [Special Access Programme for medical devices](#) provides access to custom-made or unlicensed devices, if certain criteria are met.

In this program, access is provided to an individual healthcare practitioner who is treating a specific 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. A decision to authorize or deny a request is made on a case-by-case basis. We consider the intended use of the medical device, the condition of the patient, whether there are alternative devices available, and the information provided in support of the request.

Our Special Access Programme operates 24 hours a day, 365 days a year.

In 2018, Health Canada authorized 2619 requests for special access to medical devices.

MEDICAL DEVICE APPLICATION AND REVIEW

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.

When a company decides that it would like to **market a Class II, III or IV medical device** in Canada, it files an application to us for a new medical device licence. The application contains scientific information about the medical device's safety, effectiveness and quality. Class I devices do not require a medical device licence, but are monitored through establishment licences.

Applications for higher-risk medical devices are reviewed by our scientists and engineers. 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 medical devices. They also review the information to be provided to healthcare practitioners and consumers about the medical device.

Different classes of medical devices have different target times for Health Canada to complete its review. The **Management of Applications for Medical Device Licences and Investigational Testing Authorizations** guidance document provides detailed information about the timelines and processes for the review of medical device applications.

EXPEDITED REVIEW PATHWAY: PRIORITY REVIEW

The priority review pathway provides an expedited path to a final decision for certain medical devices, including those that target specific healthcare needs. Medical devices for serious, life-threatening, or severely debilitating diseases or conditions can be given a priority review status. Products approved through expedited review pathways can be available to patients sooner.

In 2018, three of the 80 new Class IV medical devices were approved through the priority review pathway.

APPROVAL OF MEDICAL DEVICES

After its review of a medical device application, Health Canada may conclude that the benefits of the product outweigh the potential risks and approve the device for sale in Canada. When a new medical device is approved, it is issued a medical device licence.

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

In 2018, Health Canada approved 355 new Class III and 80 new Class IV medical devices, including 4 Class IV medical devices with novel technology.

For a list of what was approved in 2018, go to “[Medical Devices: Approved in 2018](#)”. You can also reference the Update on New Drug and Medical Device Authorizations, published quarterly.

To request Quarterly and Annual Medical Device Performance Reports, go to [Reports and Publications – Medical Devices](#).

POST-MARKET SURVEILLANCE

It is not possible to know or predict all of the possible adverse reactions to a medical device through clinical studies. After a product is available for sale in Canada, we continue to monitor its use in the real world, that is, in a broader population. We call this ‘post-market surveillance’. We evaluate potential safety and effectiveness issues and take action when there are identified problems.

COLLECTING INFORMATION

Health Canada collects post-market information (that is, information collected about a product after it is approved) from a variety of sources.

One source of information for Health Canada is suspected medical device incidents that are reported after products are approved for sale. These are undesirable effects potentially caused by medical devices.

In 2018, we received 28,176 medical device incident reports (27,125 in Canada and 1,051 from around the world).

You can report adverse drug 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**.

You can find information about the annual numbers and trends of adverse drug reaction case reports and medical device incident reports to Health Canada between 2008 and 2017 in the [Annual trends for the adverse reaction case reports of health products and medical device problem incidents to Health Canada \(2008-2017\)](#).

EVALUATING SAFETY SIGNALS

We evaluate the data we collect to detect new safety signals, which we then investigate more closely. A 'safety signal' can be defined as information on a new or known adverse event that may be associated with a medical device. These investigations are called signal assessments and they may result in recommendations for actions to be taken by the company, by Health Canada, or both. These actions can include informing the public and healthcare professionals of new safety information, recommending labelling changes, and even removing a medical device from the market in the most serious situations.

For example, in 2018 we conducted a signal assessment for radiofrequency ablation catheters, used for heart procedures to treat patients with irregular heartbeats, and the risk of an abnormal connection forming between the heart and the digestive tract. The signal assessment included a review of information submitted by the medical device manufacturer, the scientific literature, and an assessment of medical device incident reports (domestic and international). Following the completion of the safety review, a risk communication was issued to inform healthcare professionals and patients about this risk and the Canadian label was updated.

We publish Summary Safety Reviews (SSRs) to inform Canadians about the outcomes of any safety investigation that might affect the therapeutic products they use. In 2018, Health Canada reviewed 26 **safety and effectiveness issues** related to medical devices, resulting in 6 **Summary Safety Reviews**.

In 2018, Health Canada issued 5 Risk Communications to healthcare practitioners and Canadians related to medical devices. You can find these risk communications in the **Recalls and Safety Alerts Database**. We also publish monthly editions of the **Health Product InfoWatch**. This publication provides information about emerging health product safety risks to healthcare professionals, for use with their patients.

ADVERTISING COMPLAINTS

As part of its post-market work, Health Canada also regulates the advertising of medical devices sold in Canada to ensure that companies are not making false claims about their products. We review advertising complaints to determine if a company is complying with our requirements.

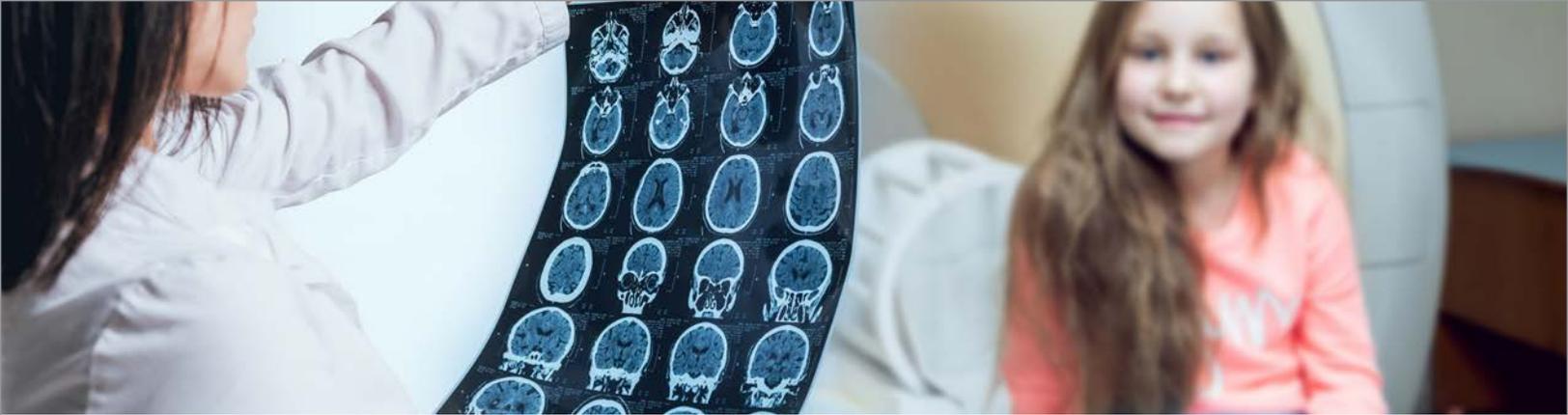
In 2018, Health Canada reviewed 18 **advertising complaints** related to medical devices. For example, in 2018, Health Canada contacted various spa centres and surgery clinics throughout the country to raise concerns regarding the advertising of medical devices such as Juvederm, a facial filler. Health Canada determined that the claims in these advertisements were not authorized, and we requested that these clinics immediately cease these illegal practices. Health Canada is still engaged in educating some of these clinics and is working collaboratively to achieve wilful compliance.

After reviewing a complaint, we take appropriate action when non-compliance is identified. This may include requesting a company to stop disseminating non-compliant advertising and taking steps towards avoiding any future issues

In addition to reviewing complaints, Health Canada recently put in place a dedicated team to identify advertising issues even before a complaint is made. This team will enforce the existing advertising rules and will take action where necessary, including recommending criminal charges where appropriate. Health Canada will post all non-compliant advertising on its website.

This initiative enhances the Department's ability to detect trends and issues which may become, or contribute to, serious public health crises.





MEDICAL DEVICES APPROVED IN 2018

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.

This section outlines the new Class IV medical devices, including those with novel technology, approved for sale in Canada in 2018, and the safety updates issued.

You can report adverse drug 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**.

HEALTH CATEGORIES

Brain and spinal cord

Breast implants

Dental health

Diabetes health

Diagnostic tests

Digestive health

Eye health

Heart health

Medical imaging

Opioid use

Organ donation

Orthopedic

Pain management

Surgery

Vascular health

Wound

management

Other

IMPORTANT DEFINITIONS

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.



Priority review

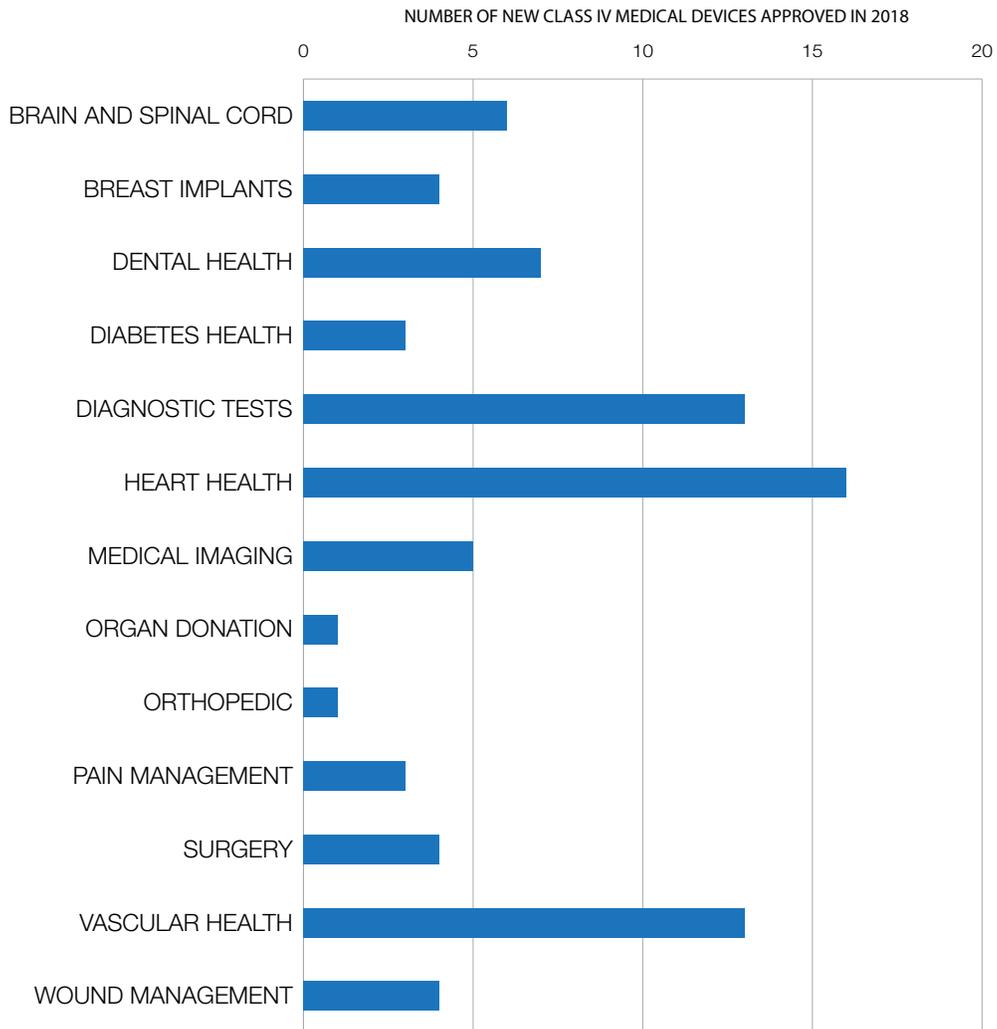
Priority review status may be granted to a medical device application for a product for a serious, life-threatening or severely debilitating disease or condition.

Safety updates

Safety updates are designed to communicate information about potential health risks, so that patients and healthcare professionals can make informed decisions about their health.

For more information about the types of risk communications that can be found on the Government of Canada's website, go to "**Healthy Clicks – Medical Devices At a Glance**".

NEW CLASS IV MEDICAL DEVICES APPROVED IN 2018



BRAIN AND SPINAL CORD

6 NEW MEDICAL DEVICES

DBS (DEEP BRAIN STIMULATION) PACKS

▶ [Decision Summary](#) 

Indication

DBS (Deep Brain Stimulation) Packs are kits that are comprised of sterile components that are sold to healthcare professionals in order to aid in the neurological medical/surgical procedure of Deep Brain Stimulation (DBS) electrode insertion into the brain.

GUARDIAN CRANIAL BURR HOLE COVER SYSTEM

▶ [Decision Summary](#) 

Indication

The Guardian Cranial Burr Hole Cover System is a temporary or permanent lead fixation device. It is intended for use as a method to secure a compatible Saint Jude Medical Deep Brain Stimulation lead.

INFINITY IMPLANTABLE PULSE GENERATOR

▶ [Decision Summary](#) 

Indication

This neurostimulation system is indicated for unilateral or bilateral stimulation of the thalamus, internal globus pallidus (GPi), or subthalamic nucleus (STN) in patients with levodopa-responsive Parkinson's disease.

INTELLIS NEUROSTIMULATION SYSTEM

▶ [Decision Summary](#) 

Indication

The Intellis Neurostimulation System is an implantable spin cord/peripheral nerve stimulation device based on the currently licensed RestoreSensor (MDL 83770, 91421). The stimulator generates and delivers weak electric pulses to the site of interest to modify the action potential generation, transmission or interpretation. The stimulator connects to licensed leads, and depending on which lead used, the system can be considered as MR conditional.

LEAD AND EXTENSION KITS FOR DEEP BRAIN STIMULATION (DBS) SYSTEMS

▶ [Decision Summary](#) 

Indication

St. Jude Medical deep brain stimulation leads are intended to deliver stimulation to target areas in the brain. Deep brain stimulation extensions are intended to connect the leads to implantable pulse generators (IPGs).

VP SHUNT PROCEDURE PACKS

▶ [Decision Summary](#)

Indication

The intended use of this kit is to relieve pressure on the brain caused by fluid accumulation. Ventriculoperitoneal (VP) shunting is a surgical procedure that primarily treats a condition called hydrocephalus. This condition occurs when excess cerebrospinal fluid (CSF) collects in the brain's ventricles.

BREAST IMPLANTS

4 NEW MEDICAL DEVICES

NATRELLE 133 PLUS TISSUE EXPANDER

▶ [Decision Summary](#) 

Indication

The Natrelle 133 Plus Microcell Tissue Expanders can be utilized for breast reconstruction after mastectomy, correction of an underdeveloped breast, scar revision and tissue defect procedures. The expander is intended for temporary subcutaneous or submuscular implantation and is not intended for use beyond six months.

NATRELLE 410 TRUFORM MICROCELL SILICONE-FILLED BREAST IMPLANTS

▶ [Decision Summary](#) 

Indication

The Natrelle 410 Truform Microcell Silicone - Filled Breast Implants are indicated for breast augmentation in women at least 22 years old, and revision of previous breast augmentation or reconstruction to correct or improve the results of the previous surgery.

NATRELLE INSPIRA TRUFORM 1 MICROCELL BREAST IMPLANTS

▶ [Decision Summary](#)

Indication

The Natrelle Inspira Truform Microcell Breast Implants are indicated for breast augmentation in women at least 22 years old, and revision of previous breast augmentation or reconstruction to correct or improve the results of the previous surgery.

NATRELLE INSPIRA TRUFORM 2 MICROCELL BREAST IMPLANTS

▶ [Decision Summary](#)

Indication

The Natrelle Inspira Truform 2 Microcell Breast Implants are indicated for breast augmentation in women at least 22 years old, and revision of previous breast augmentation or reconstruction to correct or improve the results of the previous surgery.

DENTAL HEALTH

7 NEW MEDICAL DEVICES

A-OSS BONE SUBSTITUTE

▶ [Decision Summary](#)

Indication

A-Oss is applicable in the treatment and prevention of the bone defect in the following dental areas:

- filling in the missing part of a bone due to periodontal disease, cystectomy, or dental extraction
- filling in the missing part of a bone surrounding an implant
- maxillary sinus lift for implant
- alveolar bone augmentation/restoration

GEISTLICH FIBRO-GIDE COLLAGEN MATRIX

▶ [Decision Summary](#)

Indication

Geistlich Fibro-Gide is intended for soft-tissue augmentation.

NOVOMATRIX RECONSTRUCTIVE TISSUE MATRIX

▶ [Decision Summary](#)

Indication

NovoMatrix Reconstructive Tissue Matrix is indicated for:

- localized gingival augmentation to increase keratinized tissue around teeth
- alveolar ridge reconstruction for prosthetic treatment
- guided tissue regeneration procedures in recession defects for root coverage

OCS-B COLLAGEN SPONGIOUS BONE SUBSTITUTE (BOVINE) WITH COLLAGEN

▶ [Decision Summary](#)

Indication

OCS-B Collagen is a bone mineral matrix with collagen for bone grafting in periodontal, oral and maxillofacial surgery.

OSSIX BONE

▶ [Decision Summary](#)

Indication

The Ossix Bone is an osteoconductive and biodegradable bone grafting material. It is intended for guided bone generation (GBR) procedures in periodontal defects.

STRAUMANN CERABONE

▶ [Decision Summary](#)

Indication

Straumann Cerabone is indicated for filling or reconstruction of bone defects in oral surgery.

STRAUMANN JASON MEMBRANE

▶ [Decision Summary](#) 

Indication

Straumann Jason Membrane alone or in combination with suitable augmentation materials (like autogenous bone, allogeneic, xenogeneic or alloplastic bone replacement materials) is indicated for immediate or delayed guided tissue and bone regeneration.

DIABETES HEALTH

3 NEW MEDICAL DEVICES

GUARDIAN CONNECT CONTINUOUS GLUCOSE MONITORING SYSTEM



▶ [Decision Summary](#) 

Indication

The Guardian Connect app is intended to integrate with the Guardian 3 glucose sensors for continuous monitoring of glucose levels in the interstitial fluid under the skin, in persons aged 3 years or older with diabetes mellitus.

GUARDIAN SENSOR (3)



▶ [Decision Summary](#) 

Indication

The Guardian Sensor (3) is an interstitial glucose sensor which is worn on the body and utilizes a small sensor tail inserted under the skin to measure glucose levels in the interstitial fluid. The sensor is intended for use with Medtronic diabetes CGM systems to continuously monitor glucose levels in persons with diabetes.

MINIMED 670G



▶ [Decision Summary](#) 

Indication

The MiniMed 670G system is intended for continuous delivery of basal insulin (at user-selectable rates) and administration of insulin boluses (in user-selectable amounts) for the management of type 1 diabetes mellitus in persons seven years of age and older as well as for the continuous monitoring and trending of glucose levels in the interstitial fluid under the skin. The 670G system can be programmed to automatically adjust delivery of basal insulin based on Guardian 3 glucose sensor readings.

SAFETY UPDATES

Omnipod insulin management system: [Summary Safety Review: Assessing the potential risk of malfunctions with the device](#)

DIAGNOSTIC TESTS

13 NEW MEDICAL DEVICES

ALINITY I ANTI-HBc IGM ASSAY

▶ [Decision Summary](#) 

Indication

The Alinity i Anti-HBc IgM assay is indicated for use as an aid in the diagnosis of acute or recent hepatitis B viral infection.

ALINITY I ANTI-HBc II ASSAY

▶ [Decision Summary](#) 

Indication

The Alinity i Anti-HBc II assay is intended to be used as an aid in the diagnosis of hepatitis B infection and as a screening test to prevent transmission of hepatitis B virus (HBV) to recipients of blood, blood components, cells, tissue and organs.

ALINITY I ANTI-HBe ASSAY

▶ [Decision Summary](#) 

Indication

The Alinity i Anti-HBe assay is used for the qualitative detection of antibody to hepatitis B e antigen (anti-HBe) in human serum and plasma on the Alinity i analyzer. The Alinity i Anti-HBe assay is to be used as an aid in the diagnosis and monitoring of hepatitis B viral infection.

ALINITY I ANTI-HBs ASSAY

▶ [Decision Summary](#) 

Indication

The Alinity i Anti-HBs assay is used for the quantitative determination of antibody to Hepatitis B surface antigen (anti-HBs) in human serum and plasma on the Alinity i analyzer.

ALINITY I ANTI-HCV ASSAY

▶ [Decision Summary](#) 

Indication

The Alinity i Anti-HCV assay is intended to be used as an aid in the diagnosis of Hepatitis C infection and as a screening test to prevent transmission of Hepatitis C virus (HCV) to recipients of blood, blood components, cells, tissue and organs.

ALINITY I CHAGAS ASSAY (DONOR SCREENING/ CADAVERIC)

▶ [Decision Summary](#) 

Indication

The Alinity i Chagas assay is to be used as an aid in the diagnosis of *T. cruzi* (Chagas) infection and as a screening test to prevent transmission of *T. cruzi* (Chagas) to recipients of blood, blood components, cells, tissue and organs.

ALINITY I HBEAG ASSAY

▶ [Decision Summary](#) 

Indication

The Alinity i HBeAg assay is to be used as an aid in the diagnosis and monitoring of hepatitis B viral infection.

ALINITY I HBSAG ASSAY

▶ [Decision Summary](#) 

Indication

The Alinity i HBsAg assay is used for the quantitative determination of hepatitis B surface antigen (HBsAg) in human serum and plasma on the Alinity i analyzer.

ALINITY I HIV AG/AB COMBO ASSAY (DONOR SCREENING AND CADAVERIC TESTING)

▶ [Decision Summary](#) 

Indication

The Alinity i HIV AG/AB Combo assay is to be used as an aid in the diagnosis of HIV-1/HIV-2 infection and as a screening test to prevent transmission of HIV-1/HIV-2 to recipients of blood, blood components, cells, tissue and organs.

ALINITY I RHTLV-I/II

▶ [Decision Summary](#) 

Indication

The Alinity i rHTLV-I/II assay is intended to be used as an aid in the diagnosis of HTLV-I and HTLV-II infection and as a screening test to prevent transmission of HTLV-I and HTLV-II to recipients of blood, blood components, cells, tissue and organs.

ALINITY I SYPHILIS TP ASSAY (DONOR SCREENING & CADAVERIC TESTING)

▶ [Decision Summary](#) 

Indication

The Alinity i Syphilis TP assay is intended to be used as an aid in the diagnosis of Syphilis infection and as a screening test to prevent transmission of *Treponema pallidum* to recipients of blood, blood components, cells, tissue and organs.

ELECSYS HIV DUO DONOR SCREENING

▶ [Decision Summary](#) 

Indication

The Elecsys HIV DUO is an immunoassay for the in vitro qualitative determination of HIV 1 p24 antigen and antibodies to HIV 1, including group O, and HIV 2 in human serum and plasma. This assay is indicated as an aid in the diagnosis of infection with HIV-1 and/or HIV-2 and as a donor screening test to detect HIV 1 p24 antigen and antibodies to HIV 1 and HIV 2 in serum or plasma specimens from individual human blood donors.

VIROTROL HIV-1 GO

▶ [Decision Summary](#) 

Indication

Virotrol HIV-1 gO is intended for use as an unassayed reactive quality control with in vitro assay procedures for determination of antibodies to Human Immunodeficiency Virus Type 1 (HIV-1 group O) in human serum or plasma. This product is intended to provide a means of estimating precision and has the potential for detecting systematic deviations from specific laboratory testing procedures.

DIGESTIVE HEALTH

SAFETY UPDATES

Enterra therapy system: **Summary Safety Review: Assessing the potential lack of effect**

EYE HEALTH

SAFETY UPDATES

Decorative Contact Lenses: **Information Update: Reminding Canadians of the risks of use**

Ophthalmic viscosurgical devices (OVDs): **Summary Safety Review: Assessing the potential risk of inflammation of the front part of the eye (toxic anterior segment syndrome)**

HEART HEALTH

16 NEW MEDICAL DEVICES

ACURATE NEO AORTIC BIOPROSTHESIS AND ACURATE TF TRANSFEMORAL DELIVERY SYSTEM

▶ [Decision Summary](#) 

Indication

The Acurate neo Aortic Bioprosthesis and its Delivery System is a Transcatheter Aortic Valve Implantation (TAVI) system that is indicated for use in patients 75 years of age and older with severe aortic stenosis for whom conventional surgical aortic valve replacement is considered high risk for mortality or who are not operable.

ASTRA/AZURE MRI SURESCAN PACING SYSTEM

▶ [Decision Summary](#) 

Indication

The Astra/Azure S/XT SR/DR MRI SureScan system is an implantable pacemaker that is indicated for use in patients who may benefit from rate responsive or non-rate responsive pacing to restore physiologic heart rates, improve cardiac output, prevent symptoms, or protect against arrhythmias related to cardiac impulse formation or conduction disorders.

COREVALVE EVOLUT PRO TRANSCATHETER AORTIC VALVE

▶ [Decision Summary](#) 

Indication

The CoreValve Evolut PRO system is a Transcatheter Aortic Valve Implantation (TAVI) system indicated for patients with severe symptomatic native aortic valve stenosis or a stenosed, insufficient, or combined surgical bioprosthetic valve failure necessitating valve replacement.

CRT-P MRI SURESCAN

▶ [Decision Summary](#) 

Indication

The CRT-P MRI Surescan devices are cardiac resynchronization therapy pacemakers.

DEFIGARD TOUCH 7

▶ [Decision Summary](#) 

Indication

The Defigard Touch 7 is an external defibrillator used for the treatment of ventricular fibrillation (VF) and ventricular tachycardia (VT).

EDORA 8 IMPLANTABLE PULSE GENERATOR

▶ [Decision Summary](#) 

Indication

Edora is a family of implantable pacemakers that can be implanted for all bradycardia arrhythmia indications.

FRED PA-1

▶ [Decision Summary](#) 

Indication

The FRED PA-1 is an automatic external defibrillator (AED) used for the treatment of ventricular fibrillation (VF) and ventricular tachycardia (VT).

HEARTMATE 3 LEFT VENTRICULAR ASSIST SYSTEM (LVAS)



▶ [Decision Summary](#)

Indication

HeartMate 3 LVAS is a small implantable device which helps the heart's left ventricle (the main pumping chamber of the heart) to deliver blood to all parts of the body by assuming some or all of the blood circulatory workload. The HeartMate 3 LVAS is intended for heart failure patients whose hearts are unable to pump effectively.

ILIVIA 7 CRT-D

▶ [Decision Summary](#)

Indication

The Ilivia 7 CRT-D is an implantable defibrillator that can treat life-threatening ventricular arrhythmias with antitachycardia pacing and defibrillation.

ILIVIA 7 ICD (PROMRI)

▶ [Decision Summary](#)

Indication

Ilivia 7 ICD ProMRI is an implantable defibrillator that can treat life-threatening ventricular arrhythmias with antitachycardia pacing and defibrillation.

LATITUDE PROGRAMMING SYSTEM

▶ [Decision Summary](#)

Indication

The Latitude Programming System Model 3300 is used to interrogate and program BSC Pulse Generators (PGs), display/store/transfer patient and device data, evaluate leads placement during PG implant, print reports to wired and wireless external printers, and support internet download of Programmer software updates.

MITRACLIP DELIVERY SYSTEM

▶ [Decision Summary](#)

Indication

The MitraClip NTR Clip Delivery System and the MitraClip XTR Clip Delivery System are designed to perform percutaneous mitral valve repair in the beating heart.

REPROCESSED ELECTROPHYSIOLOGY DIAGNOSTIC CATHETERS

▶ [Decision Summary](#)

Indication

The Reprocessed Electrophysiology Diagnostic Catheters are used to facilitate electrophysiological mapping of the cardiac structures and obtain electrograms in atrial regions.

REPROCESSED LASSO ELECTROPHYSIOLOGY CATHETERS

▶ [Decision Summary](#)

Indication

The Reprocessed Lasso Electrophysiology Catheters are used to facilitate electrophysiological mapping of the cardiac structures and obtain electrograms in atrial regions.

REPROCESSED SEALED ELECTROPHYSIOLOGY DIAGNOSTIC CATHETERS

▶ [Decision Summary](#)

Indication

The reprocessed sealed electrophysiology diagnostic catheters are intended for use in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.

TACTICATH CONTACT FORCE ABLATION CATHETER, SENSOR ENABLED

▶ [Decision Summary](#)

Indication

The TactiCath Contact Force Ablation Catheter, Sensor Enabled is indicated for use in cardiac electrophysiological mapping (stimulation and recording), and, when used in conjunction with a radiofrequency generator, for cardiac ablation of supraventricular arrhythmias in right and left atrium, including atrial fibrillation.

SAFETY UPDATES

Percutaneous radiofrequency ablation catheters: **Summary Safety Review: Assessing the potential risk of an abnormal connection between the heart and digestive tract (atrioesophageal fistula)**

MEDICAL IMAGING

5 NEW MEDICAL DEVICES

ADVISOR HD GRID MAPPING CATHETER, SENSOR ENABLED

▶ [Decision Summary](#)

Indication

The Advisor HD Grid Mapping Catheter, Sensor Enabled, is an electrophysiology mapping catheter that is indicated for multiple electrode electrophysiological mapping of cardiac structures in the heart, i.e., recording or stimulation only.

OPTICROSS 18 PERIPHERAL IMAGING CATHETER

▶ [Decision Summary](#)

Indication

The OptiCross 18 30MHz Peripheral Imaging Catheter is an intravascular ultrasound catheter designed to provide physicians with a 360-degree view of the inside the peripheral vessels for the examination of vascular diseases and the effects of intervention.

REFINITY ROTATIONAL INTRAVASCULAR ULTRASOUND (IVUS) CATHETER

▶ [Decision Summary](#)

Indication

The Refinity Rotational Intravascular Ultrasound (IVUS) Catheter is intended for the intravascular ultrasound examination of coronary arteries.

VISIONS PV.014P RX DIGITAL IVUS CATHETER

▶ [Decision Summary](#)

Indication

The Visions PV .014P RX Digital IVUS Catheter is designed for use in the evaluation of vascular morphology in blood vessels of the coronary and peripheral vasculature by providing a cross-sectional image of such vessels.

14L5 SP TRANSDUCER

▶ [Decision Summary](#)

Indication

The 14L5 SP is a surgical linear array ultrasound transducer used with ultrasound systems for intraoperative and body surface applications.

OPIOID USE

SAFETY UPDATES

Fentanyl test strips: **Information Update: Limitations of fentanyl test strips being used to check street drugs before consumption**

ORGAN DONATION

1 NEW MEDICAL DEVICE

LUNG TRANSPLANT PROCEDURE PACKS

▶ [Decision Summary](#)

Indication

The intended use of the Lung Transplant Procedure Packs is to aid in the medical/surgical procedure of lung transplantation, by which a lung is removed from one body (donor) and placed in another body (recipient) to replace a damaged or missing lung.

ORTHOPEDIC

1 NEW MEDICAL DEVICE

JOINTREP INJECTABLE IMPLANT

▶ [Decision Summary](#) 

Indication

JointRep injectable implant is indicated for the treatment of adult knee joint cartilage defects in conjunction with the bone marrow stimulation (BMS) technique, for reducing joint pain and improving joint functions and patient activities.

PAIN MANAGEMENT

3 NEW MEDICAL DEVICES

DRG LEADS AND ACCESSORIES

▶ [Decision Summary](#) 

Indication

The DRG leads and accessories are to be used with a dorsal root ganglion (DRG) neurostimulator.

INTELLIS NEUROSTIMULATION SYSTEM WITH WIRELESS EXTERNAL NEUROSTIMULATOR

▶ [Decision Summary](#) 

Indication

The Intellis Neurostimulation System is an implantable spinal cord/peripheral nerve stimulation device. The stimulator generates and delivers weak electric pulses to the site of interest to modify the action potential generation, transmission or interpretation.

PROCLAIM DRG IMPLANTABLE PULSE GENERATOR

▶ [Decision Summary](#) 

Indication

The Proclaim DRG Implantable Pulse Generator is a spinal cord stimulation device. This device, when used with other components (leads/extensions), it delivers weak pulses to the spinal dorsal root ganglia as an aid in the management of pain.

SURGERY

4 NEW MEDICAL DEVICES

ARTEMIS NEURO EVACUATION DEVICE

▶ [Decision Summary](#) 

Indication

The Artemis Neuro Evacuation Device is used for the controlled aspiration of tissue and/or fluid during surgery of the Ventricular System or Cerebrum in conjunction with a Penumbra Aspiration Pump.

FILAPROP STERILISED SURGICAL NEEDED SUTURE

▶ [Decision Summary](#) 

Indication

Filaprop sutures are intended for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

PLAIN AND CHROMIC GUT ABSORBABLE SURGICAL SUTURES

▶ [Decision Summary](#) 

Indication

Plain and Chromic Sutures are indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular or neural tissues.

VISUALASE MRI-GUIDED LASER ABLATION SYSTEM

▶ [Decision Summary](#) 

Indication

The Visualase MRI-Guided Laser Ablation System is indicated for use as a minimally invasive procedure to ablate, necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy under magnetic resonance imaging (MRI) guidance for wavelengths 800nm through 1064nm in cranial neurosurgery.

SAFETY UPDATES

Barbed (knotless) sutures: **Summary Safety Review: Assessing the potential risk of intestine blockage (small bowel obstruction)**

SurgiWrap adhesion barrier film: **Summary Safety Review: Assessing the potential risk of foreign body reactions that mimic local re-appearance of cancer**

VASCULAR HEALTH

13 NEW MEDICAL DEVICES

ASCYRUS MEDICAL DISSECTION STENT (AMDS)



▶ [Decision Summary](#) 

Indication

The AMDS dissection stent is intended for aortic repair, aortic remodeling and re-expansion of the intimal flap within the ascending aorta, aortic arch, and into the descending aorta for patients with acute DeBakey Type I aortic dissections and/or intramural hematomas (IMH) and preoperative clinical and/ or radiographic malperfusion undergoing open surgical repair within 0-14 days of diagnosis.

CODMAN ENTERPRISE 2 VASCULAR RECONSTRUCTION DEVICE

▶ [Decision Summary](#) 

Indication

The Codman Enterprise 2 Vascular Reconstruction Device is intended for use with embolic coils for the treatment of wide-neck, intracranial, saccular or fusiform aneurysms.

EMBOTRAP II REVASCULARIZATION DEVICE

▶ [Decision Summary](#) 

Indication

The Embotrap/Embotrap II Revascularization device is intended to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke within 8 hours of symptom onset.

HELI-FX ENDOANCHOR SYSTEM

▶ [Decision Summary](#) 

Indication

The Heli-FX EndoAnchor System is intended to provide fixation and sealing between endovascular aortic grafts and the native artery. The Heli-FX EndoAnchor System is indicated for use in patients whose endovascular grafts have exhibited migration or endoleak, or are at risk of such complications, in whom augmented radial fixation and/or sealing is required to regain or maintain adequate aneurysm exclusion.

IVASCULAR CAPTURER, THROMBUS EXTRACTION CATHETER

▶ [Decision Summary](#) 

Indication

The iVascular Capturer Thrombus Extraction Catheter is a catheter used to extract fresh thrombus. The thrombus extraction catheter is especially indicated for the removal of fresh, soft emboli and thrombi from the coronary or peripheral vasculature.

NEUROFORM ATLAS STENT SYSTEM

▶ [Decision Summary](#) 

Indication

The Neuroform Atlas Stent System is intended for use with neurovascular embolic coils in patients who are >18 years of age for the treatment of wide neck, intracranial, saccular aneurysms.

OCCLUSIN EMBOLIZATION MICROSPHERES

▶ [Decision Summary](#) 

Indication

Occlusin 500 microspheres are intended to be used for the embolization of target tissues including hypervascular tumours and enlarged prostates due to benign prostatic hypertrophy/hyperplasia.

OPTIMA COIL SYSTEM

▶ [Decision Summary](#) 

Indication

The Optima Coil System is intended for the endovascular embolization of saccular, fusiform, or dissecting; unruptured and/or ruptured intracranial aneurysms, and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The Optima Coil System is also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolizations in the peripheral vasculature.

PHOENIX ATHERECTOMY SYSTEM

▶ [Decision Summary](#) 

Indication

The Phoenix Atherectomy System is intended for use in atherectomy of the peripheral vasculature. The system is not intended for use in the coronary, carotid, iliac or renal vasculature.

PIPELINE FLEX EMBOLIZATION DEVICE WITH SHIELD TECHNOLOGY

▶ [Decision Summary](#) 

Indication

The Pipeline Flex embolization device with Shield Technology is intended for use with or without embolic coils for the treatment of wide neck intracranial aneurysms that are not amenable to treatment with surgical clipping.

PULSAR-18 PERIPHERAL SELF-EXPANDING NITINOL STENT SYSTEM

▶ [Decision Summary](#) 

Indication

The Pulsar-18 Peripheral Self-Expanding Nitinol Stent System is a self-expanding stent system indicated to improve luminal diameter in patients with symptomatic de novo, restenotic or occlusive lesions in the femoral and proximal popliteal arteries.

TIGERTRIEVER REVASCULARIZATION DEVICE

▶ [Decision Summary](#) 

Indication

The Tigertriever is designed for use in flow restoration of patients with ischemic stroke due to large intracranial vessel occlusion. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

WEB ANEURYSM EMBOLIZATION SYSTEM

▶ [Decision Summary](#) 

Indication

The WEB Aneurysm Embolization System is intended for the endovascular embolization of ruptured and unruptured intracranial aneurysms.

WOUND MANAGEMENT

4 NEW MEDICAL DEVICES

CYTAL

▶ [Decision Summary](#) 

Indication

The Cytal device family consist of resorbable, porcine-derived extracellular matrix wound dressings for various indications

ENDOFORM DERMAL TEMPLATE

▶ [Decision Summary](#) 

Indication

Endoform dermal template is indicated for the management of wounds.

MATRIDERM DERMAL MATRIX

▶ [Decision Summary](#) 

Indication

MatriDerm is used in combination with autologous split-thickness skin grafts for the reconstruction of deep dermal defects and full-thickness skin wounds in plastic reconstructive surgery and in the surgical treatment of burns, trauma, and dermatological diseases. It is also used in the treatment of graft-requiring poorly healing wounds.

MICROMATRIX

▶ [Decision Summary](#) 

Indication

MicroMatrix is intended for the management of wounds.

OTHER

SAFETY UPDATES

EasyCare hospital bed:

Health Product InfoWatch: Risk of patient entrapment





HEALTHY CLICKS

MEDICAL DEVICES AT A GLANCE

To stay informed about our activities:



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See the latest news from Health Canada **on our website**
canada.ca/en/health-canada.html



Find other Health-related information on the **Government of Canada website**
canada.ca/en/services/health.html

NEW MEDICAL DEVICES APPROVED

Health Canada **regularly tweets** about new medical devices approved.

It also publishes a **quarterly update** listing the drugs and medical devices that have been authorized during the previous three months.



NEW

Twitter #Drugandmeddevice 
twitter.com/GovCanHealth

The **Medical Devices Active Licences Listing (MDALL)** is a listing of all approvals (licences) issued for medical devices.

Medical Devices Active Licences 
health-products.canada.ca/mdall-limh/

Regulatory Decision Summaries include the purpose of an application for a medical device licence and the reasons for Health Canada's decision to approve or reject it.

Regulatory Decision Summary 
canada.ca/en/health-canada/services/drugs-health-products/drug-products/regulatory-decision-summary.html

Summary Basis of Decision documents give the detailed regulatory, safety, effectiveness and quality considerations that factored into Health Canada's decision to approve certain medical devices.

Summary Basis of Decision 
canada.ca/en/health-canada/services/drugs-health-products/drug-products/summary-basis-decision.html

POST-MARKET SURVEILLANCE OF MEDICAL DEVICES

REPORT AN ADVERSE DRUG REACTION, OR A MEDICAL DEVICE INCIDENT.

You can report adverse drug 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**.

The **Recalls and Safety Alerts Database** includes the recalls, advisories, safety alerts and other publications issued by Health Canada.

Recalls and Safety Alerts Database [↗](#)
healthy Canadians.gc.ca/recall-alert-rappel-avis

New Safety and Effectiveness Reviews are tables listing reviews that are currently ongoing in Health Canada.

New Safety Reviews [↗](#)
canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/safety-reviews/new.html

The **summary tables of advertising complaints** list the complaints about health product advertising that have been filed with Health Canada, and the action we have taken.

Health Product Advertising Complaints [↗](#)
hpr-rps.hres.ca/reg-content/summary-safety-review.php

Summary Safety Reviews summarize our completed reviews of potential safety issues for medical devices.

Summary Safety Reviews [↗](#)
hpr-rps.hres.ca/reg-content/summary-safety-review.php

Health Product InfoWatch is a monthly publication intended primarily for healthcare professionals. The Health Product InfoWatch provides clinically relevant information about health products and their safety.

Health Product InfoWatch [↗](#)
canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/health-product-infowatch.html

NEW The **Medical Devices Incident database** includes suspected medical device incidents reported to Health Canada. These reports have been submitted by consumers and health professionals as well as medical device manufacturers.

Medical Device Incidents [↗](#)
hpr-rps.hres.ca/mdi_landing.php



DRUGS FOR VETERINARY USE

2018 IN BRIEF

New drugs for veterinary use provide more ways to help maintain and improve the health of animals. We evaluate and monitor the safety, quality and effectiveness of veterinary drugs. We set standards, promote the prudent use of veterinary drugs for food-producing and companion animals, and in doing so we work to protect Canada's food supply.

The drugs we regulate range from those that prevent and/or treat serious diseases in animals to veterinary health products for maintaining their health and wellness. Our scientific reviews form the basis of our regulatory work for the drugs we regulate.

In 2018, we made important progress in our key priorities, including:

- taking measures to address antimicrobial resistance
- working with international partners to facilitate the timely access to veterinary drugs in Canada

NEW DRUGS APPROVED

In 2018, we helped make over 1300 veterinary health products available, offering more low-risk options to maintain or promote health and wellness in animals.

We approved 8 new veterinary drugs for companion and food-producing animals. This enabled access to innovative new products and therapies to help manage the health and wellness of animals. We also approved 7 new generic veterinary drugs to provide additional options for more cost effective prevention and treatment.

For a list and description of the new drugs we approved in 2018, go to [“Drugs for Veterinary Use: Approved in 2018”](#).

CLINICAL TRIALS AND EMERGENCY DRUG RELEASE PROGRAMME

We approve applications to allow companies and researchers to conduct clinical trials on veterinary drugs in Canada. New veterinary drug trials mean access to new products in the future. In 2018, 86 new Experimental Studies Certificates that support clinical trials or research activities were authorized.

Our Emergency Drug Release Programme grants access to drugs for veterinary use that have not yet been approved for sale in Canada. The Programme provides a pathway for veterinarians to request otherwise unavailable treatments. Access to unapproved drugs for veterinary use may be granted in the case of a medical emergency in an animal under a veterinarian's care. In 2018, 644 requests under the Emergency Drug Release program were authorized.

MONITORING DRUGS AFTER APPROVALS

Once drugs are available in Canada, Health Canada continues to monitor and evaluate reports of suspected adverse veterinary drug reactions. It is not possible to know or predict all of the possible adverse reactions to a veterinary drug through clinical studies at the time of market approval.

For the first time, drugs for veterinary use have been incorporated as part of the Highlights report. This “Drugs for Veterinary Use” section of the report provides more information about our activities in 2018. You’ll find an overview of the progress we made in 2018 on our key priorities. You will learn about the product life cycle of a veterinary drug and our role in ensuring the benefits of a drug outweigh the potential risks while safeguarding food safety. You will also find details about the new veterinary drugs we approved in 2018. Please also take a look at the new “Healthy clicks” section, to follow up-to-date information on our activities.



Mary-Jane Ireland

Director General,
Veterinary Drugs,
Health Canada

A handwritten signature in blue ink that reads "Mary-Jane Ireland".





DRUGS FOR VETERINARY USE

2018 ACCOMPLISHMENTS

ADDRESSING ANTIMICROBIAL RESISTANCE RELATED TO ANIMALS

Using antimicrobials in animals can affect the way that humans and animals respond to treatment

Antibiotics are used in animals to prevent and/or treat diseases. A large portion of the antibiotics used in Canada are used in food producing animals.

Bacteria, viruses, fungi and parasites can resist antimicrobials, such as antibiotics and antivirals, that are used to treat people and animals who are sick. This is known as antimicrobial resistance (AMR). The impact of AMR on human and animal health is a concern in Canada and around the world.

In animals, antimicrobial use contributes to the development and spread of resistant bacteria. These bacteria can be transferred to humans through the food we eat (animal products) and through direct contact.

Taking action to address antimicrobial resistance

Effective December 2018, many antimicrobials used in animals that were once available ‘over-the-counter’ (that is, without a prescription) became available only by prescription. Supervision by a licensed veterinarian in treatment decisions is an important part of antimicrobial oversight. For more information, go to [Responsible use of medically important antimicrobials in animals](#).

Understanding the number and kind of antimicrobials available for use in animals helps us better understand patterns and trends in antimicrobial resistance in bacteria of concern. Companies that manufacture, import and compound these antimicrobials for veterinary use now need to report the sales of medically important antimicrobials every year to Health Canada. To help companies report, we launched an online sales reporting tool. For more information, go to [Veterinary antimicrobial sales reporting](#).

We have increased the oversight of active ingredients in products for veterinary use, to continue to ensure they are made with strict quality and safety standards. Go to [Oversight on the quality of active pharmaceutical ingredients for veterinary use in Canada](#) for more information.

We also participate in international groups that help further our work on AMR, such as [Codex Alimentarius](#).

Our work to promote effective stewardship of veterinary antimicrobials is part of the **Federal Action Plan on Antimicrobial Resistance and Use in Canada** and the **Pan-Canadian Framework for Action on Tackling Antimicrobial Resistance and Antimicrobial Use**.

To learn about antimicrobial resistance related to humans, go to: “**Drugs for Human Use: 2018 Accomplishments**”.

PROVIDING MORE CHOICES TO IMPROVE ANIMAL HEALTH AND WELLNESS

We have helped make over 1300 veterinary health products available, offering more low-risk options to maintain or promote the health and wellness in animals. Veterinary health products include ingredients such as vitamins, minerals, and traditional medicines. Keeping animals healthy can reduce the reliance on drugs like antimicrobials.

We developed the Veterinary Health Products Notification Program which enables timely access to veterinary health products which are used to maintain and/or improve the health of companion and food-producing animals. For more information, go to **Veterinary Health Products**.

Many animal owners are looking for more options such as probiotics to improve animal health and reduce the need for antimicrobials. Known as ‘viable microbial products’, these are fed to livestock to improve digestion and production, to promote general health, and to treat or prevent certain conditions or diseases. We have worked with the Canadian Food Inspection Agency (CFIA) and stakeholders to clarify the process to bring these products to market with the appropriate oversight in order to make them more available as part of plans to manage overall health of animals. For more information, go to **Viable Microbial Products**.

To help dairy farmers improve the health of their cattle, we have also implemented a faster approval process for antiseptic teat solutions. These are used by dairy farmers to help reduce the spread of organisms which may cause mastitis in dairy cattle. This new process provides dairy farmers with more product options, more quickly. For more information, go to the **Antiseptic Teat Solutions Monograph**.

COLLABORATING INTERNATIONALLY

We participate actively in several important international initiatives. Collaboration with our trusted international partners:

- contributes to important public health objectives
- promotes regulation harmonization
- encourages innovation
- ultimately improves simultaneous access to safe and effective veterinary drugs around the world

International organizations allow regulators to share best practices, discuss emerging challenges, and set standards. For example, Health Canada is an observer of the **International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH)**. Through the VICH, scientific experts from around the world work together to develop guidelines that help regulators ensure that veterinary drugs are safe, effective, and of high quality.

Health Canada also participates in setting international standards for veterinary drug residues in foods under the **Codex Alimentarius** via the Codex Committee on Veterinary Drugs Residues in Foods.

For more information, go to **[Veterinary drugs – International collaboration](#)**.





DRUGS FOR VETERINARY USE

DRUG LIFE CYCLE

Every year, we approve new veterinary drugs in Canada, giving more choices to help maintain and improve the health and well-being of animals. We work to protect human and animal health and the safety of Canada's food supply.

As part of our work to protect human and animal health and the safety of Canada's food supply, we evaluate veterinary drugs before and after they reach the Canadian market. Throughout the life cycle of a drug for veterinary use, we evaluate:

- applications for clinical trials
- applications for emergency drug release
- submissions to sell the drug in Canada

Once a drug is approved for sale in Canada, we continue to monitor its safety in the real world.

CLINICAL TRIALS

Experimental studies certificates for veterinary drugs and investigational new drug applications support the development of potential new veterinary drugs or new uses of already approved products, to meet the needs of food-producing and companion animals.

Sponsors of clinical trials (including manufacturers and researchers) submit their applications to conduct a trial with a veterinary drug in Canada. We review these applications and decide whether to issue an approval for the drug to be used in the trial.

In 2018, Health Canada authorized 86 new experimental studies certificate applications for veterinary drugs.

EMERGENCY DRUG RELEASE PROGRAM

Drugs that are not approved in Canada may be available through our Emergency Drug Release program.

The **Emergency Drug Release program** provides access to veterinary drugs for the purpose of diagnosing or treating a medical emergency. Animals receiving drugs through this program must be under the care of a veterinarian.

In 2018, Health Canada authorized 644 requests for emergency veterinary drug access.

DRUG SUBMISSION AND REVIEW

When a company decides that it would like to market a veterinary drug in Canada, it files an application to us. A new drug submission contains detailed scientific information about the drug's safety, effectiveness and quality.

Submissions for drugs are reviewed by our scientists to assess the potential benefits and risks to human and animal health. They also help to ensure veterinary drug labels have clear directions for use and warning statements.

Many veterinary drugs are intended for use in food-producing animals such as cattle, chickens and pigs. We work to ensure the safety of food that comes from animals treated with veterinary drugs. We do this by setting standards such as Maximum Residue Limits for veterinary drugs in foods, and establishing withdrawal periods.

Different classes of drug submissions have different target times for Health Canada to complete its review. The **Management of Regulatory Submissions guidance document** provides detailed information about the timelines and processes for the review of drug submissions for veterinary use.

INNOVATIVE REVIEWS (INTERNATIONAL REGULATORY COOPERATION)

Through international regulatory cooperation, we conduct reviews of veterinary drug submissions with trusted partners such as the United States Food and Drug Administration's Center for Veterinary Medicines, the Australian Pesticides and Veterinary Medicines Authority, and the New Zealand Ministry of Primary Industries.

These collaborative reviews bring veterinary drugs to market in Canada at the same time as in other countries, which would otherwise not be possible. As a result, companion animal owners, veterinarians and producers have faster access to safe, effective and quality veterinary drugs, and Canadian food producers remain competitive globally.

In 2018, 22 veterinary drugs were under review through a regulatory cooperation with an international partner. By the end of 2018, eight veterinary drugs have been approved simultaneously and we continue to explore more opportunities to improve and expand this important initiative.

APPROVAL OF VETERINARY DRUGS

After its review of a drug submission, Health Canada may conclude that the benefits of the product outweigh the potential risks and approve the veterinary drug for sale in Canada. When a new veterinary drug is approved, it is issued a Notice of Compliance (NOC) and a Drug Identification Number (DIN).

This does not mean the drug will immediately be available in Canada, as many other factors can influence that timeline.

In 2018, Health Canada approved 8 new veterinary drugs and 7 new generic drugs. We also helped make over 1300 veterinary health products available.

For a list of what was approved in 2018, go to [“Drugs for Veterinary Use: Approved in 2018”](#).

POST-MARKET SURVEILLANCE

After Health Canada approves a veterinary drug, we continue to monitor its use in the real world. We call this ‘post-market surveillance’. We evaluate potential safety and effectiveness issues, and take action when there are identified problems.

COLLECTING INFORMATION

Health Canada collects post-market information (that is, information collected about a product after it is approved) from a variety of sources.

One source of information for Health Canada is suspected adverse events that are reported after products are approved for sale. Adverse events are unwanted or harmful events that occur after administration of a veterinary drug. Included are:

- adverse reactions or events in animals
- adverse reactions or events in humans involved in administering a veterinary drug to an animal
- events that result from a suspected lack of effect

EVALUATING SAFETY SIGNALS

We evaluate adverse event reports submitted by manufacturers and the public (including animal owners and veterinarians), to find out if they are related to the administered drug(s). We work with manufacturers and veterinarians to ensure that any important safety information is communicated.

You can [report a veterinary drug adverse reaction](#) to Health Canada.



DRUGS FOR VETERINARY USE APPROVED IN 2018

You can **report a veterinary drug adverse reaction** to Health Canada.

IMPORTANT DEFINITIONS

Generic drugs

A copy of a brand name product. Generic drugs contain the same medicinal ingredients as the brand name drug and are considered equivalent to the brand name drug. There may be many generic versions of one brand name drug.



Innovative Review (International Regulatory Cooperation)

Through international regulatory cooperation, we conduct reviews of veterinary drug submissions in collaboration with trusted partners such as the United States Food and Drug Administration's Center for Veterinary Medicines, the Australian Pesticides and Veterinary Medicines Authority, and the New Zealand Ministry of Primary Industries.

New drugs

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



New active substance

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 for veterinary use.

8 NEW DRUGS

CLARO

Medicinal Ingredient

Florfenicol, mometasone furoate, terbinafine hydrochloride

Indication

For the treatment of ear infections in dogs.

EUTHANSOL-D

Medicinal Ingredient

Pentobarbital sodium, phenytoin sodium

Indication

For the humane euthanasia of animals.

EXPERIOR



Medicinal Ingredient

Lubabegron

Indication

To lower ammonia emissions from beef cattle.

FORCYL

Medicinal Ingredient

Marbofloxacin

Indication

For the treatment of respiratory infection in cattle.

NEXGARD SPECTRA

Medicinal Ingredient

Afoxolaner, milbemycin oxime

Indication

For the treatment and control of internal and external parasites in dogs.

OCEANBLU

Medicinal Ingredient

Glycolic acid

Indication

An antiseptic teat dip for dairy cows.

RACTOPAMINE 4

Medicinal Ingredient

Ractopamine hydrochloride

Indication

For increased carcass leanness and improved weight gain in beef cattle.

REVOLUTION PLUS



Medicinal Ingredient

Sarolaner, selamectin

Indication

For the treatment and control internal and external parasite in cats.

7 NEW GENERIC DRUGS

Health Canada approved 7 new generic drugs for veterinary use:

- ▶ 1 product containing dexmedetomidine hydrochloride
- ▶ 1 product containing dinoprost tromethamine
- ▶ 1 product containing enrofloxacin
- ▶ 1 product containing halofuginone lactate
- ▶ 1 product containing meloxicam
- ▶ 1 product containing ractopamine hydrochloride
- ▶ 1 product containing tilimicosin phosphate



HEALTHY CLICKS

DRUGS FOR VETERINARY USE AT A GLANCE

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canada.ca/en/health-canada.html



Find other Health-related information on
the **Government of Canada website**
canada.ca/en/services/health.html

NEW DRUGS APPROVED

The **Drug Product Database** is a listing of all drugs approved for sale in Canada. In the database, many drugs are accompanied by their veterinary labelling, which describe the conditions of use of the product.

Drug Product Database 
twitter.com/GovCanHealth

The **Notice of Compliance database** lists the approvals (Notices of Compliance or NOCs) issued for new drugs.

Notice of Compliance database 
health-products.canada.ca/noc-ac/

POST-MARKET SURVEILLANCE OF VETERINARY DRUGS

REPORT A VETERINARY DRUG ADVERSE REACTION.

Adverse veterinary drug reactions 
canada.ca/en/health-canada/services/drugs-health-products/veterinary-drugs/adverse-drug-reactions-adrs.html

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