



# DRUG AND MEDICAL DEVICE HIGHLIGHTS

Helping you maintain and improve your health

# 2020



Health  
Canada

Santé  
Canada

Canada







# DRUG AND MEDICAL DEVICE HIGHLIGHTS

# 2020

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Helping you maintain and  
improve your health

Health Canada helps Canadians maintain and improve their health by providing timely access to safe and effective drugs and medical devices. Learn about the new drugs and medical devices that Health Canada approved for sale in Canada, the information we published about these products, and our other accomplishments in 2020.



**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.

Également disponible en français sous le titre :

*Faits saillants de 2020 sur les médicaments et les instruments médicaux : Pour maintenir et améliorer votre santé*

To obtain additional information, please contact:

Health Canada  
Address Locator 0900C2  
Ottawa, ON K1A 0K9

Tel.: 613-957-2991  
Toll free: 1-866-225-0709  
Fax: 613-941-5366

TTY: 1-800-465-7735  
E-mail: [publications@hc-sc.gc.ca](mailto:publications@hc-sc.gc.ca)

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Publication date: July 2021

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Cat.: H161-11E-PDF  
ISSN: 2562-9816  
Pub.: 210031



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# WELCOME TO OUR 2020 HIGHLIGHTS REPORT

We have witnessed unprecedented challenges this year, following the outbreak of COVID-19. In addition to our core responsibilities, our response to the pandemic defined much of our work in 2020.

Health Canada worked closely with stakeholders and government partners to understand and address the challenges faced by the health care system and communities across the country. We collaborated with regulators from other countries as well as international organizations to align our approach with the global response to COVID-19. We mobilized to respond to the areas of greatest priority for drugs and medical devices, as well as for disinfectants and hand sanitizers.

Of course, our core responsibilities did not stop with the pandemic. We continued to approve medical devices along with drugs for human and veterinary use, to ensure that Canadians had access to these important products. Further, we continued our work on priority projects, such as the Medical Devices Action Plan, our new Pediatric Drug Action Plan and addressing antimicrobial resistance.

This report describes the new drugs and medical devices that Health Canada approved for sale in Canada, the information we published about these products and our other accomplishments. It also provides insight into our response to the pandemic, including our role in expediting the review of needed health products and medical devices that test for, treat and prevent COVID-19.

As with previous years, the Highlights report is divided into three chapters: drugs for human use, medical devices and drugs for veterinary use. We have continued our “Focus on...” features, which provide a closer look into our priorities in 2020. In each chapter, we begin with a discussion of our response to the COVID-19 pandemic and then address other priorities.

For the most up-to-date information on our activities, see the “Healthy Clicks” sections. We also invite you to follow [@GovCanHealth](#) and [@CDNMinHealth](#) on Twitter to learn about newly approved drugs and medical devices.



Pierre Sabourin

Assistant Deputy  
Minister

A blue ink signature of Pierre Sabourin.



Manon Bombardier

Associate Assistant  
Deputy Minister

A blue ink signature of Manon Bombardier.





## RESPONDING TO THE COVID-19 PANDEMIC

At the onset of the pandemic, there was an urgent need for safe and effective health products and medical devices that would help limit the spread of the novel coronavirus.

Health Canada quickly reached out to our stakeholders and worked with our international partners. We put in place a regulatory approach that focused on flexibility, while maintaining safety and efficacy of regulated products for COVID-19.

### **Communications**

Throughout the pandemic, we engaged our stakeholders to better support access to health products for COVID-19. Our discussions focused on potential health product solutions, and collaborating with other government departments to address challenges in getting COVID-19 products to market.

We worked quickly to support businesses that were eager to mobilize needed products. We provided guidance and advice on regulatory requirements, and enhanced the information on our websites.

We also helped equip health care professionals and Canadians with information about the products we approved. This includes a new portal with information about the vaccines and treatments for COVID-19.

### **Collaborations**

The pandemic prompted an unprecedented level of collaboration among the regulatory community around the world. We worked with other regulators to align our regulatory response, coordinating our strategies and guidance.

We also worked with key regulatory partners to share information and expertise on the review and monitoring of COVID-19 health products.

### **COVID-19 health products**

In responding to the pandemic, we focussed on allowing flexibility without compromising our standards for safety, efficacy and quality. We put in place measures to prioritize and help expedite the review of:

- disinfectants and hand sanitizers,
- medical devices, such as ventilators, testing devices and personal protective equipment (PPE), and
- vaccines and treatments.

Central to this response were five Interim Orders. An interim order is one of the fastest regulatory tools available to help address large-scale public health emergencies. The Interim Orders helped to:

- facilitate the conduct of clinical trials and broaden access for trial participants,
- establish temporary approval pathways to expedite the review of medical devices and drugs,
- allow exceptional importation of drugs, medical devices or foods for a special dietary purpose, and
- provide additional tools to help prevent and alleviate shortages of drugs and medical devices that may have been caused or worsened by the COVID-19 pandemic.

Additional measures and guidance helped to support industry in meeting the incredible demand for health products.

In 2020 we approved the following for use in COVID-19:

- over 4,400 hand sanitizer products,
- approximately 200 disinfectants,
- 545 medical devices,
- 81 clinical trials for drugs and 18 for medical devices,
- 2 drug treatments, and
- 2 vaccines.

We will continue to monitor the safety and effectiveness of these and any additional vaccines, and all other COVID-19-related products.

These remain extraordinary times. Moving forward, we will leverage the insights learned from the pandemic response to inform future approaches to regulation that promote agility, innovation and safety, while continuing to work with our partners to provide the health products and information that Canadians need.



## Focus on... OUR TEAM

It takes a team to regulate the products that are profiled in the 2020 Drug and Medical Device Highlights report. For example, biologists, chemists, biostatisticians, medical doctors, veterinarians, engineers, economists and regulatory officers play a key role in the various steps in our regulatory processes. They are supported by administrative and human resource officers, policy and business analysts, scientific writers, lawyers and students within our workforce.

*“Our team is highly skilled, professional and dedicated to their work. In 2020 we tackled unprecedented issues and enormous workloads, all while maintaining our connections in a virtual environment. I would like to sincerely thank our employees for their extraordinary work this year, under such unique and challenging circumstances.”*

**Pierre Sabourin**  
Assistant Deputy Minister



## MESSAGE FROM THE CHIEF MEDICAL ADVISOR

This past year brought much attention to the role Health Canada plays as an integral part of the health care system. Whether it was for health products such as diagnostic tests for COVID-19, or reviews of new vaccines, the rapid pace of science innovation highlighted the key gatekeeper function of the department. Many people became aware of a regulatory system that had otherwise functioned quietly in the background, assuring that the health products they needed were diligently reviewed and met the high standards for safety, efficacy and quality that underpin all authorization decisions.

Being open and transparent brought into focus the importance of having an independent regulator that based decisions solely on science and evidence, while being flexible and agile to respond to the public health crisis that faced us all. There was interest in the details of the review processes, the competencies and experience of reviewers, the volumes of data that are assessed prior to decisions being made, and the critical role of balancing benefits, risks and uncertainties. Areas such as international cooperation and collaboration were brought to the fore as essential in coming up against a global pandemic.

All of this was in service of ensuring that people could have faith and confidence in the regulatory role and they could be assured that those who were making those decisions genuinely had “been training their whole lives for this”.

As challenging as the previous year was, one benefit has been this greater understanding of the importance of being able to equip oneself with information from trusted sources to empower people to be able to make the best decisions for their own health and wellbeing. This is as true in “non-pandemic” times as it is now.

The collective challenge to all of us is to continue this sharing of information, innovative practices, and engagement as we go forward.



Supriya Sharma  
Chief Medical Advisor

A stylized, handwritten signature in blue ink, consisting of a series of loops and a long horizontal stroke.

# MESSAGE FROM THE CHIEF REGULATORY OFFICER

The COVID-19 pandemic has led to the implementation of a series of extraordinary regulatory measures. These have provided Health Canada with the flexibilities we needed to respond effectively and efficiently to the crisis.

In March, Health Canada was part of the Government's **COVID-19 Emergency Response Act**. This legislation was enacted to stabilize the Canadian economy and protect Canadians' health and safety. Among other components, the Act gave the Government the authority to make regulations to help prevent or alleviate shortages of drugs and medical devices. This helped facilitate access for Canadians to supplies of drugs and medical devices, including personal protective equipment, that were needed to address the public health emergency.

Health Canada also put in place five Interim Orders to respond to the urgent need for access to health products as a result of the COVID-19 pandemic. An interim order is one of the fastest mechanisms available to the federal government to help address larger-scale public health emergencies.

- The **Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19** ensured that medical devices that are integral to the diagnosis, treatment, mitigation or prevention of COVID-19 could be quickly authorized for sale or importation while maintaining high scientific standards. It allowed Health Canada to impose terms and conditions on the authorization of a medical device under the Interim Order, so that we could act quickly to collect information or take action to mitigate risks associated with a product.
- The **Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in Relation to COVID-19** allowed the Minister to permit the exceptional importation and sale of drugs and medical devices experiencing a shortage in Canada that were approved in other countries with comparable approval systems. Additionally, the Interim Order introduced a mandatory mechanism for the Minister to be notified of shortages of critical medical devices.

Finally, the Interim Order allowed for the expedited authorization of hard surface disinfectants and hand sanitizers.

- The **Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19** allowed the authorization process for COVID-19-related clinical trials to be more efficient and flexible, without compromising the safety of participants or the reliability of trials' findings. This flexibility also facilitated broader patient participation across the country by allowing a wider range of health professionals or investigators to be involved in carrying out clinical trials. For example, the Interim Order allowed for remote patient consent; this was not only critical during the pandemic but in the future it could become a policy to help patients participate in clinical trials from more remote communities.
- The **Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19** introduced expedited authorization pathways for the importation, sale and advertising of drugs (human and veterinary) used in relation to COVID-19. The Interim Order established expedited processes including rolling submissions, where companies provide data to Health Canada as it becomes available. Companies must continue to demonstrate that their drugs (including vaccines) are safe, effective and of high quality. Health Canada can impose terms and conditions on the authorization of a drug, allowing us to act quickly to gather important safety information or mitigate risk.
- The **Interim Order on Preventing and Alleviating Drug Shortages in Relation to COVID-19** provided Health Canada with more tools to urgently address drug shortages related to COVID-19. This authority will help safeguard Canada's drug supply and ensure that Canadians have access to the medicines they need.

In 2020 we also **finalized changes to the Food and Drug Regulations** to modernize the Special Access Program for human drugs, and the Emergency Drug

Release program for drugs for veterinary use. These changes improved the processes used by health care providers and reduced the administrative burden for requests to access drugs that are not yet authorized for sale in Canada, for COVID-19 and other medical emergencies.

In order to appropriately implement a life-cycle approach for medical devices, Health Canada required additional authorities to monitor devices once they are on the market. **Vanessa's Law** amended the *Food and Drugs Act* to strengthen our ability to collect post-market safety information and take appropriate action when needed. In 2020 we published **regulations relating to the post-market surveillance of medical devices**, which implemented certain provisions of Vanessa's Law and additional measures to improve post-market surveillance. Together these efforts have helped to reduce the risk of medical devices and improve their safety, quality and effectiveness.

Our regulatory work in 2020 has focused primarily on Health Canada's urgent response to the COVID-19 pandemic. We will continue our work to maintain the

flexibilities and regulatory oversight provided by the Interim Orders until at least the fall of 2021. By then, Health Canada intends to bring forward regulatory amendments that would allow for the transition of products already authorized so that they can continue to be sold.

Moving forward, we will turn our attention back to the activities we had previously planned, related to regulatory innovation. We will continue to build on the lessons learned from our regulatory response to COVID-19 to shape our new, agile regulatory frameworks.



David K. Lee  
Chief Regulatory Officer

A blue ink signature of David K. Lee, written in a cursive style.

## Focus on... ADVANCING OUR POLICY AND REGULATORY AGENDA

At the core of our mandate is a set of legislative and regulatory frameworks that allow Health Canada to maintain high safety, quality, and efficacy standards for drugs and medical devices. We are dedicated to transforming our regulations to become more agile, transparent, and aligned with our counterparts in other countries.

Our strong relationships with partners and stakeholders help us advance our policy and regulatory agenda. We provide leadership and strategic advice in addressing emerging issues, collaborate with international counterparts, and communicate priorities and plans to Canadians,

Parliamentarians and stakeholders.

The foresight activities we conduct will also help inform agile approaches to regulation that support innovation and safety. Stakeholder forums and scientific advisory committees help strengthen our evidence-based policy development and decision making, and help maintain our strong commitment to transparency.

To learn more about our future regulatory initiatives, go to [Health Canada's Forward Regulatory Plan for 2021-23](#).

**Ed Morgan**  
Director General, Policy,  
Planning and International  
Affairs



## Focus on... ENSURING A PROPERLY FUNDED AND TRANSPARENT REGULATORY SYSTEM

Following extensive consultation with stakeholders, Health Canada successfully implemented our new cost recovery regime on April 1, 2020 using the new authorities we received in 2017.

The new regime allowed us to better align with the fees charged by other regulators such as the European Medicines Agency and the United States Food and Drug Administration for the delivery of similar regulatory services, for activities like the scientific review of new drugs and medical devices. The new regime also introduced a small business strategy to reduce barriers to innovation by providing fee relief to qualifying businesses, and waiving fees for publicly-funded health care institutions.

The new authorities used to implement the new regime allow us to set and adjust fees in a timely and flexible manner, to respond to regulatory challenges. For example, we were able to swiftly waive fees for the scientific review of COVID-19 drugs and medical

devices filed under the interim orders, to better respond to the public health emergency.

In 2020, we also continued to make great strides in openness and transparency. Although we just began to publish clinical information about safety and efficacy of drugs and medical devices in 2019, we published over 124 packages in just two years of operation, containing over 2.5 million pages of clinical information. The value of this initiative was also demonstrated in the context of the pandemic, when we published clinical data for nine COVID-related drugs and medical devices. Three of these were published as a result of a close working relationship with the European Medicines Agency.

To learn more about these initiatives please visit the following pages: [Funding and Fees](#) and [Clinical Information on Drugs and Health Products](#).

**Etienne Quimette**  
Director General,  
Resource Management  
and Operations







## DRUGS FOR HUMAN USE 2020 IN BRIEF

One of Health Canada's roles is to regulate drugs that can help Canadians maintain and improve their health. These include prescription and non-prescription ("over-the-counter") medicines, as well as vaccines.

The COVID-19 pandemic created an urgent need for access to safe, effective and high quality health products. Our response to the pandemic addressed critical issues related to drugs, as well as disinfectants and hand sanitizers, across product life-cycles.

### RESPONSE TO THE COVID-19 PANDEMIC

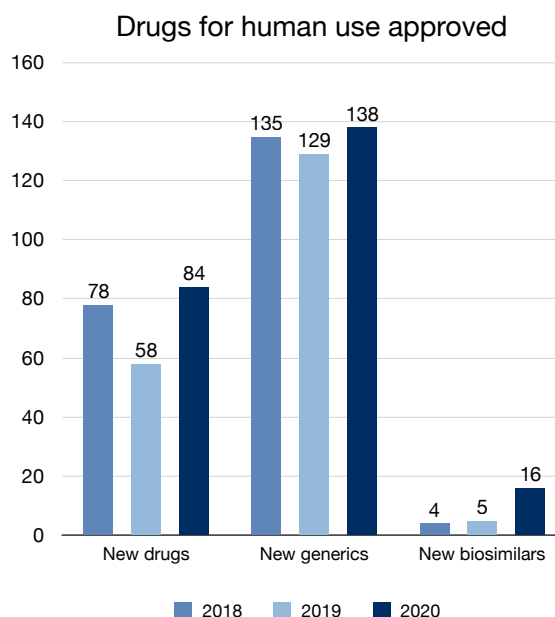
As part of the government's response to the pandemic, we introduced innovative and agile regulatory measures. These measures expedited the regulatory review of COVID-19 health products without compromising safety, efficacy and quality standards.

In 2020 we authorized 81 clinical trials related to drugs or vaccines for COVID-19. As a result of the pandemic, hundreds of clinical trials had to be amended in order to avoid contracting the infection through visits at trial sites. These amendments allowed for remote consent and visits, telemedicine, and different ways of dispensing and administering trial drugs. The pandemic also allowed for the decentralization of some clinical trials.

We approved two drugs to treat COVID-19, Veklury (remdesivir) and Bamlanivimab. We approved two vaccines, the Pfizer-BioNTech COVID-19 Vaccine and the COVID-19 Vaccine Moderna. As of December 31, 2020, two other vaccines and one other treatment were [under review](#). We monitored the safety and effectiveness of health products related to COVID-19, and took action as needed. We also created the [COVID-19 vaccines and treatments portal](#), which provides up-to-date information for consumers, health care professionals and researchers.

The regulation of hand sanitizers and disinfectants was an important part of our response to the COVID-19 pandemic. In 2020 we authorized over 4,400 new hand sanitizer products and approximately 200 new disinfectants.

For more information about our response to the COVID-19 pandemic, go to "[Drugs for human use: 2020 accomplishments](#)".



### NEW DRUGS APPROVED

In 2020 we approved 84 new drugs, including three new drugs (one treatment and two vaccines) that were authorized under the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19. These give patients more options for the treatment, prevention and diagnosis of various health conditions.

Forty of the new drugs we approved in 2020 contained medicinal ingredients that have never been approved for sale in Canada, what we call "new active substances". Forty-two percent of these were approved through an expedited pathway, including those that target specific health care needs. For example, Zolgensma is a one-time gene therapy for the treatment of spinal muscular atrophy. This is a rare disease and a leading genetic cause of infant mortality, for which few therapies exist. In addition, Givlaari was approved for the treatment of acute hepatic porphyria, a rare inherited disease.

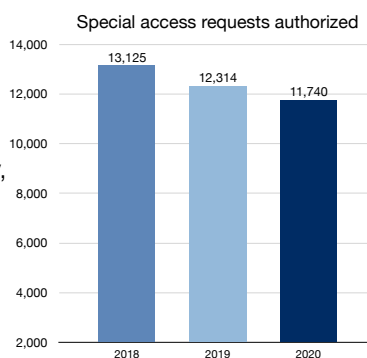
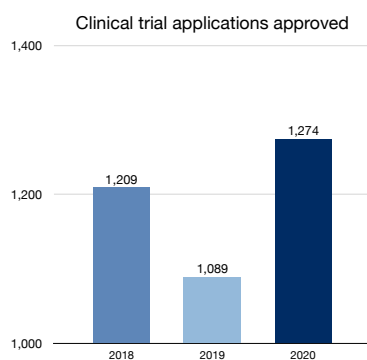
It is also important to bring more choice and more affordable options to Canadians. We approved 138 new generic drugs and 16 new biosimilars in 2020. Generic drugs contain the same medicinal ingredients as the brand name drug, and are considered bioequivalent to the brand name drug. Biosimilars are biologic drugs that enter the market subsequent to a previously authorized drug in Canada with a demonstrated similarity to the previously authorized biologic drug. One of the new drugs (Sani-Cide EX3) and two of the generic drugs (clotrimazole and loperamide) we approved in 2020 were for non-prescription (“over-the-counter”) use.

For a list and description of the new drugs we approved in 2020, go to [“Drugs for human use: Approved in 2020”](#).

## CLINICAL TRIALS AND SPECIAL ACCESS PROGRAM

We review applications to allow companies and researchers to conduct clinical trials in Canada. New clinical trials mean Canadians may have access to more innovative treatment options. In 2020, 1,274 new clinical trial applications for drugs were approved.

Through our Special Access Program, we give access to drugs that are not available for sale in Canada. We may grant access to doctors for emergency use or for the treatment of serious or life-threatening conditions. In 2020, 11,740 requests for special access to drugs were authorized. This included an array of drugs for infections, epilepsy, cancer and rare diseases. In 2020 etomidate, a drug that had been available through



the program for more than 20 years, received market authorization and was transitioned from the Special Access Program to the market.

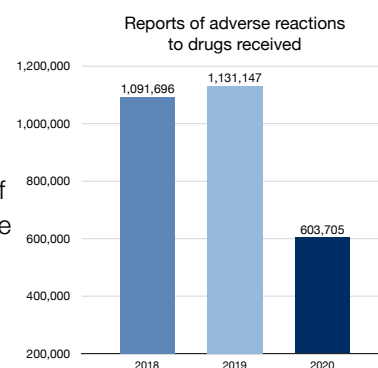
## SURVEILLANCE

After we approve a drug for sale in Canada, we continue to monitor and evaluate reports of suspected adverse reactions.

In 2020 we received 603,705 reports of adverse

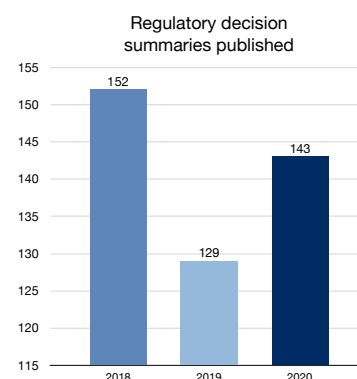
reactions to drugs for human use and undertook 1,034 actions related to drugs. Adverse drug reactions come from domestic and international sources. Actions can include informing the public and health care professionals of safety information or recommending labelling changes. In cases where a serious risk is identified, we may remove a drug from the market.

To learn how we addressed safety issues that arose for drugs in Canada in 2020, go to [“Drugs for human use: Approved in 2020”](#).



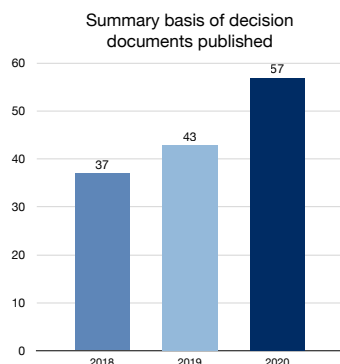
## TRANSPARENCY OF DECISION MAKING

In 2020 we continued to advance our openness and transparency efforts by expanding the amount of regulatory health and safety information that is made available to Canadians. We published 143 [regulatory decision summaries](#) and 57 [summary basis of decision documents](#), which explain Health Canada’s decisions for certain drugs seeking market authorization.





Through our “**Clinical Information Portal**”, we published 2,185,079 pages of clinical information on 79 drugs. This clinical information is provided by companies when they seek approval to sell a drug in Canada, and is made publicly available after we decide to approve or reject the drug.



Health Canada also publishes **summaries of its safety reviews**, which describe Health Canada’s decisions related to potential safety issues. In 2020 we published 19 such summaries for human drugs. These summaries complement other safety-related information to help Canadians make informed decisions about their medication choices.

This “Drugs for Human Use” chapter gives you more information about our work in 2020. For up-to-date information about our activities see the “**Healthy clicks – Drugs for human use at a glance**” section, and follow us on social media.



**John Patrick Stewart**  
Director General,  
Therapeutic Products



**Celia Lourenco**  
Director General,  
Biologic and  
Radiopharmaceutical Drugs



**Robin Churchill**  
Director General,  
Natural and Non-Prescription  
Health Products



**Kelly Robinson**  
Director General,  
Marketed Health Products



# DRUGS FOR HUMAN USE: WHAT'S NEW IN 2020

In 2020 Health Canada approved 84 new drugs, including 16 new biosimilars. More detail is available in the section “Drugs for Human Use: Approved in 2020”.

## Alimentary tract and metabolism

- Givlaari
- Ibsrela
- Mar-Trientine
- Rybelsus
- Trurapi\*
- Uceris

## Antiinfectives for systemic use

- Amoxicillin Sodium and Potassium Clavulanate for Injection
- Anthim
- Bamlanivimab
- Cabenuva / Vocabria
- COVID-19 Vaccine Moderna
- Menquadfi
- Pfizer BioNTech COVID-19 Vaccine
- Veklury
- Vocarvi
- Xenlata
- Xofluza

## Antineoplastic and immunomodulating agents

- Amgevita\*
- Avsola\*
- Daurismo
- Enspryng
- Gleolan
- Hulio\*
- Hyrimoz\*
- Idacio\*
- Inqovi
- Inrebic
- Kanjinti\*
- Mayzent
- Nivestym\*
- Nubeqa
- Nyvepria\*
- Odomzo
- Piqray

## Antineoplastic and immunomodulating agents (cont.)

- Polivy
- Qinlock
- Riximyo\*
- Rozlytrek (two submissions)
- Ruxience\*
- Sarclisa
- Tukysa
- Verity-BCG
- Zeposia
- Ziextenzo\*

## Blood and blood forming organs

- Addnutriv
- Bivalirudin Injection
- Cablivi
- Essepna
- Inclunox, Inclunox HP\*
- Noromby, Noromby HP\*
- Reblozyl
- Redesca, Redesca HP\*
- Regiocit
- Tavalisse

## Cardiovascular system

- Corzyna

## Dermatologicals

- Duobrii
- Teva-Betamethasone/Calcipotriol

## Genito urinary system and sex hormones

- Bijuva
- Imvexxy
- Nexplanon

## Musculo-skeletal system

- Zolgensma

## Nervous system

- Ajovy
- Dayvigo
- Firdapse
- Kynmobi
- Perseris
- Peyona
- Ruzurgi
- Spravato
- Suvexx
- Tomvi
- Vyndaquel

## Respiratory system

- Ateectura Breezhaler
- Enerzair Breezhaler

## Sensory organs

- Beovu
- Luxturna

## Systemic hormonal preparations, excluding sex hormones and insulins

- Increlex
- Osnuvo\*
- Tirosint

## Various

- Galliapharm
- Itulatek
- Sani-Cide EX3
- Sodium Pertechnetate <sup>99m</sup>Tc Injection

\* New biosimilar



# DRUGS FOR HUMAN USE: 2020 ACCOMPLISHMENTS

## RESPONDING TO THE COVID-19 PANDEMIC

The COVID-19 pandemic has had a profound impact on the health and well-being of Canadians. It has created an unprecedented demand on Canada's health care system and has led to an urgent need for access to health products.

Health Canada's response to the pandemic addressed critical issues related to drugs for human use across product life-cycles, from clinical trials to authorizations of drugs to surveillance.

### Clinical trials

In May 2020, the Minister of Health signed the [Interim Order Respecting Clinical Trials for Medical Devices and Drugs related to COVID-19](#).

This temporary measure facilitated a more efficient and flexible authorization process for clinical trials in Canada, allowing broader types of COVID-19 clinical trials to take place more efficiently. It offered greater patient access to potential COVID-19 drugs, while upholding strong patient safety requirements.

In addition, we expedited the authorization of trials for COVID-19 and published a [Notice on the management of clinical trials during the pandemic](#). Applications were reviewed faster than usual, to speed up access without compromising patient safety. We worked with companies, academic research centres and investigators who had products in development, to provide guidance and help bring clinical trials to Canada.



## Focus on... THE COVID-19 REGULATORY RESPONSE TEAM

The COVID-19 Regulatory Response Team was created to be the focal point for COVID-19 drugs and vaccines. The team supports the review areas in engaging with industry and other stakeholders. It also engages with partners across the Government of Canada to provide the regulatory perspective into the response to the COVID-19 pandemic.

*"The dedication and hard work since the beginning of the pandemic has been incredible. I'm so proud of what we have all been able to do to support bringing tests, treatments, vaccines and other products to Canadians."*

**Megan Bettle**  
Director General,  
COVID-19 Regulatory Response Team

In 2020 we authorized 81 clinical trials related to drugs or vaccines for COVID-19.

For more information, go to [Drugs and vaccines for COVID-19: Clinical trials for drugs and vaccines](#).

## Special Access Program

The Special Access Program is for health care professionals who are treating seriously ill patients where conventional therapies have failed, are unsuitable or are unavailable. The Special Access Program worked to help resolve critical shortages within the health care system during the pandemic. In addition, in 2020 we **modernized the regulations** for the program by improving processes used by health care providers and by reducing the administrative burden for requests. These changes will facilitate access to non-marketed drugs for Canadians, for COVID-19 and other medical emergencies.

For more information, go to [Health Canada's special access programs: Overview](#).

## Focus on... ACCESS TO TREATMENTS DURING THE PANDEMIC

The COVID-19 pandemic caused border closures and restricted air transportation. As a result, some patients had difficulty accessing necessary medical treatments. The Special Access Program played a key role in preventing and resolving critical shortages within the health care system. For example, prior to the pandemic, the program considered requests for medicinal leeches used to treat venous congestion post surgery. However, because of COVID-19, importing leeches from France to the American distributor required extraordinary efforts by the Special Access Program. The program coordinated with various government departments such as Health Canada, Canada Border Services Agency and Global Affairs Canada, as well as regulators in the United States and France.

**Ian MacKay**  
Manager, Therapeutic Products

## Drugs and vaccines

Drugs and vaccines will play an essential role in Canadians' ability to recover safely from the COVID-19 pandemic.

As part of the government's response to the pandemic, Health Canada introduced innovative and agile regulatory measures. These allowed us to expedite the regulatory review of COVID-19 drugs and vaccines, without compromising our high standards for safety, efficacy and quality.

For more information on the Interim Orders that were published to address the COVID-19 pandemic, go to "[Message from the Chief Regulatory Officer](#)".

In 2020 we approved two vaccines under the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19, the **Pfizer-BioNTech COVID-19 Vaccine** and the **COVID-19 Vaccine Moderna**. We also approved two drugs to treat COVID-19, **Veklury** and **Bamlanivimab**. As of December 31, 2020, two other vaccines and one other treatment were **under review**.

We will closely monitor the use of these products in the real world, evaluate potential safety and effectiveness issues and take action where there are identified problems.

## Disinfectants and hand sanitizers

The COVID-19 pandemic created an urgent need for disinfectants and hand sanitizers. These products were an important part of Health Canada's response to the pandemic to prevent the spread of COVID-19. To increase supply and ensure Canadians have access to these products, our work included:

- expediting the review of disinfectants and hand sanitizers,
- introducing interim measures such as:
  - allowing the importation of products that may not fully meet regulatory requirements, but do not compromise the safety of Canadians, to expedite access to disinfectants and hand sanitizers to address product shortages



- temporarily authorizing technical grade ethanol in the production of disinfectants and hand sanitizers to address an identified shortage of pharmaceutical-grade ethanol,
- providing guidance on obtaining a licence to sell alcohol- and non-alcohol-based sanitizers, on producing ethanol and isopropyl alcohol to make sure the alcohol used was safe, and on obtaining an authorization to manufacture and sell disinfectants,
- working with companies who entered the hand sanitizer market, such as distilleries, to help them navigate our regulations to manufacture and sell their new products, and
- working with the disinfectant industry to inform Canadians of products that can be used to help against the spread of COVID-19.

In 2020 we authorized over 4,400 hand sanitizer products and approximately 200 disinfectants. We also developed an [online list of hard-surface disinfectants with evidence for use against COVID-19](#), which included over 500 products as of December 31, 2020.

For more information, go to [Hard-surface disinfectants and hand sanitizers \(COVID-19\)](#).

## Focus on... OUR SCIENCE

In 2020 Dr. Sean Li published a paper entitled “[The Impact of Mutations in SARS-CoV-2 Spike on Viral Infectivity and Antigenicity](#)”. The publication investigated which mutations in the coronavirus spike protein led to resistance against neutralising antibodies and the importance of glycosylation in viral infectivity. The spike protein is the main surface antigen and the target in vaccine development. This work contributes to the development of vaccines and therapeutic antibodies.

**Dr. Sean Li**  
Research Scientist,  
Biologic and Radiopharmaceutical Drugs

## Surveillance of COVID-19 health products

We monitored the safety and effectiveness of health products related to COVID-19, and took action as needed to protect Canadians.

Our work on drugs and vaccines included:

- working with the Public Health Agency of Canada to continuously monitor COVID-19 vaccines on the market in Canada,

## Focus on... MONITORING COVID-19-RELATED DRUGS AND VACCINES

On December 9, 2020 – the day that Health Canada authorized the Pfizer BioNTech COVID-19 Vaccine – Health Canada learned of two reports of anaphylactoid reactions that had occurred following immunization on the first day of the United Kingdom’s mass immunization campaign. Through our existing relationships with our partner regulators, we were able to gather additional information about these events, as well as the perspectives of other regulators who were also reviewing the vaccine in their jurisdictions. In addition, we reached out to stakeholders with expertise in allergies and immunology for advice in responding to this emerging information. On December 12, 2020, prior to the initiation of the mass immunization campaign in Canada, we [issued an advisory](#). The advisory warned Canadians with allergies to any of the ingredients in the vaccine not to receive it, and recommended those with any serious allergies to speak with a health professional before receiving the vaccine. Health care professionals were also advised to follow guidance and recommendations for identifying and managing serious allergic reactions following immunization. This was aligned with advice from the Canadian Society for Allergists, the National Advisory Council on Immunization and Clinical Immunologists and Food Allergy Canada, among others.

**Sophie Sommerer**  
Senior Executive Director, Marketed Health Products

- taking proactive steps to identify adverse events from drugs and vaccines used for COVID-19 (products explicitly approved for use in COVID-19 as well as those that were being used “off-label”, or outside of the approved use of the product),
- monitoring retailers and advertisements that were making false, misleading and illegal claims related to COVID-19,
- publishing risk communications about potential safety and effectiveness concerns, and
- working closely with international partners to monitor the safety and effectiveness of COVID-19 treatments in the real world.

## Focus on... THE COVID-19 VACCINES AND TREATMENTS PORTAL

Health Canada is committed to providing Canadians, health practitioners and researchers with timely and trusted information related to vaccines and treatments for COVID-19. To that end, we created the **COVID-19 vaccines and treatments portal**. The portal is an easy-to-navigate, mobile-friendly interface that provides information about each product in one place. It contains product information for consumers including what the product is used for, precautions and adverse events so that consumers can make informed decisions. For health practitioners and researchers, the portal provides the rationale for Health Canada’s decision to approve the product, a copy of the Canadian label, guidance on how to administer the product, clinical information and how we are continuing to monitor its safety and effectiveness.

*“Our objective was to provide a user-friendly, easily-navigated interface so that consumers, health practitioners and researchers can find timely and trusted regulatory information and have confidence in the products authorized for the prevention and treatment of COVID-19.”*

**Shannon Laforce**  
Executive Director,  
Resource Management and Operations

Our work on disinfectants and hand sanitizers included:

- monitoring the safety of disinfectants and hand sanitizers on the market in Canada,
- monitoring retailers and advertisements that were making false, misleading and illegal claims related to COVID-19, and
- publishing risk communications on safety concerns associated with disinfectants and hand sanitizers.

## Drug shortages

Early in the pandemic, it was clear that COVID-19 was having an impact on the supply of critical health products in Canada. We worked with our partners within Health Canada to introduce regulatory measures that provided more tools to urgently address drug shortages related to COVID-19. We also worked with provinces and territories, companies and manufacturers, health care providers and patient groups to strengthen the drug supply chain. These collaborations helped us to identify, prevent and ease shortages for Canadians.

For more information, go to [Addressing critical product shortages](#).

## Communications and collaborations

Throughout the pandemic, Health Canada published a number of web pages to provide information to Canadians and regulatory partners. Our web pages provide information about the various health products we regulate, including [clinical trials authorized](#), applications for drugs that have been [submitted](#) and [approved](#), [disinfectants](#) and [hand sanitizers](#) that have been authorized, and more.

We also published web pages that [provided critical information to the health product industry](#) about our regulation of health products for COVID-19. We developed guidance to support industry in developing health products to help in the crisis.

Health Canada also published a number of risk communications to Canadians to provide important information about drugs for human use, disinfectants and hand sanitizers.

We worked closely with our domestic partners including provincial and territorial governments, health technology assessment organizations, health care providers and patient groups. We sought their perspectives on the priorities and challenges they were facing within the health care system as a result of the pandemic. Through webinars, we were able to share information with health care practitioners about important topics such as the regulatory approval of treatments for COVID-19.

## Focus on... THE COVID-19 HEALTH PRODUCT INDUSTRY WEBSITE

At the start of the pandemic, Health Canada rapidly established a centralized [website](#) to inform health product stakeholders about regulatory requirements in the context of COVID-19. The website communicates priority information, guidance and advice to stakeholders on COVID-19-related health products, including disinfectants and hand sanitizers, as well as drugs and vaccines.

It includes easy-to-access information on the new temporary measures put in place to expedite review of these products. In this way it supports traditional stakeholders as well as those new to the sector who require additional guidance.

The website has been maintained and updated throughout the pandemic, receiving close to 10 million visits between its launch in March 2020 and the end of December. With an average of 230,000 visits per week it remains a useful resource for stakeholders.

*"In March 2020 our teams were facing an incredible volume of COVID-19-related regulatory questions from stakeholders. Recognizing the urgent need to communicate with new and regular stakeholders, we established a website that would serve as a central hub of key information and help manage the volume of inquiries."*

**Elizabeth Toller**  
Executive Director, Policy,  
Planning and International Affairs

We [collaborated with regulators from other countries](#) on issues related to clinical trials, drug review, risk assessments and potential drug shortages. This sharing of information and expertise helped ensure that health products are safe and effective, and are available quickly to Canadians. This is taking place as part of the European Medicines Agency's OPEN project and through the Access Consortium. We also worked closely with the [International Coalition for Medicines Regulatory Authorities](#), the [World Health Organization](#) and the Pan American Health Organization's [COVID-19 task group](#). These partnerships have helped us to align our approach with the global response to COVID-19.

We began 2021 in the midst of the second wave of the pandemic. We will continue this critical work to ensure Canadians continue to have access to COVID-19-related health products.

## REGULATORY INNOVATION

The current pace of innovation is unprecedented. This has led to new health products that are increasingly complex and personalized. We need new regulatory approaches to better support access to these health technologies, while continuing to protect patient safety.

Health Canada continued to prioritize regulatory innovation in 2020. The COVID-19 pandemic affected the timelines of this work. However, it also provided an opportunity to test certain temporary agile measures. We will be using the lessons learned from our regulatory response to COVID-19 to inform our regulatory innovation work, including:

- modernizing clinical trial regulations to create an environment that supports more innovative trials,
- enabling access to advanced therapeutic products that do not fit our current system,
- agile licensing for drugs, using flexible tools to oversee products across their life-cycle, and
- updating how we communicate to Canadians about health product information.

For more information, go to [Regulatory innovation for health products](#).



## BUILDING INTERNATIONAL PARTNERSHIPS

For many years, Health Canada has worked closely with regulators around the world on issues related to drugs. This cooperation continued in 2020, both on COVID-19-related files (see “[Drugs for Human Use: 2020 Accomplishments – Responding to the COVID-19 pandemic](#)”) and in our day-to-day work.

For example, we have built on the collaborative review initiatives between Health Canada and other regulators. These include the Access Consortium and Project Orbis. Through the [Access Consortium](#), we work with partners to review new drugs together, to get them to market quickly and efficiently. [Project Orbis](#) is an initiative of the United States Food and Drug Administration Oncology Center of Excellence. Project Orbis brings together regulators from multiple countries to review cancer drugs at the same time so that patients can receive earlier access to needed treatments.

Through these key work-sharing initiatives, we authorized a number of new drugs and new uses for already-approved drugs in 2020. Two examples of new drugs include Nubeqa for the treatment of prostate cancer, and Xofluzza for the treatment of influenza.

By sharing information and expertise with other regulators, we have also optimized our understanding of how drugs are being used after they are available for sale. This information is called “real world evidence” and is used by Health Canada and other regulators to make regulatory decisions about drugs.

We updated our agreements with various regulators including the European Union’s European Medicines Agency, the United Kingdom’s Medicines and Healthcare products Regulatory Agency and the Health Science Authority of Singapore. These agreements allow regulators to share information about drug submissions, and helped us further align our approaches with our global partners.

### Focus on... COLLABORATING INTERNATIONALLY ON PRODUCT SAFETY

In the summer of 2018 several medications were recalled in Canada and elsewhere in the world, due to a nitrosamine impurity. Long-term exposure to nitrosamine impurities at a level above what is considered safe may increase the risk of cancer. To better understand this global issue, we are collaborating and sharing information with other major regulators around the globe. Health Canada is also the chair of two international working groups on nitrosamines. The groups meet regularly to foster global alignment on new developments, technical and regulatory positions, and on risk management for nitrosamines. This work has been critical to providing unified expectations and guidelines for industry and minimizing the health risk to consumers.

## MANDATORY REPORTING OF SERIOUS ADVERSE DRUG REACTIONS BY HOSPITALS

In 2020 Health Canada supported the implementation of [new regulations for mandatory reporting by hospitals](#) that came into force in December 2019. These regulations are expected to increase the quantity and improve the quality of reports of serious adverse drug reactions. Hospitals are now required to report to Health Canada all serious adverse drug reactions 30 days from being documented within the hospital.

Health Canada developed tools to support hospitals including a [guidance document](#), [education modules](#) and [promotional materials](#).

The number of adverse drug reaction reports submitted to Health Canada by hospitals for drugs increased by 336 percent in 2020. After the implementation of mandatory reporting, several data elements in the report form became mandatory to ensure that important details were provided to Health Canada. This additional information aims to expand the data used by Health Canada to monitor the safety and effectiveness of drugs for human use.

## ADDRESSING ANTIMICROBIAL RESISTANCE

Antimicrobials, such as antibiotics and antifungals, are essential to modern health care. However, the widespread use of these products over past decades has resulted in increasing levels of antimicrobial resistance. Commonly used antimicrobials become less effective as the pathogens they target (bacteria, viruses, fungi and parasites) become resistant to them.

Antimicrobial resistance is a global challenge and a growing threat to public health, the health care system, economic prosperity and health security. When there are fewer effective antimicrobials available, it will be harder to protect Canadians from common infectious diseases. The COVID-19 pandemic provides a clear example of the challenges created by infections that are difficult to treat.

Health Canada continues to take important steps to encourage the development of new and innovative therapeutic products, to help combat antimicrobial resistance.

In 2020 we [launched a consultation on updates to the Pathogens of Interest List](#), inviting feedback from a wide range of stakeholders. This list is an important tool that lets companies know which pathogens are in most urgent need of additional therapeutic options. The list is having an impact; this year we approved Xenleta for the treatment of community-acquired pneumonia. Xenleta was granted priority review status because it targets difficult-to-treat pathogens on our [Pathogens of Interest List](#).

Also in 2020, Health Canada provided funding to four companies that were successful in the first phase of the [Innovative Solutions Canada challenge](#) that was launched in 2019. This funding supports the

### Focus on... WORLD ANTIMICROBIAL AWARENESS WEEK, NOVEMBER 18-24, 2020

Every year Health Canada joins the World Health Organization, international health agencies and other national authorities to support World Antimicrobial Awareness Week. This global initiative aims to raise awareness about antimicrobial resistance and to encourage best practices to avoid the spread of drug-resistant infections in humans and animals. In 2020 we welcomed a panel of international speakers to discuss the challenges associated with antimicrobial research, development and access to therapies.

development of novel tools so that health care providers can detect or diagnose antibiotic-resistant bacteria in humans or animals. These tools will aid in decision making about possible treatments.

We continue to work closely with regulators from other countries, including through the International Coalition of Medicines Regulatory Authorities. [This Coalition](#) has called on global health leaders to develop incentives for research and development, the pharmaceutical industry to continue to invest in research and development, and the media to keep the issue of antimicrobial resistance on the front page.

To learn about antimicrobial resistance related to animals and veterinary drugs, go to [“Drugs for veterinary use: 2020 accomplishments”](#).



## DRUGS FOR USE IN CHILDREN

Children are different from adults, in their physiology and their anatomy. Therefore, they can respond differently to health products. Medicines need to be studied in pediatric populations to ensure that they are safe and effective. However, these studies are complex and challenging. Currently, up to 80% of drugs prescribed to children in Canada are considered “off-label”, which means outside of the approved use of the drug.

To address these challenges, in 2020 Health Canada established the Pediatric Drug Action Plan. The goal of the plan is to improve children’s access to safe and effective health products.

Early work on the plan has begun, and activities include:

- Collaborating with regulators around the world, including the European Medicines Agency, the United States Food and Drug Administration, and the World Health Organization. These collaborations help to strengthen our pediatric expertise and align our activities.

- Working with the Goodman Pediatric Formulation Centre of the Centre hospitalier universitaire Sainte-Justine to improve access to pediatric formulations in Canada.
- Analyzing ways to encourage companies to test health products in pediatric populations, when appropriate, and submit pediatric data to Health Canada.
- Developing a Canadian pediatric data strategy to analyse the availability of health products for use in children, trends in pediatric trials and drug safety issues associated with pediatrics.





## NON-PRESCRIPTION DRUGS

Health Canada is responsible for the review of non-prescription drugs, also known as “over-the-counter” products, to ensure that they are safe, effective and of high quality. These products include, but are not limited to:

- antiseptics,
- pain relievers,
- cold and cough medicines,
- sunscreens, and
- hard surface disinfectants.

The nature of our review of non-prescription drugs depends on a number of factors. These include the ingredients, the health claims and the evidence that is needed to support the safety, efficacy and quality of the product. Health Canada issues a Drug Identification Number (DIN) to every approved non-prescription drug. Canadians should look for this number on the product label, which indicates that the drug has met our requirements.

Presently, products that contain a phytocannabinoid produced by or found in the cannabis plant can only be prescribed by a health care practitioner for medicinal purposes. We are aware that some Canadians are interested in potential therapeutic uses of cannabis for purposes such as pain relief, without the need for practitioner oversight (that is, in “over-the-counter” products). In 2019 Health Canada consulted on the potential market for such health products. We published a [summary report](#) in 2020, which provides an overview of the comments received from Canadians. As part of this consultation, we also established a [Scientific Advisory Committee on Health Products Containing Cannabis](#). This committee will provide us with independent scientific and clinical advice about appropriate safety, efficacy and quality considerations for health products containing cannabis. Health Canada will use this information to inform its regulatory path forward on these products.

## Focus on... OUR SCIENCE

In 2020 our research scientists teamed up to evaluate the effects of excipients on the structure and dynamics of active ingredients in recombinant protein biologics. In biological drugs, the excipients are substances that protect or enhance stability and/or bioavailability of the active pharmaceutical ingredients (the substance[s] responsible for the pharmaceutical activity or prevention of disease). The study was titled “[Effects of Excipients on the Structure and Dynamics of Filgrastim Monitored by Thermal Unfolding Studies by CD and NMR Spectroscopy](#)”. This work contributes to the development and regulation of formulations for biologics.

### Dr. Yves Aubin

Research Scientist, Biologic and Radiopharmaceutical Drugs

### Grant Frahm

Research Chemist, Biologic and Radiopharmaceutical Drugs

### Dr. Houman Ghasriani

Research Chemist, Biologic and Radiopharmaceutical Drugs

### Dr. Michael Johnston

Research Scientist, Biologic and Radiopharmaceutical Drugs





## HEALTHY CLICKS DRUGS FOR HUMAN USE AT A GLANCE

To stay informed about our activities:



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



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

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



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

You can also find specific information about drugs by following the links below.

## DRUGS AND VACCINES FOR USE IN COVID-19

### NEW

The **COVID-19 vaccines and treatments portal** provides information for consumers, health

care professionals and researchers on vaccines and treatments authorized for COVID-19, as well as those currently under review.

**COVID-19 vaccines and treatments portal**   
[covid-vaccine.canada.ca/](https://covid-vaccine.canada.ca/)

The **List of authorized drugs** shows the drugs that are currently authorized for use in relation to the COVID-19 pandemic.

**Drug and vaccine authorizations for COVID-19: List of authorized drugs and expanded indications**   
[canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/authorization/list-drugs.html](https://canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/authorization/list-drugs.html)

The **List of applications received** shows the drugs that are currently being reviewed for use in relation to the COVID-19 pandemic.

**Drug and vaccine authorizations for COVID-19: List of applications received**   
[canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/authorization/applications.html](https://canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/authorization/applications.html)

Health Canada publishes up-to-date information about the **use of disinfectants, hand sanitizers, cleaners and soaps** in relation to COVID-19.

**COVID-19 Disinfectants, sanitizers, cleaners and soaps**   
[canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/disinfectantst-sanitizers-cleaners-soaps.html](https://canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/disinfectantst-sanitizers-cleaners-soaps.html)



## DRUGS AND VACCINES FOR USE IN COVID-19 (cont.)

The **List of authorized clinical trials** shows the COVID-19 drugs, including vaccines, which are currently being investigated in clinical trials authorized by Health Canada.

**Drugs and vaccines for COVID-19: List of authorized clinical trials** [canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/list-authorized-trials.html](https://canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/list-authorized-trials.html)

## NEW DRUGS APPROVED

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](https://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/index-eng.jsp](https://health-products.canada.ca/dpd-bdpp/index-eng.jsp)

**Search for data** about the tests and trials that were performed on drugs to evaluate their safety and efficacy.

**Clinical information on drugs and health products** [canada.ca/en/health-canada/services/drug-health-product-review-approval/clinical-information-drugs-health-products.html](https://canada.ca/en/health-canada/services/drug-health-product-review-approval/clinical-information-drugs-health-products.html)

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

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

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

**Generic Submissions Under Review List** [canada.ca/en/health-canada/services/drug-health-product-review-approval/generic-submissions-under-review.html](https://canada.ca/en/health-canada/services/drug-health-product-review-approval/generic-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** [health-products.canada.ca/noc-ac/index-eng.jsp](https://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** [canada.ca/en/health-canada/services/drugs-health-products/drug-products/regulatory-decision-summary.html](https://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 drug submissions.

**Summary Basis of Decision** [canada.ca/en/health-canada/services/drugs-health-products/drug-products/summary-basis-decision.html](https://canada.ca/en/health-canada/services/drugs-health-products/drug-products/summary-basis-decision.html)

## DRUG SHORTAGES

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

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

## CLINICAL TRIALS FOR DRUGS

The **Clinical Trials Database** provides a listing of specific information relating to phase I, II and III clinical trials, conducted in patients, which have been approved for drugs in Canada.

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

## SURVEILLANCE OF DRUGS

### REPORT AN ADVERSE DRUG REACTION

**Canada Vigilance Program** [canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html](https://canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html)

[canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html](https://canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html)

You can report adverse drug reactions to your medical professional, to a hospital or to the company that made the product. You can also report them to Health Canada through the **Canada Vigilance Program** [canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html](https://canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) 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](https://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](https://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. 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](https://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.

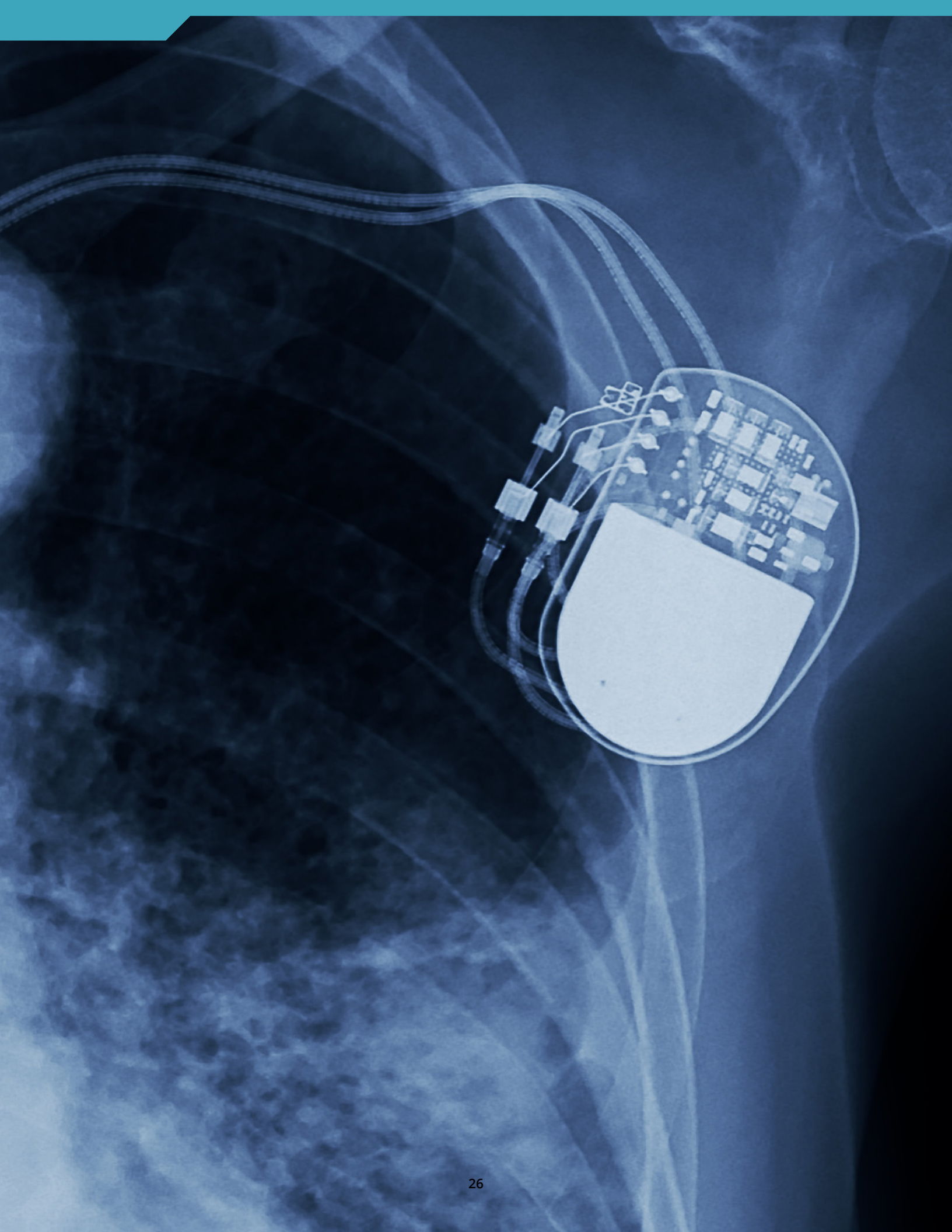
**Summary Safety Reviews** [hpr-rps.hres.ca/reg-content/summary-safety-review.php](https://hpr-rps.hres.ca/reg-content/summary-safety-review.php)

**Health Product InfoWatch** is a monthly publication intended primarily for health care 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](https://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** [canada.ca/en/health-canada/services/drugs-health-products/regulatory-requirements-advertising/health-product-advertising-complaints.html](https://canada.ca/en/health-canada/services/drugs-health-products/regulatory-requirements-advertising/health-product-advertising-complaints.html)





## MEDICAL DEVICES: 2020 IN BRIEF

One of Health Canada's roles is to regulate medical devices that can help Canadians maintain and improve their health. Medical devices are used in the treatment, diagnosis or prevention of diseases or abnormal physical conditions.

In Canada, medical devices are categorized into four groups based on the level of risk associated with their use. These groups are called "Classes" and range from I to IV. Class I devices are considered low-risk devices – for example, a wheelchair. Class IV devices present the greatest potential risk – for example, a defibrillator.

In 2020 we launched a new Medical Devices Directorate, which is responsible for regulating medical devices throughout their life-cycle. This new structure is helping us adapt to the rapid growth and change in the medical device industry, and has allowed us to grow our capacity to regulate this industry.

The COVID-19 pandemic created an urgent need for access to safe, effective and high quality medical devices. Our response to the pandemic addressed critical issues related to medical devices across product life-cycles.

### RESPONSE TO THE COVID-19 PANDEMIC

As part of the government's response to the pandemic, we introduced innovative and agile regulatory measures. These measures expedited the regulatory review of COVID-19 medical devices without compromising safety, effectiveness and quality standards.

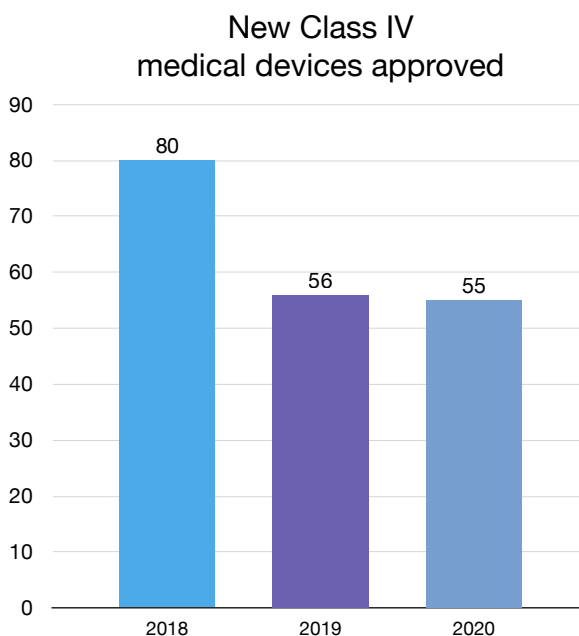
In 2020 we authorized 545 COVID-19 medical devices and 18 clinical trials for medical devices related to COVID-19.

For more information about our response to the COVID-19 pandemic, go to "[Medical devices: 2020 accomplishments](#)".

### NEW MEDICAL DEVICES APPROVED

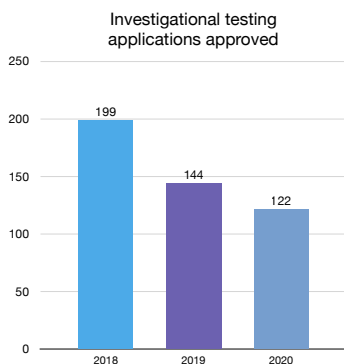
In 2020 we approved 332 new medical devices in the highest risk categories (Classes III and IV). These devices provide patients and health care professionals with new and innovative options for the treatment, prevention and diagnosis of various health conditions. For example, we approved the INSTI Rapid HIV test, the first home-based self test for HIV approved in Canada.

For a list and description of the 55 new Class IV (highest-risk) medical devices we approved in 2020, go to "[Medical devices: Approved in 2020](#)".



## INVESTIGATIONAL TESTING (CLINICAL TRIALS) AND SPECIAL ACCESS PROGRAM

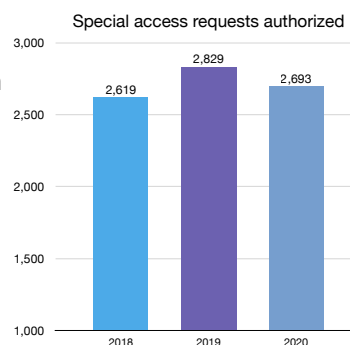
We review applications to allow companies to conduct investigational testing (clinical trials) on medical devices in Canada. New trials mean Canadians may have access to more innovative choices. In 2020, 122 new investigational testing applications for medical devices were approved.



We authorized investigational testing for leadless pacemakers as part of a global study, and a point-of-care HIV and syphilis antibody test for use in vulnerable populations and remote communities. We also authorized investigational testing for medical devices that used artificial intelligence for the early detection of COVID-19 in the lung, and for touch-free vital sign assessment.

Through our Special Access Program, we grant access to health care professionals to medical devices that have not been approved for sale in Canada for emergency use or when alternatives are unsuitable or unavailable. In

2020, 2,693 requests for special access to medical devices were authorized. These included hand-held scanners to facilitate screening of COVID-19 patients and ventilators that were in short supply early in the pandemic.



The program also facilitated the supply of medical devices that were in critical need after delays were created by the pandemic (for example, in transport).

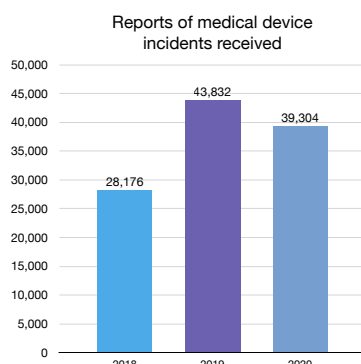
In 2020 we also authorized:

- cardiovascular devices that allow for less traumatic procedures,
- devices treating complex recurrent aneurysms for compassionate use,
- devices related to organ transplant for young patients, and
- MRI-compatible infant incubators.



## SURVEILLANCE

After we approve a medical device for sale in Canada, we continue to monitor and evaluate reports of suspected incidents involving that medical device.



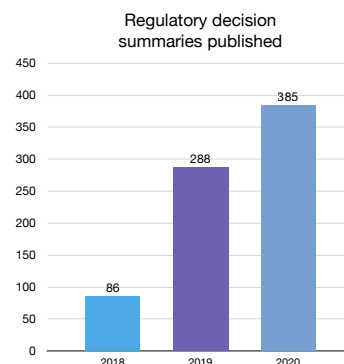
In 2020 we received 39,304 reports of medical device incidents and undertook 2 actions related to medical devices. Incident reports come from domestic and international sources. Actions can include informing the public and health care professionals of safety information or recommending labelling changes, or affirming our current understanding. For example, following a recent review of dental amalgam, we reported that the most current data still showed no clear link between dental amalgam and harms from mercury. In cases where a serious risk is identified, we may remove a medical device from the market.

To learn how we addressed safety issues that arose for medical devices in Canada in 2020, go to [“Medical devices: Approved in 2020”](#).

## TRANSPARENCY OF DECISION MAKING

In 2020 we continued to advance our openness and transparency efforts by expanding the amount of regulatory health and safety information that is made available to Canadians. We published 387 [regulatory decision summaries](#) and 1 [summary basis of decision document](#), which explain Health Canada’s decisions for certain medical devices seeking market authorization.

Through our [“Clinical Information Portal”](#), we published 1,859 pages of clinical information on 8 medical devices. This clinical information is provided by companies when they seek approval to sell a medical device in Canada, and is made publicly available on request after we decide to approve or reject the product.



Health Canada also publishes [summaries of its safety reviews](#), which describe Health Canada’s decisions related to potential safety issues. In 2020 we published one such summary for medical devices. These summaries complement other safety-related information to help Canadians make informed decisions about their medical device choices.

This [“Medical Devices”](#) chapter gives you more information about our work in 2020. For up-to-date information about our activities see the [“Healthy clicks – Medical devices at a glance”](#) section, and follow us on social media.



David Boudreau  
Director General,  
Medical Devices

*David Boudreau*



Kelly Robinson  
Director General,  
Marketed Health Products

*Kelly Robinson*





# MEDICAL DEVICES: WHAT'S NEW IN 2020

In 2020 we approved 55 new Class IV (highest-risk) medical devices. More detail is available in the section “Medical devices: Approved in 2020”.

## Body fluid and tissue management devices

- CliniMACS Prodigy T Cell Transduction (TCT) System
- Sonopet iQ Ultrasonic Aspirator System

## Body tissue manipulation and reparation devices

- Chondro-Gide Bilayer Collagen Membrane
- Myriad
- Puracol Plus
- Regeneten Bioinductive Implant System

## Cardiovascular devices

- Agilis HisPro Steerable Catheter With Electrodes
- Athletic Over-The-Wire PTA Balloon Dilatation Catheter
- Attain Stability Quad MRI SureScan 4798
- Cardiac Resynchronization Therapy Defibrillator (CRT-DS)
- Cobalt XT / Cobalt / Crome ICD and CRT-D MRI SureScan
- Diamondback 360 Coronary Orbital Atherectomy System
- Eluvia Over-the-Wire Drug-Eluting Vascular Stent System
- EPstar Fixed Electrophysiology Catheter
- Evolut PRO+ Transcatheter Aortic Valve
- Implantable Cardioverter Defibrillator (ICDS)
- IntellaNav ST

## Cardiovascular devices (cont.)

- IntellaNav StablePoint Ablation Catheter
- Jade PTA Balloon Dilatation Catheter
- Konect Resilia Aortic Valved Conduit
- Lotus Edge Valve System
- Micra AV MC1AVR1
- Penumbra LP Coil System
- QDot Micro Navigation Catheter
- Ranger and Ranger SL Over-the-Wire Paclitaxel-Coated PTA Balloon Catheter
- Reprocessed ViewFlex Xtra ICE Catheter
- Sapphire II NC Coronary Dilatation Catheter
- Scoreflex NC Coronary Dilatation Catheter
- Scoreflex PTA Balloon Dilatation Catheter
- Sentinel Cerebral Protection System
- Smart Touch Programming System
- Surpass Evolve Flow Diverter System
- Synergy Monorail Everolimus-Eluting Platinum Chromium Coronary Stent System
- Synergy XD Monorail Everolimus-eluting Platinum Chromium Coronary Stent System
- TriClip System
- Vega Endocardial Pacing Lead
- Wattson Temporary Pacing Guidewire
- Xience Pro A Everolimus Eluting Coronary Stent System
- Zoll X Series Advanced

## Gastro-urolological devices

- InterStim Micro SureScan MRI

## General hospital devices

- EPstar Fixed Electrophysiology Catheter with Lumen / EPstar Electrophysiology Cable
- MiniMed 770G
- t:slim X2 Insulin Pump with Control-IQ Technology

## In vitro diagnostic medical devices

- ADVIA Centaur HBC Total 2 (HBcT2) (Donor Screening for Transplantation)
- ADVIA Centaur Quantitative HBsAg (QHBs)
- Alinity s HIV Ag/Ab Combo Assay (Donor Screening and Cadaveric Testing)
- Atellica IM Quantitative HBsAg (QHBs)
- INSTI HIV Self Test
- Liaison XL Murex HCV AB
- PK CMV-PA System Control Set
- PK7400 TP HA Reagent and Controls

## Neurological devices

- Percept PC
- Proclaim Implantable Pulse Generators

## Plastic surgery and cosmetic devices

- Natrelle Inspira Cohesive Breast Implant

## Radiological devices

- Acist HDi System



## MEDICAL DEVICES: 2020 ACCOMPLISHMENTS

### RESPONDING TO THE COVID-19 PANDEMIC

The COVID-19 pandemic has had a profound impact on the health and well-being of Canadians in 2020. It has created an unprecedented demand on Canada's health care system and has led to an urgent need for access to health products.

Health Canada's response to the pandemic addressed critical issues related to medical devices across product life-cycles, from investigational testing (clinical trials) to authorizations of medical devices and surveillance.

### Investigational testing (clinical trials)

In May 2020, the Minister of Health signed the [Interim Order Respecting Clinical Trials for Medical Devices and Drugs Related to COVID-19](#).

This temporary measure facilitated a more efficient authorization process for investigational testing (clinical trials) in Canada, expanding the range of sponsors who may submit an investigational testing application. It offered greater flexibility in terms of administrative requirements, without compromising patient safety or the validity of trial results.

### Focus on...

### ACCESS TO MEDICAL DEVICES DURING THE PANDEMIC

As a result of the pandemic, Canadians experienced shortages of much-needed medical devices due to manufacturing and shipping delays. Through the Special Access Program's emergency access mandate, the team worked directly with health care professionals and foreign manufacturers to obtain information on alternative devices. Early in 2020 this included wireless handheld ultrasound scanners that were used to diagnose respiratory failure in patients suspected to have COVID-19. As the pandemic progressed, ventilators and respiratory accessories for ventilators were also needed. Health Canada determined the safety and effectiveness of these new devices and worked closely with health care professionals and the manufacturers to ensure rapid access and delivery.

*"Members of the medical devices Special Access Program Team include one supervisor, two administrative clerks and one student. Our team worked diligently with the health care practitioners and foreign manufacturers by phone and email throughout the work week, as well as the weekend with our 24/7 emergency phone line, to provide guidance and obtain sufficient information for our evaluation bureau."*

**Leo Periard**  
Clerk, Medical Devices

**Marina Whyte**  
Clerk, Medical Devices

**Peggy Seely**  
Supervisor, Medical Devices

**Erica Pierre-Pierre**  
Student, Medical Devices

In addition, we expedited the authorization of trials for COVID-19. Applications were reviewed faster than usual, to speed up access without compromising patient safety. We worked with companies, academic research centres and investigators who had products in development, to provide guidance and help bring clinical trials to Canada.

In 2020 we authorized 18 clinical trials for medical devices relating to COVID-19.

For more information, go to [Medical devices for COVID-19: Conducting a clinical trial](#).

### Special Access Program

The Special Access Program is for health care professionals who are treating seriously ill patients where conventional therapies have failed, are unsuitable or are unavailable. In 2020 the pandemic created supply chain issues, resulting in shortages of needed medical devices. When these were not available in Canada, the program facilitated rapid access to medical devices that could respond to the urgent needs of health care professionals and their patients.

For more information, go to [Health Canada's special access programs: Overview](#).

### Medical devices

Medical devices play an important role in diagnosing, treating, mitigating or preventing COVID-19. Typical medical devices used in relation to COVID-19 include [masks](#), [N95 respirators](#), [gloves](#), [gowns](#), [ventilators](#) and [testing devices](#).

As part of the government's response to the pandemic, Health Canada introduced innovative and agile regulatory measures. These allowed us to expedite the regulatory review of COVID-19 medical devices, without compromising our high standards for safety, effectiveness and quality. They also allowed certain medical devices that may not fully meet regulatory requirements to be imported and sold in Canada.

For more information on the Interim Orders that were published to address the COVID-19 pandemic, go to ["Message from the Chief Regulatory Officer"](#).

In 2020 we approved 545 medical devices for use in relation to COVID-19. For lists of authorized medical devices, go to [Authorized medical devices for uses related to COVID-19: Overview](#).

We will closely monitor the use of these products in the real world, evaluate potential safety and effectiveness issues and take action where there are identified problems.

## Focus on... ENCOURAGING 3D PRINTING OF MEDICAL DEVICES

In March 2020, the demand for certain medical devices, including personal protective equipment (PPE), exceeded the available supply in Canada. Research centres, academic institutions and other industry sectors became interested in 3D printing personal protective equipment to assist with the shortage. We reached out urgently to our contacts in industry, hospitals, universities, colleges and industrial manufacturing facilities. A national network of 3D printing experts was quickly created that included over 80 organizations across Canada.

Through the network, we shared technical and regulatory information to help ensure that 3D-printed personal protective equipment were safe, effective,

and of high quality. The network allowed open and transparent communication among regulators, physicians and non-traditional medical device manufacturers. Based on the information provided in this form, we published guidance for industry on 3D printing of personal protective equipment in response to COVID-19. This guidance helped ensure that safe, effective, and high quality personal protective equipment were produced for Canadian health care workers.

*"It was incredible not only to see Canadians willing to help out during a time of crisis, but to see the passion and dedication from all those who stepped up to help raise the bar for the safety and quality of 3D-printed personal protective equipment for our Canadian health care workers."*

**Marc Lamoureux**  
Manager, Medical Devices



## Surveillance of medical devices related to COVID-19

We monitored the safety and effectiveness of medical devices related to COVID-19, and took action as needed to protect Canadians.

Our work included:

- taking proactive steps to identify incidents related to medical devices used for COVID-19 (products explicitly approved for use in COVID-19 as well as those that were being used “off-label”, or outside of the approved use of the product),
- monitoring retailers and advertisements that were making false, misleading and illegal claims related to COVID-19,
- publishing risk communications about potential safety and effectiveness concerns, and
- working closely with international partners to monitor the safety and effectiveness of medical devices related to COVID-19 in the real world.

## Medical device shortages

Early in the pandemic, it was clear that COVID-19 was having an impact on the supply of critical medical devices in Canada. We introduced regulatory measures that provided more tools to urgently address medical device shortages related to COVID-19. We also worked with provinces and territories, companies and manufacturers, health care providers and patient groups to strengthen access to medical devices in Canada. These measures helped us to identify, prevent and ease shortages for Canadians.

For more information, go to [Addressing critical product shortages](#).

## Communications and collaborations

Throughout the pandemic, Health Canada published a number of web pages to provide information to Canadians and regulatory partners. Our web pages provide information about the various health products we regulate, including [clinical trials authorized](#), medical devices [authorized](#), testing devices that are [under evaluation](#) and more.

## Focus on... N95 RESPIRATORS

Single use N95 respirators are a type of personal protective equipment (PPE) that protects health care workers from airborne particles. They are considered essential when working around airborne pathogens like SARS-CoV-2. As the COVID-19 pandemic unfolded, the shortage of N95 respirators in Canada reached a critical point where it threatened the ability of health care workers to deliver care to COVID-19 patients without risking their own health.

N95 respirators are normally disposed after a single use. To help address the shortage of N95 respirators, Health Canada collaborated extensively with stakeholders. We worked swiftly to establish the regulatory requirements for reprocessing of N95 respirators. We invited industry to provide innovative solutions for the reprocessing of N95 respirators and provided regulatory guidance as needed.

Interim regulatory measures were also put in place to expedite the approval of medical devices that met regulatory requirements for the safe and effective reprocessing of N95 respirators.

While reprocessing single use devices is not a new concept, the reprocessing of N95 masks was an entirely new way of doing things. We conducted outreach to health authorities and health care providers to reassure them that the medical devices approved for the reprocessing of N95 respirators met regulatory standards, and would provide an option when new N95 respirators were not available.

*“In the early days of the pandemic, health care professionals were faced with a dire situation as N95 respirators were in shortage. I was incredibly touched by the way we all came together and worked tirelessly to address this critical issue.”*

**Evelyn Soo**  
Director, Therapeutic Products

We also published web pages that provided critical information to the medical device industry about our regulation of products for COVID-19. We developed guidance to support industry in developing medical devices to help in the crisis.

We also published a number of risk communications to Canadians to provide important information about medical devices relating to COVID-19.

We worked closely with our domestic partners including provincial and territorial governments, health care providers and patient groups. We sought their perspectives on the priorities and challenges they were facing within the health care system as a result of the pandemic. Through webinars, we were able to share information with health care practitioners about important topics such as the reprocessing of N95 respirators.

We collaborated with regulators from other countries on issues related to investigational testing (clinical trials), medical device review, risk assessments and potential medical device shortages. This work helped ensure that medical devices are safe and effective, and are available quickly to Canadians. We also worked closely with the [World Health Organization](#) and the Pan American Health Organization's

**COVID-19 task group.** These partnerships have helped us to align our approach with the global response to COVID-19.

We began 2021 in the midst of the second wave of the pandemic. We will continue this critical work to ensure Canadians continue to have access to COVID-19-related medical devices.

## REGULATORY INNOVATION

The current pace of innovation is unprecedented. This has led to new health products that are increasingly complex and personalized. We need new regulatory approaches to better support access to these health technologies, while continuing to protect patient safety.

Health Canada continued to prioritize regulatory innovation in 2020. The COVID-19 pandemic affected the timelines of this work. However, it also provided an opportunity to test certain temporary agile measures. We will be using the lessons learned from our regulatory response to COVID-19 to inform our regulatory innovation work, including these related to medical devices:

- modernizing investigational testing (clinical trials) regulations to create an environment that supports more innovative trials,

## Focus on... THE COVID-19 HEALTH PRODUCT INDUSTRY WEBSITE

At the start of the pandemic, Health Canada rapidly established a centralized website to inform health product stakeholders about regulatory requirements in the context of COVID-19. The website communicates priority information, guidance and advice to stakeholders on COVID-19-related health products, including medical devices (such as personal protective equipment and ventilators).

It includes easy-to-access information on the new temporary measures put in place to expedite review of these products. In this way it supports traditional stakeholders as well as those new to the sector who require additional guidance.

The website has been maintained and updated throughout the pandemic, receiving close to 10 million visits between its launch in March 2020 and the end of December. With an average of 230,000 visits per week it remains a useful resource for stakeholders.

*"In March 2020 our teams were facing an incredible volume of COVID-19-related regulatory questions from stakeholders. Recognizing the urgent need to communicate with new and regular stakeholders, we established a website that would serve as a central hub of key information. The resulting website helped to reduce the volume of inquiries and enabled our staff to focus their efforts on core activities critical to the COVID-19 response."*

**Elizabeth Toller**  
Executive Director,  
Policy, Planning and International Affairs

- enabling access to advanced therapeutic products that do not fit our current system,
- agile licensing for medical devices, using flexible tools to oversee products across their life-cycle, and
- updating how we communicate to Canadians about health product information.

For more information, go to [Regulatory innovation for health products](#).

### BUILDING INTERNATIONAL PARTNERSHIPS

For many years, Health Canada has worked closely with regulators around the world on issues related to medical devices. This cooperation continued in 2020, both on COVID-19-related files (see “[Medical Devices: 2020 Accomplishments – Responding to the COVID-19 pandemic](#)”) and in our day-to-day work.

We continued to build on our work with the [International Medical Devices Regulators Forum](#).

This group of medical device regulators works to harmonize the regulation of medical devices. This cooperation can make innovative medical devices available to patients more quickly around the world.

In 2020 we co-chaired an International Medical Devices Regulators Forum working group on cybersecurity, which published [Principles and Practices for Medical Device Cybersecurity](#). We also participated in a new working group on artificial intelligence medical devices.

Under the [Regulatory Co-operation Council](#), Health Canada continued to work with the United States Food and Drug Administration, through the International Medical Devices Regulators Forum, to build a Medical Device Single Review Program. This program will improve patient access to medical devices, support innovation and strengthen the development of standards. Health Canada and the Food and Drug Administration collaborated on the review of the Affinity NT Oxygenator with Balance Biosurface medical device, which was approved in both countries.

### MEDICAL DEVICES ACTION PLAN

[Health Canada’s Medical Devices Action Plan](#) was launched in 2018 with the aim of strengthening the regulatory system for medical devices. Through the Action Plan, we aim to continuously improve the safety, effectiveness and quality of devices in Canada. In 2020 we remained focussed on the three components of the Medical Devices Action Plan.

#### Improving how medical devices get on the Canadian market

We continued to seek advice from the scientific, medical and patient communities about current and emerging issues. We held meetings of the Scientific Advisory Committees on [Medical Devices Used in the Cardiovascular System](#) and [Health Products for Women](#). These committees provide us with ongoing advice and recommendations on regulatory issues for medical devices.

#### Strengthening monitoring and follow-up of medical devices

To improve our surveillance of medical devices once they are on the market, we published [regulations relating to the post-market surveillance of medical devices](#). These regulations brought certain provisions of Vanessa’s Law into effect for medical devices and introduced additional measures to gather safety information. They strengthen our ability to collect post-market information, and take appropriate action when a serious safety issue is identified.

#### Providing more information to Canadians

In 2020 we continued to advance our openness and transparency efforts by expanding the amount of regulatory health and safety information that is made available to Canadians. For more information about the clinical information portal and regulatory decision summaries, go to “[Medical Devices: 2020 in brief](#)”.



## MANDATORY REPORTING OF MEDICAL DEVICE INCIDENTS BY HOSPITALS

In 2020 Health Canada supported the implementation of [new regulations for mandatory reporting by hospitals](#) that came into force in December 2019. These regulations will increase the quantity and improve the quality of reports of medical device incidents. Hospitals are now required to report to Health Canada all medical device incidents within 30 days of being documented within the hospital.

Health Canada developed tools to support hospitals including a [guidance document](#), [education modules](#) and [promotional materials](#).

The number of medical device incident reports submitted to Health Canada by hospitals for medical devices increased by 620 percent in 2020. After the implementation of mandatory reporting, several data elements in the report form became mandatory, to ensure that important details were provided to Health Canada. This additional information aims to expand the data used by Health Canada to monitor the safety and effectiveness of medical devices.





## HEALTHY CLICKS MEDICAL DEVICES AT A GLANCE

To stay informed about our activities:



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



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



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

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



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

You can also find specific information about medical devices by following the links below.

## MEDICAL DEVICES FOR USE IN COVID-19

### NEW

The **Lists of medical devices** show the various medical devices that have been authorized for use in relation to the COVID-19 pandemic.

**Authorized medical devices for uses related to COVID-19: Overview** [↗](https://canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/authorized.html)  
[canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/authorized.html](https://canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/authorized.html)

Health Canada publishes up-to-date information about **personal protective equipment** in relation to COVID-19.

**COVID-19 personal protective equipment (PPE)** [↗](https://canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/personal-protective-equipment.html)  
[canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/personal-protective-equipment.html](https://canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/personal-protective-equipment.html)

The **List of authorized clinical trials** shows the COVID-19 medical devices that are currently being investigated in clinical trials authorized by Health Canada.

**Conducting a clinical trial for COVID-19 medical devices: List of authorized clinical trials** [↗](https://canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/list-authorized-trials.html)  
[canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/list-authorized-trials.html](https://canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/list-authorized-trials.html)

## NEW MEDICAL DEVICES APPROVED

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

**Medical Devices Active Licences** [↗](https://health-products.canada.ca/mdall-limh/)  
<https://health-products.canada.ca/mdall-limh/>

**Search for data** about the tests and trials that were performed on medical devices to evaluate their safety and efficacy.

**Clinical information on drugs and health products** [↗](https://www.canada.ca/en/health-canada/services/drug-health-product-review-approval/clinical-information-drugs-health-products.html)  
<https://www.canada.ca/en/health-canada/services/drug-health-product-review-approval/clinical-information-drugs-health-products.html>

**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** [↗](https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/regulatory-decision-summary.html)  
<https://www.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** [↗](https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/summary-basis-decision.html)  
<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/summary-basis-decision.html>





## SURVEILLANCE OF MEDICAL DEVICES

### REPORT A MEDICAL DEVICE INCIDENT

#### Canada Vigilance Program [↗](#)

<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>

You can report 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 the **Canada Vigilance Program** 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](https://healthy.canadians.gc.ca/recall-alert-rappel-avis)

The **searchable extract of medical device incidents, complaints and recalls** includes suspected medical device incidents reported to Health Canada. These incidents have been submitted by consumers and health professionals as well as medical device manufacturers and importers.

#### Medical Device Incidents [↗](#)

[hpr-rps.hres.ca/mdi\\_landing.php](https://hpr-rps.hres.ca/mdi_landing.php)

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 [↗](#)

[canada.ca/en/health-canada/services/drugs-health-products/regulatory-requirements-advertising/health-product-advertising-complaints.html](https://canada.ca/en/health-canada/services/drugs-health-products/regulatory-requirements-advertising/health-product-advertising-complaints.html)

**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](https://hpr-rps.hres.ca/reg-content/summary-safety-review.php)

**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](https://canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/safety-reviews/new.html)

**Health Product InfoWatch** is a monthly publication intended primarily for health care 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](https://canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/health-product-infowatch.html)





## DRUGS FOR VETERINARY USE: 2020 IN BRIEF

One of Health Canada's roles is to regulate drugs for veterinary use, which play an important role in protecting human and animal health. We evaluate and monitor the safety, quality and effectiveness of veterinary drugs. In doing so, we work to protect animals and Canada's food supply.

The COVID-19 pandemic created an urgent need for access to safe, effective and high quality health products, including veterinary drugs should the specific need to treat animals arise. Although COVID-19 is understood to be primarily a new human disease, its impacts on animal health may not be fully known at this time.

### RESPONSE TO THE COVID-19 PANDEMIC

As part of the government's response to the pandemic, we introduced innovative and agile regulatory measures, including for veterinary drugs. These measures expedited the regulatory review of COVID-19 health products, without compromising safety, efficacy and quality standards.

In 2020 we modernized the regulations for the Emergency Drug Release program to facilitate emergency access to unapproved drugs for veterinary use.

For more information about our response to the COVID-19 pandemic, go to "[Drugs for veterinary use: 2020 accomplishments](#)".

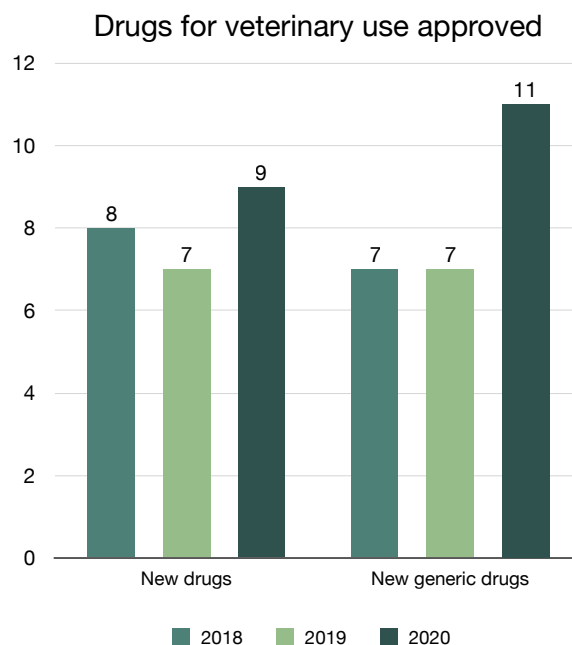
### NEW HEALTH PRODUCTS APPROVED

In 2020 we approved nine new drugs for companion or food-producing animals. This enabled access to innovative new products and therapies to help maintain and improve the health of animals.

We also approved 11 new generic drugs to provide additional options for more cost-effective prevention and treatment.

For a list and description of the new drugs we approved in 2020, go to "[Drugs for veterinary use: Approved in 2020](#)".

This year, 761 veterinary health products were notified within our veterinary health product program. These offer more low-risk options to maintain or promote health and wellness in animals.

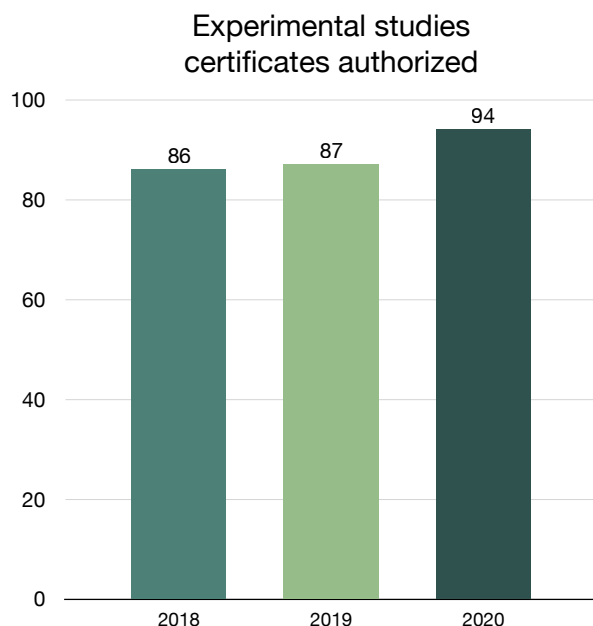




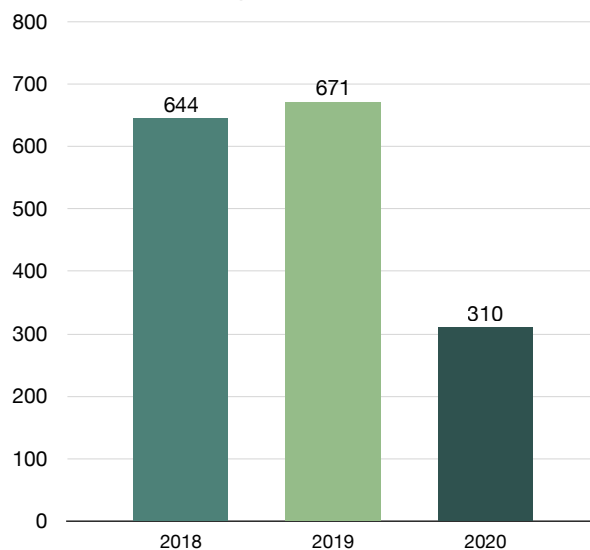
## CLINICAL TRIALS AND EMERGENCY DRUG RELEASE PROGRAM

We review applications to allow companies and researchers to conduct studies on veterinary drugs in Canada. New veterinary drug trials (called investigational new drugs and experimental studies) mean Canadians may have access to new products in the future. In 2020, 94 Experimental Studies Certificates that support clinical trials or research activities were authorized.

Through our Emergency Drug Release program, veterinarians can request authorization for drugs for veterinary use that are not available in Canada for emergency situations. In 2020, 310 requests under the Emergency Drug Release program were authorized.



## Emergency drug release requests authorized



## SURVEILLANCE

After we approve a drug for sale in Canada, we continue to monitor and evaluate reports of suspected adverse veterinary drug reactions.

This “Drugs for Veterinary Use” chapter gives you more information about our work in 2020. For up-to-date information about our activities see the [“Healthy clicks – Drugs for veterinary use at a glance”](#) section, and follow us on social media.



Marilena Bassi  
Director General,  
Veterinary Drugs

*MBassi*



## DRUGS FOR VETERINARY USE: WHAT'S NEW IN 2020

In 2020 Health Canada approved nine new drugs for veterinary use. More detail is available in the section “[Drugs for Veterinary Use: Approved in 2020](#)”.

### New Drugs for Veterinary Use

- Amodip Flavoured Tablets
- Aserve Equihaler
- Bravecto One
- Comfortan
- Cosacthen
- Eradia
- Gonabreed
- Mirataz
- Zeleris







## DRUGS FOR VETERINARY USE: 2020 ACCOMPLISHMENTS

### RESPONDING TO THE COVID-19 PANDEMIC

COVID-19 is understood to be primarily a human disease and the virus is believed to spread mainly from person-to-person. However, COVID-19 is a new disease and its impacts on animal health may not be fully known at this time.

#### Emergency Drug Release program

Drugs that are not approved in Canada may be accessible through Health Canada's Emergency Drug Release (EDR) program. Veterinarians may request access to unapproved veterinary drugs to treat patients (an animal or group of animals) with serious or life-threatening conditions. Access to these drugs is only considered when conventional therapies have failed, are unsuitable or unavailable.

In 2020 we **modernized the regulations** for the Emergency Drug Release program to facilitate emergency access to unapproved drugs for veterinary use.

For more information, go to **Health Canada's special access programs: Request a veterinary drug through EDR**.

#### Drugs for veterinary use

As part of the government's response to the pandemic, Health Canada introduced innovative and agile regulatory measures. This will allow us to expedite the regulatory review of COVID-19 veterinary drugs, without compromising our high standards for safety, efficacy and quality if a manufacturer files an application in the future.

### Focus on... EMERGENCY DRUG RELEASE PROGRAM

*"Reviewing applications received through the Emergency Drug Release program puts us in direct contact with veterinarians in clinical practice. We are fortunate to have updated regulations in place to help ensure that life-saving and welfare-improving drugs are made available to animals, especially when veterinarians are faced with treating emerging diseases in their patients. It is a rewarding experience to be part of the multifaceted collaborative effort to support animal health and welfare."*

**Shaunna Lucas**

Information Officer, Veterinary Drugs

**Annie Tourangeau**

Veterinary Information Analyst, Veterinary Drugs

**Julie Burke**

Veterinary Information Analyst, Veterinary Drugs

For more information on the Interim Orders that were published to address the COVID-19 pandemic, go to **"Message from the Chief Regulatory Officer"**.

#### Drug shortages

Early in the pandemic, it was clear that COVID-19 was having an impact on the supply of critical health products in Canada. We worked with companies and manufacturers, as well as other regulators globally,



to identify and respond to potential shortages. These helped us to identify, prevent and ease shortages for Canadians.

For more information, go to [Addressing critical product shortages](#).

### Communications and collaborations

Throughout the pandemic, Health Canada published a number of web pages to provide information to Canadians, regulatory partners and the health product industry about our [response to the COVID-19 pandemic](#). Our websites provide information about the various health products we regulate, including applications for drugs that have been [submitted](#) and [approved](#).

We worked closely with our domestic partners including manufacturers, practitioners and food producers. We sought their perspectives on the priorities and challenges they were facing as a result of the pandemic.

## ADDRESSING ANTIMICROBIAL RESISTANCE RELATED TO ANIMALS

Antimicrobial resistance is a growing public health threat in Canada and worldwide. The overuse and misuses of antimicrobial drugs allow illness-causing germs like bacteria and fungi to evolve and become resistant to antimicrobials.

Antimicrobial use in animals can contribute to the development and spread of resistant bacteria in humans. A “One Health” approach acknowledges the interconnection between the health of humans, animals and their shared environment, and the need for collaborative efforts across sectors to improve health for all.

In 2020 Health Canada continued to focus on our next set of veterinary drug antimicrobial resistance initiatives on keeping animals healthy to reduce the use of antimicrobials, and to promote their responsible use when they are needed. This included:

- [Publishing the post-market re-evaluation framework](#) for antimicrobials important to human medicine to strengthen their responsible use in animals.

- Completing the [analysis of the first year \(2018\) of veterinary antimicrobial sales data](#) collected under the Veterinary Antimicrobial Sales Reporting program to support surveillance efforts. Analysis is underway for the data collected in the second year (2019) of the program.
- Launching a pilot project that expands access to veterinary health products that could be used in livestock feed, in partnership with the Canadian Food Inspection Agency. This project aims to facilitate increased access to general health and wellness products to improve animal health and reduce the reliance on conventional drugs, including antimicrobials.

These initiatives are in line with 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: 2020 accomplishments”](#).

### Focus on... WORLD ANTIMICROBIAL AWARENESS WEEK, NOVEMBER 18-24, 2020

Every year Health Canada joins the World Health Organization, international health agencies and other national authorities to support World Antimicrobial Awareness Week. This global initiative aims to raise awareness about antimicrobial resistance in animals and humans and to encourage best practices to avoid the spread of drug-resistant infections. In 2020 we welcomed a panel of international speakers to discuss the challenges associated with antimicrobial research, development and access to therapies.

### REGULATORY INNOVATION

The current pace of innovation is unprecedented. This has led to new health products that are increasingly complex. We need new regulatory approaches to better support access to these health technologies, while continuing to protect patient safety.

Health Canada continued to prioritize regulatory innovation in 2020. The COVID-19 pandemic affected the timelines of this work. However, it also provided an opportunity to test certain temporary agile measures (for more information, go to “[Message from the Chief Regulatory Officer](#)”). We will be using the lessons learned from our regulatory response to COVID-19 to inform our regulatory innovation work, including these related to drugs for veterinary use:

- modernizing regulations for investigational studies, including experimental studies certificates,
- enabling access to advanced therapeutic products that do not fit our current system, and
- agile licensing for drugs, using flexible tools to oversee products across their life-cycle.

For more information, go to “[Regulatory innovation for health products](#)”.

### COLLABORATING INTERNATIONALLY

For many years, Health Canada has worked closely with regulators around the world on issues related to drugs for veterinary use. This cooperation progressed significantly in 2020.

We continued our simultaneous reviews of veterinary drugs in partnership with the United States Food and Drug Administration’s Center for Veterinary Drugs. This partnership offers manufacturers access to two major markets, expands the access to treatment options for animals in Canada, and helps Canadian food producers stay competitive globally.

In 2020 we published the [Guidance on Veterinary Drug Joint Reviews](#) with Australia and New Zealand, which outlines the joint review process for veterinary drugs. Also in 2020, we launched a process for simultaneous reviews with the United Kingdom. As of December 31, 2020, we had 1 joint review ongoing with Australia/New Zealand, and 10 simultaneous reviews ongoing with the United States.



## PROVIDING MORE CHOICES TO IMPROVE ANIMAL HEALTH AND WELLNESS

By keeping animals healthy, we can reduce the need to use drugs, including antimicrobials. Veterinary health products are low-risk products that can help maintain or promote the health and wellness of animals. They include ingredients such as vitamins, minerals and traditional medicines.

Presently, products that contain a phytocannabinoid produced by or found in the cannabis plant can only be prescribed by a health care practitioner for medicinal purposes. Health Canada is aware that some Canadians are interested in potential therapeutic uses of cannabis for purposes such as pain relief for animal use, without the need for practitioner oversight. In 2019 Health Canada consulted on the potential market for such health products. We published a [summary report](#) in 2020, which provides an overview of the comments received from Canadians.

As part of this consultation, we also established a [Scientific Advisory Committee on Health Products Containing Cannabis](#), which includes a subcommittee to address issues related to health products containing cannabis for use in animals. This committee will provide us with independent scientific and clinical advice about appropriate safety, efficacy and quality considerations for health products containing cannabis, including for veterinary use. Health Canada will use this information to inform its regulatory path forward on these products.

## CONSULTING ON CHANGES TO OUR REGULATORY APPROACH

Many veterinary drugs are intended for use in food-producing animals such as cattle, chickens and pigs. Health Canada works 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. In 2020 we consulted on a [proposal to amend the list of maximum residue limits for veterinary drugs in foods](#).

## Focus on... VETERINARY HEALTH PRODUCTS

Health Canada has in place a flexible and risk-appropriate framework for low risk health products for both food-producing and companion animals. This framework facilitates access to these veterinary health products. There are now over 2300 such products notified for sale in Canada. As the Notification Program for veterinary health products grows in popularity with Canadians and stakeholders, we continue to expand the type of ingredients and products included in the program. We do so without compromising the safety of animals or humans, including food safety. Our program also provides extensive and searchable information to Canadians.

*“Our program provides information to Canadians about veterinary health products – the web-based application is user-friendly and information is easy to find and search.”*

**Femma Van As**  
Drug Evaluator, Veterinary Drugs

We also consulted in 2020 on a [proposed regulatory classification of products that contain acid based products intended for livestock species](#). Historically, these products may have been classified as either a veterinary drug, veterinary health product or livestock feed. This proposal will provide clarification about how these important products should be classified and subsequently regulated.





# HEALTHY CLICKS

## DRUGS FOR VETERINARY USE AT A GLANCE

To stay informed about our activities:



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



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



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

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



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

You can also find specific information about veterinary drugs by following the links below.

## 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**   
[health-products.canada.ca/dpd-bdpp/index-eng.jsp](https://health-products.canada.ca/dpd-bdpp/index-eng.jsp)

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/](https://health-products.canada.ca/noc-ac/)

## 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](https://canada.ca/en/health-canada/services/drugs-health-products/veterinary-drugs/adverse-drug-reactions-adrs.html)









# DRUGS FOR HUMAN USE: LIFE-CYCLE

As part of Health Canada's mission to help Canadians maintain and improve their health, we evaluate drugs before they reach the Canadian market and continue to monitor real world evidence while they are on the market. Health Canada is involved throughout the life-cycle of a drug for human use, from clinical trials to after the drug is being sold 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. Sponsors of clinical trials submit their applications to conduct a clinical trial with a drug in Canada. Health Canada reviews these applications before the trial is conducted in Canada.

## SPECIAL ACCESS PROGRAM

Drugs that are not approved in Canada may be available through our [Special Access Program](#). In this program, access is given to an individual health care 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.

## DRUG SUBMISSION AND REVIEW

When a company decides that it would like to market a drug in Canada, it files a submission with Health Canada. A new drug submission contains detailed scientific information about the drug's safety, quality and efficacy.

Our scientists and medical officers [perform a thorough review of the information submitted](#). Sometimes we also consult with advisory committees or external consultants. Reviewers evaluate the safety, efficacy and quality data to assess the benefits and potential risks of the drug. They also review the information that will be provided to health care practitioners and consumers about the drug.

## Expedited review pathways

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

**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.

**Notice of Compliance with conditions:** When a new drug is approved it is issued a Notice of Compliance (NOC). A Notice of Compliance 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, and also commits to undertake additional studies to verify the clinical benefit of the drug. Submissions that are reviewed under this pathway are subject to an expedited review 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.

## 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 approved and available for sale in Canada, we continue to monitor its use in the real world, that is, in the broader Canadian population that may be taking other medications. We evaluate potential safety and effectiveness issues, and take action when there are identified problems.

## Collecting information

Health Canada collects safety information about a product after it is approved from a variety of sources. One source of information is suspected adverse reactions that are reported after products are approved for sale. Adverse reactions are undesirable effects potentially caused by drugs.

You can report adverse drug reactions to your medical professional, to a hospital or to the company that made the product.

You can also report them to Health Canada through the [Canada Vigilance Program](#) or by phone at [1-866-234-2345](tel:1-866-234-2345).

Another source of information are documents called Risk Management Plans that are submitted by manufacturers as part of their drug submissions. A Risk Management Plan 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 effectiveness of the drug.

## Evaluating safety signals

Health Canada evaluates 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 health care professionals of new safety information or recommending labelling changes. In the most serious situations, we may remove a drug from the market.

## Advertising complaints

Health Canada also regulates the advertising of drugs 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, and 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.



# DRUGS FOR HUMAN USE: APPROVED IN 2020

This section outlines the new drugs, generic drugs and biosimilars approved for sale in Canada in 2020, and the safety updates issued.

## HEALTH CATEGORIES

The drugs listed have been divided into categories according to the **Anatomical Therapeutic Chemical Classification System**, a system of codes developed by the World Health Organization. These 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 and drugs for diabetes.

**Antiinfectives for systemic use** – for example, antibacterials, 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 anticoagulants.

**Cardiovascular system** – for example, drugs for high blood pressure and anticholesterol agents.

**Dermatologicals** – for example, drugs to treat psoriasis.

**Genito urinary system and sex hormones** – for example, hormonal contraception and drugs for the urinary tract system.

**Musculo-skeletal system** – for example, drugs such as anti-inflammatories and muscle relaxants.

**Nervous system** – for example, analgesics and antidepressants.

**Respiratory system** – for example, drugs to treat asthma and antihistamines.

**Sensory organs** – for example, drugs to treat vision loss.

**Systemic hormonal preparations, excluding sex hormones and insulins** – for example, drugs to treat hypothyroidism.

**Various** – for example, drugs unable to be classified into the other categories such as diagnostic agents.



## 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.



### Approved under an interim order

This indicates the drug was approved under the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19.



### Biologic drug

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

### Biosimilar

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



### COVID-19

This indicates the drug was approved for use in the treatment or prevention of COVID-19.



### 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 \(EUNDS\)](#) 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 drug

A generic drug is 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 health care system.



### 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.

### New drug

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



### Non-prescription (“over-the-counter”) drug

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



### 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, and also commits to undertake additional studies to verify the clinical benefit of the drug. Submissions that are reviewed under this pathway are subject to shorter review targets.



### Orphan drug

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



### Pediatric indication

This indicates that the drug has been approved for use in children less than 18 years old.



### 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.



### Review with international partners

A review with international partners is one where Health Canada worked with certain regulators to share the work of drug reviews. For more information, go to “[Drugs for Human Use: 2020 Accomplishments](#)”.

## 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.

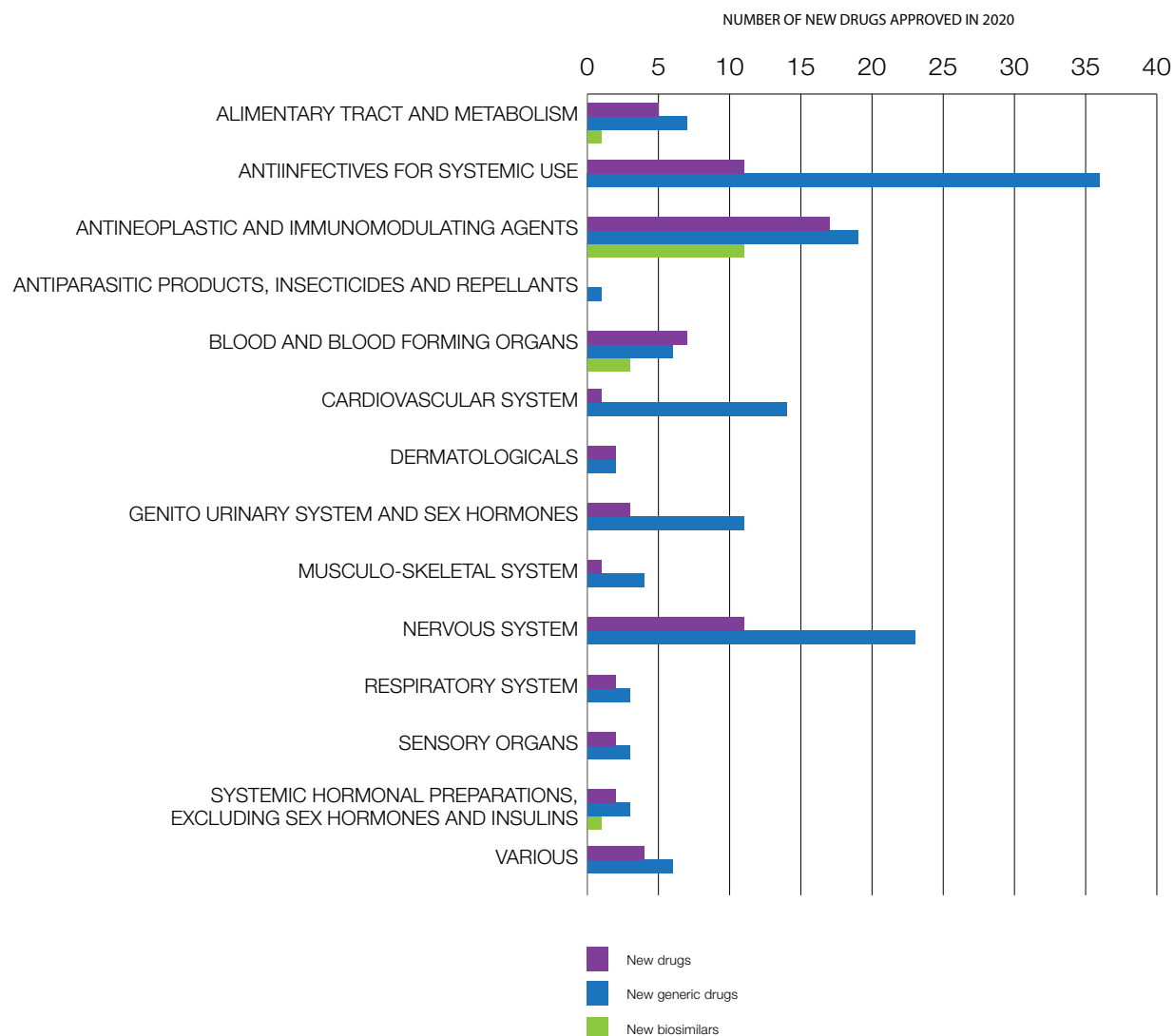
For more information about the types of risk communications that can be found on the Government of Canada’s website, go to “[Healthy Clicks – Drugs for Human Use At a Glance](#)”.

You can report adverse drug reactions to your medical professional, to a hospital or to the company that made the product.

You can also report them to Health Canada through the [Canada Vigilance Program](#) or by phone at [1-866-234-2345](#).



# NEW DRUGS, NEW GENERIC DRUGS, AND NEW BIOSIMILARS APPROVED IN 2020





## ALIMENTARY TRACT AND METABOLISM

For example, drugs for the gastrointestinal tract and drugs for diabetes.

### 5 NEW DRUGS

#### GIVLAARI



##### Medicinal Ingredient

Givosiran

##### Indication

Givlaari is used to treat acute hepatic porphyria in adults.

#### IBSRELA



##### Decision Summary

##### Medicinal Ingredient

Tenapanor

##### Indication

Ibsrela is used in adults (18 years of age and older) to treat a condition called irritable bowel syndrome with constipation (IBS-C).

#### MAR-TRIENTINE



##### Medicinal Ingredient

Trientine hydrochloride

##### Indication

MAR-Trientine is used for the treatment of Wilson's disease. It is used in patients who cannot take the drug penicillamine.

#### RYBELSUS



##### Decision Summary

##### Medicinal Ingredient

Semaglutide

##### Indication

Rybelsus contains the active substance semaglutide. It is used to lower blood sugar (glucose) in adults with type 2 diabetes. Rybelsus is used on its own if a patient's blood sugar level is not properly controlled by diet and exercise alone and they cannot use metformin. Rybelsus is used in combination with one or more other medicines for diabetes when they are not enough to control a patient's blood sugar levels.

#### UCERIS

##### Decision Summary

##### Medicinal ingredient

Budesonide

##### Indication

Uceris is used to treat mild to moderate ulcerative colitis and to get this condition under control (induced remission).

### 1 NEW BIOSIMILAR

#### TRURAPI



##### Decision Summary

##### Medicinal Ingredient

Insulin aspart

##### Indication

Trurapi is used for the treatment of patients with diabetes mellitus who require insulin for the control of hyperglycemia (high blood sugar).

## 7 NEW GENERIC DRUGS

- 1 product containing calcitriol
- 1 product containing famotidine
- 1 product containing hyoscine butylbromide
- 1 product containing loperamide hydrochloride (non-prescription drug)
- 2 products containing ondansetron
- 1 product containing prucalopride

## SAFETY UPDATES

Apo-Metformin ER (extended release): [Information Update: Apotex Inc. recalls certain lots of the diabetes medication](#)

Axid (nizatidine): [Advisory: Axid \(nizatidine\) drug recalled due to presence of NDMA](#)

GUM Paroex (anti-gingivitis oral rinse): [Advisory: GUM Paroex \(anti-gingivitis oral rinse\) being recalled due to microbial contamination that could lead to respiratory and other infections in patients](#)

Mesalazine-containing products: [Summary Safety Review: Mesalazine-containing products - Assessing the Potential Risk of Birth Defects](#)

Metformin:

[Information Update: Ranbaxy Pharmaceuticals recalls six lots of RAN-Metformin due to the presence of NDMA](#)

[Information Update: JAMP Pharma recalls all 26 lots of metformin](#)

[Information Update: Certain Metformin diabetes drugs were recalled due to the presence or possible presence of NDMA](#)

PMS-Nystatin Oral Suspension: [Advisory: Pharmascience Inc. recalls one lot of prescription antifungal drug PMS-Nystatin Oral Suspension: Product may pose a choking risk](#)

Ranitidine:

[Advisory: Status of ranitidine drugs in Canada](#)

[Information Update: Ranitidine products recalled because of a nitrosamine impurity](#)

Zofran and Zofran ODT (Oral Disintegrating Tablets) (ondansetron): [Health Product InfoWatch: Risks during pregnancy](#)

## ANTIINFECTIVES FOR SYSTEMIC USE

*For example, antibacterials, antivirals and vaccines.*

## 11 NEW DRUGS

### AMOXICILLIN SODIUM AND POTASSIUM CLAVULANATE FOR INJECTION



► [Decision Summary](#)

#### Medicinal Ingredients

Amoxicillin, clavulanic acid

#### Indication

Amoxicillin Sodium and Potassium Clavulanate for Injection is used to treat certain bacterial infections including infections of the:

- nose, ear, and throat,
- respiratory tract,
- genitals and urinary tract,
- skin and soft tissue,
- bone and joints, and
- abdominal organs.

Amoxicillin Sodium and Potassium Clavulanate for Injection is also used to help stop infections in patients having surgery.

## ANTHIM



### ► Decision Summary [↗](#)

#### Medicinal Ingredient

Obiltoximab

#### Indication

Anthim is used along with antibiotic medicines to treat people with inhalational anthrax. Anthim can also be used to prevent anthrax disease after exposure to anthrax spores when there are no other treatment options.

The effectiveness of Anthim has been studied only in animals with inhalational anthrax. There have been no studies in people who have inhalational anthrax.

The safety of Anthim was studied in healthy adults. There have been no studies of Anthim in children younger than 18 years.

Anthim is not used in prevention or treatment of anthrax meningitis.

## BAMLANIVIMAB



### ► Decision Summary [↗](#)

#### Medicinal Ingredient

Bamlanivimab

#### Indication

Bamlanivimab is a medicine being studied for the treatment of COVID-19. Bamlanivimab may help limit the amount of virus in a patient's body; this may help them get better faster. Bamlanivimab may be given to children 12 years of age or older who weigh at least 40 kilograms and are not already in the hospital. Bamlanivimab is only given to patients at high-risk of having the disease get worse.

## CABENUVA / VOCABRIA



### ► Decision Summary [↗](#)

#### Medicinal Ingredients

Cabotegravir, rilpivirine / cabotegravir

#### Indication

Cabenuva is used to treat human immunodeficiency virus (HIV) infection in adults. Cabenuva replaces a patient's current HIV treatment.

Vocabria is taken together with Edurant (rilpivirine) to treat HIV infection in adults:

- in the month before a patient begins treatment on Cabenuva to test how well they tolerate these medicines (cabotegravir and rilpivirine), and
- as a replacement for Cabenuva injections if a patient needs to miss their next scheduled injection (e.g. vacation).

## COVID-19 VACCINE MODERNA



### ► Decision Summary [↗](#)

#### Medicinal Ingredient

mRNA-1273 SARS-CoV-2

#### Indication

Moderna COVID-19 Vaccine is a vaccine used to prevent the coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus. It can be given to adults aged 18 years and older.



## MENQUADFI



### ► Decision Summary [↗](#)

#### Medicinal Ingredient

Meningococcal groups a, c, w and y polysaccharide-tetanus toxoid conjugates, tetanus toxoid

#### Indication

MenQuadfi is a vaccine. It is used to help protect against infections caused by bacteria (germs) called “Neisseria meningitides” types A, C, W and Y. Neisseria meningitidis can be passed from person to person and can cause meningitis, an inflammation of the tissues that surround the brain and spinal cord, or septicemia, an infection of the blood. Both can result in serious disease with lasting effects and possibly death. MenQuadfi will not protect against disease caused by any other infectious agents.

## PFIZER BIONTECH COVID-19 VACCINE



### ► Decision Summary [↗](#)

#### Medicinal Ingredient

Tozinameran

#### Indication

Pfizer-BioNTech COVID-19 Vaccine is a vaccine used to prevent COVID-19 disease caused by the SARS-CoV-2 virus. Pfizer-BioNTech COVID-19 Vaccine can be given to people from 16 years of age and older.

## VEKLURY



### ► Decision Summary [↗](#)

#### Medicinal Ingredient

Remdesivir

#### Indication

Veklury is indicated for the treatment of COVID-19 in adults and adolescents (aged 12 years and older with body weight at least 40 kilograms) with pneumonia requiring supplemental oxygen.

## VOCARVI

### ► Decision Summary [↗](#)

#### Medicinal Ingredient

Foscarnet sodium

#### Indication

Vocarvi is an antiviral agent which is injected. Vocarvi is usually used to treat retinitis (inflamed condition of the eye) caused by cytomegalovirus (CMV) in patients who have acquired immunodeficiency syndrome (AIDS). Vocarvi can also be used to treat acyclovir-resistant mucocutaneous herpes simplex virus in patients who are immunocompromised (have a weak immune system).

## XENLETA



### ► Decision Summary [↗](#)

#### Medicinal Ingredient

Lefamulin

#### Indication

Xenleta is used in adults to treat an infection of the lungs called community-acquired pneumonia (CAP). CAP develops in adults with limited or no contact with hospitals or healthcare centers. Adults with CAP get infected in a community setting. Antibacterial drugs like Xenleta treat only bacterial infections. They do not treat viral infections.

## XOFLUZA



### ► Decision Summary [↗](#)

#### Medicinal Ingredient

Baloxavir marboxil

#### Indication

Xofluza is used to treat influenza (the flu) in patients 12 years or older who have had flu symptoms for no more than 48 hours. It is given to healthy patients or patients that are more likely to have health problems from the flu.

## 36 NEW GENERIC DRUGS

- 2 products containing abacavir, lamivudine
- 1 product containing amikacin
- 1 product containing amoxicillin
- 1 product containing amoxicillin, clavulanic acid
- 1 product containing azithromycin
- 1 product containing cefazolin
- 1 product containing cefepime
- 1 product containing ceftriaxone
- 2 products containing cephalexin
- 4 products containing daptomycin
- 5 products containing darunavir
- 2 products containing ertapenem
- 1 product containing itraconazole
- 1 product containing lamivudine
- 1 product containing lamivudine, zidovudine
- 1 product containing levofloxacin
- 1 product containing nitrofurantoin
- 5 products containing oseltamivir
- 1 product containing posaconazole
- 1 product containing tobramycin
- 1 product containing valganciclovir
- 1 product containing vancomycin

## SAFETY UPDATES

Bacitracin for Injection:

**Dear Healthcare Professional Letter: Bacitracin for Injection (50,000 IU per vial) and the Risk of Nephrotoxicity and Anaphylactic Reactions**

**Summary Safety Review: Bacitracin for Injection Products - Assessing the Potential Risks of Nephrotoxicity and Anaphylactic Reactions**

Bamlanivimab: **Dear Healthcare Professional Letter: Authorization of Bamlanivimab with English-only Labels for Use in Relation to the COVID-19 Pandemic**

COVID-19 Vaccine Moderna: **Dear Healthcare Professional Letter: Authorization of Moderna COVID-19 Vaccine with English-only Vial and Carton Labels**

Direct-acting antivirals:

**Summary Safety Review: Direct-acting antivirals - Assessing the potential risk of abnormal blood sugar levels (dysglycemia)**

**Summary Safety Review: Direct-Acting Antivirals - Assessing the Potential Risk of New or Returning Liver Cancer named Hepatocellular Carcinoma**

**Summary Safety Review: Direct-acting antiviral products containing a Protease Inhibitor - Assessing the Potential Risks of Hepatic Decompensation and Hepatic Failure**

Pfizer-BioNTech COVID-19 Vaccine:

**Advisory: Pfizer-BioNTech COVID-19 vaccine: Health Canada recommendations for people with serious allergies**

**Dear Healthcare Professional Letter: Authorization of Pfizer-BioNTech COVID-19 Vaccine with English-only Carton and Vial Labels**

Rifampin: **Advisory: Update on the rifampin drug shortage**

Tygacil (tigecycline): **Health Product InfoWatch: Risk of hypofibrinogenemia and recommendations on monitoring of blood coagulation parameters**

Valcyte (valganciclovir): **Health Product InfoWatch: Change in graduation on the oral dosing dispenser from milligrams (mg) to millilitres (mL)**

Veklury (remdesivir):

**Advisory: Remdesivir authorized with conditions for the treatment of patients in Canada with severe COVID-19 symptoms**

**Dear Healthcare Professional Letter: Importation of US Clinical Trial-Labelled Remdesivir for Injection Due to Shortage of Canadian-Labelled Remdesivir**

WinRho SDF: **Health Product InfoWatch: Labelling error for WinRho SDF (Rho(D) Immune Globulin (Human) for Injection)**

## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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

### 17 NEW DRUGS

#### DAURISMO



##### Medicinal Ingredient

Glasdegib

##### Indication

Daurismo is indicated, in combination with low-dose cytarabine, for the treatment of newly diagnosed and previously untreated acute myeloid leukemia (AML) in adult patients who are age 75 or more or who are not eligible to receive intensive induction chemotherapy.

#### ENSPRYNG



##### ► Decision Summary [↗](#)

##### Medicinal Ingredient

Satralizumab

##### Indication

Enspryng is for treatment of neuromyelitis optica spectrum disorders (NMOSD). It is used in adults and young people from 12 years of age. Enspryng reduces the risk of a relapse or attack of NMOSD.

#### GLEOLAN



##### Medicinal Ingredient

Aminolevulinic acid hydrochloride

##### Indication

Gleolan is used to help visualize certain brain tumours (called malignant glioma) during tumour surgery.

#### INQOVI



##### Medicinal Ingredients

Cedazuridine, decitabine

##### Indication

Inqovi is used to treat adults with myelodysplastic syndromes (MDS) or chronic myelomonocytic leukemia (CMML). In MDS and CMML, the bone marrow does not make enough healthy mature blood cells. MDS and CMML are types of cancer.

#### INREBIC



##### Medicinal Ingredient

Fedratinib

##### Indication

It is used to treat adults with an enlarged spleen and/or the associated symptoms caused by certain types of myelofibrosis. Myelofibrosis is a rare form of blood cancer.

#### MAYZENT



##### ► Decision Summary [↗](#)

##### Medicinal Ingredient

Siponimod

##### Indication

Mayzent is used to treat adults with a form of multiple sclerosis (MS) known as secondary progressive MS (SPMS), specifically SPMS with active disease. This means that patients still have relapses or signs of inflammation that can be seen in scans (magnetic resonance imaging, or MRI). Mayzent is used to slow down the progression of physical disability.



## NUBEQA



### ► Decision Summary [↗](#)

#### Medicinal Ingredient

Darolutamide

#### Indication

Nubeqa is used in adults 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.

Nubeqa has not been studied in patients with low risk of the cancer spreading to other parts of the body.

## ODOMZO



#### Medicinal Ingredient

Sonidegib

#### Indication

Odomzo is used to treat adults with a type of skin cancer, called basal cell carcinoma. It is used when the cancer has spread to surrounding areas (called “locally advanced” basal cell carcinoma [BCC]) and it cannot be treated with surgery or radiation.

## PIQRAY



### ► Decision Summary [↗](#)

#### Medicinal Ingredient

Alpelisib

#### Indication

Piqray is used to treat breast cancer, which has spread to other parts of the body, in post-menopausal women and in men. The breast cancer must be hormone receptor-positive and with a specific gene mutation (PIK3CA). Piqray is used with another drug for breast cancer called fulvestrant. This is used when the cancer gets worse after other therapies.

## POLIVY



### ► Decision Summary [↗](#)

#### Medicinal Ingredient

Polatuzumab vedotin

#### Indication

Polivy is given to adults to treat relapsed or refractory diffuse large B-cell lymphoma that has come back or has not responded to at least one previous therapy and who cannot receive a stem cell transplant. Diffuse large B-cell lymphoma is a cancer that develops from B-lymphocytes, a type of blood cell in the lymphatic system. Polivy is given in combination with two other medicines for cancer called rituximab and bendamustine.

## QINLOCK



#### Medicinal Ingredient

Ripretinib

#### Indication

Qinlock is used to treat adults with gastrointestinal stromal tumor (GIST), which is a type of soft tissue cancer (sarcoma). The cancer must have been treated before with other cancer drugs for GIST including imatinib, sunitinib, and regorafenib.

## ROZLYTREK



#### Medicinal Ingredient

Entrectinib

#### Indication

Rozlytrek is used to treat adults with solid tumours that have a Neurotrophic Tyrosine Receptor Kinase (NTRK) gene fusion without a known resistance mutation. Rozlytrek can treat cancers that have spread to different parts of the body. It is for patients without other treatment options. To benefit from Rozlytrek, the patient must have a tumour that has an NTRK gene fusion. This can be checked by a test that is done before a patient starts Rozlytrek.

## ROZLYTREK



### Medicinal Ingredient

Entrectinib

### Indication

Rozlytrek is used to treat adults with a kind of lung cancer called non-small cell lung cancer (NSCLC). The non-small cell lung cancer:

- is “ROS1-positive” (this means that a patient’s cancer cells have a fault in a gene called ‘ROS1’),
- may have spread to other parts of a patient’s body, and
- has not been treated with another drug called crizotinib.

To benefit from Rozlytrek, the patient must have non-small cell lung cancer (NSCLC) that is ROS1-positive. This can be checked by a test that is done before a patient starts Rozlytrek.

- cannot be removed by surgery,
- has spread outside the breast to other parts of the body such as the brain. This is called locally advanced or metastatic disease, and
- has been treated previously with the medications trastuzumab, pertuzumab, and trastuzumab emtansine.

## SARCLISA



### ► Decision Summary

### Medicinal Ingredient

Isatuximab

### Indication

Sarclisa is used in adults 18 years or older to treat a type of cancer called multiple myeloma. This is a cancer of the plasma cells which are found in the bone marrow.

## VERITY-BCG



### ► Decision Summary

### Medicinal Ingredient

Bacillus Calmette-Guérin (BCG) – strain Russian BCG-I

### Indication

Verity-BCG contains Bacillus Calmette-Guérin. These bacteria have been weakened, so that they can be used as a safe medicine. Verity-BCG is used to treat early bladder cancer that has not invaded the muscle wall of the bladder. It is used after bladder surgery – to prevent or delay bladder cancers from growing back or spreading into the deeper layers of the bladder.

## TUKYSA



### Medicinal Ingredient

Tucatinib

### Indication

Tukysa is used with the medications trastuzumab and capecitabine. It is used to treat adults with breast cancer that:

- is positive for human epidermal growth factor receptor 2 (HER2 positive),

## ZEPOSIA



### ► Decision Summary

### Medicinal Ingredient

Ozanimod

### Indication

Zeposia is used to treat adult patients with the relapsing and remitting form of multiple sclerosis (RRMS). Zeposia is not authorized for use in children.

## 11 NEW BIOSIMILARS

### AMGEVITA



#### ► Decision Summary [↗](#)

#### Medicinal Ingredient

Adalimumab

#### Indication

Amgevita is a medicine that is used in:

- Adults with rheumatoid arthritis which is an inflammatory disease of the joints.
- Patients 2 years of age and older who have polyarticular juvenile idiopathic arthritis.
- 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.
- Children 13 to 17 years weighing 40 kg or more who have severe Crohn's disease or who have Crohn's disease which has not responded to other usual treatments.
- Adults with ulcerative colitis, which is an inflammatory disease of the bowel (colon).
- Adults or adolescents (12 to 17 years of age, weighing 30 kg or more) 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. A doctor may prescribe Amgevita to reduce the signs and symptoms of plaque psoriasis.
- Adults with uveitis, which is an inflammatory disease of the eye.
- Children with chronic non-infectious uveitis from 2 years of age with inflammation affecting the front of the eye.

Patients with rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, hidradenitis suppurativa, psoriasis, or uveitis may be given other medicines for their disease before they are given Amgevita. If a patient has ulcerative colitis or Crohn's disease, they will first be given other medicines. If they do not respond well enough to these medicines, they will be given Amgevita to reduce the signs and symptoms of the disease.

### AVSOLA



#### ► Decision Summary [↗](#)

#### Medicinal Ingredient

Infliximab

#### Indication

Avsola is a medicine that is used in people with moderate to severe rheumatoid arthritis (in combination with methotrexate) and ankylosing spondylitis. A doctor may choose to treat rheumatoid arthritis with Avsola because a patient has moderately to severely active rheumatoid arthritis. A doctor may choose to treat ankylosing spondylitis with Avsola because a patient has had an inadequate response to other treatments or because they cannot tolerate other treatments.

Avsola is also used in people with moderate to severe plaque psoriasis. A doctor may choose to treat plaque psoriasis with Avsola because a patient's disease is still active even though they have tried other treatments.

Avsola is also used in people with active psoriatic arthritis. A doctor may choose to treat psoriatic arthritis with Avsola because a patient's disease is still active even though they have tried other treatments.

Avsola is also used in adults, children and teenagers with moderate to severe Crohn's disease or with moderate to severe ulcerative colitis. A doctor may choose to treat Crohn's disease or ulcerative colitis with Avsola because a patient's disease is still active even though they have tried other treatments.



## HULIO



### ► Decision Summary [↗](#)

#### Medicinal Ingredient

Adalimumab

#### Indication

Hulio 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.
- Patients 2 years of age and older who have polyarticular juvenile idiopathic arthritis.
- Children 13 to 17 years weighing 40 kg or more who have severe Crohn's disease or who have Crohn's disease which has not responded to other usual treatments.
- Adults with ulcerative colitis, which is an inflammatory disease of the bowel (colon).
- Adults or adolescents (12 to 17 years of age, weighing 30 kg or more) 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. A doctor may prescribe Hulio to reduce the signs and symptoms of plaque psoriasis.
- Adults with uveitis, which is an inflammatory disease of the eye.
- Children with chronic non-infectious uveitis from 2 years of age with inflammation affecting the front of the eye.

Patients with rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, hidradenitis suppurativa, psoriasis, or uveitis may be given other medicines for their disease before they are given Hulio. If a patient has ulcerative colitis or Crohn's disease, they will first be given other medicines. If they do not respond well enough to these medicines, they will be given Hulio to reduce the signs and symptoms of the disease.

## HYRIMOZ



### ► Decision Summary [↗](#)

#### Medicinal Ingredient

Adalimumab

#### Indication

Hyrimoz 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.
- Patients 2 years of age and older who have polyarticular juvenile idiopathic arthritis.
- 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. A doctor may prescribe Hyrimoz to reduce the signs and symptoms of plaque psoriasis.
- Adults with uveitis, which is an inflammatory disease of the eye.

Patients with rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, hidradenitis suppurativa, psoriasis, or uveitis may be given other medicines for their disease before they are given Hyrimoz. If a patient has ulcerative colitis or Crohn's disease, they will first be given other medicines. If they do not respond well enough to these medicines, they will be given Hyrimoz to reduce the signs and symptoms of the disease.

## IDACIO



### ► Decision Summary

#### Medicinal Ingredient

Adalimumab

#### Indication

Idacio 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.
- Patients 2 years of age and older who have polyarticular juvenile idiopathic arthritis.
- Children 13 to 17 years weighing 40 kg or more who have severe Crohn's disease or who have Crohn's disease which has not responded to other usual treatments.
- Adults with ulcerative colitis, which is an inflammatory disease of the bowel (colon).
- Adults or adolescents (12 to 17 years of age, weighing 30 kg or more) 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. A doctor may prescribe Idacio to reduce the signs and symptoms of plaque psoriasis.
- Adults with uveitis, which is an inflammatory disease of the eye.
- Children with chronic non-infectious uveitis from 2 years of age with inflammation affecting the front of the eye.

Patients with rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, hidradenitis suppurativa, psoriasis, or uveitis may be given other medicines for their disease before they are given Idacio. If a patient has ulcerative colitis or Crohn's disease, they will first be given other medicines. If they do not respond well enough to these medicines, they will be given Idacio to reduce the signs and symptoms of the disease.

## KANJINTI



### ► Decision Summary

#### Medicinal Ingredient

Trastuzumab

#### Indication

Kanjinti is a cancer medicine. Kanjinti is used to slow down the growth of specific breast cancer cells that produce large amounts of HER2 protein. It is used only for patients whose tumours are growing more rapidly than normal because of a genetic problem in the cells. This occurs in about 25 to 30% of breast cancer tumours.

Kanjinti is used for certain patients with gastric cancer that has spread to other parts or organs of the body to slow down the growth of specific gastric cancer cells that produce large amounts of HER2 protein. Kanjinti is used in combination with chemotherapy (capecitabine or intravenous 5-fluorouracil and in combination with cisplatin) for the treatment of gastric cancer that has spread to other parts or organs of the body.

## NIVESTYM



### ► Decision Summary [↗](#)

#### Medicinal Ingredient

Filgrastim

#### Indication

Nivestym is used to treat neutropenia, a condition where the body makes too few neutrophils. Neutropenia may be a long-standing condition where a patient's body does not make enough neutrophils, or it may be caused by drugs used to treat cancer. In some cases, the body may make enough neutrophils, but as part of the treatment for cancer, a doctor may want to increase the number of certain blood cells (CD34 cells) and collect them. The cells are collected using a process called apheresis. These collected cells are given back to the patient after they receive very high doses of treatment for cancer to make their blood counts get back to normal more quickly.

## NYVEPRIA



### ► Decision Summary [↗](#)

#### Medicinal Ingredient

Pegfilgrastim

#### Indication

Nyvepria 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 the body to infections and prevents a patient from fighting them. A doctor may prescribe Nyvepria to increase the number of neutrophils, which will fight infections.

## RIXIMYO



### ► Decision Summary [↗](#)

#### Medicinal Ingredient

Rituximab

#### Indication

Riximyo is a cancer medicine that is used to stop cancer cell growth and ideally cause the death of cancer cells. It is used to treat patients with certain types of non-Hodgkin's lymphoma and chronic lymphocytic leukemia.

Riximyo is an injectable medicine that is used to reduce signs and symptoms of rheumatoid arthritis (in combination with methotrexate).

## RUXIENCE



### ► Decision Summary [↗](#)

#### Medicinal Ingredient

Rituximab

#### Indication

Ruxience is a cancer medicine that is used to stop cancer cell growth and ideally cause the death of cancer cells. It is used to treat patients with certain types of non-Hodgkin's lymphoma and chronic lymphocytic leukemia.

Ruxience is an injectable medicine that is used to reduce signs and symptoms of rheumatoid arthritis (in combination with methotrexate). Ruxience in combination with glucocorticoids or steroids is also used to reduce inflammation associated with severe granulomatosis with polyangiitis (GPA, also known as Wegener's granulomatosis) and microscopic polyangiitis (MPA) and helps to control a patient's disease.



## ZIEXTENZO



### ► Decision Summary

#### Medicinal Ingredient

Pegfilgrastim

#### Indication

Ziextenzo 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 the body to infections and prevents a patient from fighting them. A doctor may prescribe Ziextenzo to increase the number of neutrophils, which will fight infections.

## 19 NEW GENERIC DRUGS

- 3 products containing azacitidine
- 3 products containing bortezomib
- 2 products containing cabazitaxel
- 1 product containing cyclosporine
- 2 products containing dasatinib
- 1 product containing daunorubicin
- 1 product containing everolimus
- 1 product containing fingolimod
- 1 product containing gefitinib
- 1 product containing irinotecan hydrochloride
- 1 product containing melphalan
- 1 product containing methotrexate
- 1 product containing pemetrexed

## SAFETY UPDATES

Cabazitaxel products: [Health Product InfoWatch: Did you know? Cabazitaxel products with different instructions for dilution](#)

Carboplatin-containing products: [Summary Safety Review: Carboplatin-containing products - Assessing the Potential Risk of Posterior Reversible Encephalopathy Syndrome](#)

Esbriet (pirfenidone): [Dear Healthcare Professional Letter: Esbriet \(pirfenidone\) and the Risk of Drug-Induced Liver Injury](#)

Hydrea (hydroxyurea): [Health Product InfoWatch: Risk of interstitial lung disease](#)

Imbruvica (ibrutinib):

[Health Product InfoWatch: Risk of cerebrovascular accidents](#)

[Summary Safety Review: Imbruvica \(ibrutinib\) - Assessing the Potential Risk of Hemophagocytic Lymphohistiocytosis](#)

Imuran (azathioprine): [Health Product InfoWatch: Increased risk for severe 6-mercaptopurine toxicity in patients with inherited mutated NUDT15 gene](#)

Kyprolis (carfilzomib): [Health Product InfoWatch: Risks of hepatitis B virus \(HBV\) reactivation and progressive multifocal leukoencephalopathy \(PML\)](#)

MabCampath (alemtuzumab): [Dear Healthcare Professional Letter: Risk of Haemophagocytic Lymphohistiocytosis, Stroke \(including ischaemic and haemorrhagic stroke\), and Glomerulonephritis](#)

Mekinist (trametinib) and Tafinlar (dabrafenib mesylate): [Health Product InfoWatch: Risk of severe cutaneous adverse reactions \(SCARs\)](#)

Opdivo (nivolumab): [Health Product InfoWatch: Additional guidance on monitoring, testing and management of myocarditis for Opdivo, when used alone or in combination with Yervoy \(ipilimumab\)](#)

Vascular endothelial growth factor receptor tyrosine kinase inhibitors (VEGFR TKIs): [Health Product InfoWatch: Risks of artery dissection and aneurysm](#)

Xeljanz and Xeljanz XR (tofacitinib), and Jakavi (ruxolitinib) - Janus Kinase (JAK) inhibitors: [Summary Safety Review: Xeljanz and Xeljanz XR \(tofacitinib\) and Jakavi \(ruxolitinib\) - Janus Kinase \(JAK\) inhibitors - Assessing the Potential Risk of Blood Clots in the Deep Veins \(Venous Thromboembolic Events\)](#)

## ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLANTS

For example, drugs to treat infestations of parasites.

### 1 NEW GENERIC DRUG

- 1 product containing hydroxychloroquine sulfate

### SAFETY UPDATES

Chloroquine and hydroxychloroquine: **Information Update: Chloroquine and hydroxychloroquine can have serious side effects. These drugs should be used only under the supervision of a physician.**

Plaquenil (hydroxychloroquine sulfate): **Health Product InfoWatch: New safety information concerning drug-drug interactions**

## BLOOD AND BLOOD FORMING ORGANS

For example, drugs such as anticoagulants.

### 7 NEW DRUGS

#### ADDNUTRIV

- ▶ [Decision Summary](#)

##### Medicinal Ingredients

Chromium, copper, fluoride, iodine, iron, manganese, molybdenum, selenium, zinc

##### Indication

Addnutriv is used along with other products that contain nutrients that are given through an infusion into a vein. It contains trace elements which are nutrients that the body needs in very small amounts. It is given to meet the body's trace element needs when a patient cannot eat normally. It is used in adults only. It prevents reduction of trace elements in the body and feeling unwell due to their lack.

## BIVALIRUDIN INJECTION

- ▶ [Decision Summary](#)

##### Medicinal Ingredient

Bivalirudin

##### Indication

Bivalirudin Injection is an anticoagulant drug that is used to prevent blood from clotting. It is used in adults to treat:

- patients with ST-segment elevation myocardial infarction (STEMI [a severe type of heart attack]) undergoing percutaneous coronary intervention (PCI), (a procedure that unblocks narrowed coronary arteries without having to perform surgery), and
- patients with moderate- to high-risk acute coronary syndromes (ACS) due to unstable angina or non-ST segment elevation myocardial infarction (a type of heart attack) undergoing PCI, or who will be managed with medicines only, or who will have cardiac (heart) surgery called a coronary artery bypass graft (CABG) (sometimes referred to as "bypass" surgery).

Bivalirudin Injection is intended for use with acetylsalicylic acid (ASA or aspirin). It can also be used instead of a drug called heparin if a patient is at risk of having low blood cell counts due to heparin.

#### CABLIVI



- ▶ [Decision Summary](#)

##### Medicinal Ingredient

Caplacizumab

##### Indication

Cablivi is used to treat an episode of acquired thrombotic thrombocytopenic purpura (aTTP) in adults. aTTP is a rare blood clotting disorder in which clots form in small blood vessels. These clots can block blood vessels and damage the brain, heart, kidneys, or other organs. Cablivi prevents the formation of these blood clots by stopping platelets in the blood from clumping together.

## ESSEPNA

### ► Decision Summary

#### Medicinal Ingredient

Alanine, arginine, glycine, histidine, isoleucine, leucine, lysine, methionine, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine

#### Indication

Essepna is used along with other products that contain nutrients that are given through an infusion into a vein. It contains amino acids which are nutrients the body needs to make proteins. It is given when a patient cannot eat normally. It is used in adults only.

## REBLOZYL



### ► Decision Summary

#### Medicinal Ingredient

Luspatercept

#### Indication

Reblozyl is used to treat adults who have low red blood cell counts (anemia) and require red blood cell transfusions due to a blood disorder (β-thalassemia) that affects the production of hemoglobin (a protein in the red blood cells that transports oxygen throughout the body).

## REGIOCIT

### ► Decision Summary

#### Medicinal Ingredients

Sodium chloride, sodium citrate

#### Indication

Regiocit is a solution for hemofiltration and prevents blood clotting during continuous renal replacement therapy (CRRT), which is a form of dialysis treatment. This medicine is used for critically ill patients particularly when other medicine used to prevent blood clotting is not an appropriate choice.

## TAVALISSE



### ► Decision Summary

#### Medicinal Ingredient

Fostamatinib

#### Indication

Tavalisse is used to treat adults with a bleeding disorder known as chronic immune thrombocytopenia when other treatments have not worked well enough.

## 3 NEW BIOSIMILARS

## INCLUNOX, INCLUNOX HP



### ► Decision Summary

#### Medicinal Ingredient

Enoxaparin sodium

#### Indication

Inclunox is used:

- To prevent the formation of deep vein thrombosis (blood clots), which can occur as a complication of orthopedic surgery such as hip or knee surgery or of intra-abdominal (inside the body cavity below diaphragm which contains stomach, intestines, liver, and other organs) surgeries.
- To prevent the formation of deep vein thrombosis in medical patients who are at risk of thromboembolic (blockage of blood vessel by a blood clot) complications due to severely restricted mobility during acute illnesses (cardiac insufficiency [reduced ability of heart to pump blood], respiratory failure or severe chest infections).
- To treat the deep vein thrombosis with or without pulmonary embolism (blockage of blood vessel in the lungs).
- To treat the unstable angina and non-Q-wave myocardial infarction (death of a part of the heart muscle that does not involve full thickness of the heart wall), concurrently with acetylsalicylic acid (ASA).



- To treat the acute ST-segment Elevation Myocardial Infarction (STEMI), a particular form of heart attack. This indication includes patients to be managed medically or those with subsequent percutaneous coronary intervention (PCI), a procedure that opens up a coronary artery (blood vessel that brings blood and oxygen to the heart muscle) and restores blood flow.
- To prevent clotting in the extra-corporeal circulation during hemodialysis.

## NOROMBY, NOROMBY HP



### ► Decision Summary

#### Medicinal Ingredient

Enoxaparin sodium

#### Indication

Noromby is used:

- To prevent the formation of deep vein thrombosis (blood clots), which can occur as a complication of orthopedic surgery such as hip or knee surgery or of intra-abdominal (inside the body cavity below diaphragm which contains stomach, intestines, liver, and other organs) surgeries.
- To prevent the formation of deep vein thrombosis in medical patients who are at risk of thromboembolic (blockage of blood vessel by a blood clot) complications due to severely restricted mobility during acute illnesses (cardiac insufficiency [reduced ability of heart to pump blood], respiratory failure or severe chest infections).
- To treat the deep vein thrombosis with or without pulmonary embolism (blockage of blood vessel in the lungs).
- To treat the unstable angina and non-Q-wave myocardial infarction (death of a part of the heart muscle that does not involve full thickness of the heart wall), concurrently with acetylsalicylic acid (ASA).
- To treat the acute ST-segment Elevation Myocardial Infarction (STEMI), a particular form of heart attack. This indication includes patients to be managed medically or those with subsequent percutaneous coronary intervention (PCI), a

procedure that opens up a coronary artery (blood vessel that brings blood and oxygen to the heart muscle) and restores blood flow.

- To prevent clotting in the extra-corporeal circulation during hemodialysis.

## REDESCA / REDESCA HP



### ► Decision Summary

#### Medicinal Ingredient

Enoxaparin sodium

#### Indication

Redesca is used:

- To prevent the formation of deep vein thrombosis (blood clots), which can occur as a complication of orthopedic surgery such as hip or knee surgery or of intra-abdominal (inside the body cavity below diaphragm which contains stomach, intestines, liver, and other organs) surgeries.
- To prevent the formation of deep vein thrombosis in medical patients who are at risk of thromboembolic (blockage of blood vessel by a blood clot) complications due to severely restricted mobility during acute illnesses (cardiac insufficiency [reduced ability of heart to pump blood], respiratory failure or severe chest infections).
- To treat the deep vein thrombosis with or without pulmonary embolism (blockage of blood vessel in the lungs).
- To treat the unstable angina and non-Q-wave myocardial infarction (death of a part of the heart muscle that does not involve full thickness of the heart wall), concurrently with acetylsalicylic acid (ASA).
- To treat the acute ST-segment Elevation Myocardial Infarction (STEMI), a particular form of heart attack. This indication includes patients to be managed medically or those with subsequent percutaneous coronary intervention (PCI), a procedure that opens up a coronary artery (blood vessel that brings blood and oxygen to the heart muscle) and restores blood flow.
- To prevent clotting in the extra-corporeal circulation during hemodialysis.

## 6 NEW GENERIC DRUGS

- 1 product containing ibuprofen, pseudoephedrine hydrochloride
- 1 product containing iron
- 1 product containing prasugrel
- 3 products containing tranexamic acid

## SAFETY UPDATES

Brilinta (ticagrelor):

**Summary Safety Review: Brilinta (ticagrelor) - Assessing the Potential Risks of a Worsening of a Slow and Irregular Heartbeat (Bradyarrhythmia) and Partial or Complete Block in the Transmission of Heart Impulses (Second- and Third-Degree Atrioventricular Block)**

**Summary Safety Review: Brilinta (ticagrelor) - Assessing the Potential Risk of Central Sleep Apnea**

Cannabis and warfarin: **Health Product InfoWatch: Potential drug interaction**

Hemlibra (emicizumab): **Dear Healthcare Professional Letter: Clinical management support: Known interference between Hemlibra (emicizumab injection) and lab assays used to diagnose coagulopathy / DIC caused by COVID-19 infection**

## CARDIOVASCULAR SYSTEM

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

## 1 NEW DRUG

### CORZYNA



#### ► Decision Summary

#### Medicinal Ingredient

Ranolazine

#### Indication

Corzyna is a medicine used to treat chest pain (stable angina) in adults. It is used along with other medicines in patients who cannot tolerate other antianginal therapies or for whom other antianginal therapies do not work to control their chest pain (this includes beta-blockers and calcium channel blockers)

## 14 NEW GENERIC DRUGS

- 1 product containing amiodarone hydrochloride
- 1 product containing atorvastatin
- 1 product containing candesartan cilexetil
- 1 product containing candesartan cilexetil, hydrochlorothiazide
- 1 product containing digoxin
- 2 products containing labetalol hydrochloride
- 1 product containing nadolol
- 1 product containing nebivolol
- 1 product containing nifedipine
- 1 product containing olmesartan medoxomil
- 2 products containing rosuvastatin
- 1 product containing sodium nitroprusside

## SAFETY UPDATES

Elmiron (pentosan polysulfate sodium): **Dear Healthcare Professional Letter: Elmiron (pentosan polysulfate sodium) and the Risk of Pigmentary Maculopathy**

MAR-Diltiazem CD capsules: **Advisory: All strengths of MAR-Diltiazem CD, a drug used to treat angina and hypertension, have been recalled because of dosing concerns**

Norvasc (amlodipine): **Health Product InfoWatch: New information and contraindications**

Rythmol (propafenone hydrochloride): **Health Product InfoWatch: New contraindication**

## DERMATOLOGICALS

*For example, drugs to treat psoriasis.*

## 2 NEW DRUGS

### DUOBRII



#### Medicinal Ingredients

Halobetasol propionate, tazarotene

#### Indication

Duobrii is indicated for improving the signs and symptoms of plaque psoriasis in adult patients with moderate to severe plaque psoriasis.

### TEVA-BETAMETHASONE/ CALCIPOTRIOL

#### Medicinal Ingredients

Betamethasone, calcipotriol

#### Indication

Teva-Betamethasone/ Calcipotriol should be used topically for up to four weeks to treat psoriasis plaques on a patient's body. Teva-Betamethasone/ Calcipotriol should not be used on the face.

## 2 NEW GENERIC DRUGS

- 1 product containing betamethasone, clotrimazole
- 1 product containing clobetasol propionate

## SAFETY UPDATES

Picato (ingenol mebutate):

**Information Update: Use of the drug Picato may increase the risk of skin cancer**

**Summary Safety Review: Picato (ingenol mebutate) - Assessing the Potential Risk of Skin Cancer**

**Dear Healthcare Professional Letter: Picato (ingenol mebutate gel, 0.015% and 0.05%) - Product Withdrawal in Canada due to Potential Increased Risk of Skin Cancer**

**Information Update: LEO Pharma Inc. is withdrawing the drug Picato (Ingenol mebutate), used to treat skin lesions, due to the potential increased risk of skin cancer**

## GENITO URINARY SYSTEM AND SEX HORMONES

*For example, hormonal contraception and drugs for the urinary tract system.*

## 3 NEW DRUGS

### BIJUVA

#### Medicinal Ingredients

Estradiol, progesterone

#### Indication

Bijuva is used to reduce and relieve vasomotor symptoms (hot flashes and night sweats). It is only used in postmenopausal women with an intact uterus.



## IMVEXXY

### Medicinal Ingredient

Estradiol

### Indication

Imvexxy is used to treat postmenopausal women who experience pain before, during or after sex. This is a symptom of vulvar and vaginal atrophy. The safe and effective use of Imvexxy for more than 12 weeks has not been studied.

## NEXPLANON

### Medicinal Ingredient

Etonogestrel

### Indication

Nexplanon is used to prevent pregnancy in adult women for up to three years.

## 11 NEW GENERIC DRUGS

- 1 product containing clotrimazole (non-prescription drug)
- 2 products containing dienogest
- 2 products containing drospirenone, ethinyl estradiol
- 1 product containing ethinyl estradiol, norgestimate
- 1 product containing fesoterodine fumarate
- 1 product containing sildenafil
- 1 product containing tadalafil
- 1 product containing tolterodine tartrate
- 1 product containing trospium chloride

## SAFETY UPDATES

Fibristal (ulipristal acetate):

**Advisory: Allergan Inc. voluntarily withdraws its drug Fibristal, used to treat uterine fibroids, from the Canadian market**

**Dear Healthcare Professional Letter: Fibristal (ulipristal acetate tablets, 5 mg) - Voluntary Withdrawal in Canada due to Risk of Drug-Induced Liver Injury**

## MUSCULO-SKELETAL SYSTEM

*For example, drugs such as anti-inflammatories and muscle relaxants.*

## 1 NEW DRUG

## ZOLGENSMA



### ► Decision Summary

### Medicinal Ingredient

Onasemnogene abeparvovec

### Indication

Zolgensma is a type of medicine called a gene therapy. It contains the active ingredient onasemnogene abeparvovec, which contains human genetic material. Zolgensma is used to treat babies and young children who have a rare, serious inherited condition called spinal muscular atrophy (SMA).

## 4 NEW GENERIC DRUGS

- 1 product containing alendronic acid
- 1 product containing diphenhydramine hydrochloride, naproxen sodium
- 1 product containing indomethacin
- 1 product containing rocuronium bromide

## SAFETY UPDATES

Cisatracurium Besylate Injection: **Dear Healthcare Professional Letter: Cisatracurium Omega Multi-Dose (Cisatracurium Besylate Injection): Temporary change of ferrule (metal seal) colour to maintain continued supply in Canada**

Ibuprofen and other non-steroidal anti-inflammatory drugs (NSAIDs): **Information Update: No scientific evidence that ibuprofen worsens COVID-19 symptoms**

Ibuprofen-containing products used in children: **Summary Safety Review: Ibuprofen- Assessing the Potential Risk of Serious Infection of the Deep Layers of the Skin (Necrotising Fasciitis) in Children with Chickenpox Infection**

Pancuronium bromide injection: **Dear Healthcare Professional Letter: Importation of US-Labelled Pancuronium Bromide Injection Due to Shortage of Neuromuscular Blocker Products**

Prescription and over-the-counter non-steroidal anti-inflammatory drugs (NSAIDs): **Advisory: Use of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) beyond 20 weeks of pregnancy and risk of kidney damage in unborn babies, leading to low amniotic fluid**

Quelicin (succinylcholine chloride injection): **Dear Healthcare Professional Letter: Importation of US-Labelled Quelicin (succinylcholine chloride injection) due to Shortage of Canadian-labelled Quelicin**

Rocuronium Bromide for Injection:

**Dear Healthcare Professional Letter: Importation of US-Labelled Rocuronium Bromide Injection Due to Shortage of Canadian-labelled Rocuronium**

**Dear Healthcare Professional Letter: Importation of US-Labelled Rocuronium Bromide Injection distributed by Avir Pharma Inc. Due to Shortage of Canadian-labelled Rocuronium**

**Dear Healthcare Professional Letter: Importation of US-Labelled Rocuronium Bromide Injection Due to Shortage of Canadian-labelled Rocuronium**

Taro-Zoledronic acid injection 5mg/100mL: **Advisory: Certain Lots of Taro-Zoledronic acid injection drug, used for osteoporosis and Paget's disease, recalled due to potential presence of particulate matter**

Vecuronium bromide for injection: **Dear Healthcare Professional Letter: Importation of US-Labelled Vecuronium Bromide for Injection due to Shortage of Neuromuscular Blocker Products**

## NERVOUS SYSTEM

*For example, analgesics and antidepressants.*

### 11 NEW DRUGS

#### AJOVY



► **Decision Summary** [↗](#)

##### Medicinal Ingredient

Fremanezumab

##### Indication

Ajovy is used for the prevention of migraine in adults who have at least four migraine days per month.

#### DAYVIGO



► **Decision Summary** [↗](#)

##### Medicinal Ingredient

Lemborexant

##### Indication

Dayvigo is used in adults who have trouble falling asleep and/or staying asleep (insomnia). Dayvigo is not for use in children under the age of 18 years.

## FIRDAPSE



### ► Decision Summary [↗](#)

#### Medicinal Ingredient

Amifampridine

#### Indication

Firdapse is used to treat the symptoms of Lambert-Eaton myasthenic syndrome (LEMS) in adults.

## KYNMOBI

### ► Decision Summary [↗](#)

#### Medicinal Ingredient

Apomorphine hydrochloride

#### Indication

Kynmobi is used, as needed, to treat OFF episodes in adults with Parkinson's disease. An OFF episode is when a patient's Parkinson's movement symptoms (e.g., tremor, slowness, stiffness and difficulty moving) are unexpectedly not controlled by their regular Parkinson's medication. Kynmobi is for use with other drugs to treat Parkinson's disease and does not replace the other drugs prescribed by a doctor to treat Parkinson's symptoms.

## PERSERIS

### ► Decision Summary [↗](#)

#### Medicinal Ingredient

Risperidone

#### Indication

Perseris is used to treat schizophrenia in adults.

## PEYONA



### ► Decision Summary [↗](#)

#### Medicinal Ingredient

Caffeine citrate

#### Indication

Peyona is used for the treatment of interrupted breathing (apnea) in premature babies.

## RUZURGI



### ► Decision Summary [↗](#)

#### Medicinal Ingredient

Amifampridine

#### Indication

Ruzurgi is used to treat the symptoms of Lambert-Eaton myasthenic syndrome (LEMS) in patients 6 years of age and older. It is not known if Ruzurgi works or is safe in children less than 6 years old.

## SPRAVATO



### ► Decision Summary [↗](#)

#### Medicinal Ingredient

Esketamine

#### Indication

Spravato is a nasal spray used to treat adults with major depressive disorder that:

- is moderate to severe in intensity, and
- has not responded to two or more separate courses of treatment in the current episode of depression.

Separate courses refers to previous treatment with different antidepressants, each given at adequate doses for an adequate amount of time.

Spravato nasal spray is used together with an antidepressant taken by mouth that is either:

- a selective serotonin reuptake inhibitor (SSRI), or
- a serotonin and norepinephrine reuptake inhibitor (SNRI).

Spravato is not for use in children or adolescents.

If a patient is 65 years or older, they should talk to their doctor before starting Spravato. Spravato may not be an effective treatment for them and they may be more sensitive to experiencing side effects.



## SUVEXX

### ► Decision Summary

#### Medicinal Ingredients

Naproxen sodium, sumatriptan

#### Indication

Suvexx is used in adults for the acute treatment of migraine attacks with or without aura. It should only be used in patients who have been diagnosed with migraines. Suvexx is not for preventing migraines and it is not for the treatment of cluster headaches. Suvexx is not for use in patients younger than 18 years of age.

## TOMVI



### ► Decision Summary

#### Medicinal Ingredient

Etomidate

#### Indication

Tomvi is an anesthetic that is used in adults:

- to help make them asleep (unconscious) for a surgery or other medical procedure, or
- with other anesthetics to help keep them asleep for a short surgery.

## VYND AQEL



### ► Decision Summary

#### Medicinal Ingredient

Tafamidis meglumine

#### Indication

Vyndaqel is used to treat adults with cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) to reduce death and hospitalization related to heart problems.

## 23 NEW GENERIC DRUGS

- 1 product containing atomoxetine
- 1 product containing bupivacaine hydrochloride
- 2 products containing buspirone hydrochloride
- 1 product containing citalopram
- 1 product containing clomipramine hydrochloride
- 1 product containing desflurane
- 1 product containing duloxetine
- 1 product containing escitalopram
- 2 products containing fampridine
- 3 products containing fentanyl
- 2 products containing frovatriptan
- 1 product containing levetiracetam
- 1 product containing midazolam
- 1 product containing paroxetine
- 2 products containing pilocarpine hydrochloride
- 2 products containing pyridostigmine bromide

## SAFETY UPDATES

Clobazam-containing products: [Summary Safety Review: Clobazam-containing products - Assessing the Potential Risk of Drug Reaction with Eosinophilia and Systemic Symptoms \(DRESS\)](#)

Fresenius Propoven 2% (Propofol): [Dear Healthcare Professional Letter: Importation of Fresenius Propoven 2% due to Shortage of Canadian Labelled Propofol Injection 1% Products](#)

HYDROMorph Contin and generic hydromorphone controlled release capsules: [Summary Safety Review: Hydromorphone Controlled Release Capsules - Assessing the Increased Risk of Serious Infections Linked to the Injection of the Content of the Capsules into Veins](#)

Ketamine:

**Dear Healthcare Professional Letter: Importation of US-Labelled Ketamine Hydrochloride for Injection due to Potential Shortage of Canadian-labelled Ketamine**

**Summary Safety Review: Ketamine - Assessing the Potential Risk of Liver and Bile Duct Damage**

Methadone:

**Dear Healthcare Professional Letter: Methadone Treatment of Opioid Dependence and Potential Differences in Product Effect**

**Dear Healthcare Professional Letter: Methadone Treatment of Opioid Dependence and Potential Risk of Lack of Effect when Switching between Different Products**

**Summary Safety Review: Methadone-Containing Products Used to Treat Opioid Dependence - Assessing the Potential Risk of Lack of Effect when Switching between Different Products**

Nardil (phenelzine sulfate): **Dear Healthcare Professional Letter: Nardil (phenelzine sulfate) Shortage**

Non-prescription pain relief products containing codeine: **Advisory: Non-prescription pain relief products containing codeine are not recommended for use in people under 18 years of age**

Prescription opioids: **Health Product InfoWatch: Opioid Safety Reminders**

Sativex (delta-9-tetrahydrocannabinol [THC] and cannabidiol [CBD]): **Health Product InfoWatch: Removal of Notice of Compliance with Conditions indications, Inclusion of information concerning use in moderate or severe hepatic impairment and drug interactions**

Tramadol-containing products: **Summary Safety Review: Tramadol-containing products - Assessing the Potential Risk of Hallucinations**

## RESPIRATORY SYSTEM

*For example, drugs to treat asthma and antihistamines.*

### 2 NEW DRUGS

## ATECTURA BREEZHALER



### ► Decision Summary

#### Medicinal Ingredients

Indacaterol, mometasone furoate

#### Indication

Ateectura Breezhaler a combination of a long-acting beta2-adrenergic agonist (LABA) and an inhaled corticosteroid (ICS). It is used to treat asthma in adults and adolescents (12 years of age and older) with reversible obstructive airways disease.

Patients should only take this medication if their:

- asthma is not adequately controlled on a long-term asthma medication (such as a ICS), or
- disease condition requires treatment with both a LABA and ICS.

Patients should not take this medication:

- if they can manage their asthma by occasionally using a rapid onset, short duration, inhaled beta2-agonist, or
- if they can manage their asthma by using ICS along with occasional use of a rapid onset, short duration, inhaled beta2-agonist, or
- for the relief of the sudden (acute) symptoms of asthma (i.e. as rescue therapy for the treatment of sudden episodes of bronchospasm).

## ENERZAIR BREEZHALER

### ► Decision Summary [↗](#)

#### Medicinal Ingredients

Glycopyrronium, indacaterol, mometasone furoate

#### Indication

Enerzair Breezhaler is a combination of a long-acting beta2-adrenergic agonist (LABA), a long-acting muscarinic antagonist (LAMA) and an inhaled corticosteroid (ICS). It is used as a maintenance treatment for asthma in adults:

- whose asthma is not being adequately controlled with a maintenance long-acting beta2-agonist (LABA) and a medium or high dose of an inhaled corticosteroid (ICS), and
- who have experienced one or more asthma attacks in the previous year.

Patients should not take this medication for the relief of the sudden (acute) symptoms of asthma (i.e. as rescue therapy for the treatment of sudden episodes of bronchospasm).

## 3 NEW GENERIC DRUGS

- 1 product containing cetirizine hydrochloride
- 1 product containing fluticasone propionate, salmeterol
- 1 product containing montelukast

## SAFETY UPDATES

ATLAS - Codeine phosphate syrup 5 mg/mL:

**Advisory: Laboratoire Atlas Inc. is recalling one lot of “ATLAS - Codeine phosphate syrup 5 mg/mL” because some bottles contain isopropyl rubbing alcohol**

Benzodiazepines and Benzodiazepine-like prescription drugs: **Advisory: Updates to safety labelling for benzodiazepines and benzodiazepine-like drugs**

Over-the-counter benzocaine products:

**Advisory: Benzocaine products should not be used in children under two years of age**

**Dear Healthcare Professional Letter: Benzocaine-Containing Products and the Risk of Methemoglobinemia in Children under Two Years of Age**

Prescription Cough and Cold Products Containing Opioids: **Dear Healthcare Professional Letter: Prescription Cough and Cold Products Containing Opioids and the Risk of Opioid Use Disorder in Children and Adolescents (< 18 years of age)**

Salbutamol:

**Advisory: Shortage of salbutamol inhalers in Canada**

**Dear Healthcare Professional Letter: Important Safety Information - Importation of Teva UK-labelled Salamol CFC-Free (Salbutamol Sulfate) Inhaler due to Shortage**

**Dear Healthcare Professional Letter: Importation of Spanish-Labelled Salbutamol Aldo-Union inhalers due to Shortage of Canadian-Labelled Salbutamol**

Singulair (montelukast): **Health Product InfoWatch: Risk of serious neuropsychiatric events**



## SENSORY ORGANS

For example, drugs to treat vision loss.

### 2 NEW DRUGS

#### BEOVU



► [Decision Summary](#)

##### Medicinal Ingredient

Brolucizumab

##### Indication

Beovu is a medicine that is injected into the eye by a doctor to treat an eye disorder called neovascular (wet) age-related macular degeneration (AMD). Beovu contains the active substance brolucizumab, which belongs to a group of medicines called anti-neovascularization agents ("anti-VEGF"). Beovu is used to treat wet AMD, which occurs when abnormal blood vessels form and grow underneath the macula. The macula is located at the back of the eye, and it is responsible for clear vision. These abnormal blood vessels may be weak and leak fluid or blood in the eye. This can interfere with the macula's function, resulting in reduced vision.

#### LUXTURNA



► [Decision Summary](#)

##### Medicinal Ingredient

Voretigene neparvovec

##### Indication

Luxturna is used for the treatment of adults and children with vision loss due to inherited retinal dystrophy caused by mutations in the *RPE65* gene. These mutations prevent the body from producing a protein needed for vision which can lead to loss of sight and eventual blindness.

### 3 NEW GENERIC DRUGS

- 1 product containing brimonidine tartrate
- 1 product containing ciprofloxacin, dexamethasone
- 1 product containing travoprost

## SYSTEMIC HORMONAL PREPARATIONS, EXCLUDING SEX HORMONES AND INSULINS

For example, drugs to treat hypothyroidism.

### 2 NEW DRUGS

#### INCRELEX



► [Decision Summary](#)

##### Medicinal Ingredient

Mecasermin

##### Indication

Increlex is used to treat children and adolescents from 2 to 18 years old who are very short for their age because their body does not make enough IGF-1. This condition is called primary IGF-1 deficiency. Increlex has not been studied in children younger than 2 years.

#### TIROSINT



##### Medicinal Ingredient

Levothyroxine sodium

##### Indication

Tirosint is used in adults and children 6 years of age and older:

- To treat hypothyroidism. This condition happens when the thyroid gland does not produce enough of the hormone, thyroxine.
- In combination with surgery and radioactive iodine therapy to treat certain types of thyroid cancer.

## 1 NEW BIOSIMILAR

### OSNUVO



#### ► Decision Summary [↗](#)

#### Medicinal Ingredient

Teriparatide

#### Indication

Osnuvo is used to treat osteoporosis by forming new bone. Osnuvo is approved for use in both men and postmenopausal women with severe osteoporosis. Osnuvo is also approved for use in both men and women with severe osteoporosis related to use of corticosteroid medicines, such as prednisone, who are at high risk for having broken bones (fractures). These include men and women with either a history of broken bones or those with a low bone mineral density (BMD).

## 3 NEW GENERIC DRUGS

- 2 products containing octreotide
- 1 product containing teriparatide

## SAFETY UPDATES

Cetrotide 0.25mg: **Advisory: Certain vials of fertility drug Cetrotide recalled because of potential contamination**

DDAVP Spray (desmopressin acetate nasal solution, 10 micrograms/spray): **Advisory: Three lots of antidiuretic DDAVP Spray recalled because of potential overdose risk**

Propyl-Thyracil (propylthiouracil): **Summary Safety Review: Propyl-Thyracil (propylthiouracil): Assessing the Potential Risk of Birth Defects**

Tapazole (methimazole):

**Health Product InfoWatch: Risk of acute pancreatitis**

**Summary Safety Review: Methimazole - Assessing the Potential Risk of Inflammation of the Blood Vessels (Vasculitis)**

## VARIOUS

*For example, drugs unable to be classified into the other categories such as diagnostic agents.*

## 3 NEW DRUGS

### GALLIAPHARM



#### ► Decision Summary [↗](#)

#### Medicinal Ingredient

Gallium 68 Ga Chloride

#### Indication

The eluate from the radionuclide generator (gallium [68Ga] chloride solution) is indicated for *in vitro* labelling of specific carrier molecules developed and approved for radiolabelling with such solution to be used for positron emission tomography (PET) imaging. The gallium (68Ga) chloride eluate from the GalliaPharm generator is not intended for direct use in patients.

### ITULATEK



#### ► Decision Summary [↗](#)

#### Medicinal Ingredients

Standardized allergen extract, white birch

#### Indication

Itulatek is for adults aged 18 to 65 who are allergic to tree pollen from birch, alder and/or hazel and have allergic rhinitis (with or without conjunctivitis). Symptoms of allergic rhinitis include sneezing, runny or itchy nose, stuffed up nose (with or without symptoms of conjunctivitis such as itchy, burning, red, or watery eyes). Before a patient begins treatment with Itulatek, their allergy to tree pollen will be confirmed by a doctor who will perform skin and/or blood tests. Itulatek is NOT a medication that gives immediate relief for symptoms of tree pollen allergy.

Itulatek has not been tested in patients younger than 12 years or older than 65 years of age. The efficacy and safety of Itulatek have not been established in subjects between the ages of 12 and 18.

## SANI-CIDE EX3



### Medicinal Ingredients

L-lactic acid

### Indication

Sani-Cide EX3 is used to disinfectant airplane hard, non-porous surfaces such as tray tables, armrests, lavatory door handles, galley workspaces and on any other objects or surfaces which passengers and crew may come in contact with. Sani-Cide EX3 is an effective disinfectant against *Staphylococcus aureus* (ATCC 6538) and *Salmonella enterica* (ATCC 10708).

## SODIUM PERTECHNETATE 99mTc INJECTION



### ► Decision Summary [↗](#)

### Medicinal Ingredient

Sodium pertechnetate Tc-99m

### Indication

Sodium pertechnetate (99m Tc) may be used for preparing diagnostic radiopharmaceuticals.

## 6 NEW GENERIC DRUGS

- 1 product containing calcium polystyrene sulphonate
- 1 product containing deferasirox
- 1 product containing exametazime
- 1 product containing gadopentetate dimeglumine
- 1 product containing lanthanum
- 1 product containing leucovorin

## SAFETY UPDATE

Dexrazoxane for Injection: [Dear Healthcare Professional Letter: Importation of US-labelled Dexrazoxane for Injection distributed by Mylan Pharmaceuticals ULC due to shortage of Canadian-labelled Dexrazoxane](#)





# MEDICAL DEVICES: 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, from investigational testing (clinical trials) to after the device is being sold in Canada.

## INVESTIGATIONAL TESTING (CLINICAL TRIALS)

Clinical trials are conducted by sponsors (manufacturers or importers) to gather information on a medical device's safety and effectiveness in humans. Sponsors of investigational tests submit their applications to conduct investigational testing with a medical device in Canada. Health Canada reviews these applications before the testing is conducted in Canada.

## SPECIAL ACCESS PROGRAMME

Medical devices that are not approved in Canada may be available through our [Special Access Programme](#). In this program, access is given to an individual health care practitioner who is treating a specific patient. Access may be granted for emergency use, or when conventional therapies have failed, are unavailable or are unsuitable.

## MEDICAL DEVICE APPLICATION AND REVIEW

In Canada, medical devices are categorized in four groups based on their risk of use. These groups are called "Classes" and range from I to IV. Class I devices are considered low-risk devices – for example, a wheelchair. Class IV devices present the greatest potential risk – for example, a defibrillator.

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 Health Canada 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. Sometimes we also consult with advisory committees or external consultants. Reviewers evaluate the safety, effectiveness and quality data submitted to assess the potential benefits and risks of the medical devices. They also review the information that will be provided to health care practitioners and consumers about the medical device.

## 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 health care 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 because they have shorter review targets.

## 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.

### SURVEILLANCE

It is not possible to know or predict all of the possible problems related to a medical device through clinical studies. After a product is approved and available for sale in Canada, we continue to monitor its use in the real world, that is, in the broader Canadian population. We evaluate potential safety and effectiveness issues and take action when there are identified problems.

#### Collecting information

Health Canada collects safety information about a product after it is approved from a variety of sources. One source of information is suspected medical device problems that are reported after products are approved for sale. These are undesirable effects potentially caused by medical devices.

You can report 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 the **Canada Vigilance Program** [↗](#) or by phone at **1-866-234-2345**.

### Evaluating safety signals

Health Canada evaluates 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 health care professionals of new safety information or recommending labelling changes. In the most serious situations, we may remove a medical device from the market.

#### Advertising complaints

Health Canada also regulates the advertising of medical devices 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, and we take appropriate action when non-compliance is identified.



# MEDICAL DEVICES: APPROVED IN 2020

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 approved for sale in Canada in 2020, and the safety updates issued.

## HEALTH CATEGORIES

The medical devices listed have been divided into categories according to the [Global Medical Device Nomenclature](#) system for naming and grouping medical devices.

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

The categories are

- | **Blood fluid and tissue management devices** – for example, blood separation systems.
- | **Body tissue manipulation and reparation devices** – for example, bone grafts and dermal dressings.
- | **Cardiovascular devices** – for example, cardiovascular catheters and pacemakers.
- | **Gastro-uological devices** – for example, incontinence control systems.
- | **General hospital devices** – for example, infusion pumps.
- | **In vitro diagnostic medical devices** – for example, instrument/analyser and viral infection disease *in vitro* devices.
- | **Neurological devices** – for example, neurological stimulation devices.
- | **Plastic surgery and cosmetic devices** – for example, breast implants.
- | **Radiological devices** – for example, ultrasound image systems.
- | **Various** – applicable to medical devices generally.



## IMPORTANT DEFINITIONS

### **C** Licence with conditions

A medical device licence may be issued with conditions set out by Health Canada. For example, the manufacturer may be required to submit additional information on an on-going basis for the medical device to demonstrate that it continues to meet our regulatory requirements.

### Medical device

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.

### **N** 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.

## Safety updates

Safety updates are designed to communicate information about potential health risks, so that patients and health care 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](#)".

You can report medical device incidents to your medical professional, to a hospital or to the company that made the product.

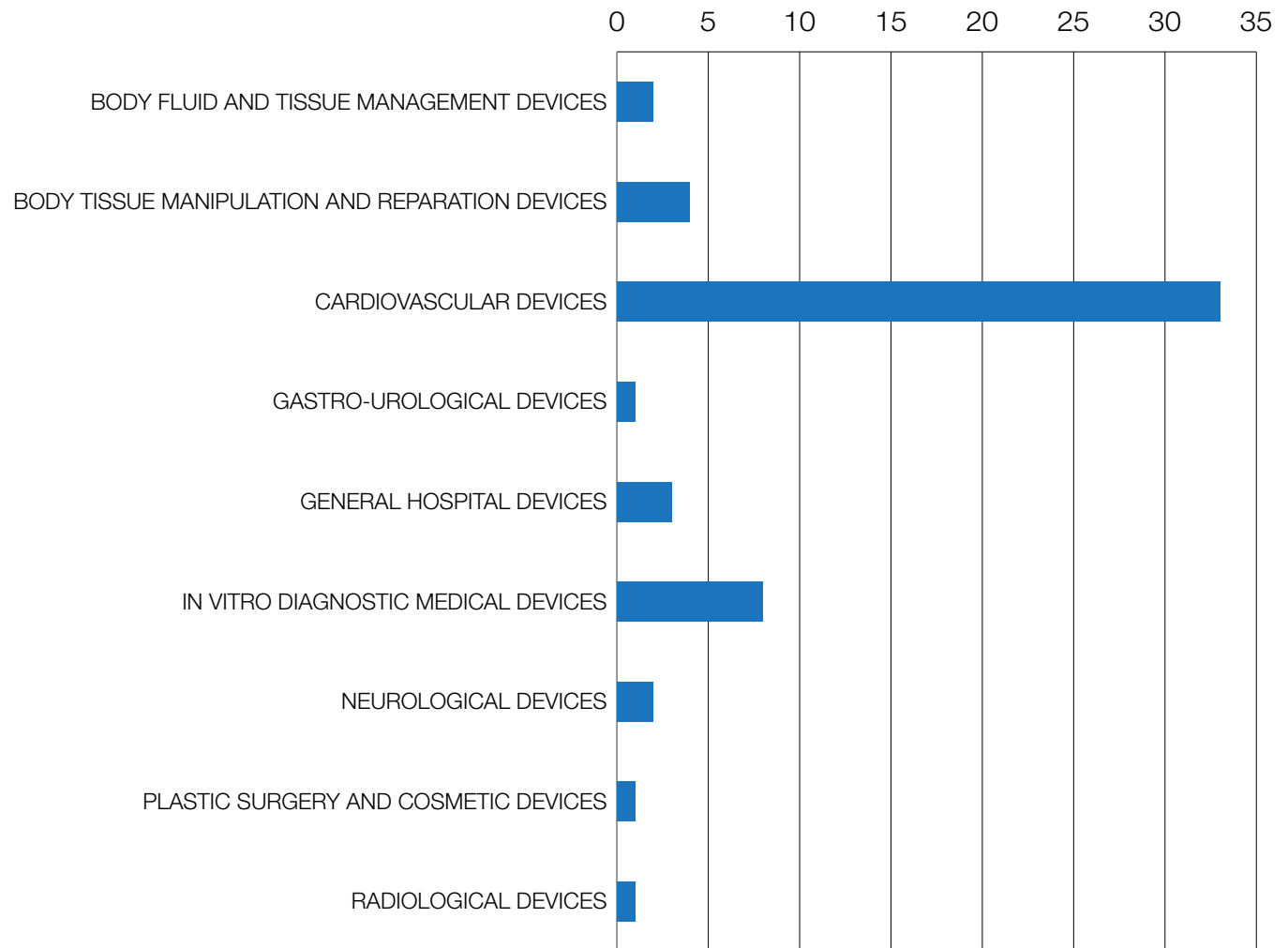
You can also report them to Health Canada through the [Canada Vigilance Program](#) or by phone at **1-866-234-2345**.





# NEW CLASS IV MEDICAL DEVICES APPROVED IN 2020

NUMBER OF NEW CLASS IV MEDICAL DEVICES APPROVED IN 2020



## BODY FLUID AND TISSUE MANAGEMENT DEVICES

*For example, blood separation systems.*

### 2 NEW MEDICAL DEVICES

#### CLINIMACS PRODIGY T CELL TRANSDUCTION (TCT) SYSTEM



##### Indication

The CliniMACS Prodigy T Cell Transduction (TCT) System is an automated cell processing for the generation of gene modified T cells from heterogeneous, hematological cell populations for clinical purposes.

#### SONOPET IQ ULTRASONIC ASPIRATOR SYSTEM

► [Decision Summary](#)

##### Indication

The Sonopet iQ Ultrasonic Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification, and aspiration of soft and hard tissue is desirable.

## BODY TISSUE MANIPULATION AND REPARATION DEVICES

*For example, bone grafts and dermal dressings.*

### 4 NEW MEDICAL DEVICES

#### CHONDRO-GIDE BILAYER COLLAGEN MEMBRANE

► [Decision Summary](#)

##### Indication

The Chondro-Gide Bilayer Collagen Membrane is a bilayer collagen membrane of porcine origin to be used to cover cartilage defects treated with microfracturing techniques.

#### MYRIAD

► [Decision Summary](#)

##### Indication

Myriad is intended to cover, protect and provide a moist wound environment. The device may be fixed via sutures, staples or tacks to surround the tissue if desired.

#### PURACOL PLUS

► [Decision Summary](#)

##### Indication

The Puracol Plus is a highly porous collagen matrix for wound healing, it is a wound dressing.

#### REGENETEN BIOINDUCTIVE IMPLANT SYSTEM



► [Decision Summary](#)

##### Indication

The Regeneten Bioinductive Implant is indicated for the management and protection of rotator cuff tendon injuries in which there has been no substantial loss of tendon tissue.

## CARDIOVASCULAR DEVICES

*For example, cardiovascular catheters and pacemakers.*

### 33 NEW MEDICAL DEVICES

#### AGILIS HISPRO STEERABLE CATHETER WITH ELECTRODES

##### Indication

The Agilis HisPro Steerable Catheter with Electrodes is a delivery tool indicated to provide transvenous access during a cardiac procedure or device implant (i.e. lead placement) to structures in the heart.

#### ATHLETIS OVER-THE-WIRE PTA BALLOON DILATATION CATHETER

##### Indication

The Athletis Percutaneous Transluminal Angioplasty (PTA) Balloon Dilatation Catheter is indicated for percutaneous transluminal angioplasty in the peripheral vasculature including upper extremity, renal, iliac, and infrainguinal vessels and the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. It is also indicated for post-dilatation of stents and stent grafts in the peripheral vasculature.

#### ATTAIN STABILITY QUAD MRI SURESCAN 4798

##### ► Decision Summary

##### Indication

The Attain Stability Quad MRI SureScan 4798 is a left ventricular (LV) lead to be used in a Medtronic Cardiac Resynchronization Therapy (CRT) system. This device incorporates an active fixation side helix to assist the implanter in lead placement in the cardiac vein and to prevent dislodgement once implanted.

#### CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATOR (CRT-DS)

##### Indication

The Implantable Cardioverter Defibrillator (ICD) and Cardiac Resynchronization Therapy Defibrillator (CRT-D) devices are indicated for automated treatment of life-threatening ventricular arrhythmias. CRT-D devices are also indicated to treat symptoms in patients who have congestive heart failure with ventricular dyssynchrony.

#### COBALT XT / COBALT / CROME ICD AND CRT-D MRI SURESCAN

##### ► Decision Summary

##### Indication

The Cobalt XT/Cobalt/Crome Implantable Cardioverter Defibrillator (ICD) and Cardiac Resynchronization Therapy Defibrillator (CRT-D) magnetic resonance imaging (MRI) SureScan device is indicated for the automated treatment of patients who have experienced, or are at significant risk of developing, life-threatening ventricular arrhythmias through the delivery of antitachycardia pacing, cardioversion, and defibrillation therapies.

#### DIAMONDBACK 360 CORONARY ORBITAL ATHERECTOMY SYSTEM

##### Indication

The Diamondback 360 Coronary Orbital Atherectomy System (OAS) is a percutaneous orbital atherectomy system indicated to facilitate stent delivery in patients with coronary artery disease who are acceptable candidates for percutaneous transluminal coronary angioplasty or stenting due to de novo, severely calcified coronary artery lesions.

## ELUVIA OVER-THE-WIRE DRUG-ELUTING VASCULAR STENT SYSTEM



### ► Decision Summary [↗](#)

#### Indication

The Eluvia Over-the-Wire Drug Eluting Vascular Stent System is a drug eluting vascular stent. It is intended to improve luminal diameter in the treatment of symptomatic de-novo or restenotic lesions in the native superficial femoral artery (SFA) and/or proximal popliteal artery with reference vessel diameters (RVD) ranging from 4.0-6.0 mm and total lesion lengths up to 190 mm.

## EPSTAR FIXED ELECTROPHYSIOLOGY CATHETER / EPSTAR ELECTROPHYSIOLOGY CABLE



### ► Decision Summary [↗](#)

#### Indication

The EPstar Fixed Electrophysiology Catheter is intended for electrogram recording and pacing during diagnostic electrophysiology studies.

## EVOLUT PRO+ TRANSCATHETER AORTIC VALVE



### ► Decision Summary [↗](#)

#### Indication

Evolut PRO+ System is a transcatheter aortic valve replacement system. This device replaces the existing aortic valve.

## IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICDS)



#### Indication

The Implantable Cardioverter Defibrillator (ICD) and Cardiac Resynchronization Therapy Defibrillator (CRT-D) devices are indicated for automated treatment of life-threatening ventricular arrhythmias. CRT-D devices are also indicated to treat symptoms in patients who have congestive heart failure with ventricular dyssynchrony.

## INTELLANAV ST



### ► Decision Summary [↗](#)

#### Indication

The IntellaNav ST is a standard power temperature-controlled ablation catheter. When used with a compatible radiofrequency controller, is indicated for interruption of accessory atrioventricular (AV) conduction pathways associated with tachycardia, for treatment of AV nodal reentrant tachycardia and for creation of complete AV block in patients with a rapid ventricular response to an atrial arrhythmia.

## INTELLANAV STABLEPOINT ABLATION CATHETER



### ► Decision Summary [↗](#)

#### Indication

The IntellaNav StablePoint Catheter is indicated for use in patients who require catheter-based cardiac electrophysiological mapping (stimulating and recording) and, when used in conjunction with a radio frequency (RF) generator, for cardiac ablation.



## JADE PTA BALLOON DILATATION CATHETER



### Indication

The Jade Percutaneous Transluminal Angioplasty (PTA) Balloon Dilatation Catheter is a rapid exchange balloon catheter for peripheral indications. It is used for percutaneous transluminal angioplasty in the peripheral vasculature, including iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

## KONECT RESILIA AORTIC VALVED CONDUIT



### ► Decision Summary [↗](#)

### Indication

The Konect Resilia Valved Graft Conduit is indicated for patients who require replacement of their native or prosthetic aortic valve and the associated repair or replacement of a damaged or diseased ascending aorta.

## LOTUS EDGE VALVE SYSTEM



### ► Decision Summary [↗](#)

### Indication

The Lotus Edge Valve System is a pre-loaded, stent-mounted tissue valve prosthesis for transcatheter aortic valve replacement (TAVR). It is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are at high or greater risk for open surgical therapy.

## MICRA AV MC1AVR1



### Indication

The Micra AV is a leadless pacemaker delivering VDD therapy that is implanted directly into the right ventricle by a delivery catheter through the femoral vein. Atrial-Ventricular (AV) synchrony is provided through use of an on-board accelerometer that senses atrial contractions.

## PENUMBRA LP COIL SYSTEM



### Indication

The Penumbra LP Coil System is indicated for the embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, arterial and venous embolizations in the peripheral vasculature.

## QDOT MICRO NAVIGATION CATHETER



### ► Decision Summary [↗](#)

### Indication

The QDot Micro Navigation Catheter is a steerable, multi-electrode luminal catheter with a deflectable tip designed to facilitate electrophysiological mapping of the heart and to transmit radiofrequency (RF) energy to the catheter tip electrode for ablation purposes.

## RANGER AND RANGER SL OVER-THE WIRE PACLITAXEL-COATED PTA BALLOON CATHETER



### ► Decision Summary

#### Indication

The Ranger is a Drug Coated Balloon (DCB). The device is used in angioplasty procedures in the leg.

## REPROCESSED VIEWFLEX XTRA ICE CATHETER



#### Indication

The Reprocessed ViewFlex Xtra ICE catheter is indicated for use in adult and adolescent pediatric patients to visualize cardiac structures, blood flow and other devices within the heart.

## SAPPHIRE II NC CORONARY DILATATION CATHETER



#### Indication

Sapphire II NC Coronary Dilatation Catheter is used for balloon dilatation of a stenotic portion of a coronary artery in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion.

## SCOREFLEX NC CORONARY DILATATION CATHETER



#### Indication

The Scoreflex NC is intended for balloon dilatation of a stenotic portion of a coronary artery in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion.

## SCOREFLEX PTA BALLOON DILATATION CATHETER



#### Indication

The Scoreflex Percutaneous Transluminal Angioplasty (PTA) Balloon Dilatation Catheter is indicated for percutaneous transluminal angioplasty in the peripheral vasculature, including iliac, femoral, ilio-femoral, popliteal, infra-popliteal, renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

## SENTINEL CEREBRAL PROTECTION SYSTEM



### ► Decision Summary

#### Indication

The Sentinel Cerebral Protection System is indicated for use as an embolic protection device to capture and remove thrombus/debris while performing transcatheter aortic valve replacement procedures.

## SMART TOUCH PROGRAMMING SYSTEM



#### Indication

The Smart Touch Programming System is a programmer system for implanted devices (pacemakers, defibrillators, and cardio resynchronization therapy-defibrillator). The software interrogates and programs the devices. Additionally, it provides measurement, electrocardiogram (ECG) display and report printing functions.

## SURPASS EVOLVE FLOW DIVERTER SYSTEM



### Indication

The Surpass Evolve Flow Diverter System is a flow diverter comprised of a self-expandable braided implant preloaded on a delivery wire, housed inside an introducer sheath designed for endovascular treatment of intracranial aneurysms. The Surpass Evolve Flow Diverter System is indicated for use for the treatment of saccular or fusiform intracranial aneurysms arising from a parent vessel with a diameter between 2.0 mm and 5.0 mm.

## SYNERGY MONORAIL EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM



### Indication

The Synergy Everolimus-Eluting Platinum Chromium Coronary Stent System is a medical device that provides a mechanical structure for vascular lumen support (the stent component) and a pharmacological agent (everolimus) targeted towards reducing the injury response that leads to restenosis after stent implantation.

## SYNERGY XD MONORAIL EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM



### Indication

The Synergy XD Monorail Everolimus-eluting Platinum Chromium Coronary Stent System is used for improving luminal diameter in patients, including those with diabetes mellitus, with symptomatic heart disease, stable angina, unstable angina, non-ST elevation MI or documented silent ischemia due to atherosclerotic lesions in native coronary arteries between 2.25 mm and 5.00 mm in diameter in lesions 44 mm or less in length.

## TRICLIP SYSTEM



► [Decision Summary](#)

### Indication

The TriClip System is a transcatheter Tricuspid Valve Repair System (TVRS) intended for use in reconstruction of the tricuspid valve (TV) through tissue approximation.

## VEGA ENDOCARDIAL PACING LEAD



► [Decision Summary](#)

### Indication

The Vega pacing lead is a bipolar, endocardial, steroid eluting, silicone-insulated lead with an extendable/retractable active-fixation screw, intended for permanent pacing and sensing of either the right atrium or right ventricle.

## WATTSON TEMPORARY PACING GUIDEWIRE



► [Decision Summary](#)

### Indication

The Wattson temporary pacing guidewire is a dual purpose guidewire designed for the delivery of devices (e.g. Transcatheter Aortic Valve Replacement) and temporary rapid pacing of the heart when used with an external pulse generator.

## XIENCE PRO A EVEROLIMUS ELUTING CORONARY STENT SYSTEM

► [Decision Summary](#)

### Indication

The Xience ProA Everolimus Eluting Coronary Stent System (Xience ProA) consists of a drug and polymer coated stent pre-mounted on a balloon catheter delivery system. The Xience ProA stent system is indicated for improving coronary artery luminal diameter in patients, and for treating de novo chronic total coronary occlusions.

## ZOLL X SERIES ADVANCED

► [Decision Summary](#)

### Indication

The Zoll X Series Advanced devices are portable, lightweight defibrillators that combine defibrillation and external pacing with several monitoring capabilities. The X Series Advanced system is indicated for defibrillation on victims of cardiac arrest where there is apparent lack of circulation as indicated by unconsciousness, absence of breathing, or absence of pulse.

## GASTRO-UROLOGICAL DEVICES

*For example, incontinence control systems.*

### 1 NEW MEDICAL DEVICE

## INTERSTIM MICRO SURESCAN MRI



### Indication

The InterStim system is an implantable programmable neuromodulation system that delivers electrical stimulation to the sacral nerve. Sacral neuromodulation therapy provided by the InterStim system is indicated for the management of the following chronic intractable (functional) disorders of the pelvis and lower urinary or intestinal tract: overactive bladder, fecal incontinence, and non-obstructive urinary retention.

## SAFETY UPDATE

Single incision mini-sling (SIMS) made from non-absorbable synthetic material (polypropylene):

[Summary Safety Review: Single Incision Mini-sling - Assessing the Long-term \(beyond 3 years\) Safety and Effectiveness](#)



## GENERAL HOSPITAL DEVICES

*For example, infusion pumps.*

### 3 NEW MEDICAL DEVICES

#### EPSTAR FIXED ELECTROPHYSIOLOGY CATHETER WITH LUMEN/EPSTAR ELECTROPHYSIOLOGY CABLE

► [Decision Summary](#) 

##### Indication

The EPstar Fixed Electrophysiology Catheter with Lumen/ EPstar Electrophysiology Cable can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.

#### MINIMED 770G

► [Decision Summary](#) 

##### Indication

The MiniMed 770G 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 two years of age and older requiring insulin as well as for the continuous monitoring and trending of glucose levels in the fluid under the skin, in the abdomen and buttock, or back of upper arm, depending on the person's age.

#### T:SLIM X2 INSULIN PUMP WITH CONTROL-IQ TECHNOLOGY

► [Decision Summary](#) 

##### Indication

The t:slim X2 Insulin Pump with Control-IQ Technology is an insulin delivery system, intended to treat people with Type 1 diabetes, over the age of 6. It is intended for the subcutaneous delivery of insulin. The Control-IQ technology is intended for use with a compatible continuous glucose monitor (CGM) and the t:slim X2 insulin pump to automatically increase, decrease, and suspend delivery of basal insulin based on CGM readings and predicted glucose values.

### SAFETY UPDATES

Respirators:

**Advisory: Important safety information for certain respirator masks**

**Information Update: Medical Device Respirator recalls**

## IN VITRO DIAGNOSTIC MEDICAL DEVICES

For example, instrument/analyser and viral infection disease in vitro devices.

### 8 NEW MEDICAL DEVICES

#### ADVIA CENTAUR HBC TOTAL 2 (HBCT2) (DONOR SCREENING FOR TRANSPLANTATION)

► Decision Summary [↗](#)

##### Indication

The Advia Centaur HBCT2 assay is an *in vitro* diagnostic device which measures total antibodies to the core antigen of hepatitis B virus in human serum and plasma. The presence of anti-HBc indicates previous or ongoing infection with hepatitis B virus.

#### ADVIA CENTAUR QUANTITATIVE HBSAG (QHBS)

##### Indication

The Advia Centaur Quantitative HBsAg (QHBS) assay is for *in vitro* diagnostic use in the quantitative determination of hepatitis B surface antigen (HBsAg) in human serum and plasma (lithium heparin, sodium heparin, and dipotassium EDTA) that are confirmed positive for HBsAg using the Advia Centaur XP and Advia Centaur XPT systems.

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

► Decision Summary [↗](#)

##### Indication

The Alinity s HIV Ag/Ab Combo Assay is intended for blood donor screening and it is run off the Alinity s platform.

#### ATELLICA IM QUANTITATIVE HBSAG (QHBS)

##### Indication

The Atellica IM Quantitative HBsAg (QHBS) assay is for *in vitro* diagnostic use in the quantitative determination of hepatitis B surface antigen (HBsAg) in human serum and plasma (dipotassium EDTA, lithium heparin, and sodium heparin) that are confirmed positive for HBsAg using the Atellica IM Analyzer.

#### INSTI HIV SELF TEST

► Decision Summary [↗](#)

##### Indication

The INSTI HIV Self Test is a single use *in vitro* self-test for the detection of antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in whole blood. The test is intended for use as a self-test by users 18 years or older.

#### LIAISON XL MUREX HCV AB

► Decision Summary [↗](#)

##### Indication

The Liaison XL Murex HCV AB is intended to be used as an aid in the diagnosis of hepatitis C virus (HCV) infection. The assay may also be used as an aid in the diagnosis of HCV infection in pediatric subjects and in pregnant women.

## PK CMV-PA SYSTEM CONTROL SET



### ► Decision Summary [↗](#)

#### Indication

The PK CMV-PA System Control Set is an *in vitro* diagnostic device. This application for a new medical device license for the PK CMV-PA System Control Set (PA2302) is to add the Beckman Coulter PK7400 Automated Microplate System as an intended use for this control set.

## PK7400 TP HA REAGENT AND CONTROLS



### ► Decision Summary [↗](#)

#### Indication

PK7400 TP HA reagent is intended for the qualitative screening of blood donors for the detection of *Treponema pallidum* IgG and IgM antibodies to syphilis in human serum, EDTA plasma, or CPDA plasma.

## NEUROLOGICAL DEVICES

*For example, neurological stimulation devices.*

### 2 NEW MEDICAL DEVICES

## PERCEPT PC



#### Indication

Bilateral anterior thalamic nucleus (ATN) stimulation using the Medtronic DBS System for epilepsy is indicated as adjunctive therapy for reducing the frequency of seizures in adults diagnosed with epilepsy characterized by partial-onset seizures, with or without secondary generalization, that are refractory to antiepileptic medications.

## PROCLAIM IMPLANTABLE PULSE GENERATORS

#### Indication

The Proclaim XR Implantable Pulse Generator (IPG) is a spinal cord stimulation device. This device generates weakly electric pulses and delivers them to the site of interest in the spinal cord for pain control.

## PLASTIC SURGERY AND COSMETIC DEVICES

*For example, breast implants.*

### 1 NEW MEDICAL DEVICE

## NATRELLE INSPIRA COHESIVE BREAST IMPLANT



#### Indication

Indications for use include breast augmentation, breast reconstruction, and revision for previous breast augmentation or reconstruction to correct or improve the result of the previous surgery.

## RADIOLOGICAL DEVICES

*For example, ultrasound imaging systems.*

### 1 NEW MEDICAL DEVICE

#### ACIST HDI SYSTEM

##### ► Decision Summary [↗](#)

##### Indication

The Acist HDi System is intended to be used for the ultrasound examination of coronary and peripheral intravascular pathology. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal interventional procedures.

## VARIOUS

*Applicable to medical devices generally.*

### SAFETY UPDATE

Some medical devices that use Bluetooth Low Energy (BLE) chips: Information Update: Cybersecurity vulnerabilities associated with some medical devices with Bluetooth Low Energy chips











## DRUGS FOR VETERINARY USE: 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 this work, we evaluate veterinary drugs throughout the life-cycle, from research/studies to after the drug is sold in Canada.

### CLINICAL TRIALS

Experimental studies certificates and investigational new drug applications support the development of potential new veterinary drugs or new uses of already approved products. Sponsors of such research/studies (including manufacturers and researchers) submit their applications for Health Canada review before the trial is conducted in Canada.

### EMERGENCY DRUG RELEASE PROGRAM

Drugs that are not approved in Canada may be available through our [Emergency Drug Release program](#).

Veterinarians may request access to veterinary drugs to treat patients (an animal or group of animals) with serious or life-threatening conditions. Access to these drugs is only considered when conventional therapies have failed, are unsuitable or are unavailable.

### DRUG SUBMISSION AND REVIEW

When a company decides that it would like to market a veterinary drug in Canada, it files a submission with Health Canada. A new drug submission contains detailed scientific information about the drug's safety, efficacy 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.

### INNOVATIVE REVIEWS (INTERNATIONAL REGULATORY COOPERATION)

Through international regulatory cooperation, we conduct reviews of submissions for new veterinary drugs with certain partners. These include the United States Food and Drug Administration 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.

### 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 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.

### SURVEILLANCE

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

#### Collecting information

Health Canada collects information about a product after it is approved from a variety of sources.

One source of information 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 who administered a veterinary drug to an animal, and
- events that result from a suspected lack of effect.

#### Veterinary drug reaction [↗](#)

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

#### Evaluating safety signals

Health Canada evaluates 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.





# DRUGS FOR VETERINARY USE: APPROVED IN 2020

## IMPORTANT DEFINITIONS

### Generic drug

A generic drug is 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.

### 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 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.

### New drug

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

#### Veterinary drug reaction

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

## 9 NEW DRUGS

### AMODIP FLAVOURED TABLETS

#### Medicinal Ingredient

Amlodipine besylate

#### Indication

Amodip is indicated for the reduction of systolic blood pressure in cats with systemic hypertension.

### ASERVO EQUIHALER

#### Medicinal Ingredient

Ciclesonide

#### Indication

For the management of clinical signs associated with severe equine asthma in horses.

### BRAVECTO ONE

#### Medicinal Ingredient

Fluralaner

#### Indication

For the treatment and prevention of flea infestations and for the treatment and control of tick infestations in dogs and puppies.

### COMFORTAN

#### Medicinal Ingredient

Methadone hydrochloride

#### Indication

As part of a pre-medication regimen, for the control of post-operative pain associated with ovariohysterectomy and castration in cats.

## COSACTHEN

### Medicinal Ingredient

Tetracosactide

### Indication

To evaluate adrenal function as part of the diagnosis of adrenocortical insufficiency (Addison's) or hyperadrenocorticism (Cushing's) in dogs.

## ERADIA

### Medicinal Ingredient

Metronidazole

### Indication

For the treatment of *Giardia duodenalis* infection in dogs.

## GONABREED

### Medicinal Ingredient

Gonadorelin acetate

### Indication

For use with cloprostenol sodium injectable solution to synchronize estrous cycles to allow for fixed time artificial insemination in lactating dairy cows and beef cows.

## MIRATAZ

### Medicinal Ingredient

Mirtazapine

### Indication

For body weight gain in cats with a poor appetite and weight loss.

## ZELERIS

### Medicinal Ingredient

Florfenicol, meloxicam

### Indication

For therapeutic treatment of bovine respiratory disease, with accompanying pyrexia, associated with *Mannheimia haemolytica*, *Pasteurella multocida* and *Histophilus somni* susceptible to florfenicol in beef and non-lactating dairy cattle.

## 11 NEW GENERIC DRUGS

- 1 product containing butorphanol
- 1 product containing florfenicol
- 1 product containing meloxicam
- 1 product containing miconazole nitrate, polymyxin B sulfate, prednisolone acetate
- 2 products containing selamectin
- 1 product containing sulfadiazine, trimethoprim
- 4 products containing tulathromycin





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