HEALTH PRODUCT HIGHLIGHTS

Helping you maintain and improve your health

2021

Health Canada Santé Canada

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HEALTH PRODUCT HIGHLIGHTS 2021

Helping you maintain and improve your health

Health Canada helps Canadians maintain and improve their health by providing timely access to safe, effective and high-quality health products, including prescription and non-prescription drugs, medical devices, natural health products and veterinary health products. Learn about the new health products that Health Canada approved for sale in Canada, the information we published about these products, and our other accomplishments in 2021.

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 2021 sur les produits de santé :
Pour maintenir et améliorer votre santé

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WELCOME TO OUR 2021 HIGHLIGHTS REPORT

2021 was the second year of an unprecedented global pandemic. The Health Products and Food Branch of Health Canada was proud to play its part as Canada's health products regulator to ensure Canadians had access to safe, effective and high-quality COVID-related products, including vaccines, tests, treatments, personal protective equipment, disinfectants and sanitizers – in addition to the great number of non-COVID health products Canadians rely on every day.

The COVID-19 response has required a massive collective effort. Our team showed up every day – in the labs, at their desks, from their homes – all while facing the same struggles as their fellow Canadians. Through it all, they delivered by reviewing critically needed COVID-19 products on shortened timelines while maintaining Health Canada's rigorous scientific standards.

Our work continues even after we review and authorize health products for use in Canada. We continue to monitor COVID-19 products and provide updated safety information as additional data becomes available. Combatting misinformation in marketing has been more important than ever. We track false and misleading claims about COVID-19 products and issue science-based advice. This, along with our efforts to enhance the transparency of health product information provided to Canadians, helps to ensure that they are able to make informed decisions.

Nancy Hamzawi

Assistant Deputy Minister

Pamela Aung Thin

Associate Assistant Deputy Minister

We want to acknowledge the extraordinary efforts of our employees – a team highly specialized across a variety of disciplines – in bringing their expertise to bear to help Canadians through this health crisis. Their work has built trust in our regulatory system, provided clear, authoritative information to the public, and above all, ensured the safety, efficacy and quality of thousands of new products – enabling access to both COVID-related products while continuing to review and authorize the many other health products Canadians rely on.

We would be remiss if we did not also mention the contributions of Pierre Sabourin, who retired from the public service in December 2021. He led the Health Products and Food Branch as Assistant Deputy Minister for six years, including through the demanding first 20 months of the COVID-19 pandemic. His dedication and commitment to public service have been outstanding.

An enormous amount of stakeholder collaboration has also taken place over the past two years. We are one piece of the broader COVID-19 response, and we have worked with our federal government partners, provincial and territorial governments, product sponsors, including manufacturers and researchers, and health care practitioners on a scale that we have never seen before. This included scanning for emerging COVID-19 products, and proactively engaging with manufacturers to encourage them to submit their products for approval in Canada. We also continued to prioritize collaboration with our international regulatory partners, in order to support timely access to new products for Canadians. We hope to build on these relationships going forward.

We deepened our relationship with patients and strengthened our efforts to support underserved and/or underrepresented populations, as well as to address rare diseases. In this report, we profile our new Sex- and Gender-Based Analysis Plus Action Plan which is designed to help those who live in Canada make informed decisions regarding treatment options that are based on safety and efficacy profiles of people like them.

This report describes the new health products Health Canada approved for sale in Canada in 2021, the information we published about these products, and how we continued to monitor approved products once on the Canadian market. It also speaks to our efforts to continuously improve our work, ensure that our regulatory system is agile and responsive to innovation, and maintain our rigorous safety standards.

For information on our activities, we invite you to follow @GovCanHealth on Twitter to learn about newly approved drugs and medical devices.

Focus on…
COVID-19 PRODUCTS BY THE NUMBERS

From the start of the COVID-19 pandemic to December 2021, we approved:

- **4 vaccines**
- **4 drug treatments**
- **113 clinical trial applications** for drugs and vaccines
- **62 investigational testing applications** for medical devices
- **783 medical devices**, including **102 testing devices**
- Over **700 disinfectants** as effective against COVID-19
- Over **4,000 hand sanitizers**

Health Canada continues to monitor the safety and efficacy of all COVID-19-related products. We issued 21 risk communications for COVID-19 treatments and vaccines, and took action on 530 COVID-19-related false and misleading advertisements.

MESSAGE FROM THE CHIEF MEDICAL ADVISOR

The second year of a pandemic demanded much from Health Canada in its regulatory work: resilience, endurance and persistence.

As days turned into weeks, weeks into months, and now months into years, those at the forefront of making and supporting important decisions on access to COVID-19 tests, treatments and vaccines found themselves continuing to work "flat out." Although we are not personally at the front lines of the health care system, the products that we regulate play a crucial role in every moment of care offered to Canadians.

Waves of the pandemic brought increased demands on energy and resources for key time-sensitive decisions, and once those were completed, the resilience to quickly move onto the next critical task at hand. This of course was set against the backdrop of the challenges that we all were collectively facing outside of work, as well.

Sustaining that level of effort over the long run requires endurance. For COVID-19 health products, the volume of work, the long days necessary to support international collaboration and attention to detail that would be scrutinized to the highest degree were part and parcel of our day-to-day work. Likewise, maintaining standards for non-COVID-related products that are equally important in helping to improve and maintain the health of Canadians meant that reviews and assessments continued to be completed within committed timelines.

Supriya Sharma
Chief Medical Advisor

Lastly, communicating our work necessitated a great deal of persistence. Continuing the journey along the path of greater openness and transparency required consistent and clear messaging on all decisions. Cutting through the reams of information and often misinformation is still challenging, but we all recognize that accurate and reliable information is the cornerstone to informed decision-making. Undoubtedly, there will be lessons learned on how to best operate in these charged environments.

If this seems like a very personal message this year, it's because it is. The strength and achievements of the Health Products and Food Branch of Health Canada rest with the individuals who gave their best every day to support Canadians through these challenging times.

MESSAGE FROM THE CHIEF REGULATORY OFFICER

Health Canada's Regulatory Innovation Agenda responds directly to calls from stakeholders for more modern, agile regulations. These modernization efforts will help to strengthen the health care system by enabling access to more diverse treatment options for Canadians. In 2021, we continued to advance the five key pillars of the agenda:

- Modernizing clinical trial regulations
- Enabling Advanced Therapeutic Products
- Agile licensing for drugs
- Agile licensing for medical devices
- Mobile-first communications strategy

The COVID-19 pandemic has reinforced the importance of agile regulations to enable us to rapidly respond to extraordinary health events and accommodate innovative new products. Some of the agile regulatory tools we used during the pandemic were already a part of our modernization plans. These regulatory measures, in addition to the exceptional response from our staff, allowed us to expedite reviews of COVID-19 health products without compromising safety, efficacy and quality standards. These measures included, for example, reviewing evidence on a rolling basis as it became available, instead of waiting for completed submission packages, and using terms and conditions on product approvals to facilitate continued monitoring once the products were available to Canadians.

David K. Lee
Chief Regulatory Officer

One of the key ways in which we were able to advance our agile regulatory response to the pandemic was through Interim Orders – one of the fastest mechanisms available to the federal government to help make health products available to address larger-scale public health emergencies. In 2021, we made sure that the regulatory flexibilities from these Interim Orders remained in place so that Canadians continued to benefit from timely access to COVID-19 health products.

Despite the demands of the pandemic, in 2021, we advanced a wide array of regulatory initiatives to update Canada's regulatory system for health products. These included consulting on our proposed approach to modernize Canada's clinical trial regulations, as well as publishing a Notice of Intent in the *Canada Gazette*, on our intentions to expand the use of some key agile regulatory tools used in COVID-19 for other types of drugs and devices. We also published proposed regulations for formal consultation in the *Canada Gazette*, Part I, to improve the labelling of natural health products.

We look forward to continued collaboration with stakeholders and health care system partners in developing regulatory and policy changes that will contribute to the health and safety of Canadians and modernize our regulatory frameworks.

Focus on… ENHANCING OUR COLLABORATION

Over the past five years, Health Canada has increased its efforts to collaborate with stakeholders and partners in Canada and around the world. These relationships have helped us come together to respond to the pandemic, and also to advance key health system priorities such as increasing access to drugs designed to treat rare diseases.

From an international perspective, we have worked to enhance regulatory alignment and scientific cooperation, as well as conducting more collaborative reviews of health products, all with the goal of enhancing our product approval processes, and bringing needed drugs and medical devices to Canadians more quickly.

Examples of these efforts include our work as part of the Access Consortium, with the United States Food and Drug Administration through Project Orbis, as well as through the International Coalition of Medicines Regulatory Authorities and the European Medicines Agency's OPEN initiative – which are all discussed in more detail in this report.

Collaboration at home and internationally helps us to fulfill our mandate to ensure that Canadians have access to safe, high-quality and effective health products.

Ed Morgan
Director General, Policy, Planning and International Affairs

Focus on… ENSURING TRANSPARENCY

Health Canada has been steadily increasing transparency about our decisions, and the data that underpin them, as demonstrated by the information we provide to Canadians on COVID-19 vaccines and treatments via our portal.

Our Public Release of Clinical Information initiative continues to support Canada's response to COVID-19 while expanding its work to proactively make more anonymized clinical information publicly available. The initiative supports Canada's objective for transparent decision-making and provides valuable information that could help with the use or development of drugs and medical devices. In 2021, we published 1.8 million pages of anonymized clinical data. Part of this work focused on expedited publication of clinical information for COVID-19 vaccines and treatments, many in collaboration with the European Medicines Agency.

This level of transparency supports our overall goal of providing timely, evidence-based and authoritative information to enable Canadians to make informed decisions.

Etienne Ouimette
Director General, Resource Management and Operations

Focus on…
SEX- AND GENDER-BASED ANALYSIS PLUS

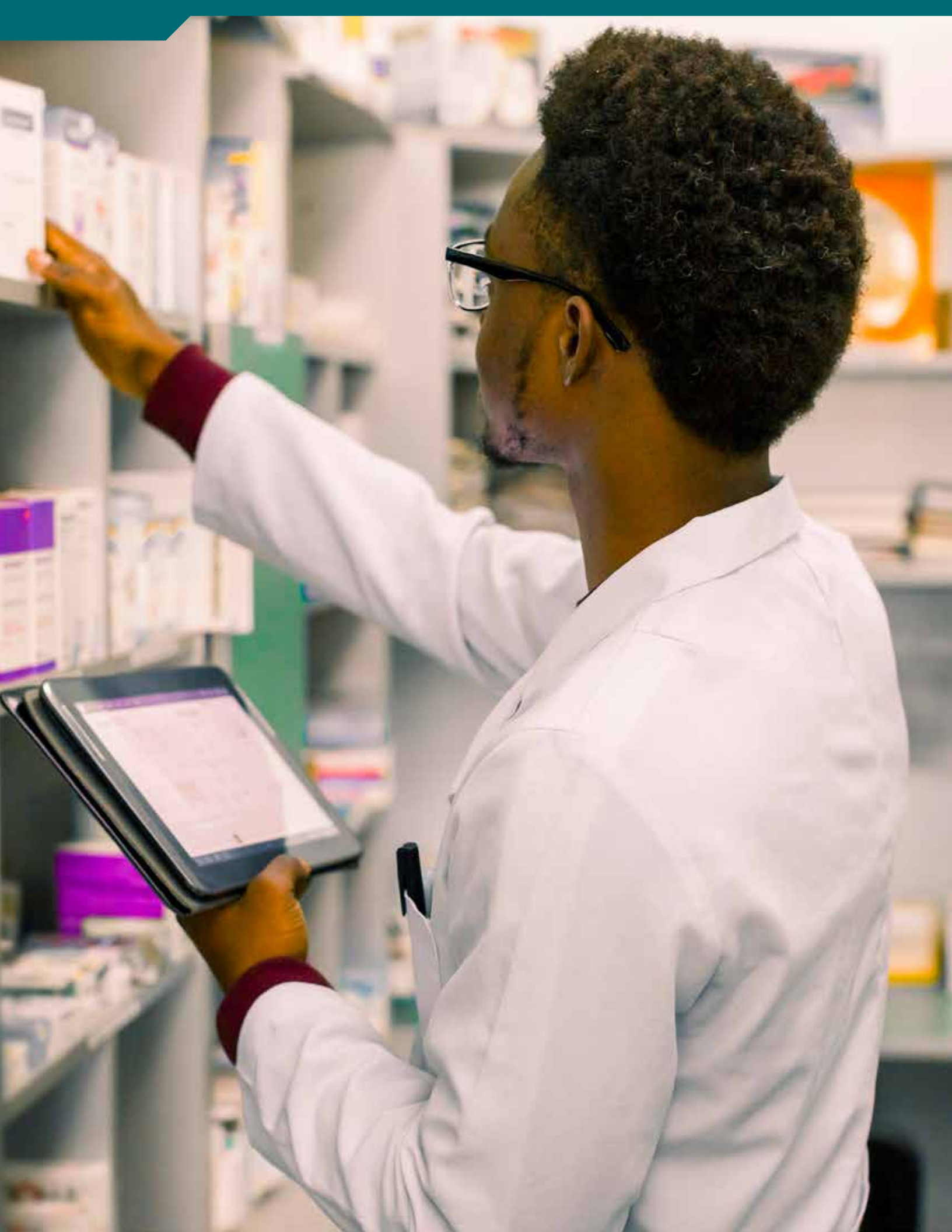
Health Canada continues to strengthen the integration and application of Sex- and Gender-Based Analysis Plus (SGBA Plus) within all our activities to advance equity, diversity and inclusion. Incorporating diverse identity factors, such as sex, gender, race, age and geography, into data collection and decision-making helps us assess the impacts of biological and social differences on how health products work in different populations.

In June 2021, HPFB's SGBA Plus Action Plan was endorsed by the Deputy Minister. Ultimately, the vision of the plan is that Canadians have access to information to support informed decision-making regarding their treatment options based on safety and efficacy profiles of people like them. Specifically, the goals of the action plan are to:

1. Improve the equity-related data that gets submitted to Health Canada (e.g., submission of disaggregated data, increased diversity in clinical trials leading to better data submission, etc.);
2. Enhance the way equity-related data is analyzed and reported on by Health Canada; and
3. Increase the SGBA Plus information available to the users of the data to build trust and transparency.

In 2021, we also continued to leverage the Scientific Advisory Committee on Health Products for Women (SAC-HPW) to advance work to improve the safety of health products for women. This included engaging the Committee and patient representatives on how to better communicate information to existing and prospective consumers of breast implants and urinary meshes through our website and advisories, as well as initiating discussions on enhanced integration of SGBA Plus into our scientific and policy activities.

We also consulted on draft guidance for clinical evidence requirements for medical devices in November 2021. The draft guidance provides advice to manufacturers on how to incorporate SGBA Plus into their applications for a medical device license. This analysis supports Health Canada's review of a medical device, helping to confirm safety and that the devices function appropriately for different groups of patients.



DRUGS FOR HUMAN USE

Message from the Directors General

John Patrick Stewart

Director General,
Therapeutic Products

Celia Lourenco

Director General,
Biologic and
Radiopharmaceutical Drugs

Kelly Robinson

Director General,
Marketed Health Products

One of Health Canada's roles is to regulate drugs that can help Canadians maintain and improve their health. This section will discuss drugs, including prescription medicines, vaccines and blood and plasma for human use. Health Canada evaluates drugs before they reach the Canadian market and continues to monitor real world evidence after they are on the market. We are involved throughout the lifecycle of drugs for human use, from clinical trials to once a drug is in use in Canada.

The COVID-19 pandemic created an urgent need for access to safe, effective and high-quality vaccines and treatments. At the end of 2021, 4 COVID-19 vaccines were approved for use in Canada. Our vaccine work also included dedicated reviews to ensure the safety and efficacy of booster shots and a pediatric formulation for children aged 5-12 years. In 2021, we also approved 2 new COVID-19 treatments, bringing us to 4 approved COVID-19 treatments in total and with the review of other treatment submissions received continuing into 2022. We expedited the review of these products while maintaining our rigorous scientific standards by using agile regulatory tools, such as rolling submissions, along with staff surge capacity and increased resources within Health Canada.

While responding to the pandemic, we continued to review products not related to COVID-19 to ensure their safety, efficacy and quality. We continued to strengthen our focus on diversity and vulnerable populations, such as children. For example, we worked to enhance access to treatments for rare diseases, approving 10 new drugs for rare diseases in 2021. We advanced implementation of the Pediatric Drug Action Plan to further increase access to drugs for pediatric populations in Canada. Health Canada also supported access to treatments not available in Canada through our Special Access Program.

Our post-market risk management planning starts at the pre-market stage. We review risk management plans which help ensure that appropriate risk mitigation measures for known and potential safety risks and uncertainties are in place. These risk management plans are updated as new safety information became available. We also enhanced our monitoring and assessment activities of emerging safety issues, including for products used for COVID-19, while collaborating and sharing information with our partners in Canada and around the world.

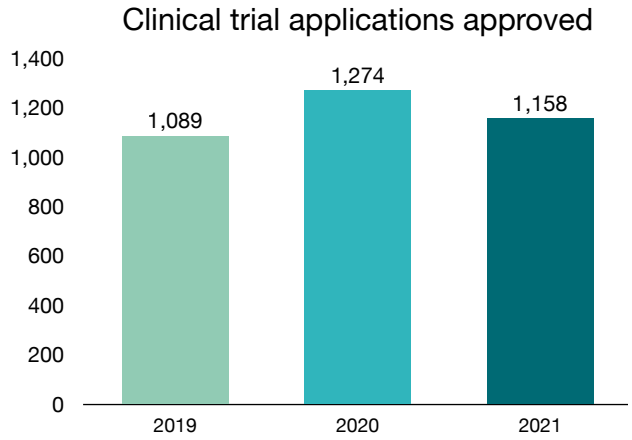
In 2021, we continued to see the benefit of mandatory reporting of serious adverse drug reactions by hospitals, which was implemented in 2019. Since these regulations have been in force, the number of serious adverse drug reaction reports submitted by hospitals has increased significantly – with 4,500 reports in 2021 alone. This reporting strengthens our post-market knowledge base to reduce uncertainty associated with the real-world benefits and risks of therapeutic products.

CLINICAL TRIALS

Clinical trials are conducted by sponsors (manufacturers or researchers) to gather information on a drug's safety and efficacy in humans. Sponsors of clinical trials submit their applications to conduct a clinical trial with a drug in Canada. Health Canada reviews these applications to ensure that trials are well designed and that participants are not exposed to undue risk.

In 2021, we authorized the use of investigational drugs in 1,158 new clinical trial applications for drugs. Of these, 32 were for COVID-related products (13 vaccines and 19 drugs).

The trials varied significantly in type, size and intent. For example, we authorized the use of investigational products in a phase II/III trial designed to rapidly evaluate several different novel products with the potential to be effective therapies for non-hospitalized COVID-19 patients.



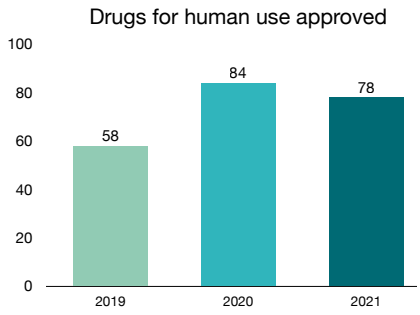
We authorized the MOSAIC Study, led by the Canadian Immunization Research Network, which is examining the safety and immune response of mixing and matching approved COVID-19 vaccines using various time intervals in adults.

Further, in March 2021, Medicago's Recombinant Coronavirus-Like Particle COVID-19 Vaccine entered phase III clinical trials. Medicago's COVID-19 vaccine was the first Canadian manufactured vaccine in a phase III trial. It is also unique in that it incorporates a plant-based protein.

In November 2021, Health Canada authorized the use of the investigational drug ION582 in an early stage, open-label clinical trial. This trial was designed to evaluate the safety and tolerability of ascending doses of this drug in patients with Angelman Syndrome. Angelman Syndrome is an incurable genetic disorder resulting in delayed development, problems with speech and balance, intellectual disability and seizures. Current treatment focuses on managing medical, sleep and developmental issues.

In 2021, we dedicated significant effort to continuing to provide enhanced regulatory advice for clinical trials and drug reviews, including guidance on the management of clinical trials during the pandemic and the publication of a dedicated list of authorized clinical trials for COVID-19-related drugs and vaccines. We also continued to engage the Canadian Institutes of Health Research and the Canadian Association of Research Ethics Boards, along with provincial stakeholders, to share information on clinical trials and COVID-19.

NEW DRUGS FOR HUMAN USE APPROVED



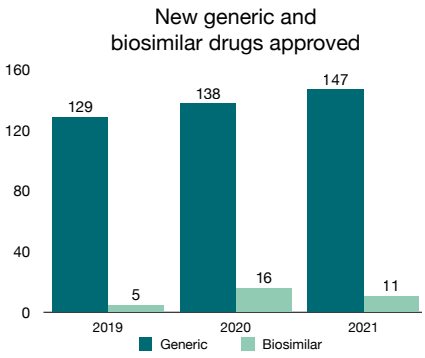
When a company decides that it would like to market a drug in Canada, it files a submission with Health Canada. A new drug submission contains detailed scientific information about the drug's safety, efficacy and quality. Our scientists and medical officers perform a thorough review of the information submitted, and may 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, and review the information that will be provided to health care practitioners and consumers about the drug.

In 2021, we approved 78 new drugs, providing patients with more options for the treatment, prevention and diagnosis of various health conditions. Of these:

- 10 were drugs for rare diseases
- 8 were new drugs with pediatric indications

Forty-three of the new drugs approved in 2021 contained medicinal ingredients that had never been approved for sale in Canada, or what we call "new active substances." Of these, 37% were approved through an expedited pathway, including those that target specific health care needs.

One such example is Trikafta, a breakthrough therapy authorized by Health Canada in June following a priority review. Trikafta is indicated for all cystic fibrosis patients aged 12 years and older with the most common gene mutation, providing access to an additional effective therapy for cystic fibrosis patients, including adolescents.



Focus on… **BLOOD AND PLASMA FOR HUMAN USE**

Health Canada is responsible for the regulatory oversight of the blood system in Canada to help ensure the safety of blood and blood components for Canadians. Under the *Blood Regulations*, those Canadian establishments that collect blood, blood components and plasma are required to make submissions for any proposed changes to Health Canada. These submissions must contain scientific data from studies that support the safety of any proposed changes. Health Canada considers the risks and benefits of any proposed changes to blood operations before granting approval. In 2021, we also approved 23 submissions of blood and plasma products for human use.

We have continued to advance work on pathogen reduction technologies for platelets. For example, we approved the Canadian Blood Services' submission pertaining to the use of the Intercept pathogen inactivation technology for platelets with a 5-day shelf life. This technology is used to inactivate a broad range of pathogens in order to reduce the risk of transfusion-transmitted infections, and serves as a replacement for sterility testing.

Another example is Rukobia, an HIV drug which represents a new hope for patients facing multi-drug resistant HIV—a rare subset of the overall HIV population—who may otherwise have no treatment options. Given the importance of this new treatment for HIV patients, the drug submission was granted priority review status and approved in October 2021.

In 2021, we also approved 147 new generic drugs. A generic drug contains the same medicinal ingredients as the brand name drug, and is considered bioequivalent to the brand name drug. These products bring greater choice and affordable options for Canadians. We also approved 11 new biosimilars, which are biologic drugs that are highly similar to a biologic drug already authorized for sale.

In 2021, we also continued to prioritize the review and approvals of biologic drug lots for release, maintaining Canadians' access to their biological drugs or enabling

equivalent alternative treatments. The lot release program provides Health Canada with a real-time system to monitor product quality, through review and testing, of many of the biological drugs that we regulate. The program covers both pre- and post-market stages for biologic drugs, with each subject to a lot release program based on the degree of risk linked to the product, in order to ensure proper oversight.

SPECIAL ACCESS PROGRAM

Through our Special Access Program, we enable access to a wide range of drugs not available for sale in Canada for serious diseases such as cystic fibrosis, rare forms of epilepsy, complicated infections, cancers, ALS, cardiac diseases, hemophilia and other blood disorders. In 2021, we authorized 12,456 requests for special access to drugs and added 140 new drugs to the program. These drugs are either in development or have been approved in other jurisdictions.

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

We also continue to actively reduce the need for the Special Access Program by working with regulatory partners to approve needed drugs, including through information sharing and parallel reviews as well as by encouraging industry to submit drug applications in Canada. For example, following their Canadian market authorization in 2021, 35 drugs released through the program will no longer require special access. These included Ranexa (ranolazine) to treat heart-related chest pains, Evrysdi (risdiplam) to treat spinal muscular atrophy and Effient (prasugrel) to prevent the formation of blood clots. Health professionals previously requested these drugs on average more than 50 times per year through the Special Access Program, but they can now be prescribed directly.

POST-MARKET VIGILANCE

After we approve a drug for sale in Canada, we continue to monitor and evaluate reports of suspected adverse reactions. Adverse reactions are undesirable effects that may be associated with a drug.

We evaluate potential safety and efficacy issues, and take action when there are identified problems. As part of the Canada Vigilance Program, Health Canada collects safety information about a product from a variety of sources, including suspected adverse reactions reported after products are approved for sale. Health Canada evaluates the data from several sources 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 regulatory 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.

Health Canada is continuously looking for ways to strengthen the post-market knowledge base to reduce the uncertainty associated with the real-world benefits and harms of therapeutic products. In 2021, Health Canada received over 1.1 million reports of suspected adverse reactions to drugs for human use, including those submitted by Canadian hospitals as part of mandatory reporting obligations that came into force in December 2019. These reports help Health Canada further investigate potential risks to Canadians' health and safety.

In 2021, we investigated 12 safety signals and undertook 9 regulatory actions resulting from the assessments for COVID-19 vaccines and treatments. We also completed 14 safety signal assessments and undertook 10 regulatory actions stemming from these assessments for non-COVID-19 pharmaceutical and biologic drugs. In 2021, we also completed 4 medication incident analyses and undertook 3 regulatory actions stemming from these analyses.

Health Canada also uses Risk Management Plans to support ongoing evaluation of information that could have an impact on a drug's benefit-risk profile. The decision to approve a drug is based on its benefit-risk profile, based on the information available at the time of approval. The knowledge related to the safety profile of the drug can change over time through expanded use in terms of patient characteristics and the number of patients using the drug. Risk Management Plans describe activities to be undertaken following marketing authorization to identify, characterize, prevent or minimize risks related to drugs once they are in use. In 2021, we reviewed 413 Risk Management Plans for drugs, 35 of which were for COVID-19 treatments and vaccines.

In 2021, we also issued an increased number of Health Product Risk Communications, with a continued focus on issues related to the availability of and safety risks related to COVID-19 vaccines and treatments. Health Product Risk Communications are designed to clearly and effectively communicate new and clinically significant information to healthcare professionals about new health-related risks associated with marketed health products. Improved collaboration with stakeholders also contributed to the successful issuance of 33 Health Product Risk Communications, 21 of which were related COVID-19 vaccines and treatments, between January 1, 2021 and December 31, 2021.

In addition, Health Canada continued to identify a large number of advertising incidents, including through active monitoring of COVID-19-related advertisements. From January to December 2021, we took action on more than 1,100 false and misleading advertisements, 530 of which were related to COVID-19.

TRANSPARENCY OF DECISION MAKING

In 2021, we continued to advance our openness and transparency efforts by expanding the amount of regulatory health and safety information that was made available to Canadians. We published 147 regulatory decision summaries and 48 summary basis of decision documents, which explain Health Canada's decisions for certain drugs seeking market authorization.

We continue to publish regulatory and product information on the Health Canada website and the COVID-19 vaccines and treatments portal to respond to the high demand for credible scientific data. Health Canada also continues to work with the Public Health Agency of Canada to provide weekly updates on reported side effects following COVID-19 vaccination in Canada.

BUILDING PARTNERSHIPS

Health Canada has increased its efforts to collaborate with regulators in other countries in recent years. We have worked to enhance regulatory alignment, scientific cooperation and undertake more collaborative reviews, all with the goal of enhancing our approval processes and bringing needed drugs to Canadians more quickly.

Our international cooperation related to drugs continued in 2021, both on COVID-19-related files and in our core activities. We completed 17 drug reviews in collaboration with other regulators.

For example, as a founding member of the Access Consortium, we have continued to work with Australia, Singapore, Switzerland, and as of last year the United Kingdom, to get products to market faster. Through

Access we have completed reviews of numerous new drugs by using a work-sharing model that represents a collective population base of 150 million. This included, for example, Kesimpta – a treatment for relapsing multiple sclerosis that was authorized as part of Access with work sharing alongside Australia and Switzerland. We were also able to leverage the Access partnership on COVID-19 vaccine and treatment safety monitoring and surveillance.

We also collaborated with the United States Food and Drug Administration and other partners as part of Project Orbis, to provide patients with enhanced and earlier access to promising cancer treatments. Through Orbis, cancer drugs were approved on average 109 days earlier than the regular 300 day service standard.

Focus on… NITROSAMINES

Nitrosamines are compounds that can form in certain drugs during the manufacturing process. In recent years, they have been found in an increasing number of drugs. Some nitrosamines may increase the risk of cancer if people are exposed to them over long periods of time.

In response to this important challenge, Health Canada has taken a leadership role internationally by chairing the Nitrosamines International Strategic Group and the Nitrosamines International Technical Working Group, to coordinate the activities of the different regulators and facilitate the rapid exchange of information with respect to the management of nitrosamine impurities in pharmaceutical products. These groups are forums for regulators, including from the European Union, United States, Japan, Australia, Singapore and Switzerland, to share intelligence on new risk signals, converge on acceptable limits for specific nitrosamines, develop technical and regulatory positions and address new and emerging concerns.

Health Canada will continue to work with industry and partners to better understand the causes of this contamination, and to determine how to prevent these impurities in the future. Most importantly, we will continue to communicate with Canadians regarding affected drugs so they can make informed decisions about their health.

Health Canada participated in the European Medicines Agency's OPEN initiative, along with the European Union, Australia, Japan, Switzerland and the World Health Organization. The initiative helped to increase international collaboration in the evaluation of COVID-19 vaccines and treatments as well as ongoing vaccine safety monitoring. Collaboration with the European Medicines Agency also continued with the publication of clinical information about drugs.

We continued to be an active member of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), and acted as both vice-chair of the ICH Assembly and as chair of the ICH Financial Committee. We continued our work with regulators and industry globally to develop internationally harmonized technical guidelines to ensure that safe, effective and high-quality medicines are developed, registered and maintained in the most resource efficient manner while meeting high standards.

We also continued to participate actively in the International Pharmaceutical Regulators Programme (IPRP). The purpose of IPRP is to create a forum for regulatory members and observers to exchange information on issues of mutual interest, enable cooperation and promote convergence of regulatory approaches for pharmaceutical medicinal products for human use. Through its Management Committee and various working groups, IPRP facilitates discussions on global regulatory issues and on emerging technologies.

Health Canada is also an executive committee member of the International Coalition of Medicines Regulatory Authorities (ICMRA), and plays an integral role in setting its strategic direction. ICMRA includes 37 participating regulatory organizations from jurisdictions around the world. In response to the COVID-19 pandemic, ICMRA expanded its scope of work to provide a global strategy for aligning the approaches of regulators to COVID-19 treatments and vaccines. Health Canada led and contributed directly to this work.

Along with ICMRA members, Health Canada has collaborated with our international partners to publish statements on COVID-19 diagnostics, therapeutics, clinical trials and vaccine confidence. These statements provide important COVID-19 information to a wide variety of audiences.

Domestically, we have similarly enhanced our collaboration with health system partners. For example, through the Regulatory Review of Drugs and Devices initiative, we worked with Health Technology Assessment organizations to help reduce the time between our approvals and their reimbursement recommendations – helping speed patient access to drugs. In 2021, we completed 20 aligned reviews alongside the Canadian Agency for Drugs and Technologies in Health (CADTH) and the Institut national d'excellence en santé et en services sociaux (INESSS). This process reduced the overall time needed for Health Canada, CADTH and INESSS to complete their reviews and recommendations, supporting faster access to medicines for Canadians.

ADDRESSING ANTIMICROBIAL RESISTANCE

Antimicrobials, such as antibiotics and antifungals, are essential to modern health care. However, the widespread use of these products 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 and health security. When there are fewer effective antimicrobials available, it will be harder to protect Canadians from common infectious diseases. In 2021, we continued to take important steps to encourage the development of new and innovative therapeutic products to help combat antimicrobial resistance.

For example, in March 2021, we published the first update to Health Canada's Pathogens of Interest List following the completion of a public consultation. The List contains bacterial and fungal pathogens that may cause serious, life-threatening infections in the Canadian population, and for which there are (or exists the potential to be) limited or no treatment options available.

In October 2021, in collaboration with the Public Health Agency of Canada and Canadian Institutes of Health Research, Health Canada hosted a Best Brains Exchange meeting that convened relevant policymakers, subject matter experts and industry stakeholders to discuss challenges with the business model for antimicrobials and potential incentives to improve access and promote innovation in Canada.

Every year Health Canada joins the World Health Organization, international health agencies and other national authorities to support World Antimicrobial Awareness Week. In 2021, we collaborated with the Public Health Agency of Canada to host a One Health webinar, featuring sessions on innovative approaches and products to combat AMR in humans, foodborne AMR as well as strategies to combat AMR in food-producing animals. Presentations were delivered by experts from Health Canada as well as other departments and stakeholder groups.

These efforts, involving collaboration within government, with multi-stakeholder groups and with national and international partners, are important steps as we move forward on this issue.

ENHANCING OUR REGULATORY APPROACH

In 2021, we worked to ensure that Canadians continued to benefit from access to needed COVID-19 vaccines and treatments by maintaining some of the key flexibilities leveraged under our agile regulatory response to the pandemic. These flexibilities included expanded access to clinical trials for COVID-19 health products, the use of terms and conditions to better manage products across their lifecycle as well as accepting rolling submissions, which allowed us to review evidence and information about a product as soon as it became available.

In March 2021, transitional provisions to the *Food and Drug Regulations* which maintained certain of these key flexibilities for COVID-19 vaccines and treatments were published in the *Canada Gazette*, Part II. Further, in May 2021, the Minister of Health approved a second Interim Order which maintained flexibilities for clinical trials related to COVID-19 drugs and medical devices. The insights learned from these flexibilities have reinforced the importance of being an agile regulator. We will continue to build on these insights as we advance our broader regulatory innovation plans.

Focus on…
INNOVATION – FECAL MICROBIOTA THERAPY

Fecal Microbiota Therapy (FMT) involves the transfer of bacteria from a healthy donor into a patient's intestinal tract to establish a healthy microbial community to help fight antimicrobial resistance, such as when treating recurrent *C. difficile* infections. Health Canada currently oversees FMT using an Interim Policy, and is limited to classical FMT dosage forms (i.e., fresh or frozen) used for the treatment of patients with recurrent *C. difficile* that are not responsive to conventional therapies. By creating a tailored advanced therapeutic product pathway for FMT, it will allow for appropriate oversight under a pathway that has the force of law, with more enforcement tools and will provide a path to market for researchers and innovators.

Regulatory Innovation

Modernizing clinical trial regulations

Over the last decade, we have observed a shift in the focus of clinical trials. Increasingly, trials aim to find a therapy for a serious, life-threatening or rare condition where an unmet medical need exists. The operational complexity and expense of running a clinical trial has also increased dramatically. As a result of these changes, clinical trial design is evolving quickly. These changes are occurring in tandem with the increased development of personalized health products, gene therapies and products intended for the treatment of rare diseases, each of which poses its own unique challenges regarding the conduct of clinical trials. Appropriate trial design and requirements are therefore critical to support the introduction of novel safe and effective therapies to the Canadian market.

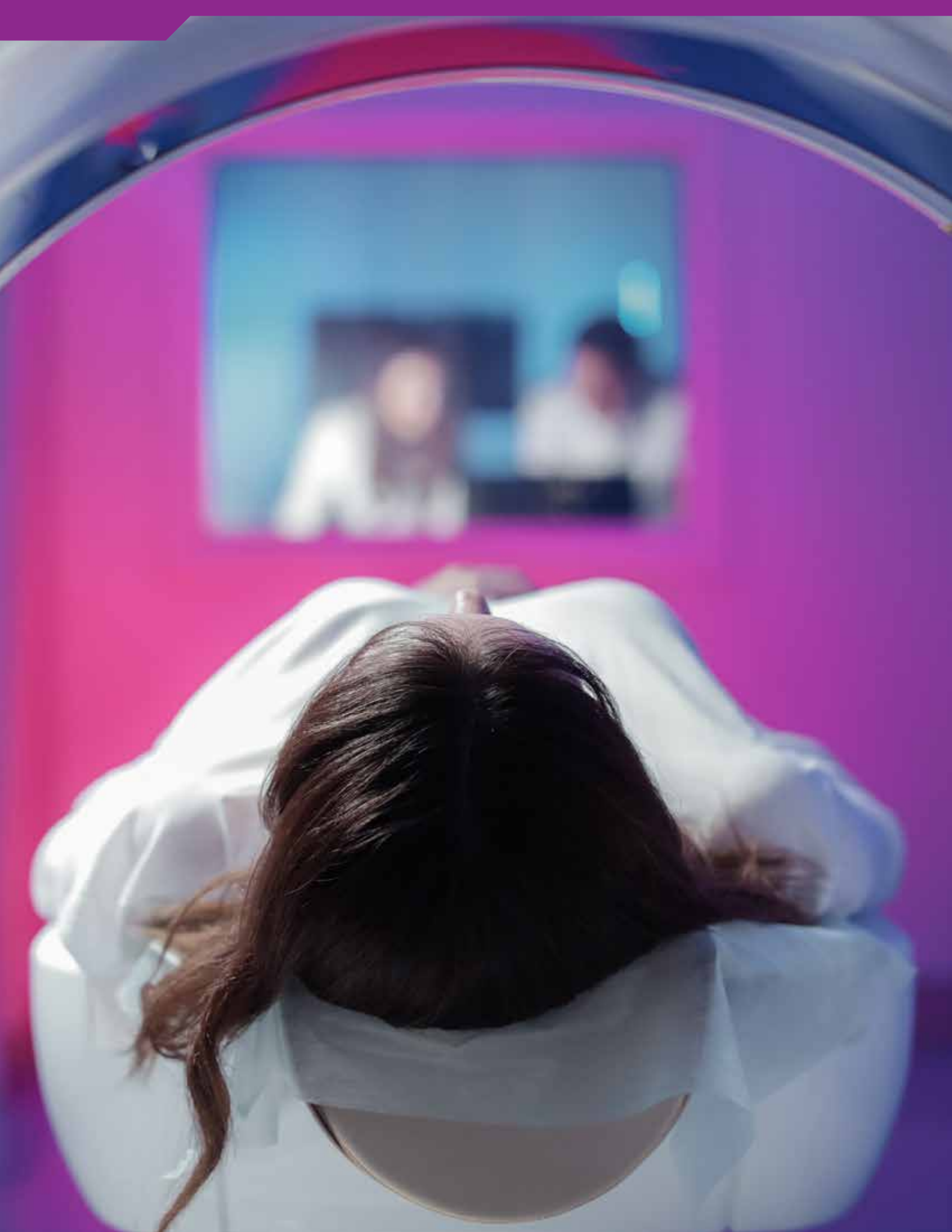
In response, Health Canada has put forward a vision for the modernization of Canada's clinical trial regulatory framework. The new framework will better respond to these changes and help encourage clinical trials in Canada by creating an environment that supports the safe innovation of health products. In May 2021, we published a consultation document outlining our plans to modernize Canada's clinical trial regulations to improve access to novel therapies, while continuing to ensure patient safety. This was complemented by stakeholder consultations through the spring and summer.

Agile licensing for drugs

In the past, a common set of regulatory rules worked well for most products. However, as the market has evolved and now includes a much larger number of drugs, including more complex and personalized therapies, our regulatory system also needs to evolve. To continue to advance our work in this area, we posted a Notice of Intent in the *Canada Gazette* informing stakeholders of plans to amend the *Food and Drug Regulations*. These planned amendments would give the Minister of Health the ability to accept submissions on a rolling basis in certain circumstances, impose terms and conditions on drug authorizations if needed and require Risk Management Plans. These regulatory abilities were leveraged as part of our response to COVID-19 and which we can now build on to better support the oversight of a broader range of products.

Advanced therapeutic products pathway

Some products are so innovative or complex that they need a different regulatory approach – we refer to these as advanced therapeutic products. In 2021, we established an External Reference Group to help guide early thinking around requirements to establish a tailored regulatory pathway for fecal microbiota therapy. The intent of this External Reference Group is to bring relevant experts together to provide evidence-based advice to help tackle regulatory issues and enable safe patient access. We will continue to leverage the insight and feedback of stakeholders as this initiative moves forward.



MEDICAL DEVICES

Message from the Directors General

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 physical conditions. In Canada, we categorize medical devices into four groups based on the level of risk associated with their use. These groups are called "Classes" and they 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 2021, Health Canada continued to prioritize our response to the COVID-19 pandemic, while also advancing key non-COVID-related priorities. In particular, we made efforts to increase the number of self-tests for COVID-19 available on the Canadian market. The rate at which the Omicron variant spread across the world reinforced the importance of these devices, which help to slow transmission by allowing individuals to quickly identify if they are infected. Over 115 COVID-19 testing devices are now available in Canada, and there are more in the pipeline.

We also actively scanned for emerging COVID-19 products, enabling us to seek out and encourage submissions for important and innovative technologies that otherwise may not have been filed in Canada.

David Boudreau

Director General,
Medical Devices

Kelly Robinson

Director General,
Marketed Health Products

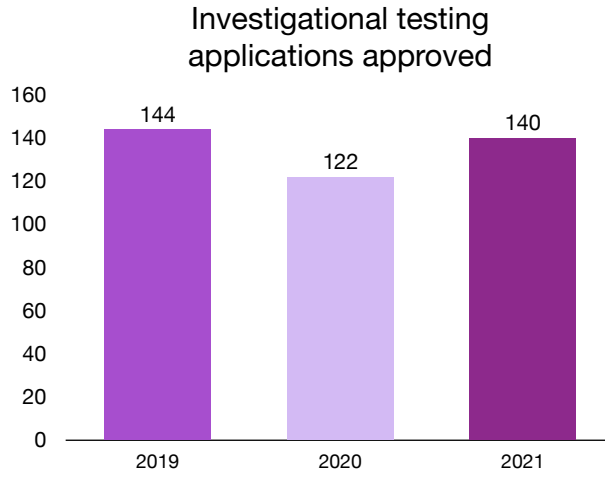
Building on the progress made through the Medical Devices Action Plan (MDAP), Health Canada is advancing regulatory changes as part of the Agile Licensing initiative. A Notice of Intent was published in 2021 outlining our plans to amend the *Food and Drug Regulations* and the *Medical Devices Regulations* to support enhanced regulatory agility. The expanded ability to use terms and conditions on medical device licenses will better support the effective oversight of devices across their lifecycle.

As we move forward responding to COVID-19 and advancing our key priorities, we will continue to put the health and safety of Canadians first, while supporting innovation and improved regulatory solutions.

INVESTIGATIONAL TESTING (CLINICAL TRIALS)

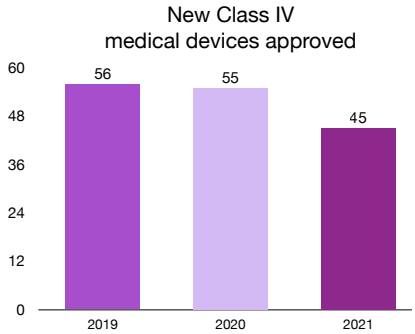
Clinical trials are conducted by sponsors (manufacturers or importers) to gather information on a medical device's safety and efficacy in humans. Sponsors of investigational tests submit their applications to conduct investigational testing (clinical trials) with a medical device in Canada. Health Canada reviews these applications before the testing is conducted in Canada. New trials mean Canadians may have access to more innovative product choices. In 2021, 140 new investigational testing applications for medical devices were approved.

We enabled the testing of new COVID-19-related medical devices, including COVID-19 diagnostic test kits, physiological monitoring devices and respiratory treatment-related devices.



We also authorized investigational testing for a number of novel devices used for certain cardiovascular surgical procedures, as well as for a point-of-care magnetic resonance imaging device to be used for imaging in remote regions. This device allows health professionals to carry out imaging where patients are located, instead of requiring them to travel to larger centres.

NEW MEDICAL DEVICES APPROVED



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 lifecycle of a medical device, from investigational testing to after the device is being sold in Canada.

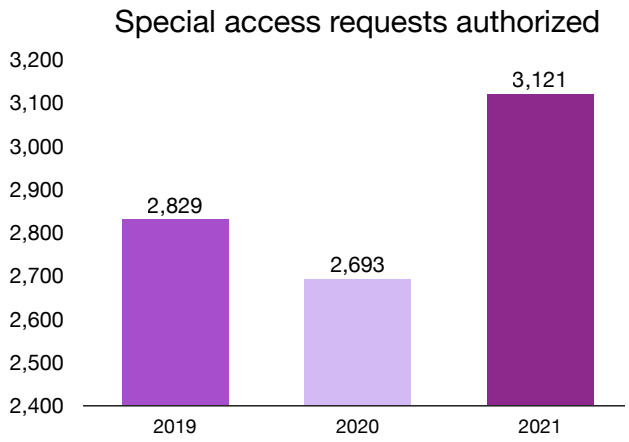
In 2021, we licensed 272 new Class III and 45 new Class IV medical devices. These new devices provide patients and health care professionals with new and innovative options for the treatment, prevention and diagnosis of various health conditions. For example, in 2021, we licensed the first medical implant made in Canada with a 3D printer. The technology used makes it possible to produce custom jaw prosthesis, adapted to the anatomy of each patient. For a list and description of the new Class IV medical devices approved in 2021, please see Annex II.

In 2021, we prioritized the review of testing device applications in support of public health needs. We approved 55 COVID-19-related diagnostic test devices. This included tests for use in asymptomatic populations, the first rapid self-tests for home use, and multiplex tests that can be used to simultaneously diagnose other respiratory viruses as well as COVID-19.

In addition, we authorized the sale of 10 ventilators, and expanded the intended use of some continuous glucose monitors to include pregnant women, following a Health Canada review and recommendation. Continuous glucose monitors offer the ability for healthcare providers to remotely view patients' glucose control data and conduct virtual clinic visits, which has helped reduce the need for in-person visits for pregnant women who were identified as having a higher risk of serious COVID-19 outcomes.

SPECIAL ACCESS PROGRAM

Through the Special Access Program, we grant healthcare professionals access to custom-made devices and unlicensed medical devices for emergency use or when conventional therapies have failed, are unavailable or are unsuitable to treat a patient. In 2021, we authorized 3,121 requests for medical devices under this program.



POST-MARKET VIGILANCE

After a medical device is approved and available for sale in Canada, we continue to monitor its use in the broader Canadian population. We evaluate potential safety and efficacy issues and take action when there are identified problems. Actions can include informing the public and health care professionals of safety information, requesting labelling changes or affirming our current understanding recommending compliance actions. For example, we implemented comprehensive labelling changes for breast implants, similar to those required by the United States Food and Drug Administration.

In 2021, we received 39,601 reports of suspected medical device incidents and undertook 5 regulatory actions related to medical devices. This follows the coming into force of regulations requiring hospitals to report serious adverse drug reactions and medical device incidents in December 2019. Since the regulations came into force, we have seen an increase in the number of medical device incident reports received – almost 1,200 in 2021 alone. This helps Health Canada take action against products that may pose a risk to Canadians' health and safety.

In 2021, we continued to monitor the safety and efficacy of health products related to COVID-19, and took action as needed to protect Canadians where there were issues with safety or efficacy of a device. This included taking proactive steps to identify incidents related to medical devices used for COVID-19 and working with government partners to monitor retailers and advertisements making false, misleading and illegal claims related to COVID-19. We worked closely with domestic and international partners and published risk communications about potential safety and efficacy concerns (for example, a notice on limitations and best practices to ensure accurate readings when using non-contact infrared thermometers).

New medical device post-market surveillance regulations came into effect in 2021, which further support the lifecycle approach to the regulation of medical devices by strengthening post-market authorities. We published guidance documents to inform manufacturers how to comply with the new regulations related to foreign risk notification, issue-related analyses and summary reports for licensed medical devices. Together these will help to reduce risks associated with medical devices, and improve their safety, efficacy and quality.

TRANSPARENCY OF DECISION MAKING

In 2021, we continued to advance our openness and transparency efforts by expanding the amount of health and regulatory safety information that is made available to Canadians.

Through our Clinical Information Portal, we published 2,100 pages of clinical information on 13 medical devices. Companies provide this information when they seek approval to sell a medical device in Canada.

We also published summaries of our safety reviews, which describe Health Canada's decisions related to potential safety issues, for dental amalgam and contact lenses in 2021. These summaries complement other safety-related information to help Canadians make informed decisions.

The Canada Vigilance Program collects suspected adverse drug reactions and medical device incidents. For medical devices, incident and recalls data are made publically available through the Medical Devices Incidents Database, and are updated on a quarterly basis.

BUILDING PARTNERSHIPS

We have continued to collaborate with our international counterparts, as well as with the World Health Organization, to harmonize regulatory and communication strategies and guidance on medical device management. In 2021, we participated in discussions on safety and quality issues observed with several COVID-19 medical devices, including respirators, serological and antibody diagnostic tests, reprocessed and decontaminated ventilators, facemasks and 3D printed testing swabs.

Under the International Medical Device Regulators Forum (IMDRF), Health Canada contributed to the guidance document on terms and definitions for machine learning-enabled medical devices and on the recognition process of conformity assessment bodies conducting regulatory reviews, both published in 2021. We also continue our routine work with the IMDRF Adverse Events Working Group to harmonize patient and device codes for medical device incident reports.

Under the Regulatory Co-operation Council, Health Canada continued to work with the United States Food and Drug Administration to build a Medical Device Single Review Program. This program works to improve patient

access to medical devices, support innovation and strengthen the development of standards. Through the initiative, we have finished a first review under a pre-pilot proof of concept of the Affinity NT Oxygenator and will begin a second simultaneous review of a percutaneous transluminal coronary angioplasty catheter in 2022.

As part of our COVID-19 regulatory response, we have worked closely with companies in the Canadian ventilator sector, the Public Health Agency of Canada, Public Services and Procurement Canada, Innovation, Science and Economic Development Canada and the National Research Council, to provide guidance regarding Health Canada's ventilator requirements and application process. In addition, Health Canada worked with companies by providing guidance about the Health Canada Interim Order authorization process and communicating Health Canada ventilator requirements with respect to the necessary safety and efficacy information to be submitted for an Interim Order authorization.

ENHANCING OUR REGULATORY APPROACH

In 2021, we worked to ensure that Canadians continued to benefit from access to needed COVID-19 medical devices by maintaining several key flexibilities leveraged under our agile regulatory response to the pandemic.

In March 2021, the Minister of Health approved a second Interim Order which maintained the expedited pathway and regulatory flexibilities for the import and sale of needed COVID-19 medical devices. Further, in May 2021, the Minister of Health approved a second Interim Order which maintained a number of regulatory flexibilities for the conduct of clinical trials related to COVID-19 drugs and medical devices. The insights learned from these interim measures have reinforced the importance of being an agile regulator. We will continue to build on these insights as we advance our broader regulatory innovation plans.

Regulatory Innovation

Modernizing clinical trial regulations

In May 2021, we published a consultation document outlining our plans to modernize Canada's clinical trial regulations to improve access to novel therapies, while continuing to ensure patient safety. This was complemented by stakeholder consultations through the spring and summer. The new framework will help encourage clinical trials in Canada by creating an environment that supports safe innovation. The proposed regulations would allow independent researchers and medical professionals to conduct clinical trials on medical devices.

Advanced therapeutic products pathway

As discussed above in the Drugs for Human Use section, some products are so innovative or complex that they need a different regulatory approach, and we refer to these as advanced therapeutic products. In 2021, we established an External Reference Group to help guide early thinking around requirements to establish a tailored pathway for adaptive machine-learning enabled medical devices. The intent of this External Reference Group is to bring relevant experts together to provide evidence-based insight and advice on the development of requirements to bring adaptive machine-learning enabled medical devices to the Canadian market while effectively managing the risks, benefits and uncertainties of these products. We will continue to leverage the insight and feedback of stakeholders as this initiative moves forward.

Agile licensing for medical devices

In 2021, we posted a Notice of Intent in the *Canada Gazette* informing stakeholders of plans to make improvements to the *Medical Devices Regulations*. These proposed amendments would help to enable more adaptive licensing of medical devices and provide Health Canada with agile regulatory tools to protect the health and safety of Canadians. The planned amendments would broaden the scope of terms and conditions for medical devices, to help manage known risks or uncertainties relating to the benefits or risks of the device. This would build on our experience with the use of terms and conditions as part of our response to COVID-19.

Medical Devices Action Plan

In May of 2021, Health Canada published a progress report on the Medical Devices Action Plan outlining activities undertaken to improve the safety and efficacy of medical devices, including:

- consulting Health Canada's Scientific Advisory Committees with respect to health products for women, digital health technologies and medical devices used in the cardiovascular system, and
- hosting four webinars to provide guidance on the strengthened final regulations regarding the post-market surveillance of medical devices.

Furthermore, additional regulations related to post-market surveillance came into force in December 2021 and will enable Health Canada to better monitor medical devices through annual or bi-annual summary reports prepared by the manufacturer.

Focus on…
INNOVATION – ADAPTIVE MACHINE LEARNING-ENABLED MEDICAL DEVICES (MLMD)

Adaptive machine learning-enabled medical devices are highly sophisticated tools that leverage artificial intelligence to learn and improve over time, particularly for medical imaging. Currently, Health Canada has well-established protocols for oversight of traditional devices with static algorithms.

These medical devices with adaptive algorithms have the potential to revolutionize health care, and by creating a tailored advanced therapeutic product pathway to enable their use, this will allow patients to gain access to these complex and unique products.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LOWER-RISK HEALTH PRODUCTS

Message from the Directors General

One of Health Canada's roles is to regulate lower-risk health products – including non-prescription ("over-the-counter") drugs and natural health products so that Canadians can have confidence that the products they use are safe, effective and of high quality. These include important products that Canadians use every day, such as painkillers, heartburn drugs, vitamins, minerals, probiotics, homeopathic and traditional products. Demand for them has increased in recent years, and accelerated since the pandemic began, as more Canadians are relying on lower-risk health products to support their own health and that of their families.

Our focus for 2021 was to continue our pandemic response as well as to advance regulations that modernize our approach to lower-risk health products and biocides.

This year, we continued to respond to increased demand for disinfectants and hand sanitizers due to the COVID-19 pandemic. Early in the pandemic, Health Canada responded quickly to introduce interim measures, new guidance and streamlined applications to facilitate the availability of these products on the Canadian market. Since March 2020, we have approved over 4,000 hand sanitizers alone, and temporarily authorized over 2,000 sites to manufacture, package, label and/or import them. Throughout the pandemic, we have collaborated closely with stakeholders and other regulators to expedite access to urgently needed products.

Natalie Page

Director General,
Natural and Non-prescription Health Products

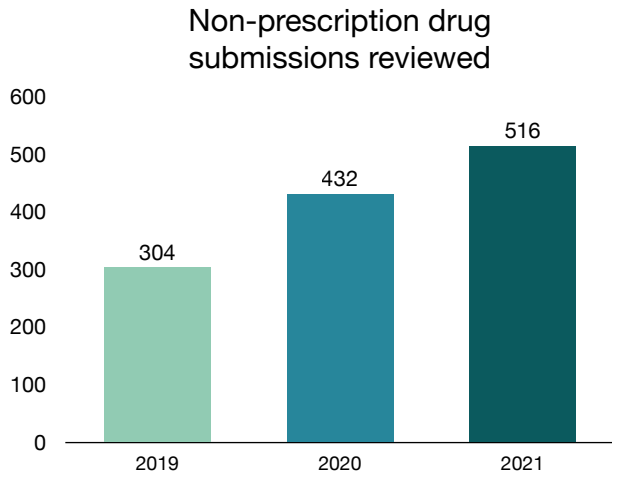
Kelly Robinson

Director General,
Marketed Health Products

In 2021, the Commissioner of the Environment and Sustainable Development tabled his spring report and presented the results of an Audit on Health Canada's Natural Health Products Program. The Audit focused on natural health products available for sale in Canada to ensure that they are safe, effective and accurately represented to consumers. Overall, it identified both strengths and areas for improvement within the program. Health Canada has accepted all of the Commissioner's recommendations and has begun taking steps to strengthen the program, including the advancement of the Self-Care Framework – a multi-year initiative to update our regulatory approach for self-care products, including natural health products.

LOWER-RISK HEALTH PRODUCTS APPROVED

Non-prescription drugs are health products that can be bought without a doctor's prescription. Health Canada regulates non-prescription drugs to make sure they are safe to use and reduce health risks to Canadians.



In 2021, we reviewed 516 non-prescription drug submissions, including new products and changes to existing products such as antiseptics, pain relievers, cold and cough medicines and sunscreens. Of the total reviewed, 495 submissions were approved.

We also reviewed 559 surface disinfectant submissions, with 400 of these approved for direct and indirect claims against SARS-CoV-2 (the virus which causes COVID-19). You can find more information on the List of disinfectants with evidence for use against COVID-19. More information on all other approved disinfectants and other drug products can be found on Health Canada's Drug Product Database.

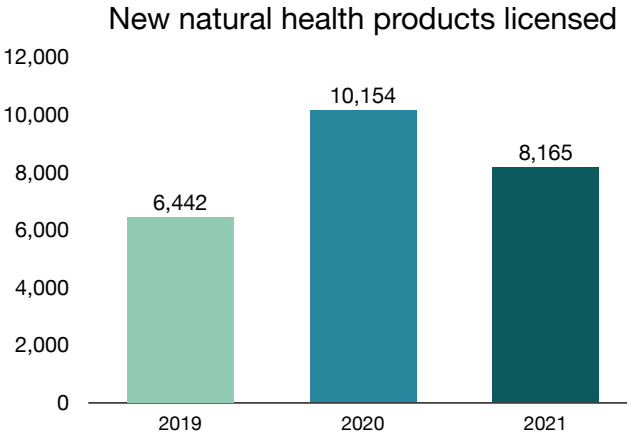
We reviewed 11,697 natural health product applications, including sanitizers, probiotics, herbal remedies, vitamins and minerals. This resulted in 8,165 new products being licensed. Of these new natural health products, 176 were alcohol-based hand sanitizers, which may be used as part of hand hygiene practices to help reduce the spread of micro-organisms. More information can be found within the Licensed Natural Health Products Database.

POST-MARKET VIGILANCE

After we approve a non-prescription drug or natural health product for sale in Canada, Health Canada continues to monitor and evaluate reports of suspected adverse reactions. We evaluate potential safety and efficacy issues, and take action when there are identified problems.

In 2021, Health Canada launched a proactive surveillance program, enhanced with an augmented artificial intelligence tool, to detect and take action against false and misleading advertising for COVID-19 health products. Building on this success, we expanded the scope of the initiative to detect non-compliant cancer-related claims in advertising of natural health products. Since its launch, over 3,000 cases of potentially misleading advertising incidents have been assessed, with subsequent regulatory action taken to protect the health and safety of Canadians.

We have also increased quality requirements for natural health product site licensing by transitioning temporary COVID-19 site licenses to regular site licenses in full compliance with the natural health product quality standard. In addition, a natural health product inspection pilot program was launched in March 2021 that will inform the development of a permanent inspection program.



BUILDING PARTNERSHIPS

A key part of our core business is to engage both internationally and domestically to help provide Canadians with timely access to health products, including non-prescription drugs and natural health products. Our valued relationships with stakeholders are critical to advancing this work.

In an effort to bring greater consistency and alignment in the regulatory approach to non-prescription drugs and natural health products, Health Canada continued regular engagement with our key international regulatory counterparts to share information and advance mutual priorities.

We continued to participate in quarterly meetings with the United States Food and Drug Administration, with discussions including areas of common interest such as health products containing cannabis or cannabis-derived compounds. We also met regularly with the United States Environmental Protection Agency to discuss trends in the disinfectant industry.

As part of the COVID-19 response, we collaborated with the United Kingdom Medicines and Healthcare products Regulatory Agency from May to July 2021 to support the development of interim measures to expedite the review and licensing of sanitizers.

We are also part of the World Health Organization's International Regulatory Cooperation for Herbal Medicines steering committee, where we work with other regulators to enhance our knowledge and evidence base when developing policies and approaches related to the regulation of herbal medicines.

Domestically, we engaged regularly with stakeholders, including industry associations, medical professionals, patient and consumer groups and academics, on key program priorities. Input from stakeholders has been integral to advancing regulatory priorities and meeting operational targets, as well as understanding the important issues that stakeholders face to make sure the program is responsive and agile. We continued to meet quarterly with industry associations to provide updates on natural health product workload and progress in eliminating remaining submission backlogs resulting from efforts to increase the supply of hand sanitizers for Canadians at the onset of the pandemic.

ENHANCING OUR REGULATORY APPROACH

Improved labelling for natural health products

A significant milestone in advancing the Self-Care Framework and responding to the Audit of the Natural Health Products Program by the Commissioner of the Environment and Sustainable Development was achieved in June 2021 with the publication of proposed regulations to improve natural health product labelling for formal consultation in *Canada Gazette*, Part I. The proposed regulatory changes are intended to make natural health product labels clearer, more legible and easier to understand so that consumers can make informed purchasing decisions and use these products safely. The regulations and guidance were available for comment for 90 days, and Health Canada held five technical sessions to provide more information to stakeholders and gather feedback.

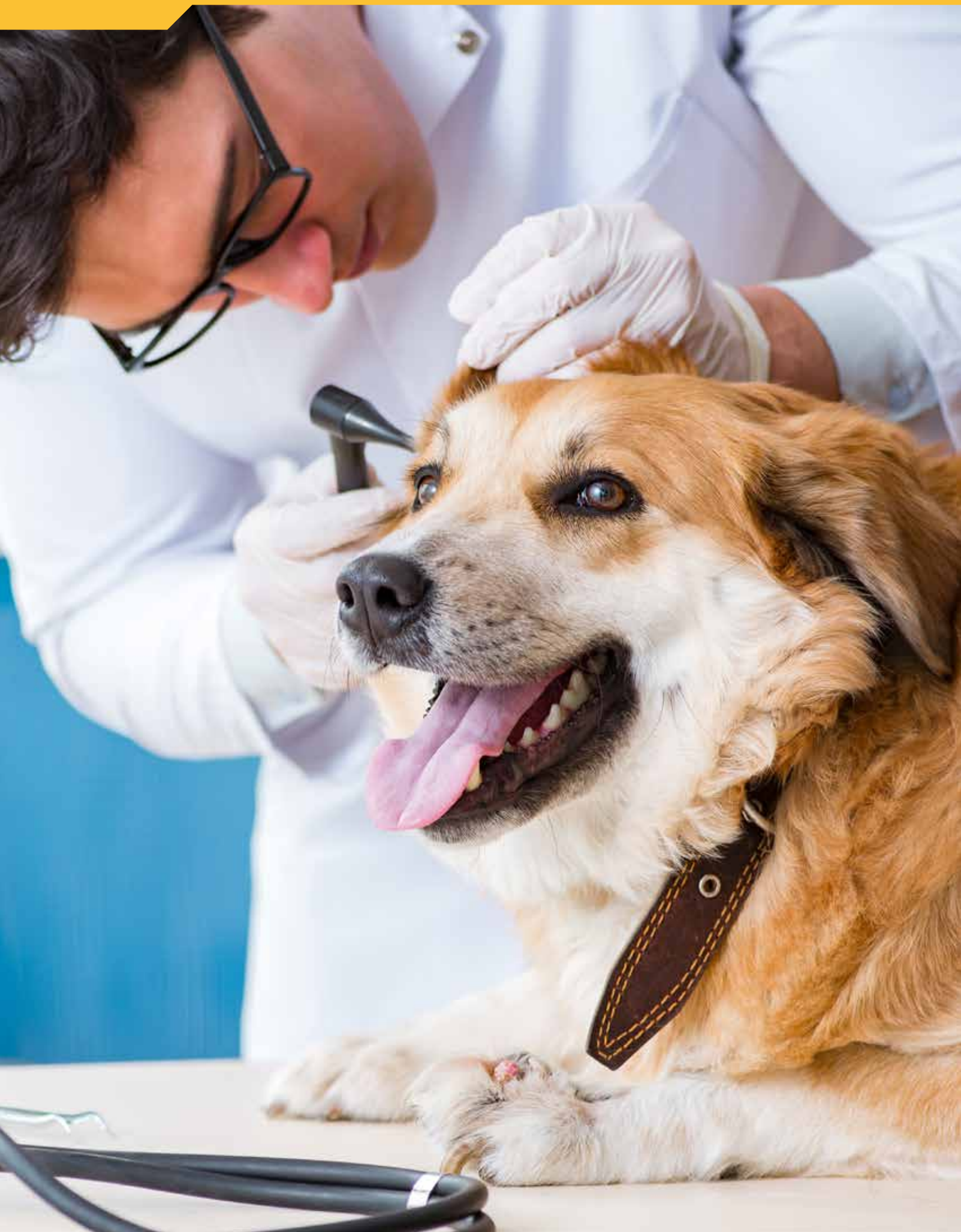
Advancing a tailored framework to regulate biocides

In an effort to further expedite access to surface sanitizers and disinfectants, we advanced policy development on a regulatory framework for biocides. Currently, biocides are regulated under several regulatory frameworks with rules that are not in line with the lower-risk nature of these products. Our goal is to create a standalone set of regulations for biocides to reduce the regulatory burden for industry and increase access for Canadians. This framework would enable Health Canada to leverage regulatory decisions by other international regulators for biocides to expedite products to the Canadian market, facilitate entry of innovative products, promote trade and eliminate duplicative reviews. These efforts will ensure appropriate oversight while expediting access to these important products.

Focus on…
AUDIT OF NATURAL HEALTH PRODUCTS PROGRAM

In April 2021, the Commissioner of the Environment and Sustainable Development tabled his spring report and presented the results of the Audit on Health Canada's Natural Health Products Program, identifying both strengths and areas for improvement. The Audit found that Health Canada licensed natural health products appropriately, based on evidence of safety and efficacy, and found that when an issue was brought to Health Canada's attention, immediate action was taken. However, the Audit presented several recommendations on how to further strengthen the program. Health Canada has accepted all of the Commissioner's recommendations and is actively working to increase oversight of quality, advertising and labelling, enhance compliance and enforcement efforts as well as ensure the Department has the tools to protect the health and safety of Canadians when a serious health risk arises.

Preliminary consultations with key stakeholders took place in spring 2021. Health Canada will continue to leverage the insight and feedback of stakeholders as this initiative moves forward.



DRUGS FOR VETERINARY USE

Message from the Director General

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, efficacy and quality of veterinary drugs. In doing so, we work to protect animals and Canada's food supply.

This year we continued to advance work on several key priorities, including the implementation of a pilot project for veterinary health products that can be mixed into livestock feed. A partnership with the Canadian Food Inspection Agency, this initiative offers additional tools for the maintenance of animal health and wellness and may help to reduce the need for the routine use of antimicrobials.

We also continued our tracking and analysis of veterinary antimicrobial sales data to better support surveillance efforts. This report marks the third year of sales reporting, with its key findings painting a comprehensive picture of antimicrobials available for veterinary use broken down by species, and province or territory. These annual reports play a key role in our antimicrobial resistance surveillance program and stewardship efforts.

Marilena Bassi

Director General,
Veterinary Drugs Directorate

EXPERIMENTAL STUDIES

We review applications to allow companies and researchers to conduct studies on drugs for veterinary use in Canada. New veterinary drug trials (called investigational new drugs and experimental studies) support access to new products in the future. In 2021, we authorized 125 experimental studies that support clinical trials or research activities.

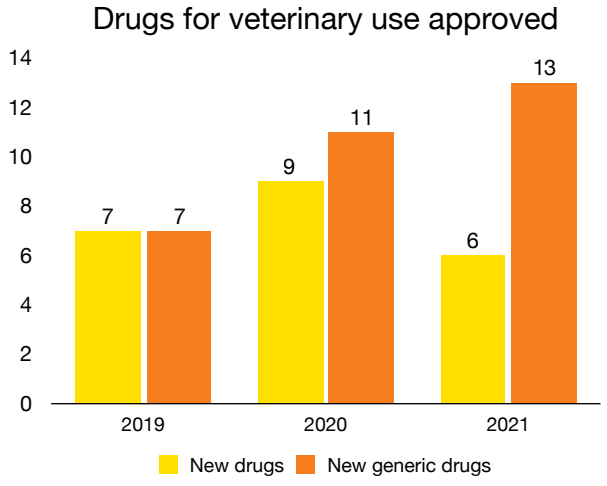
NEW DRUGS FOR VETERINARY USE APPROVED

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

In 2021, we approved 6 new drugs for companion or food-producing animals. This enabled greater stakeholder access to innovative new products and therapies to help maintain and improve the health of animals. We also approved 13 new generic drugs, which provide additional options for cost-effective prevention and treatment.

We approved the first two monoclonal antibody products authorized as veterinary drugs. The two products, Librela and Solensia (Zoetis), are indicated for the treatment of osteoarthritis pain in dogs and cats respectively. Methods to reduce pain other than non-steroidal anti-inflammatories (NSAIDs) are of interest to owners of aging pets, which may be sensitive to the effects of NSAIDs on the kidney, liver and gastrointestinal system.

To allow sponsors to send in their veterinary drug submissions easily and securely, all submissions became electronic either through the Regulatory Enrolment Process or through new tools such as the Secure File Transfer Protocol. In addition, the Drug Product Database, which contains product-specific information on veterinary, human and disinfectant products approved for use in Canada, was updated to permit product searches by species. This is particularly useful for veterinary health care practitioners and producers interested in finding out which drugs are available to treat particular animals.



EMERGENCY DRUG RELEASE PROGRAM

Through our Emergency Drug Release (EDR) program, veterinarians are able to request authorization for drugs for veterinary use that are not available in Canada, for emergency situations. 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. In 2021, we authorized 333 requests under the Emergency Drug Release program.

Health Canada continued to implement the changes made in October 2020 to the *Food and Drug Regulations*, which minimized the burden associated with providing access to unauthorized veterinary drugs. This included working to streamline the process for veterinarians. In addition, we worked with manufacturers to permit the early importation and placement in Canadian facilities. This process, also known as "pre-positioning," facilitates the immediate distribution of a drug once authorized, making it available as early as possible.

Focus on…
SIMULTANEOUS REVIEW WITH THE UNITED KINGDOM

Building on other veterinary drug international collaborative successes, Health Canada advanced the process for simultaneous reviews with the United Kingdom. In 2021, Health Canada began its first simultaneous review with the United Kingdom. The Guidance on Veterinary Drug Simultaneous Reviews with the United Kingdom was also published and outlines the simultaneous review process for veterinary drugs.

POST-MARKET VIGILANCE

After we approve a drug for sale in Canada, we continue to monitor and evaluate reports of suspected adverse veterinary drug reactions to improve information and access to animal owners, veterinary health professionals and drug manufacturers. The Adverse Event Reporting form for veterinary drugs was updated to improve its usability with clearer and more comprehensive information provided about adverse event reporting. A new PDF-fillable and more accessible Adverse Event Reporting form was created and made available on July 15, 2021, making it easier to report any adverse events.

ADDRESSING ANTIMICROBIAL RESISTANCE RELATED TO USE OF ANTIMICROBIALS IN ANIMALS

Antimicrobial resistance is a growing public health threat in Canada and worldwide. The overuse and misuse 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 2021, Health Canada continued to focus on our veterinary drug antimicrobial resistance initiatives, to reduce the routine use of antimicrobials and promote their responsible use when they are needed.

For example, in collaboration with the Public Health Agency of Canada we published the 2019 Veterinary Antimicrobial Sales Highlights Report in August 2021.

This report marks the second year of sales reporting, which supports our antimicrobial resistance surveillance program and stewardship. This annual report provides a comprehensive picture of antimicrobials available in 2019 for veterinary use broken down by species and by province/territory.

By keeping animals healthy, we can also reduce the need to use drugs, including antimicrobials. This past year we implemented a pilot project for veterinary health products that can be mixed into livestock feed, in partnership with the Canadian Food Inspection Agency. In 2021, 12 products were notified through the veterinary health product web application that were allowed to be mixed into livestock feed as an interim pilot. This initiative provides access to additional tools for maintaining the health and wellness of animals.

We also made significant online updates to List C, the list of permitted substances used to make veterinary health products. In 2021, 97 new substances were added and 106 modifications were made to current listings, including substances used for a number of species such as fin fish and dairy cattle. As of December 2021, List C included a total of 781 active substances, with almost 300 for food producing animals. Expanding the number of substances creates more opportunities for industry to bring a wider range of products to market in support of animal health. In 2021, a total of 496 veterinary health products were notified through the veterinary health products notification program.

BUILDING PARTNERSHIPS

In 2021, Health Canada has continued to work closely with domestic stakeholders and regulators around the world on issues related to drugs for veterinary use, supporting expanded access to treatment options for animals in Canada while reducing regulatory burden for industry.

We continued our simultaneous reviews of veterinary drugs in partnership with the United States Food and Drug Administration's Center for Veterinary Medicine, along with collaborating on joint reviews with Australia and New Zealand.

In January 2021, Canada and the United Kingdom also published new guidance on the veterinary drug simultaneous review processes for regulatory cooperation. This collaboration creates opportunities for manufacturers to access two major markets simultaneously, helping to expand treatment options for animals and support food producers stay competitive globally.

ENHANCING OUR REGULATORY APPROACH

Regulatory Innovation

Agile licensing for drugs

In 2021, a Notice of Intent was published in the *Canada Gazette* informing stakeholders of plans to amend the *Food and Drug Regulations*. These planned amendments would give the Minister of Health the ability to impose terms and conditions on drug authorizations that will better support the oversight of products at the time of approval and afterwards. The proposed amendments would also create an optional application pathway for rolling submissions to facilitate timely access to veterinary drugs that address significant new and emerging infectious diseases, and for the treatment, prevention or diagnosis of serious or severely debilitating diseases or conditions.

Focus on…

HEALTH CANADA'S ROLE IN FOOD SAFETY

Human safety assessment of veterinary drugs used in food producing animals helps to ensure that food derived from treated animals is safe for human consumption. Product sponsors are required to provide to Health Canada scientific data or relevant information necessary to demonstrate that residues of the veterinary drug in edible tissues of treated animals are safe for human consumption. Health Canada establishes food safety standards in the form of maximum residue limits, which are levels of residue that could safely remain in the tissue or food product derived from a food-producing animal that has been treated with a veterinary drug. Health Canada consulted on establishing maximum residue limits for 6 new drugs in 2021. These will be added to the List of Maximum Residue Limits for veterinary drugs in foods in early 2022.

DRUGS FOR HUMAN USE: APPROVED IN 2021

This section outlines the new drugs, generic drugs and biosimilars approved for sale in Canada in 2021, 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

AR Aligned review

An aligned review is one where the drug company allowed information to be shared between Health Canada and health technology assessment organizations.

IO 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.

B 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.

EUND 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.

NAS 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.

C 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.

O Orphan drug

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

PI Pediatric indication

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

P 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.

I 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.

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.

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 2021

ALIMENTARY TRACT AND METABOLISM

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

7 NEW DRUGS

DOJOLVI

P NAS PI

Medicinal Ingredient
Triheptanoin

Indication
DOJOLVI is indicated as a source of calories and fatty acids for the treatment of adults and pediatric patients with long-chain fatty acid oxidation disorders (LC-FAOD).

LYUMJEV

B

Decision Summary

Medicinal Ingredient
Insulin lispro

Indication
The treatment of adults with diabetes mellitus who require insulin for the control of high blood sugar. The treatment of people with type 2 diabetes, generally used in combination with an intermediate- or long-acting insulin for the control of high blood sugar.

NEXVIAZYME

NAS B PI I

Decision Summary

Medicinal Ingredient
Avalglucosidase alfa

Indication
NEXVIAZYME is a medicine that is used to treat adults, children and adolescents who have a confirmed diagnosis of late-onset Pompe disease.

OCTASA

Decision Summary

Medicinal ingredient
Mesalazine

Indication
OCTASA (mesalamine or 5-aminosalicylic acid) is used to treat ulcerative colitis. This is a disease of the large bowel (colon) or back passage (rectum), in which the lining of the bowel becomes inflamed (red and swollen).

VITAMIN D3 ORAL SOLUTION

Decision Summary

Medicinal ingredient
Cholecalciferol 625 mcg (25,000 IU)

Indication
VITAMIN D3 ORAL SOLUTION is used to treat vitamin D deficiency. This is when your body does not have enough Vitamin D, which is used to build and maintain healthy bones.

WAYMADE-TRIENTINE

NAS PI

Decision Summary

Medicinal Ingredient

Trientine hydrochloride

Indication

WAYMADE-TRIENTINE is used for the treatment of Wilson's disease in those who cannot take the drug penicillamine.

WEGOVY

B

Decision Summary

Medicinal Ingredient

Semaglutide

Indication

WEGOVY is used for chronic weight management in addition to reduced calorie diet and increased physical activity in adults, who have: a BMI of 30 kg/m^2 or greater (with obesity), or a BMI of 27 kg/m^2 and less than 30 kg/m^2 (overweight) and weight-related health problems.

1 NEW BIOSIMILAR

KIRSTY

B PI

Decision Summary

Medicinal Ingredient

Insulin aspart

Indication

The treatment of patients with diabetes mellitus who require insulin for the control of hyperglycemia.

16 NEW GENERIC DRUGS

- 1 product containing hyoscine butylbromide
- 1 product containing alfacalcidol
- 3 products containing saxagliptin hydrochloride
- 1 product containing ondansetron
- 1 product containing glycopyrrolate
- 2 products containing metformin
- 1 product containing pioglitazone hydrochloride
- 1 product containing vancomycin hydrochloride
- 2 products containing metoclopramide hydrochloride
- 1 product containing ondansetron hydrochloride
- 1 product containing pantoprazole sodium
- 1 product containing domperidone maleate

ANTIINFECTIVES FOR SYSTEMIC USE

For example, antibacterials, antivirals and vaccines.

9 NEW DRUGS

COMIRNATY

NAS B

Decision Summary

Medicinal Ingredient

Tozinameran

Indication

COMIRNATY is a vaccine used to prevent COVID-19 disease caused by the SARS-CoV-2 virus. COMIRNATY can be given to people from 5 years of age and older.

FOCLIVIA

B PI

Decision Summary

Medicinal Ingredient

Pandemic influenza vaccine (surface antigen, inactivated, adjuvanted with MF59C.1)

Indication

FOCLIVIA is a vaccine intended to be given to prevent influenza (flu) in an officially declared pandemic situation in individuals 6 months of age and older. Pandemic flu is a type of influenza that happens infrequently, but spreads rapidly around the world. It is caused by a new influenza virus to which people have no prior immunity. The signs of pandemic flu are similar to those of ordinary flu but may be more serious.

JANSSEN COVID-19 VACCINE

NAS B

Decision Summary

Medicinal Ingredient

AD26.COV2.S (recombinant)

Indication

JANSSEN COVID-19 VACCINE is a vaccine used to prevent COVID-19 disease caused by the SARS-CoV-2 virus. JANSSEN COVID-19 VACCINE can be given to protect people aged 18 years and older.

RUKOBIA

P NAS

Medicinal Ingredient

600 mg fostemsavir (as fostemsavir tromethamine)

Indication

RUKOBIA is used to treat HIV (human immunodeficiency virus) infection in adults who have had difficulty in controlling their HIV with many other antiretroviral medicines. It is used in patients who have HIV that is resistant to many antiretroviral medicines. RUKOBIA is used in combination with other antiretroviral medicines.

SPIKEVAX

NAS B

Decision Summary

Medicinal Ingredient

Elasomeran (mRNA)

Indication

SPIKEVAX is a vaccine used to prevent the coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus. It can be given to people aged 12 years and older.

SUPEMTEK

NAS B

Decision Summary

Medicinal Ingredient

Quadrivalent Recombinant Influenza Vaccine

Indication

SUPEMTEK is a vaccine used to prevent influenza. This vaccine may be given to adults 18 years and older.

TPOXX

NAS PI

Medicinal Ingredient

200 mg Tecovirimat (as tecovirimat monohydrate)

Indication

TPOXX is used to treat smallpox disease. It can be given to people weighing at least 13 kg.

VAXNEUVANCE

NAS B

Decision Summary

Medicinal Ingredient

Pneumococcal 15-valent Conjugate Vaccine (CRM197 Protein), adsorbed

Indication

VAXNEUVANCE is a vaccine for adults 18 years of age and older to help protect against invasive disease caused by 15 types of bacteria called pneumococcus. Invasive disease includes: an infection in the blood; an infection of the lungs (pneumonia) that comes with an infection in the blood; an infection of the coverings of the brain and spinal cord (meningitis). VAXNEUVANCE will not give you disease caused by pneumococcus. VAXNEUVANCE may not protect against diseases caused by types of pneumococcus that are not covered by the vaccine.

VAXZEVRIA

NAS B

▸ Decision Summary

Medicinal Ingredient

ChAdOx1-S [recombinant]

Indication

VAXZEVRIA 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 18 years of age and older.

15 NEW GENERIC DRUGS

- 1 product containing posaconazole
- 1 product containing ritonavir
- 1 product containing azithromycin dihydrate
- 2 products containing daptomycin
- 1 product containing ertapenem sodium
- 1 product containing abiraterone acetate
- 1 product containing atazanavir sulfate
- 1 product containing efavirenz, emtricitabine, tenofovir disoproxil fumarate
- 1 product containing emtricitabine, tenofovir disoproxil fumarate
- 1 product containing tenofovir disoproxil fumarate
- 1 product containing lamivudine
- 1 product containing linezolid
- 1 product containing amoxicillin, clavulanate potassium
- 1 product containing duranavir

SAFETY UPDATES

Pfizer-BioNTech COVID-19 Vaccine:

Dear Healthcare Professional Letter: Pfizer-BioNTech COVID-19 Vaccine: Updated Dosage and Administration and Post-Market Adverse Reaction Information

Dear Healthcare Professional Letter: Pfizer-BioNTech COVID-19 Vaccine: Updated Storage and Transportation Conditions

Health Product Risk Communication: COMIRNATY (COVID-19 Vaccine, mRNA, also referred to as Pfizer-BioNTech COVID-19 Vaccine): New Formulation for Use in Children Aged 5 Years to Less Than 12 Years

COVID-19 Vaccine Moderna:

Dear Healthcare Professional Letter: COVID-19 Vaccine Moderna: Updated English-only Global Vial and Carton Labels and Post-Market Adverse Reaction Information

Health Product Risk Communication: Importation of COVID-19 Vaccine Moderna with up to 15 Doses per Vial and English-only Vial and Carton Labels (US-Labelled Supply) [updated June 24, August 3 and October 29, 2021]

AstraZeneca COVID-19 Vaccine:

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

Dear Healthcare Professional Letter: Importation of AstraZeneca COVID-19 Vaccine with English-only Vial and Carton Labels (US-Labelled Supply)

COVISHIELD: Dear Healthcare Professional Letter: Authorization of COVISHIELD with English-only Vial and Carton Labels

AstraZeneca COVID-19 Vaccine and COVISHIELD:

- Dear Healthcare Professional Letter: AstraZeneca COVID-19 Vaccine and COVISHIELD: Risk of Thrombosis with Thrombocytopenia
- Dear Healthcare Professional Letter: AstraZeneca COVID-19 Vaccine and COVISHIELD: Risk of Capillary Leak Syndrome

Janssen COVID-19 Vaccine:

- Dear Healthcare Professional Letter: Authorization of Janssen COVID-19 Vaccine with English-only Vial and Carton Labels
- Dear Healthcare Professional Letter: Importation of Janssen COVID-19 Vaccine with Two Types of English-only Vial and Carton Labels
- Dear Healthcare Professional Letter: Janssen COVID-19 Vaccine and the Risk of Thrombosis with Thrombocytopenia
- Health Product Risk Communication: Importation of Janssen COVID-19 Vaccine with European Union (EU) English-only Vial and Carton Labels

Bamlanivimab: Dear Healthcare Professional Letter: Bamlanivimab — Potential Risk of Treatment Failure Due to Circulation of Resistant SARS-CoV-2 Variants

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

Sotrovimab: Dear Healthcare Professional Letter: Authorization of Sotrovimab for Injection for Use in Relation to the COVID-19 Pandemic

SPIKEVAX: Health Product Risk Communication: Distribution of SPIKEVAX (elasomeran) COVID-19 Vaccine with English-only Vial and Carton Labels

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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

27 NEW DRUGS

ABECMA

Decision Summary

Medicinal Ingredient

Idecabtagene vicleucel

Indication

ABECMA is used to treat adults with a type of cancer called multiple myeloma which is a cancer of the bone marrow. It is given when your cancer has not responded to at least three different treatments or has come back after these treatments. It is used as a treatment of adult patients with multiple myeloma who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and who are refractory to their last therapy.

BRAFTOVI

Medicinal Ingredient

Encorafenib

Indication

BRAFTOVI is used with a drug called binimetinib to treat adults with a type of skin cancer called melanoma. This type of skin cancer must have a change (mutation) in the BRAF gene, and spread to other parts of the body, or cannot be removed by surgery. Braftovi is also used with a drug called cetuximab to treat adults with a type of large intestine cancer called metastatic colorectal cancer (mCRC). This type of intestine cancer must have a change (mutation) in the BRAF gene, and spread to other parts of the body and has already been treated with other cancer drugs.

BRUKINSA

P NAS O

Medicinal Ingredient

Zanubrutinib

Indication

BRUKINSA is used to treat cancers such as: Waldenström's Macroglobulinemia (WM) and Mantle Cell lymphoma (MCL). BRUKINSA is only used in patients who already have received at least one treatment for MCL.

CAMCEVI

Medicinal Ingredient

Leuprolide mesylate

Indication

CAMCEVI is used for the treatment of adult patients with advanced prostate cancer.

ENHERTU

AR NAS B C I

Decision Summary

Medicinal Ingredient

Trastuzumab deruxtecan

Indication

ENHERTU is used in adults who have: HER2-positive breast cancer that has spread to other parts of the body (metastatic) or cannot be taken out by surgery and also received prior trastuzumab emtansine (T-DM1). ENHERTU (trastuzumab deruxtecan) is used in adults who have HER2-positive breast cancer that has spread to other parts of the body (metastatic) or cannot be taken out by surgery and also received prior trastuzumab emtansine (T-DM1).

GAVRETO

NAS C I

Medicinal Ingredient

Pralsetinib

Indication

For the following indication GAVRETO has been approved with conditions (NOC/c). GAVRETO is used to treat adults with a type of lung cancer called non-small cell lung cancer (NSCLC). The non-small cell lung cancer: is caused by abnormal Rearranged During Transfection (RET) gene(s) and cannot be removed by surgery or has spread to other parts of the body. A test will be done to determine if the non-small cell lung cancer is caused by RET genes.

ILUMYA

AR NAS B

Decision Summary

Medicinal Ingredient

Tildrakizumab

Indication

ILUMYA is a prescription medicine used to treat adults with moderate to severe plaque psoriasis, an inflammatory condition affecting the skin and nails. Plaque psoriasis can cause raised, thick, red and scaly patches ("psoriatic lesions") that can appear anywhere on your body.

JEMPERLI

AR NAS B C

Medicinal Ingredient

Dostarlimab

Indication

For the following indication(s), JEMPERLI has been approved with conditions (NOC/c). JEMPERLI is a prescription medicine used in adults to treat: a kind of cancer called endometrial cancer (cancer of the lining of the womb) in adults that is shown by a laboratory test to be mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) that has progressed on or following prior treatment with a platinum containing regimen.

KESIMPTA

Decision Summary

Medicinal Ingredient
Ofatumumab

Indication
KESIMPTA is used for the treatment of adults with relapsing remitting multiple sclerosis.

LEDAGA

Medicinal Ingredient
Chlormethine hydrochloride

Indication
LEDAGA is a medicine used on the skin (topical) to treat adults: with Stage 1A and 1B mycosis fungoides-type cutaneous T-cell lymphoma (MF-CTCL) who have received previous skin treatment. LEDAGA is not approved for use in children and adolescents under 18 years of age.

LUMAKRAS

Decision Summary

Medicinal Ingredient
Sotorasib

Indication
For the following indication LUMAKRAS has been approved with conditions (NOC/c). LUMAKRAS is used to treat adults with non-small cell lung cancer (NSCLC) with an abnormal gene called KRAS G12C. This cancer cannot be removed by surgery or other treatment, or has spread to other parts of the body, and has been treated with at least one type of cancer treatment before. LUMAKRAS is not approved for use in children and adolescents under 18 years of age.

MEKTOVI

Medicinal Ingredient
Binimetinib

Indication
MEKTOVI is used with a drug called encorafenib to treat adults with a type of skin cancer called melanoma. This type of skin cancer must have a change (mutation) in the BRAF gene, and spread to other parts of the body, or cannot be removed by surgery.

MINJUVI

Decision Summary

Medicinal Ingredient
Tafasitamab

Indication
For the following indication, MINJUVI has been approved with conditions (NOC/c). MINJUVI (tafasitamab for injection) is indicated in combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, who are not eligible for autologous stem cell transplant (ASCT).

ONUREG

Medicinal Ingredient
Azacitidine

Indication
ONUREG is a nucleoside metabolic inhibitor indicated for maintenance therapy in adult patients with acute myeloid leukemia (AML) who achieved complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following induction therapy with or without consolidation treatment, and who are not eligible for hematopoietic stem cell transplantation (HSCT).

PADCEV

P NAS AR B I

Decision Summary

Medicinal Ingredient

Enfortumab vedotin

Indication

PADCEV is a medicine used to treat adults with bladder cancer and cancer of the urinary tract (renal pelvis, ureter or urethra) that has spread or cannot be removed by surgery. PADCEV may be used if you have received chemotherapy that contains platinum and an immunotherapy medicine.

PEMAZYRE

B NAS C O

Decision Summary

Medicinal Ingredient

Pemigatinib

Indication

For the following indication, PEMAZYRE has been approved with conditions (NOC/c). PEMAZYRE is used to treat adults with a type of cancer called cholangiocarcinoma (bile duct cancer) when it: has a type of abnormality in a specific gene called Fibroblast Growth Factor Receptor 2 (FGFR2); and has been treated previously cannot be removed with surgery; and is at an advanced stage or has spread to other parts of the body (called metastatic). A test will be done to find out if the cancer has an FGFR2 gene abnormality.

PHESGO

B

Decision Summary

Medicinal Ingredients

Pertuzumab, trastuzumab

Indication

PHESGO is used to treat people with breast cancer when: there are a large number of "HER2-positive" cancer cells involved; the cancer has spread to areas near the breast or to other parts of your body (metastasized); the cancer may have advanced in one region and has not spread to other parts of the body and treatment is going to be given before surgery (treatment before surgery is called neoadjuvant therapy); or the cancer has not spread to other parts of the body and treatment is going to be given after surgery (treatment after surgery is called adjuvant therapy). As well as PHESGO you will also receive medicines called chemotherapy.

PONVORY

NAS

Decision Summary

Medicinal Ingredient

Ponesimod

Indication

PONVORY is used to treat adults with relapsing remitting Multiple Sclerosis (RRMS).

RETEVMO

NAS AR C PI I

Medicinal Ingredient

Selpercatinib

Indication

For the following indications, RETEVMO has been approved with conditions (NOC/c). RETEVMO is used to treat certain cancers caused by abnormal RET genes in: adults with a type of lung cancer called non-small cell lung cancer (NSCLC). It is used when your cancer has spread to other parts of your body.

Adults and children 12 to 17 years old with medullary thyroid cancer. It is used when: your cancer is advanced or has spread to other parts of your body, and your cancer cannot be removed using surgery.

Adults with differentiated thyroid cancer. It is used when: your cancer is advanced or has spread to other parts of your body, your cancer cannot be removed using surgery, radioactive iodine therapy did not work, is no longer working or is not appropriate, and you have tried treatment with sorafenib and/or lenvatinib.

SAPHNELO

NAS B

Decision Summary

Medicinal Ingredient

Anifrolumab

Indication

SAPHNELO is used for the treatment of: active lupus (systemic lupus erythematosus, SLE) in adults whose disease is not well controlled by other standard therapies (oral corticosteroids and/or immunosuppressants and/or antimalarials) they are also receiving. You will be given SAPHNELO as well as your standard therapy for lupus. Lupus is a disease in which the immune system (the system that fights infection) attacks your own cells and tissues, causing inflammation and organ damage.

TECARTUS

P NAS AR B O

Decision Summary

Medicinal Ingredient

Brexucabtagene autoleucel

Indication

TECARTUS is a treatment for your mantle cell lymphoma – a form of white blood cell cancer. It is used when at least two other available medicines have stopped working for you.

TEPMETKO

NAS C I

Medicinal Ingredient

Tepotinib (as tepotinib hydrochloride)

Indication

TEPMETKO is used to treat a type of lung cancer called non-small cell lung cancer (NSCLC). It is used in adults: whose cancer has spread to other parts of the body or is advanced and cannot be removed by surgery, and whose tumors have a specific change (abnormality) in the mesenchymal epithelial transition (MET) gene.

TRECONDYV

P

Medicinal Ingredient

Treosulfan

Indication

TRECONDYV is used together with fludarabine to prepare patients for a blood stem cell transplant from a donor: in adults with the blood cancers Acute Myeloid Leukemia (AML) or Myelodysplastic Syndrome (MDS) who are not able to tolerate the standard preparation therapies, in children and adolescents older than one year of age with AML or MDS.

TRODELVY

P NAS AR B I

Decision Summary

Medicinal Ingredient

Sacituzumab govitecan

Indication

TRODELVY is a prescription medicine used to treat adults 18 years or older with breast cancer that is: estrogen and progesterone hormone receptor (HR) negative, and human epidermal growth factor receptor 2 (HER2)-negative (also called triple-negative breast cancer), and that has spread to other parts of the body or cannot be removed by surgery (metastatic), and who previously received two or more prior therapies, at least one of them for metastatic disease.

TRUSELTIQ

NAS C I

Medicinal Ingredient

Infigratinib (as infigratinib phosphate)

Indication

For the following indication TRUSELTIQ has been approved with conditions (NOC/c). TRUSELTIQ is used to treat adult patients with a type of cancer called cholangiocarcinoma (bile duct cancer) when it: has a type of abnormality in a specific gene called Fibroblast Growth Factor Receptor 2 (FGFR2); and has been treated previously, it cannot be removed with surgery, and is at an advanced stage or has spread to other parts of the body (called metastatic). A test will be done to find out if the cancer has an FGFR2 abnormality.

VYXEOS

P O

Medicinal Ingredients

Daunorubicin, cytarabine

Indication

VYXEOS is used to treat adults with newly diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC).

ZEPZELCA

NAS C I

Medicinal Ingredient

Lurbinectedin

Indication

For the following indication(s) ZEPZELCA has been approved with conditions (NOC/c). ZEPZELCA is used to treat a type of cancer called Stage III or metastatic small cell lung cancer (SCLC). It is used in adults who have received treatment with chemotherapy that contains platinum and it did not work or is no longer working.

10 NEW BIOSIMILARS

ABEVMY

B O

Decision Summary

Medicinal Ingredient

Bevacizumab

Indication

ABEVMY is used in combination with a specific type of chemotherapy ([5-FU)-based chemotherapy) for first time treatment of people diagnosed with metastatic colorectal cancer.

ABEVMY is used in combination with a specific type of chemotherapy (carboplatin and paclitaxel) for the treatment of people diagnosed with metastatic non small cell lung cancer.

ABEVMY is used in combination with a specific type of chemotherapy (paclitaxel, topotecan, or pegylated liposomal doxorubicin) for the treatment of people diagnosed with recurrent, platinum-resistant, epithelial ovarian, fallopian tube or primary peritoneal cancer who received no more than two prior chemotherapy regimens.

ABEVMY is used in combination with lomustine (a specific type of chemotherapy) for the treatment of patients with a particular type of brain cancer called glioblastoma in which the cancer recurred after a previous treatment.

ADALIMUMAB INJECTION

B

Decision Summary

Medicinal Ingredient

Adalimumab

Indication

ABRILADA (adalimumab injection) treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), adult and pediatric (13 to 17 years of age weighing ≥ 40 kg) Crohn's disease (CD), ulcerative colitis (UC), adult and adolescent (12 to 17 years of age weighing ≥ 30 kg) hidradenitis suppurativa (HS), psoriasis (Ps) or adult and pediatric uveitis and familiar with the ABRILADA efficacy and safety profile.

AYBINTIO

B O

Decision Summary

Medicinal Ingredient

Bevacizumab

Indication

AYBINTIO is used in combination with a specific type of chemotherapy (intravenous 5-fluorouracil [5-FU]-based chemotherapy) for treatment of people diagnosed with metastatic colorectal cancer for the first time.

AYBINTIO is used in combination with a specific type of chemotherapy (carboplatin and paclitaxel) for the treatment of people diagnosed with metastatic non-small cell lung cancer.

AYBINTIO is used in combination with a specific type of chemotherapy (carboplatin and gemcitabine) for the treatment of people diagnosed with recurrent,

platinum-sensitive, epithelial ovarian, fallopian tube, or primary peritoneal cancer that comes back at least 6 months after the last time the patient responded to a chemotherapy regimen containing a platinum agent.

AYBINTIO is used in combination with a specific type of chemotherapy (paclitaxel, topotecan or pegylated liposomal doxorubicin) for the treatment of people diagnosed with recurrent, platinum-resistant, epithelial ovarian, fallopian tube or primary peritoneal cancer who received no more than two prior chemotherapy regimens.

AYBINTIO is used in combination with lomustine (a specific type of chemotherapy) for the treatment of patients with a particular type of brain cancer called glioblastoma in which the cancer recurred after a previous treatment.

BAMBEVI

AR B O

Decision Summary

Medicinal Ingredient

Bevacizumab

Indication

Metastatic Colorectal Cancer: BAMBEVI is used in combination with a specific type of chemotherapy (intravenous 5-fluorouracil [5-FU]-based chemotherapy) for treatment of patients diagnosed with metastatic colorectal cancer for the first time. Metastatic colorectal cancer is cancer of the colon or rectum that has spread to other organs in the body.

Metastatic Lung Cancer: BAMBEVI is used in combination with a specific type of chemotherapy (carboplatin and paclitaxel) for the treatment of people diagnosed with metastatic non-small cell lung cancer. Metastatic non-small cell lung cancer is cancer of the lungs that has spread to other organs in the body.

Recurrent Platinum-Resistant Ovarian Cancer: BAMBEVI is used in combination with a specific type of chemotherapy (paclitaxel, topotecan, or pegylated liposomal doxorubicin) for the treatment of people diagnosed with recurrent, platinum-resistant, epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than two prior chemotherapy regimens. Recurrent platinum-resistant ovarian cancer is the type of cancer that progresses within 6 months after the last time the patient responded to chemotherapy regimen containing a platinum agent.

Recurrent Glioblastoma: BAMBEVI is used in combination with lomustine (a specific type of chemotherapy) for the treatment of patients with a particular type of brain cancer called glioblastoma in which the cancer recurred after a previous treatment.

IXIFI

B PI

Decision Summary

Medicinal Ingredient

Infliximab

Indication

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

NYPOZI

B PI

Decision Summary

Medicinal Ingredient

Filgrastim

Indication

NYPOZI is used to treat neutropenia, a condition where the body makes too few neutrophils. Neutropenia predisposes the body to infections and prevents it from fighting them. NYPOZI is used to increase the number of neutrophils, which will fight infections. Neutropenia may be a long-standing condition where the 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 a patient's treatment for cancer, their 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. NYPOZI is a man-made form of granulocyte colony-stimulating factor (G-CSF), which is made using the bacteria *E coli*. G-CSF is a substance naturally produced by the body.

RIABNI

AR B O

Decision Summary

Medicinal Ingredient

Rituximab

Indication

RIABNI (also known as rituximab) is a cancer medicine that is used to stop cancer cell growth and ideally cause the death of cancer cells. It is a cancer medicine that must be prescribed by a doctor. It is used to treat patients with certain types of non-Hodgkin's lymphoma and chronic lymphocytic leukemia. RIABNI is an injectable medicine that is used to reduce signs and symptoms of rheumatoid arthritis (in combination with methotrexate). RIABNI 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 your disease.

SIMLANDI

B O PI

Decision Summary

Medicinal Ingredient

Adalimumab

Indication

SIMLANDI is a medicine that is used in:

- Adults with rheumatoid arthritis, which is an inflammatory disease of the joints.
- Adults with psoriatic arthritis, which is an inflammatory disease of the joints and skin.
- Adults with ankylosing spondylitis, which is a form of arthritis.
- Adults with Crohn's disease, which is an inflammatory disease of the digestive tract.
- Pediatrics with polyarticular juvenile idiopathic arthritis who are 2 years of age and older and require a full 40 mg dose based on body weight.
- 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) 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.
- Adults with uveitis, which is an inflammatory disease of the eye.
- Children (weighing ≥ 30 kg) with chronic non-infectious uveitis from 2 years of age with inflammation affecting the front of the eye.

YUFLYMA

B PI

Decision Summary

Medicinal Ingredient

Adalimumab

Indication

Yuflyma (adalimumab injection) treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (JIA) (weighing ≥ 30 kg), psoriatic arthritis (PsA), ankylosing spondylitis (AS), adult Crohn's disease (CD), adult ulcerative colitis (UC), adult and adolescent (12 to 17 years of age weighing ≥ 30 kg) hidradenitis suppurativa (HS), psoriasis (Ps) or adult and pediatric uveitis (weighing ≥ 30 kg), and familiar with the Yuflyma efficacy and safety profile. Adalimumab injection has not been studied in pediatric patients with polyarticular JIA less than 2 years of age or in pediatric patients with a weight below 10 kg. There are no clinical trials with adalimumab injection in adolescent patients with hidradenitis suppurativa (HS). The dosage of Yuflyma in these patients has been determined based on pharmacokinetic/pharmacodynamic

modeling and simulation. Adalimumab injection has not been studied in pediatric patients with uveitis less than 2 years of age. Very limited data are available for pediatric patients with uveitis between 2 and < 3 years of age. Evidence from clinical studies and experience suggests that use of adalimumab injection in the geriatric population is not associated with differences in effectiveness.

ZIRABEV

Decision Summary

Medicinal Ingredient

Bevacizumab

Indication

Metastatic Colorectal Cancer: ZIRABEV is used in combination with a specific type of chemotherapy (intravenous 5-fluorouracil [5-FU]-based chemotherapy) for treatment of people diagnosed with metastatic colorectal cancer for the first time. Metastatic colorectal cancer is cancer of the colon or rectum that has spread to other organs in the body.

Metastatic Lung Cancer: ZIRABEV is used in combination with a specific type of chemotherapy (carboplatin and paclitaxel) for the treatment of people diagnosed with metastatic non small cell lung cancer. Metastatic non small cell lung cancer is cancer of the lungs that has spread to other organs in the body.

Recurrent Platinum-Sensitive Ovarian Cancer: ZIRABEV is used in combination with a specific type of chemotherapy (carboplatin and gemcitabine) for the treatment of people.

48 NEW GENERIC DRUGS

- 8 products containing dimethyl fumarate
- 11 products containing abiraterone
- 8 products containing lenalidomide
- 1 product containing methotrexate
- 1 product containing arsenic trioxide
- 5 products containing bendamustine hydrochloride
- 1 product containing busulfan
- 1 product containing cytarabine
- 5 products containing pirfenidone
- 1 product containing temozolomide
- 2 products containing mycophenolate mofetil
- 1 product containing mycophenolic acid
- 2 products containing pemetrexed
- 1 product containing dasatinib

SAFETY UPDATES

Gilenya (fingolimod): Health Product Risk Communication: GILENYA (fingolimod) – Risk of Liver Injury

ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLANTS

For example, drugs to treat infestations of parasites.

1 NEW GENERIC DRUG

- 1 product containing pentamidine isetionate

BLOOD AND BLOOD FORMING ORGANS

For example, drugs such as anticoagulants.

4 NEW DRUGS

GLASSIA

B

Medicinal Ingredient

Alpha1-Proteinase Inhibitor (Human) (A1-PI)

Indication

GLASSIA is a liquid medicine containing human Alpha1-Proteinase Inhibitor (Alpha1-PI) also known as alpha1-antitrypsin (AAT), which is purified from human blood. The main purpose of infusing GLASSIA is to increase the levels of the AAT protein in your blood and lungs. AAT protein protects the lung tissue by blocking certain enzyme-caused damage. Limitations of Use: The effects of increasing the AAT protein levels with GLASSIA on worsening pulmonary function and progression of emphysema have not been proven in clinical trials. The long-term effects of AAT replacement and maintenance therapy with GLASSIA have not been studied. GLASSIA is not intended as a therapy in individuals with lung disease other than severe Alpha1–PI deficiency.

REBLOZYL

B O

▸ 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 (ß-thalassemia) that affects the production of hemoglobin (a protein in the red blood cells that transports oxygen throughout the body).

TRIFERIC AVNU

NAS

Medicinal Ingredient

Ferric pyrophosphate citrate

Indication

TRIFERIC AVNU is used to maintain iron levels in adults with chronic kidney disease who are undergoing hemodialysis.

VISTASEAL

B I

▸ Decision Summary

Medicinal Ingredients

Human fibrinogen (80 mg/mL) and human thrombin (500 IU/mL)

Indication

VISTASEAL is used as a sealant during surgical operations in adults. It is applied to the surface of bleeding tissue to reduce bleeding during and after the operation when standard surgical techniques are not sufficient.

6 NEW GENERIC DRUGS

- 3 product containing ticagrelor
- 2 products containing bivalirudin
- 1 product containing treprostinil

CARDIOVASCULAR SYSTEM

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

3 NEW DRUGS

LEQVIO

Medicinal Ingredient
Inclisiran

Indication
LEQVIO is used in adults to further lower the LDL cholesterol levels. It is for patients who are currently taking a statin (a medicine used to treat high cholesterol. LEQVIO is used in addition to lifestyle changes, including diet in patients who have: Heterozygous familial hypercholesterolemia (HeFH) (an inherited genetic disorder that causes extremely high cholesterol levels), or Non-familial hypercholesterolemia (a condition that affects the body processes cholesterol) with atherosclerotic cardiovascular disease (a hardening of the arteries). The effect of LEQVIO on heart problems such as heart attacks, stroke or death is not known.

OPSYNVI

Medicinal Ingredients
Macitentan, tadalafil

Indication
OPSYNVI is used in adults to treat certain types of pulmonary arterial hypertension (PAH), which is high blood pressure in the blood vessels leading to the lungs. OPSYNVI can be taken on its own, or with other PAH medications.

VYNDAMAX

Medicinal Ingredient
Tafamidis

Indication
VYNDAMAX is used to treat adults with cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM). Cardiomyopathy is a disease of the heart muscle that makes it harder for the heart to pump blood to the rest of the body. VYNDAMAX reduces death and hospitalization related to heart problems. VYNDAMAX is not for use in patients less than 18 years of age.

17 NEW GENERIC DRUGS

- 1 product containing dronedarone
- 1 product containing diltiazem hydrochloride
- 1 product containing furosemide
- 1 product containing hydralazine hydrochloride
- 1 product containing bisoprolol
- 1 product containing midodrine
- 1 product containing olmesartan
- 1 product containing quinapril
- 1 product containing spironolactone
- 1 product containing lidocaine hydrochloride
- 1 product containing milrinone lactate
- 1 product containing rosuvastatin
- 1 product containing amlodipine
- 1 product containing atorvastatin
- 1 product containing valsartan
- 2 products containing clonidine hydrochloride

DERMATOLOGICALS

For example, drugs to treat psoriasis.

2 NEW DRUGS

ADTRALZA

NAS AR B

Decision Summary

Medicinal Ingredient
Tralokinumab

Indication
ADTRALZA (tralokinumab injection) is indicated for the treatment of moderate-to-severe atopic dermatitis in adult patients whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. ADTRALZA can be used with or without topical corticosteroids. It is not known if ADTRALZA is safe and effective in children under 18 years old.

ARAZLO

PI

Decision Summary

Medicinal Ingredient
Tazarotene

Indication
ARAZLO is used on the skin to treat people 10 years of age and older with acne vulgaris (acne). It is recommended that for children (10 to less than 12 years of age), ARAZLO should be used on the face only.

3 NEW GENERIC DRUGS

- 1 product containing ambrisentan
- 1 product containing acyclovir
- 1 product containing tretinoin

GENITO URINARY SYSTEM AND SEX HORMONES

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

5 NEW DRUGS

INPROSUB

Medicinal Ingredient
Progesterone

Indication
INPROSUB is used in adult women who need extra progesterone while undergoing *in vitro* fertilization (IVF). These women must be 34 years of age or younger. As well, they will not be able to use or tolerate other products given through the vagina. INPROSUB is intended to be used only by women who are able to get pregnant (of child-bearing age).

NEXTSTELLIS

NAS

Medicinal Ingredients
Estetrol monohydrate, drospirenone

Indication
NEXTSTELLIS is indicated to prevent pregnancy.

OSPHENA

NAS

Medicinal Ingredient
Ospemifene

Indication
OSPHENA is used in postmenopausal (after menopause) women to treat some symptoms of Genitourinary Syndrome of Menopause (GSM). OSPHENA is used to treat moderate to severe symptoms such as: pain during sex due to changes in and around the vagina; dryness due to changes in and around the vagina.

SLYND

Medicinal Ingredient
Drospirenone

Indication
SLYND is used to prevent pregnancy in girls and adult women aged 12 years and older who can become pregnant.

VABLYS

▸ Decision Summary

Medicinal Ingredient
Dequalinium chloride

Indication
VABLYS is used to treat an infection of the vagina, called bacterial vaginosis. It is used in adult women who are younger than 55 years of age.

11 NEW GENERIC DRUGS

- 3 products containing tadalafil
- 4 products containing silodosin
- 1 product containing etonogestrel, ethinyl estradiol
- 1 product containing darifenacin
- 1 product containing fesoterodine fumarate
- 1 product containing medroxyprogesterone

MUSCULO-SKELETAL SYSTEM

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

2 NEW DRUGS

EVRYSDI

P NAS O PI

Medicinal Ingredient
Risdiplam

Indication
EVRYSDI is a medicine used to treat spinal muscular atrophy (SMA), which is a condition that affects the nervous system. EVRYSDI is for use in children 2 months of age and older and in adults.

MYINFLA

P AR

Medicinal Ingredient
Colchicine

Indication
MYINFLA is used to reduce cardiovascular risks in patients with plaque build-up in the arteries, which narrows the arteries and restricts the blood supply to the heart.

5 NEW GENERIC DRUGS

- 1 product containing alendronic acid, vitamin D3
- 2 products containing ketorolac tromethamine
- 1 product containing rocuronium bromide
- 1 product containing zoledronic acid

NERVOUS SYSTEM

For example, analgesics and antidepressants.

3 NEW DRUGS

SUNOSI

NAS O

Medicinal Ingredient
Solriamfetol (as solriamfetol hydrochloride)

Indication
SUNOSI helps you feel less sleepy during the day. It is used for adults with: narcolepsy – a condition that causes you to suddenly and unexpectedly feel very sleepy at any time, as well as Obstructive Sleep Apnea (OSA) – a condition where your breathing stops for brief periods of time when you sleep.

VYEPTI

NAS B

Decision Summary

Medicinal Ingredient
Eptinezumab

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

WAKIX

NAS O

Decision Summary

Medicinal Ingredient
Pitolisant hydrochloride

Indication
WAKIX is used in adults with narcolepsy (a type of sleep disorder) to reduce: excessive sleepiness during the day; and cataplexy (sudden weak or paralyzed muscles).

14 NEW GENERIC DRUGS

- 1 product containing acetaminophen
- 1 product containing betahistine hydrochloride
- 1 product containing bupivacaine hydrochloride
- 2 products containing buspirone hydrochloride
- 1 product containing dexmedetomidine hydrochloride
- 1 product containing pregabalin
- 1 product containing tramadol hydrochloride
- 1 product containing fluoxetine hydrochloride
- 1 product containing levodopa, carbidopa, entacapone
- 1 product containing paliperidone
- 1 product containing venlafaxine hydrochloride
- 1 product containing mixed salts amphetamine
- 1 product containing buprenorphine hydrochloride, naloxone hydrochloride dihydrate

SAFETY UPDATES

HYDROMORPHONE INJECTABLE FORMULATIONS: Dear Healthcare Professional Letter: Importation of German-labelled Hydromorphone Ethypharm Kalceks (Hydromorphone Hydrochloride Solution for Injection) due to Potential Shortage of Canadian-labelled HYDROmorphone

SUBOXONE: Dear Healthcare Professional Letter: Important Safety Information on SUBOXONE (buprenorphine and naloxone) and the Risk of Overdose or Underdose when Switching Between Dosage Forms or Routes of Administration

RUZURGI (amifampridine): Dear Healthcare Professional Letter: RUZURGI (amifampridine) — Removal from Canadian Market: Options for Continued Treatment for Lambert-Eaton Myasthenic Syndrome [updated June 25, 2021]

CHAMPIX (varenicline): Dear Healthcare Professional Letter: CHAMPIX (varenicline) — Potential Risk Posed by Long-Term Exposure to Nitrosamine Impurity, N-nitrosovarenicline, Exceeding Acceptable Intake Limit

RESPIRATORY SYSTEM

For example, drugs to treat asthma and antihistamines.

2 NEW DRUGS

BREZTRI AEROSPHERE

AR

Decision Summary

Medicinal Ingredients

Budesonide, glycopyrronium (as bromide), formoterol fumarate dihydrate

Indication

BREZTRI AEROSPHERE is used in adults for the long-term treatment of a lung disease called chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

TRIKAFTA

P NAS AR O PI

Decision Summary

Medicinal Ingredients

Elexacaftor, tezacaftor, ivacaftor

Indication

TRIKAFTA is used for the treatment of cystic fibrosis (CF) in patients 12 years of age and older who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. It is not known if TRIKAFTA is safe and effective in children under 12 years of age.

3 NEW GENERIC DRUGS

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

SENSORY ORGANS

For example, drugs to treat vision loss.

2 NEW DRUGS

CEQUA

Decision Summary

Medicinal Ingredient

Cyclosporine

Indication

CEQUA is used to treat a condition called keratoconjunctivitis sicca also known as dry eye disease. CEQUA makes your eyes produce more tears.

TISSUEBLUE

NAS O

Medicinal Ingredient

Brilliant blue G

Indication

TISSUEBLUE is used as an aid in eye surgery. It is used to stain a part of your eye called the internal limiting membrane (ILM).

3 NEW GENERIC DRUGS

- 1 product containing dorzolamide hydrochloride
- 1 product containing dorzolamide hydrochloride, timolol maleate
- 1 product containing olopatadine hydrochloride

AR ALIGNED REVIEW | IO INTERIM ORDER | B BIOLOGIC DRUGS | COVID-19 | EUND EXTRAORDINARY USE NEW DRUG | NAS NEW ACTIVE SUBSTANCE | C NOTICE OF COMPLIANCE WITH CONDITIONS | O ORPHAN DRUGS | OTC OVER THE COUNTER | PI PEDIATRIC INDICATION | P PRIORITY REVIEW | I REVIEW WITH INTERNATIONAL PARTNERS

SYSTEMIC HORMONAL PREPARATIONS, EXCLUDING SEX HORMONES AND INSULINS

For example, drugs to treat hypothyroidism.

1 NEW DRUG

NGENLA

NAS B O PI

Decision Summary

Medicinal Ingredient

Somatrogon

Indication

NGENLA is used for the long-term treatment of children who are not growing because of low growth hormone levels.

2 NEW GENERIC DRUGS

- 1 product containing desmopressin acetate
- 1 product containing methylprednisolone

VARIOUS

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

3 NEW GENERIC DRUGS

- 1 product containing sodium pyrophosphate, stannous fluoride, total tin
- 2 products containing naloxone hydrochloride dihydrate

MEDICAL DEVICES: APPROVED IN 2021

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 2021, 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.
- ***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.
- **Various** – applicable to medical devices generally.

IMPORTANT DEFINITIONS

License with conditions

A medical device license 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.

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.

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.**

CLASS IV MEDICAL DEVICES: APPROVED IN 2021

BODY FLUID AND TISSUE MANAGEMENT DEVICES

For example, blood separation systems.

2 NEW MEDICAL DEVICES

EMBOCUBE EMBOLIZATION GELATIN

Indication

EmboCube Embolization Gelatin is indicated for use in embolization of blood vessels to occlude blood flow for controlling bleeding or hemorrhaging. EmboCube Embolization Gelatin occludes vessels up to 5 mm. EmboCube Embolization Gelatin is intended to be used in adults.

EMBOTRAP III REVASCULARIZATION DEVICE

Indication

The EMBOTRAP III Revascularization Device is intended to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

BODY TISSUE MANIPULATION AND REPARATION DEVICES

For example, bone grafts and dermal dressings.

3 NEW MEDICAL DEVICES

LEGOGRAFT

Indication

LegoGraft is recommended for:

- Augmentation or reconstructive treatment of the alveolar ridge.
- Filling of periodontal defects.
- Filling of defects after root resection, apicoectomy, and cystectomy.
- Filling of extraction sockets to enhance preservation of the alveolar ridge.
- Elevation of the maxillary sinus floor.
- Filling of periodontal defects in conjunction with products intended to Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR).
- Filling of peri-implant defects in conjunction with products intended for Guided bone Regeneration (GBR).

GEM 21S GROWTH-FACTOR ENHANCED MATRIX

Indication

GEM 21S is intended for use as a grafting device in periodontal regenerative procedures and is indicated for:

- Augmentation or reconstructive treatment of the alveolar ridge.
- Filling of periodontal defects.
- Filling of extraction sockets to enhance preservation of the alveolar ridge.
- Elevation of the maxillary sinus floor.
- Filling of bone defects in conjunction with Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR).
- Filling of peri-implant defects in conjunction with products intended for GBR.
- Gingival recession associated with periodontal disease.

SALVINOSS COLLAGEN XENOGRAFT + COLLAGEN BONE GRAFT MATERIAL

Indication

SalvinOSS Collagen is indicated for:

- Augmentation or reconstructive treatment of the alveolar ridge.
- Filling of infrabony periodontal defects.
- Filling of defects after root resection, apicoectomy and cystectomy.
- Filling of extraction sockets to enhance preservation of the alveolar ridge.
- Elevation of the maxillary sinus floor.
- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR).
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR).

CARDIOVASCULAR DEVICES

For example, cardiovascular catheters and pacemakers.

23 NEW MEDICAL DEVICES

ORSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM

C

Indication

Orsiro is indicated for improving coronary luminal diameter in patients, including those with diabetes mellitus, with symptomatic heart disease, stable angina, unstable angina, non-ST elevation myocardial infarction or documented silent ischemia due to atherosclerotic lesions in the native coronary arteries with a reference vessel diameter of 2.25 mm to 4.0 mm and a lesion length of <= 36 mm.

ACHIEVE ADVANCE MAPPING CATHETER

Indication

The Achieve Advance mapping catheter is indicated for multiple electrode electrophysiological mapping of the cardiac structures of the heart (i.e., recording or stimulation only). The Achieve Advance mapping catheter is designed to obtain electrograms in the atrial regions of the heart.

SAPPHIRE II PRO BALLOON DILATATION CATHETER

Indication

The Sapphire II PRO Balloon Dilatation Catheter (diameter 1.0-1.25mm configurations) is indicated for:

- Balloon pre-dilatation of a stenotic portion of a coronary artery or bypass graft stenosis (>=70% stenosis) for the purpose of improving myocardial perfusion.
- Balloon pre-dilatation of a stenotic portion of a peripheral artery, including renal, femoral, popliteal, infra-popliteal, tibial and peroneal arteries.

The Sapphire II PRO Balloon Dilatation Catheter (diameter 1.5-4.0mm configurations) is indicated for:

- Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion.
- Balloon dilatation of a coronary artery occlusion for the treatment of acute myocardial infarction.
- Percutaneous transluminal angioplasty in the peripheral vasculature, including renal, femoral, popliteal, infra-popliteal, tibial and peroneal arteries.

STEALTH 360 PERIPHERAL ORBITAL ATHERECTOMY SYSTEM

Indication

The Stealth 360 Peripheral Orbital Atherectomy System is a percutaneous orbital atherectomy system indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries and who are acceptable candidates for percutaneous transluminal atherectomy.

HEARTSTART INTREPID MONITOR/DEFIBRILLATOR

Indication

The HeartStart Intrepid is intended for use in an EMS or hospital setting by qualified medical personnel trained in the operation of the device and qualified by certified training in basic life support or advanced life support.

ALTO ABDOMINAL STENT GRAFT SYSTEM

C

Indication

The Alto Abdominal Stent Graft System is indicated for treatment of patients with infrarenal abdominal aortic aneurysms having the vascular morphology suitable for endovascular repair with the device.

SOUNDBITE CROSSING SYSTEM – PERIPHERAL (14P)

C

Indication

The SoundBite Crossing System – Peripheral is indicated to facilitate the intra-luminal placement of conventional guidewires or treatment devices beyond peripheral artery chronic total occlusions via atherectomy. The SoundBite Crossing System – Peripheral is contraindicated for use in the carotid arteries.

PULSAR-18 T3 PERIPHERAL SELF-EXPANDING NITINOL STENT SYSTEM

Indication

The Pulsar-18 T3 self-expanding stent system is indicated to improve luminal diameter in patients with symptomatic de novo, restenotic or occlusive lesions in the femoral and proximal popliteal arteries.

OMNIWIRE PRESSURE GUIDE WIRE

Indication

The OmniWire pressure guide wire is indicated for use to measure pressure in blood vessels, including both coronary and peripheral vessels, during diagnostic angiography and/or any interventional procedures. It can also be used to facilitate the placement of catheters as well as other interventional devices in coronary and peripheral vessels. Blood pressure measurements provide hemodynamic information for the diagnosis and treatment of blood vessel disease.

ZOLL AED 3 AVIATION

Indication

The ZOLL AED 3 Aviation system is indicated for use when a suspected cardiac arrest victim has an apparent lack of circulation as indicated by:

- Unconsciousness.
- Absence of breathing.
- Absence of pulse and other signs of circulation.

The AED 3 system is indicated for adult and pediatric patients.

TRICLIP G4 SYSTEM

C

Indication

The TriClip G4 System is intended for reconstruction of the insufficient tricuspid valve through tissue approximation. The TriClip device is indicated for patients with severe tricuspid regurgitation who are symptomatic despite medical therapy with valve anatomies that are conducive for transcatheter repair and who have been determined to be at high or greater estimated risk for tricuspid valve surgery by a heart team.

COMET II PRESSURE GUIDEWIRE

Indication

The Comet II Pressure Guidewire is indicated to direct a catheter through a blood vessel and to measure physiological parameters in the coronary blood vessels.

TORNADO EMBOLIZATION COILS AND MICROCOILS

Indication

The Tornado Embolization Coils and Microcoils are intended for arterial and venous embolization in the peripheral vasculature.

NESTER EMBOLIZATION COILS AND MICROCOILS

Indication

The Nester Embolization Coils and Microcoils are intended for arterial and venous embolization in the peripheral vasculature.

MYNX CONTROL VASCULAR CLOSURE DEVICE

Indication

The MYNX CONTROL VASCULAR CLOSURE DEVICE is indicated for use to seal femoral arterial access sites while reducing times to hemostasis and ambulation in patients who have undergone diagnostic or interventional endovascular procedures utilizing a 5F, 6F or 7F procedural sheath.

SYNERGY MEGATRON MONORAIL EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM

C

Indication

The SYNERGY MEGATRON Everolimus-Eluting Platinum Chromium Coronary Stent System is indicated for improving luminal diameter in patients, including those at high risk for bleeding, 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.

MITRIS RESILIA MITRAL VALVE

Indication

The MITRIS RESILIA Mitral Valve Model 11400M is indicated for the replacement of native or prosthetic mitral valves. The MITRIS RESILIA Mitral Valve Model 11400M is intended for use as a heart valve replacement.

REPROCESSED DIAGNOSTIC ULTRASOUND CATHETER

Indication

The Reprocessed AcuNav Diagnostic Ultrasound Catheter is intended for intracardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult patients. The reprocessed device is not indicated for use with pediatric patients. The catheter is intended for imaging guidance only, not treatment deliver, during cardiac interventional percutaneous procedures.

REPROCESSED ADVISOR HD GRID SENSOR ENABLED HIGH DENSITY MAPPING CATHETER

Indication

The Reprocessed Advisor HD Grid Mapping Catheter, Sensor Enabled, is indicated for multiple electrode electrophysiological mapping of cardiac structures in the heart (i.e., recording or stimulation only). This catheter is intended to obtain electrograms in the atrial and ventricular regions of the heart.

EPIC PLUS/EPIC PLUS SUPRA STENTED PORCINE TISSUE VALVES

Indication

The Epic Plus valve is indicated for patients requiring replacement of a diseased, damaged or malfunctioning native aortic and/or mitral heart valve. It may also be used as a replacement for a previously implanted aortic and/or mitral prosthetic heart valve. The Epic Plus Supra valve is indicated for patients requiring replacement of a diseased, damaged, or malfunctioning native aortic heart valve. It may also be used as a replacement for a previously implanted aortic prosthetic heart valve.

PERCLOSE PROSTYLE SUTURE-MEDIATED CLOSURE AND REPAIR SYSTEM

Indication

The Perclose ProStyle SMCR System is indicated for the percutaneous delivery of suture for closing the common femoral artery and vein access site of patients who have undergone diagnostic or interventional catheterization procedures.

RENAMIC NEO

Indication

Renamic Neo is a portable programmer and monitoring device with an integrated pacing system analyzer (PSA), which is used in the implantation and follow-up of BIOTRONIK implantable pacemakers, ICDs (implantable cardioverter-defibrillator) or implantable cardiac monitors. The device provides communication with implantable pacemakers, ICDs or implantable BIOTRONIK cardiac monitors (ICMs) during the implantation or a follow-up.

CONQUEST 40 PTA DILATATION CATHETER

Indication

CONQUEST 40 PTA Dilatation Catheter is recommended for use in Percutaneous Transluminal Angioplasty of the femoral, iliac and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also recommended for post-dilatation of stents and stent grafts in the peripheral vasculature. This catheter is not for use in coronary arteries.

SAFETY UPDATE

Medtronic Heartware Ventricular Assist Device System: Dear Healthcare Professional Letter: Medtronic Heartware Ventricular Assist Device System — Recall Due to Risk of Neurological Adverse Events, Mortality and Delay or Failure to Restart

IN VITRO DIAGNOSTIC MEDICAL DEVICES

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

5 NEW MEDICAL DEVICES

MIRASOL PATHOGEN REDUCTION TECHNOLOGY (PRT) SYSTEM

Indication

The Mirasol PRT system is intended to reduce the pathogen load and inactivate residual white blood cells in donor platelet concentrates for transfusion. The system is intended for platelets (apheresis and buffy coat) treated and stored in 100% plasma.

ALINITY M HCV (CONFIRMATORY)

Indication

The Alinity m HCV assay is an *in vitro* reverse transcription-polymerase chain reaction (RT-PCR) assay for use with the automated Alinity m System to detect and quantitate hepatitis C virus (HCV) RNA in human serum or plasma.

ATELLICA IM HBC TOTAL 2 (HBCT2) (DONOR SCREENING FOR TRANSPLANTATION)

Indication

The Atellica IM HBc Total 2 (HBcT2) assay is for *in vitro* diagnostic use in the qualitative determination of total antibodies to the core antigen of the hepatitis B virus (HBV) in human serum or plasma using the Atellica IM Analyzer.

PK CMV-PA SYSTEM

Indication

The PK CMV-PA System is a passive particle agglutination assay intended for the qualitative detection of IgG and IgM antibodies to cytomegalovirus (CMV) in human EDTA plasma and serum from blood donors using the BECKMAN COULTER PK7300 and/or PK7400 Automated Microplate Systems.

VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HTLV I/II REAGENT, CALIBRATOR AND CONTROL

Indication

For the *in vitro* qualitative detection of antibodies to human T-cell lymphotropic virus Types I and/or II, (HTLV-I and HTLV-II) in human serum and plasma (heparin, EDTA and citrate) in adults, using the automated VITROS ECi/ECiQ/3600 Immunodiagnostic Systems and the VITROS 5600/XT 7600 Integrated Systems.

NEUROLOGICAL DEVICES

For example, neurological stimulation devices.

11 NEW MEDICAL DEVICES

WAVEWRITER ALPHA SPINAL CORD STIMULATOR SYSTEM

Indication

The Boston Scientific Spinal Cord Stimulator System is indicated as an aid in the management of chronic intractable pain.

VERCISE GENUS DEEP BRAIN STIMULATION SYSTEM

Indication

The Boston Scientific DBS System is indicated for use in:

- Unilateral or bilateral stimulation of the subthalamic nucleus (STN) or internal globus pallidus (GPi) for levodoparesponsive Parkinson's disease that is not adequately controlled with medication.
- Unilateral or bilateral stimulation of the subthalamic nucleus (STN) or internal globus pallidus (GPi) for treatment of intractable primary and secondary dystonia, for persons 7 years of age and older.
- Stimulation of the ventral intermediate nucleus (VIM) of the thalamus for the suppression of tremor that is not adequately controlled by medications in patients diagnosed with Essential Tremor or Parkinson's disease.

ECLIPS SYSTEM

Indication

The eCLIPs System (eCLIPs Device, Micro-introducer, Microcatheter and Detacher) is intended to treat unruptured or stable, previously ruptured (>30 days) intracranial, saccular aneurysms arising at the Internal Carotid Artery (ICA) Bifurcation or the Basilar Artery Bifurcation.

WAVEWRITER ALPHA SPINAL CORD STIMULATOR SYSTEM – ALPHA 16

Indication

The Boston Scientific Spinal Cord Stimulator System is indicated as an aid in the management of chronic intractable pain.

WAVEWRITER ALPHA SPINAL CORD STIMULATOR SYSTEM – ALPHA PRIME

Indication

The Boston Scientific Spinal Cord Stimulator System is indicated as an aid in the management of chronic intractable pain.

WAVEWRITER ALPHA SPINAL CORD STIMULATOR SYSTEM – ALPHA PRIME 16

Indication

The Boston Scientific Spinal Cord Stimulator System is indicated as an aid in the management of chronic intractable pain.

STEREOTACTIC TCD ELECTRODES

Indication

The Cosman Disposable Stereotactic TC Electrode is indicated for use in RF heat lesioning of nervous tissue, including the Central Nervous System. Examples of RF procedures include thalamotomy and pallidotomy to treat movement disorders such as Parkinson's disease, dystonia or essential tremor which are not adequately controlled by medication.

VERCISE GENUS P8 DEEP BRAIN STIMULATION SYSTEM

Indication

The Boston Scientific DBS System is indicated for use in the following:

- Unilateral or bilateral stimulation of the subthalamic nucleus (STN) or internal globus pallidus (GPi) for levodoparesponsive Parkinson's disease that is not adequately controlled with medication.
- Unilateral or bilateral stimulation of the subthalamic nucleus (STN) or internal globus pallidus (GPi) for treatment of intractable primary and secondary dystonia, for persons 7 years of age and older.
- Stimulation of the ventral intermediate nucleus (VIM) of the thalamus for the suppression of tremor that is not adequately controlled by medications in patients diagnosed with Essential Tremor or Parkinson's disease.

VERCISE GENUS P32 DEEP BRAIN STIMULATION SYSTEM

Indication

The Boston Scientific DBS System is indicated for use in the following:

- Unilateral or bilateral stimulation of the subthalamic nucleus (STN) or internal globus pallidus (GPi) for levodoparesponsive Parkinson's disease that is not adequately controlled with medication.
- Unilateral or bilateral stimulation of the subthalamic nucleus (STN) or internal globus pallidus (GPi) for treatment of intractable primary and secondary dystonia, for persons 7 years of age and older.
- Stimulation of the ventral intermediate nucleus (VIM) of the thalamus for the suppression of tremor that is not adequately controlled by medications in patients diagnosed with Essential Tremor or Parkinson's disease.

VERCISE GENUS R16 DEEP BRAIN STIMULATION SYSTEM

Indication

The Boston Scientific DBS System is indicated for use in the following:

- Unilateral or bilateral stimulation of the subthalamic nucleus (STN) or internal globus pallidus (GPi) for levodoparesponsive Parkinson's disease that is not adequately controlled with medication.
- Unilateral or bilateral stimulation of the subthalamic nucleus (STN) or internal globus pallidus (GPi) for treatment of intractable primary and secondary dystonia, for persons 7 years of age and older.
- Stimulation of the ventral intermediate nucleus (VIM) of the thalamus for the suppression of tremor that is not adequately controlled by medications in patients diagnosed with Essential Tremor or Parkinson's disease.

VERCISE GENUS R32 DEEP BRAIN STIMULATION SYSTEM

Indication

The Boston Scientific DBS System is indicated for use in the following:

- Unilateral or bilateral stimulation of the subthalamic nucleus (STN) or internal globus pallidus (GPi) for levodoparesponsive Parkinson's disease that is not adequately controlled with medication.
- Unilateral or bilateral stimulation of the subthalamic nucleus (STN) or internal globus pallidus (GPi) for treatment of intractable primary and secondary dystonia, for persons 7 years of age and older.
- Stimulation of the ventral intermediate nucleus (VIM) of the thalamus for the suppression of tremor that is not adequately controlled by medications in patients diagnosed with Essential Tremor or Parkinson's disease.

PLASTIC SURGERY AND COSMETIC DEVICES

For example, breast implants.

1 NEW MEDICAL DEVICE

NEXUS ULTRASONIC SURGICAL ASPIRATOR SYSTEM

Indication

The Misonix Inc neXus Ultrasonic Surgical Aspirator System is intended for the fragmentation, emulsification and aspiration of both soft and hard (i.e., bone) tissue.

VARIOUS

Applicable to medical devices generally.

SAFETY UPDATE

Ultrasound gels and lotions:

Dear Healthcare Professional Letter: Recall of EcoGel 200 Ultrasound Gel – MediChoice (M500812) – Contamination with Burkholderia stabilis [updated August 19, 2021]

Dear Healthcare Professional Letter: Important Safety Information on Ultrasound Gels and Lotions Manufactured by Eco-Med Pharmaceuticals, Inc. – Potential Contamination with Burkholderia stabilis

DRUGS FOR VETERINARY USE: APPROVED IN 2021

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.

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.

You can report a veterinary drug reaction to Health Canada

6 NEW DRUGS

NEXGARD COMBO

Medicinal Ingredients

Esafoxolaner, eprinomectin, praziquantel

Indication

Topical solution for cats indicated for:

- The treatment and control of flea infestations by killing adult fleas.
- The treatment and control of Blacklegged Ticks and Lone Star Ticks.
- The treatment of ear mites *Otodectes cynotis*.
- The prevention of heartworm disease *Dirofilaria immitis*.
- The treatment and control of intestinal cestode infections caused by the adult tapeworms.
- The treatment and control of intestinal nematode infections caused by adult *Toxocara cati* (in cats and kittens 8 weeks of age and older).

DORMAZOLAM

NAS

Medicinal Ingredient
Midazolam

Indication
For use with ketamine as an intravenous induction agent for the anaesthesia of healthy adult horses.

SOLENSIA

NAS

Medicinal Ingredient
Frunevetmab

Indication
SOLENSIA is indicated for the alleviation of pain associated with osteoarthritis in cats.

DRAXXIN KP

Medicinal Ingredients
Tulathromycin, ketoprofen

Indication
Indicated for the treatment of clinical bovine respiratory disease (BRD), with accompanying pyrexia, associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni* and *Mycoplasma bovis* susceptible to tulathromycin in beef and non-lactating dairy cattle 2 months of age and older.

SOLOFER

Medicinal Ingredient
Iron (iron dextran complex)

Indication
Indicated for the treatment and prevention of iron deficiency anemia in newborn piglets.

LIBRELA

Medicinal Ingredient
Bedinvetmab

Indication
Indicated for the alleviation of pain associated with osteoarthritis in dogs.

13 NEW GENERIC DRUGS

- 1 product containing meloxicam
- 2 products containing tilmicosin
- 2 products containing tulathromycin
- 1 product containing amprolium hydrochloride
- 1 product containing imidacloprid, moxidectin
- 1 product containing amprolium
- 1 product containing apramycin sulfate
- 1 product containing ketoprofen
- 1 product containing acitracin methylene disalicylate
- 1 product containing altrenogest
- 1 product containing monensin sodium

Canada