APPEARANCE BEFORE THE STANDING COMMITTEE ON HEALTH (HESA)
NOVEMBER 15TH, 2022

HEALTH CANADA OFFICIALS TO APPEAR TO DISCUSS THE ONGOING SHORTAGES OF CHILDREN'S PAIN MEDICATIONS

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Introductory remarks for appearance at HESA

Introduction

- Thank you, Mr. Chair, for the opportunity to appear before the Standing Committee on Health and to participate in today's discussion on the availability of non-prescription analgesics for infants and children – more commonly known as acetaminophen and ibuprofen.
- I am Stephen Lucas, and I am the Deputy Minister of Health Canada. Before I begin, I would like to acknowledge the Anishinaabe Algonquin Nation, who are the customary keepers of the unceded, unsurrendered territory that we are gathered on today.
- I am joined by my colleagues, Stefania Trombetti, Assistant Deputy Minister of the Regulatory Operations and Enforcement Branch, Dr. Supriya Sharma, Chief Medical Advisor for Health Canada, Linsey Hollett, who is the Director General of the Health Product Compliance Directorate, and Kim Godard, Director of the Health Product Inspection and Licensing Division.
- First, I want to emphasize that the shortage of pediatric and children's analgesics is a top priority for Health Canada, and all efforts are being taken to resolve this shortage.
- We share the concerns of everyone in Canada touched by this shortage. We also understand the impact that it is having on children in need of these medications, and the stress it has created for parents and caregivers.
- With the time that I have for my opening remarks, I would like to share with the committee a quick snapshot of the work that Health Canada has been undertaking to mitigate the affects of this shortage.

Health Canada Actions

- Drug shortages are a complex and multi-faceted issue, with a variety of stakeholders having a role to play. Mitigating and resolving drug shortages requires a collective effort of many players.
- Health Canada's experience in managing shortages, the regulatory tools at its disposal, and well-developed government-to-government networks and stakeholder relationships have provided Canada with a solid foundation to address shortages.
- Since hearing early signals of a potential shortage in April, Health Canada has been actively engaging and bringing together manufacturers, distributors, retailers, provinces and territories, children's hospitals, the Canadian Pharmacists' Association, and healthcare practitioners, including the Canadian Pediatric Society, to assess demand, the options for expanding supply, and implementing measures to limit the effects of the shortage.
- Our engagement has been constant. During the summer months, this engagement with key stakeholders was several times weekly. Over the last couple of months, this engagement has become daily.
- Companies who supply the Canadian market, be they large or small, have ramped-up supply. Some manufacturers are now producing these products at record levels; however, demand continues to outpace supply.
- Health Canada is using other tools at its disposal to increase the supply, including facilitating the importation of foreign products.
- When Health Canada first became aware of supply constraints for these products in April, it reached out to the suppliers and made it clear that regulatory flexibilities to permit the exceptional importation of foreign product were available, and could be used to increase the supply coming into Canada.

- With the information available at that time, the mitigation approach adopted by suppliers was to ramp up production. The Department continued to engage multiple players in the supply chain over the following months and by late August, the unprecedented spike in demand made clear that ramping up production would not be sufficient. Seeing this, the Department again sought proposals for the importation and sale of foreign authorized supply.
- In a statement released by the department yesterday, we advised Canadians that we have secured foreign supply of children's acetaminophen that will be available for sale at retail and in community pharmacies in the coming weeks.
- The amount to be imported will increase supply available to consumers and will help address the immediate situation.
- To further increase supply, Health Canada also recently approved the exceptional importation of infant and children's ibuprofen and acetaminophen to supply hospitals in Canada. The importation of ibuprofen has occurred, and distribution has begun.
- Each proposal received from a company to import a foreign authorized product undergoes careful review by Health Canada to confirm that the product was manufactured according to comparable standards of safety, quality and efficacy as all drug products approved for use in Canada.
- For foreign supply of children's analgesics, in addition to meeting the required safety standards, information related to cautions and warnings, dosing directions, ingredients, and other important details will be made available in both English and French to ensure parents and caregivers clearly understand what medication they are using and how to give it to their children.
- As foreign product generally does not have important safety information available in both official languages, Health Canada works to ensure this is not an impediment to importation.
- When this involves products at the retail level, this can be done, for example, by providing and visibly posting a QR code, website information, or paper print outs at community pharmacies and retail stores where this safety information can be accessed.
- Mr. Chair, these foreign supplies coming into the country are a good start. Health Canada is continuing to work alongside suppliers to facilitate more product coming into Canada to fill the supply gap, and we know that companies are continuing to produce at record levels to meet the needs of Canadians.
- One last thing I'd like to make the committee aware of is that through the exercise of regulatory flexibility, Health Canada has facilitated greater access to these needed medications by temporarily allowing the sale of compounded acetaminophen or ibuprofen without a prescription. Regulations on the safety and quality of these products continue to apply, and this measure will be in place until the shortage is resolved.

Conclusion

- Mr. Chair, I will conclude where I began, which is with the assurance that this issue is a top priority for Health Canada and that all possible efforts are being made to mitigate this shortage.
- The health and well-being of infants and children has been and remains our highest priority. Health Canada has been actively engaged on the file since observing early signals of a potential shortage. We have and will continue to dedicate significant resources to resolving the shortage, and, as I indicated, we are mobilizing all the players involved to end this shortage as quickly as possible. We will also continue to communicate with Canadians through the dedicated pediatric analgesics landing page on our website.
- Thank you, Mr. Chair. We look forward to today's discussion and will be happy to answer any questions that Committee members may have.

Redacted – confidential information

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HESA - Standing Committee on Health
November 15, 2022

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GENERAL CONTEXT – SUPPLY CHAIN CHALLENGES AND PEDIATRIC DRUG SHORTAGES

Q.1. How many children's analgesic products have been approved for sale in Canada (or, how many are currently marketed)
A.1. There are 22 acetaminophen products and nine ibuprofen products intended for use in infants or children that are marketed in Canada.

Q.2. Why is there a shortage of these drugs? Why is Canada the only country in the world experiencing this shortage?
A.2. Drug shortages can happen for a variety of reasons. Generally speaking, there are both supply and demand factors. Disruptions in supply can lead to shortages, as can spikes in demand. We saw both of these factors at play during the pandemic. Through our ongoing engagement with manufacturers, we have learned that the current Canadian shortage of these products is primarily due to unprecedented demand, including an unusual spike in demand late this past summer.
Manufacturers usually take advantage of the summer season to restock their supplies in anticipation of the fall and winter seasons. Manufacturers reported they did not have such an opportunity this year. In spring 2022, reports of supply constraints of analgesic products emerged in some areas in Canada. This led to a change in consumer buying patterns, and this was amplified as attention to the issue increased. While some other countries have reported signals of supply constraints (e.g., France, Germany, Ireland), none have seen the demand increase witnessed in Canada.

Q.3. Is this shortage having the same impact throughout Canada, or are there parts of the country where the problem is more acute?
A.3. Health Canada has been in regular communication with provincial and territorial officials since we first learned of supply constraints. This has allowed us to obtain some insight into how these shortages are being experienced in the various jurisdictions.
It is fair to say that the shortage is being experienced across the country, but to varying degrees. There are some jurisdictions that are particularly acute, Ontario being an example, and others where supplies are constrained but still available.

Q.4. There are media reports of amoxicillin shortages. What other pediatric drugs are in shortage?
A.4. For those less familiar, amoxicillin is an antibiotic that is available in multiple forms, such as liquid, tablet or powder for suspension. The liquid and powder for suspension forms are mostly used for treating children's infections in hospitals. A few weeks ago, Health Canada started to receive signals that one amoxicillin product was at risk of a shortage. Since that time, the situation has evolved. Today, I can report that five of the seven companies with oral suspensions of amoxicillin on the Canadian market are reporting a shortage.
Health Canada is engaged with all manufacturers and stakeholders across the supply chain to assess the supply situation in Canada. A multi-stakeholder call on November 10th brought together a wide array of stakeholders to discuss shortage mitigation measures. This includes assessing the supply of alternatives, looking at how to conserve existing supply and measures to enhance supply, including increased production of Canadian authorized product and foreign supply.
Based on information received to date, amoxicillin supply levels will remain constrained. Supply availability to pharmacies may be intermittently impacted as measures are taken to equitably distribute inventories. Health Canada will continue to lead shortage mitigation efforts and work with partners and stakeholders to implement all possible actions that can be taken to ensure sufficient supply and minimize any impact on patients in Canada.

Alternative products also remain available. Depending on the infection being treated, in most cases where amoxicillin is the first line treatment option, alternative options in children and adolescents include other classes of antibiotics, including penicillins, cephalosporins, macrolides and lincosamides. In some provinces and territories, depending on their scope of practice, pharmacists are able to make substitutions if the indication (i.e., what is being treated) is indicated on the prescription.
Caffeine citrate has also currently been reported to be in shortage. This drug is used to treat apnea in premature babies in hospitals. . A two to three week stock out is anticipated starting in late November. While other treatment alternatives exist, caffeine citrate remains the preferred option. Health Canada has approved importation of UK labelled product that is expected to arrive by the end of the week, and should fully bridge the supply gap until the expected resupply in early December.
Health Canada has also verified that the shortage of the ADHD drug Adderall being reported in the US is not expected to impact Canada.

Q.5. Isn't it clear from this and other shortages that there aren't enough manufacturers in Canada to meet our needs for important health products like these? What is the government doing to support more domestic manufacturing?
A.5. In July of last year, the federal government launched the Biomanufacturing and Life Sciences Strategy. As part of this strategy, the government will invest $2.2 billion over a seven-year period starting in 2021 to continue growing a strong and competitive biomanufacturing sector. This includes encouraging domestic manufacturing as a way to strengthen the domestic supply chain.
Health Canada is committed to working in partnership with the lead Department, Innovation, Science and Economic Development Canada, to ensure alignment of our work in this area. One area of focus for Health Canada in this space is regulatory efficiency for new industry participants.

Q.6: How does Health Canada manage shortages for other pediatric products that are important for health, like infant formula?
A.6. There is no higher priority than the health of our children. Health Canada uses all tools at its disposal to manage shortages of pediatric products, including infant formula. Regarding infant formula, Health Canada published an interim policy on March 10, 2022, to facilitate the importation of equivalent products from other countries. To date, the importation of 46 specialized products has been authorized pursuant to the interim policy and the list is updated regularly. The interim policy will be extended until December 31, 2023.
The shortage of formulas for infants with allergies has largely subsided and has been replaced by a limited but stable supply. It is anticipated that the current supply will continue meeting the needs of Canadian families for the coming months. In addition, the extension of the interim policy will help bolster the supply of regular infant formula to help mitigate a potential shortage of these types of formulas in early 2023.

Q.7. Why haven't manufacturers increased the supply of these important medicines in Canada?
A.7. Manufacturers, both large and small, are taking this shortage very seriously and have all ramped up efforts to increase supply. Some have introduced additional production lines, and are manufacturing at record levels. A number of them are prioritizing Canadian production due to the supply situation here.
Part of the challenge manufacturers are facing in increasing production is the ability to access the required materials. One large manufacturer noted that up-stream supply constraints are meaning that lead-times for securing needed production supplies are two to five times longer than normal.
In addition to increasing supply of Canadian approved product, Health Canada is also actively engaging companies on the possibility of accessing foreign supply. The Minister of Health announced yesterday

that a foreign supply of acetaminophen for retail and community pharmacies has been secured. Health Canada has been notified that the product is expected to arrive shortly.
Health Canada also recently approved the exceptional importation of infant and children's ibuprofen and acetaminophen to supply hospitals in Canada. The importation of ibuprofen has occurred, and distribution has begun.

Q.8. We have learned that larger retailers are imposing fines on manufacturers who are unable to meet their contractual obligations to supply these drugs. What impact will this have on the shortage, and what can the federal government do to help manufacturers avoid these penalties?
A.8. Health Canada is sympathetic to the financial and contractual challenges faced by suppliers of over-the-counter medications in their efforts to supply the Canadian market during a shortage. However, Health Canada has no authority to intervene in contractual disputes between members of the supply chain. The Department will continue to work with market authorization holders to understand the ongoing supply chain challenges and the associated risks to the health and safety of Canadians.

Q.9. What visibility does Health Canada have on the supply chain for these drugs? Other drugs? Why is it not better developed?
A.9. Health Canada treats every drug shortage signal seriously. One of the first steps the Department takes upon identifying or receiving a signal is to gather as much information as possible. The drug supply chain is global and complex for most drugs, complicating end-to-end supply chain visibility for Health Canada, and in some cases companies themselves.
Health Canada works with all of the players along the supply chain, as well as other international regulators, to obtain information and early signals regarding shortages so that steps can be taken quickly to mitigate the impact of shortages, and prevent them, where possible.

ACTIONS TAKEN BY HEALTH CANADA

Q.10. When can we expect to see the arrival of more product in Canada? When can parents expect to be able to go to their local pharmacy and find the products they need?
A.10. Mr. Chair, as I noted in my opening remarks, the Minister of Health announced yesterday that a foreign supply of acetaminophen for the retail and pharmacy level has been secured. Health Canada has been notified that the product is expected to arrive shortly.
The company will distribute foreign-authorized products to its customers across Canada. The Department will work with the company, distributors and retailers to promote fair distribution of supply across Canada and ensure important safety information is available in both official languages.
To further increase supply, Health Canada also recently approved the exceptional importation of infant and children's ibuprofen and acetaminophen to supply hospitals in Canada. The importation of ibuprofen has occurred, and distribution has begun.
Health Canada is continuing to work alongside suppliers to facilitate more product coming into Canada to fill the supply gap, and we know that companies large and small are ramping up production to record levels to meet the needs of Canadians.
If pressed on the quantity
Mr. Chair, The amount to be imported will increase supply available to consumers and will help address the immediate situation..
If pressed on when the product will be available
Health Canada is engaging with the company and distributors to gain a better insights into what the timelines might look like. Based on the information available to us, we are unable to provide an exact timeframe.

Q.11. What are some of the considerations regarding safety and risk that informs Health Canada's decision on exceptional importation?
A.11. Upon confirmation of the shortage in Canada, Health Canada conducts an assessment of an exceptional importation to ensure that the use of a foreign product would not pose unintended risks to Canadians.
Health Canada considers a number of aspects in the assessment to determine whether a foreign product is comparable to an existing Canadian product. For example,

- Whether the foreign product has specifications, such as directions for use which are comparable to an existing Canadian product, e.g., how much medication should a child be given to treat a symptom, how often medication can be repeated in a day;
- Whether the foreign product has sufficient information on its label such that Canadians can make informed decisions when purchasing a product and use it safely in a self-selection environment, e.g., the intended age group for the product – infants (less than 2 years old) versus children (2-12 years old);
- The ingredients found in the medication, e.g., active pharmaceutical ingredient and excipients such as binders and dyes;
- Whether the information of the foreign product is available in both official languages.

Health Canada evaluates the risk of exceptional importation and puts in place mitigation measures such that the benefits outweigh the risks for Canadians.

Q.12. When did the Health Canada receive proposals for the importation of foreign-labelled product, and how long did it take to approve these applications?
A.12. Mr. Chair, the exceptional importation of foreign-labelled product is one of the many tools used to manage drug shortages. When Health Canada first became aware of supply constraints for these products in April, it reached out to the suppliers and made it clear that regulatory flexibilities to permit the exceptional importation of foreign product were available, and could be used to increase the supply coming into Canada.
With the information available at that time, the mitigation approach adopted by suppliers was to ramp up production. The Department continued to engage multiple stakeholders regularly throughout the spring and summer and by late August, the unprecedented spike in demand made it clear that ramping up production would not be sufficient. Seeing this, the Department asked companies again to advance proposals for the importation and sale of foreign authorized supply.
The Department received proposals in October for the importation of ibuprofen for use in hospital settings, and acetaminophen destined for both hospitals and retail settings. Health Canada prioritized these reviews, and we provided approvals to import these products within days of receiving each one.
There are a number of things that Health Canada must consider upon receipt of an application for importation of a product that has been approved for use in another country, but not Canada. Health Canada conducts a comparative assessment between the Canadian and foreign product by reviewing the following:

- product labelling (e.g., conditions of use, approved indication in the country of authorization)
- product formulation (e.g,, ingredients used to make the product)
- clinical and quality information (e.g., information on chemistry and manufacturing processes).

The objective is to confirm that the product was produced to comparable standards of safety, quality and efficacy as products approved for use in Canada, Where there are differences between the Canadian and foreign product, Health Canada assesses the potential risks posed by those differences and how those risks may be mitigated.

Q.13. How are products being distributed to ensure equitable access across the country?

A.13. Manufacturers and distributors are collaborating to address the issue of equitable distribution of products where they are needed most.
Health Canada's role in this is a largely as a facilitator and the Department is actively working with manufacturers, distributors, retailers and others to promote fair distribution of supply across Canada and identify where the need is the greatest. Health Canada's engagement with all stakeholders allows the Department to bring the different players together and to share information among groups that may not otherwise have regular engagement. This allows for informed decision-making about allocation measures and equitable distribution.

Q.14. Why did you not compel companies months ago to ramp up supplies? Do you need this type of authority to make sure this type of situation does not happen again?
A.14. The decision to produce, market, and sell drugs in Canada are made by drug companies. Health Canada does not play a role in these decisions. The majority of drugs available in Canada are supplied by large multinational companies who supply the global market. Production schedules are established up to a year in advance, and pivoting to meet the needs of one particular drug may not be easy, though we have seen companies make efforts to do this in this case.
That said, production agility can also be a challenge. For example, lead times to ramp up supplies and the lack of availability of ingredients required to make a drug also present challenges. Health Canada works collaboratively with manufacturers to increase the drug supply and uses other levers such as the importation of foreign product to increase product availability.

Q.15. Why hasn't the federal government taken steps to buy these important medications from foreign suppliers to help deal with the shortage? Can this not be managed in the same way the government bought vaccines for COVID?
A.15. The federal government's involvement in the purchase and distribution of COVID-19 vaccines was a special case because those vaccines were approved for the Canadian market and could only be delivered in a clinical setting. This framework involved special agreements between the federal and provincial governments under which the provincial authorities were responsible for the distribution and administration of the vaccines. There were also contractual agreements put in place to supply the Canadian market.
Health Canada is working with manufacturers, importers and distributors to facilitate the importation of foreign-labelled product to resolve this shortage. One of the challenges is product availability. While other countries are not seeing the same shortage as in Canada, there are supply constraints that make surplus supplies scarce. Manufacturers have also indicated there is difficulty in accessing the raw materials necessary to make the products, with some lead times being two to five times longer. Health Canada will continue to work with suppliers to facilitate increased supply in Canada.

Q.16. The government set up a Critical Drug Reserve during the pandemic to help address drug shortages. Why isn't there a permanent reserve of the drugs Canadians need so that we can avoid situations like this?
A.16. Establishing a Critical Drug Reserve was a useful tool as part of the Government response to the pandemic. At the time, it was developed to help provinces and territories manage drug products determined or anticipated to be in shortage because of the COVID-19 pandemic. The focus was on key hospital-use drugs that were needed to treat patients who were critically ill with COVID-19.
The establishment of a drug reserve for the Canadian market involves multiple considerations. For example, there are currently more than 9,000 prescription drugs marketed in Canada in addition to non-prescription drugs, such as pediatric analgesics. Determining what drugs would constitute the reserve, what quantities would be required, and the cost associated with procurement, storing and rotating the

stock in the reserve to prevent the risk of losing drugs once they have expired would have to be determined.

Q.17. The Government has been told by many experts that Canada needs a critical drug list to better manage drug shortages. Why has no action been taken on this?
A.17. Before the pandemic, Health Canada had started to look at developing an essential medicines list. During the pandemic, the Department shifted its focus to prioritize drugs that were necessary to treat or prevent COVID-19, including 12 drugs that were held by the Critical Drug Reserve.
Now, there is an opportunity to explore how an essential medicines list could help with the prevention and alleviation of shortages. We can learn from other jurisdictions or organizations that have already developed similar lists.
In advancing a critical drug list, we need to be mindful of a number of challenges. First, there is no broadly accepted definition in Canada of what constitutes an essential or critical medicine. It is also important to note that there are over 9,000 prescription drugs in addition to over-the-counter drugs, and that a medicine that is considered essential in one setting may not be needed in another. As well, when identifying a medicine as essential or critical, we will have to take into account the vulnerability of a particular drug, which can impact its availability, such as those that have only a single supplier.
Notwithstanding these challenges, it is something the department is looking at.

Q.18. What actions are taken to ensure imported medicines have safety information available in both English and French?
A.18. Mr. Chair, there has been reports that bilingual labelling is preventing products from being imported into Canada. I want to assure committee members that this is not the case.
Bilingual labelling is as priority for Health Canada. Ensuring that Francophones living in Quebec, and the many who live in communities across Canada, have access to important safety information in French is something we take very seriously. In the case of this shortage, Health Canada has proactively engaged the Office of the Commissioner of Official Languages for guidance on approaches to making important product safety information available in both official languages.
To permit the safe use of the drug, Health Canada uses a number of approaches to contribute to ensuring that bilingual safety information reaches the end user or their caregiver. For example, this can take the form of:

- Distributing the product to hospitals where health care providers can counsel patients in their preferred language
- Keeping the product behind the counter in community pharmacies, allowing the pharmacist to counsel patients in their preferred language
- Placing the foreign product on retail shelves with bilingual labelling appended to the product or its packaging at the point of sale, such as through a QR code or printed documentation.

There is no 'one size fits all' solution and the implementation of one, or more of these approaches is determined on a case-by-case basis.

Q.19. Are there companies in Canada that are manufacturing these products for export? If so, have they been asked to supply the Canadian market first?
A.19. There are companies that manufacture pediatric analgesics in Canada for foreign markets. These are multinational companies with production sites in many countries, all of whom contribute to a global supply. Canadian companies can 'give' (export) some amount of what they produce to the global supply while at the same time 'taking' (importing) as they need.

In these scenarios, Canadian companies import as much if not more than they export. This model is beneficial to small markets such as Canada as it gives us access to more diverse range of products than would be the case if we relied only on domestic production.

Q.20. Is compounding one of the solutions to have more of these medications available for Canadians? Are there federal regulatory requirements that would make it difficult to see an increase in compounding?
A.20. Yes, compounding may be a solution used by pharmacists. Some pharmacists in Canada are already compounding liquid forms of acetaminophen or ibuprofen to increase supply of these medications. However, there may be variability in the approaches to compounding across the country, given the practice of pharmacy is regulated at the provincial or territorial level. It will also depend on whether the pharmacists have the raw materials required and capacity to make the product.
Health Canada has taken steps to remove federal barriers to compounding during this shortage by lifting the requirement for a prescription. The temporary measure to allow the sale of compounded acetaminophen or ibuprofen without a prescription will last until the shortage is resolved. Regulations on the safety and quality of these products continue to apply, such as the limits on quantity sold in a package or drug dosage.

Q.21. What are other regulators doing that we aren't to manage this shortage? What can we learn from their approach?
A.21. Through communication with other international regulators, we are aware that there are supply constraints being observed in many countries, including France, Germany and Ireland. However, demand for these products in other countries has remained relatively stable, and has not tracked the unprecedented demand we have seen in Canada. Global manufacturers with whom we have been working to mitigate the shortage have reinforced these observations.
Health Canada relies on similar regulatory tools and shortage mitigation approaches as other countries. As well, the Department leads a working group composed of a number of health regulators from countries around the world to discuss policy and regulatory approaches and to keep apprised of common challenges we are facing with the supply chain.

PARENTS AND CAREGIVERS

Q.22. You indicated that consumer demand has played a role in contributing to this shortage. Are you suggesting that parents and caregivers trying to buy the medication their children need are to blame for this shortage?
A.22. The demand is high, but this does not mean that parents and caregivers are to blame. There are many considerations influencing the demand and consumers behaviours. For example, the demand for various formats of non-prescription pediatric/infant and children's fever and pain reducing medicines has been high throughout the pandemic. It has grown more recently, which coincides with the lifting of public health measures and the return to school. There has also been an unexpected rise in the incidence of respiratory infections across Canada, outside of their normal season. Children's hospitals have been experiencing higher patient volumes than is expected at this time of the year with several hospitals exceeding their occupancy rate.
In addition, companies that market these products usually use the spring and summer periods to ramp up production to ensure adequate supply for the fall and winter seasons. This year not only did the demand for these drugs not decrease over the summer, but actually outpaced production, allowing no period for replenishment.

Q.23. What advice would you give to parents and caregivers who are struggling to help their children who are in need of these medications, but can't find them?
A.23. We recognize that this shortage can be a very stressful situation for parents and caregivers. Further guidance on alternative means to manage children's symptoms can be found on Health Canada's webpage. Where parents and caregivers are not able to access these medications, all efforts should be made to keep their child as comfortable as possible, for example using cold compresses and have them drink plenty of fluids. Warm baths can help manage pain.
Additionally, a pharmacist can help parents and caregivers choose the right product, based on availability. If a caregiver is concerned about their child's symptoms, they should contact their doctor or a qualified health care professional.
I would also like to mention that The Canadian Pediatric Society and the Canadian Pharmacists' Association have also provided advice to parents and caregivers on this on their respective websites.

Q.24. How has Health Canada / the government been communicating with Canadians to ensure that they are kept up-to-date on the shortage, and have the best information available about how to care for their children in the absence of these medications?
A.24. Health Canada has taken a number of steps to ensure that Canadians have the information they need to care for their children. The Department has issued a public risk communication notice that provides guidance to parents and caregivers and has also developed resources for parents that are available on the Health Canada website. On October 26, 2022, Health Canada published a landing page that will be the main hub for communicating any new and relevant information on the children's analgesic shortage. It will also include safety messaging consistent with the previously published advisory. A robust social media plan will commence later this week to raise awareness of the landing page, reiterate our safety messaging, as well as highlight the work we are doing, and drive inquiries to HC's landing page. Social media communications with run through December 2022.
Department officials have asked the media to provide additional details on the shortage to ensure parents have the best and most up-to-date information they need. More information will be released as the situation develops.
Health Canada will also continue to engage manufacturers, distributors, retailers, children's hospitals, health care professionals and patient associations to ensure they are equally equipped to provide information to support Canadian patients, children, parents and caregivers.

Q.25. Does Health Canada have any knowledge about the potential severity of what kind of flu, cold and cough season we might expect this year?
A.25. Our colleagues from the Public Health Agency informed us that the influenza (flu) season in Canada usually occurs from mid-November to mid-May. Based on trends observed near the end of October, things are pointing towards the start of the flu season in the coming weeks, in line with typical pre-pandemic timing.
We are aware of increased pressure on hospitals in some areas due to increased rates of respiratory syncytial virus (RSV) in children. RSV activity in Canada is currently low, based on surveillance data from the week ending October 22, 2022, but is above expected levels for this time of year and is increasing. Similar to what we are seeing with flu, this is expected as we head into the winter with relatively relaxed public health measures compared to earlier times during the COVID-19 pandemic.
While expected, it is of course still concerning, and is one of the reasons we continue to ask Canadians to maintain up-to-date vaccinations. With respect to flu, we ask that all Canadians over the age of six months get their flu shot. The flu shot is the most effective way to prevent the flu and flu-related complications, such as pneumonia, and protect individual health, families, communities and those at higher risk.

As RSV does not have a vaccine, we also encourage everybody to wear masks in close indoor settings, practice other public health measures such as frequent hand washing, and stay home when sick.
For COVID-19, vaccination, including getting a mRNA booster dose as eligible, continues to be important in combination with timed and targeted community-based and individual public health measures, for slowing COVID-19 infection rates and helping to reduce the impact on healthcare capacity. It is important that people in Canada do not let their guard down.

GENERAL ON DRUG SHORTAGES IN CANADA

Q.26. How much of a problem are drug shortages in Canada?
A.26. Drug shortages are a global problem, with countries around the world experiencing increased frequency and duration of shortages. Since 2017, 10-15% of drugs marketed in Canada have been in shortage at any given time, and almost half (44%) of drugs marketed in Canada have experienced at least one shortage.
Shortages are also being reported with less advance notice, and many can last one to two years before being resolved.
It is important to put these numbers into context. The majority of shortages reported have no or limited impact on Canadians. Whether it be that a problem a company had been experiencing has been resolved, or there are alternatives available, for example, most shortages do not have an impact at a patient level, and fewer still have the broad impact that this shortage is having.
Health Canada is involved in the management of approximately 20-25 shortages per year that are deemed national or critical in nature. This number is still of concern, and all efforts are being made to continually reduce this, but it is important to consider this when looking at the raw numbers.
In offering this context, I do not want to leave the impression that any shortage is something to be taken with anything less than the highest degree of seriousness. However, the context with these numbers is important.

Q.27. How vulnerable is Canada to drug shortages?
A.27. Drug shortages are a growing global problem, especially for smaller markets like Canada, which represents approximately 2% of global sales.
Canada is also a country that is reliant on imports. Sixty eight percent of the prescription drugs consumed in Canada arrive here in their final dosage form. Many of these imports are from single suppliers, making Canada particularly vulnerable to unforeseen events that disrupt manufacturing and distribution.
That said Health Canada has managed these supply constraints successfully for the past decade.

Q.28. What are the causes of drug shortages?
A.28. Drug shortages have many causes. One of the key drivers is manufacturing disruptions. Other factors could include difficulties accessing raw materials or business decisions regarding the continued supply of smaller volume drugs.
Natural disasters, such as Hurricane Maria in Puerto Rico in 2017, can also disrupt drug manufacturing and contribute to shortages.
The COVID-19 pandemic has contributed to drug shortages by disrupting the availability of drugs and due to the growing the demand for certain medicines used to treat and manage COVID-19 infections.

Q.29. What impacts are drug shortages having on Canadians?
A.29. The impact of drug shortages vary, but can be significant. We are seeing right now the impact it is having on children, as well as parents, caregivers and health care providers. When drugs are in shortage,

surgeries may need to be delayed or cancelled. Drugs may need to be rationed to the highest risk patients leaving others to find alternatives or potentially go without.
Shortages also impact health professionals, such as pharmacists, who have less time to provide guidance to patients because they are busy tracking down scarce supply or looking for alternatives.
Drug shortages affect all gender and sociodemographic groups in Canada and can have serious impacts on the healthcare system causing harm to Canadians.
Already vulnerable populations, such as children, older adults, and Indigenous populations may be disproportionately affected by a drug shortage.
Shortages are a complex global issue and are not unique to Canada.

Q.30. What kinds of drugs are most likely to be in shortage?
A.30. All types of drugs can experience shortages – cancer drugs, anti-depressants, blood pressure drugs, antibiotics, and others, including non-prescription infant and children's analgesics.

Q.31. What resources does HC have to manage drug shortages? Do you need to more capacity to do a better job?
A.31. Health Canada has had dedicated drug shortage management staff in place for the better part of a decade and has been methodically building relationships with stakeholders to collaboratively respond to drug shortages and help mitigate their effects throughout that time. Drug shortages have been a Minister of Health mandate priority since 2019. In 2020, the Department received additional funding to create a dedicated division for drug shortages. Additional team members were brought on board with pandemic funding to bolster the division's capacity to respond to drug shortage challenges brought on by COVID-19.
During the pandemic, the Department implemented new regulatory tools and programs to support the management of shortages and help Canadians access the drugs they need. The reason we were able to quickly set up new regulatory tools and approaches during that challenging time, was the extensive experience gained and analysis done in the years before the pandemic.
Along with our ongoing work to continually improve upstream supply foresight in the drug shortages space, one major lesson of the pandemic is that Canada is also vulnerable to shortages of key medical devices. We are building our capacity to identify early shortage signals and to respond to medical device shortages now.

PEDIATRIC PAIN MEDICINES APPROVAL PROCESS IN CANADA

Q.32. What are acetaminophen and ibuprofen?
A.32. Acetaminophen and ibuprofen are found in many prescription and over-the-counter medications for children and are used to reduce fever and relieve pain due to common illnesses like cold and flu.

- These drugs are available for use in infants (up to 2 years of age) and children (from 2 to 12 years of age) in forms that are easy to take, such as liquids (solution, suspension), chewable tablets and suppositories.
- There is a standard dosage for infants and another for children, each established specific to the drug ingredient.

Q.33. How are pediatric pain medicines approved in Canada?
A.33. For any prescription drug or non-prescription drug, when a company decides that it would like to market a drug in Canada, it files an application with Health Canada.

Health Canada scientists are responsible for reviewing these applications to assess the safety, efficacy and quality of the proposed drug, as necessary. Throughout the process, the safety and well-being of Canadians is the paramount concern.
If, at the completion of the review, the conclusion is that the requirements of the Food and Drug Regulations have been met, the benefits outweigh the risks, and the risks can be mitigated (for example, through labelling), authorization for the drug is granted, which permits the company to market the drug in Canada.

Q.34. How long does the non-prescription drug review process take?
A.34. Health Canada has set internationally competitive performance targets for its conduct of reviews. The length of time for review depends on the product being submitted, and may further be influenced by the complexity and quality of the submission.
The review of a non-prescription drug pain medicine typically takes between 60 days (e.g., when only a label review is required) and up to 345 days for applications requiring a more in-depth review.

Q.35. What does Health Canada evaluate in a non-prescription drug review process?
A.35. Health Canada assesses the safety, efficacy and quality of a proposed non-prescription drug. Depending on the information already known about the non-prescription drug, scientific evidence to support the safety, efficacy, and quality may be required from a company.
Based on the information made available to Health Canada, the Department provides recommended labelling information for the company to use to create a label for their products. For all non-prescription drugs, Health Canada conducts a detailed review of each product label.
Health Canada also ensures that the label information is easy to access and legible in plain language in both official languages. The Department recently completed the implementation of the amendments to the Food and Drug Regulations, commonly referred to as the Plain Language Labelling Regulations, which was launched in 2017. These regulations also introduced a Drug Facts Table for non-prescription drugs, similar to how information about nutrition appears on foods in Canada, requiring companies to submit their drug labels to Health Canada for evaluation prior to marketing

SHORTAGE OF PEDIATRIC ANALGESICS

ISSUE

- Health Canada is aware that supply of many formats of non-prescription pediatric acetaminophen and ibuprofen products remains limited in retail locations and hospitals in various parts of the country, causing significant concerns for people in Canada.

KEY FACTS

- Suppliers of pediatric acetaminophen and ibuprofen products are experiencing supply constraints and intermittent stock-outs, due to unprecedented and unexpected demand levels. It is unknown when normal supply levels will be restored.
- Supply of these products has been constrained since earlier this year, becoming more acute over the summer and fall.
- Health Canada continues to take action to address the shortage by working collaboratively with key stakeholders, including industry and health care system partners, to implement shortage mitigation measures to increase the supply of these important products, and monitor their supply across the country.

KEY MESSAGES

- Our Government shares the concerns of many parents and caregivers who may not be able to easily access these important medications to treat their children.
- To increase the supply of these products on store shelves, Health Canada has now approved the exceptional importation of acetaminophen from the global market that will be available to consumers in retail and community pharmacy locations in the coming weeks.
- This supply is in addition to the recently approved exceptional importation of ibuprofen from the U.S. and acetaminophen from Australia, to supply hospitals in Canada. Importation of ibuprofen has occurred, and distribution to hospitals has started. The importation of acetaminophen for hospitals is also expected to start soon.
- All options continue to be on the table to address this situation.
- The Department will continue to work with multiple players along the supply chain, right to patient groups, hospitals and pharmacies, to take any and all additional measures necessary to ensure access to needed supply of these important medications for our children.

IF PRESSED ON [WHY THE SHORTAGE ISN'T YET RESOLVED?]

- My Department is actively working with manufacturers and distributors of pediatric acetaminophen and ibuprofen products, the provinces and territories, children's hospitals, the Canadian Pediatric Society, the Canadian Pharmacists Association, and Food, Health and Consumer Products of Canada to help identify immediate solutions to increase the supply of these medications.
- In response to unprecedented demand, manufacturers that supply the Canadian market have increased production, some producing at record levels, and they are exploring options to further increase production and expedite re-supply where product is needed most.
- In addition to the products already authorized for exceptional importation, we will continue to work with suppliers to bring in additional imported products to increase the supply in Canada.
- I have spoken directly to the suppliers of these medications and hosted a roundtable with multiple stakeholders who are playing a role to resolve this situation.
- All options continue to be on the table.

IF PRESSED ON [WHY IS THIS SO PRONOUNCED IN CANADA? ARE OTHER COUNTRIES EXPERIENCING THE SAME SHORTAGE?]

- Other countries have reported signals of supply constraints, but none are currently experiencing shortages like those in the Canadian market.
- In Canada, demand for analgesics was on the rise into the summer months, which is the period manufacturers normally use to restock analgesics for the fall and winter seasons.
- Combined with the increased attention on the issue in Canada in mid-August, it has resulted in a drastic and unprecedented spike in demand.

IF PRESSED ON [WHY DIDN'T HEALTH CANADA PERMIT IMPORTATION OF FOREIGN PRODUCTS EARLIER?]

- Exceptional importation of foreign authorized drugs is considered when the Canadian drug is at risk, or in critical shortage. This measure is always available for any shortage and was offered to suppliers when we began to hear about supply constraints.
- When demand spiked to unprecedented levels in August, my Department intensified ongoing efforts with industry and other stakeholders to explore all possible solutions. This included options to further increase supply in the Canadian market, such as ramping up production and accessing foreign supply.
- In addition to importing products from the U.S and Australia to supply hospitals in Canada, we are continuing to work with suppliers to bring in additional foreign products to increase the supply in Canada.
- On this, Health Canada has now authorized additional acetaminophen from the global market which is expected to be available to consumers in retail and community pharmacy locations in the coming weeks.

IF PRESSED ON [WHY WILL IT TAKE SO LONG TO GET THE EXCEPTIONALLY IMPORTED ACETAMINOPHEN TO STORE SHELVES?]

- Each proposal received from a company to import a foreign authorized product undergoes careful review by Health Canada to confirm that the product was manufactured according to the same high quality standards the people of Canada expect.
- After careful review, the Department has approved the exceptional importation of acetaminophen from the global market that will be available to consumers in retail and community pharmacy locations in the coming weeks.
- Health Canada has prioritized this with suppliers so that it reaches retail and community pharmacy shelves as quickly as possible.

BACKGROUND

On August 16, 2022, media reported that the SickKids Hospital in Toronto was warning parents and caregivers that, due to nationwide shortages, a prescription would be required for liquid acetaminophen and ibuprofen products, and that a pharmacist would provide the medication to them.

CBC News and Sick Kids issued corrective statements clarifying that prescriptions for these products were not required. However, this media attention triggered a further spike in demand for these products nationally, following reports of intermittent supply constraints that had been previously reported. Companies have indicated they have ramped up production beyond normal historical demand levels but that the current demand is outpacing production.

On August 30, the Canadian Paediatric Society issued guidance directed to caregivers and parents on the use of these products.

Health Canada is actively working with the manufacturers and all stakeholders across the supply chain to identify mitigation measures to increase supply and meet demand for these products, including reviewing proposals that may require regulatory flexibility or consideration of foreign supply.

The Department has prioritized information-sharing with provinces and territories via various FPT tables. The Department has also involved PTs in broader multi-stakeholder discussions to identify solutions as quickly as possible.

Health Canada has approved the importation of foreign supply of children's ibuprofen and infant's acetaminophen for use in hospitals. Further to this, on November 4, 2022, the Department approved a proposal from Johnson & Johnson for the exceptional importation of U.S.-labelled acetaminophen that will help to fill the current supply gap in retail and community pharmacies. On November 10, 2022, the Department approved the company's proposed distribution and risk communication plan for the product, including bilingual safety information and measures to enhance the supply of bilingually labelled product to Quebec and to French language minority communities in Canada. The importation and distribution of this supply is anticipated to begin the week of November 14th, with product expected on retail shelves soon after (exact dates to be confirmed). Health Canada continues to assess additional proposals for exceptional importation to further supplement this increased supply.

Health Canada is prioritizing public communication by providing information and advice to Canadians. This was done via a Departmental Statement, and Public Advisory issued on October 7, 2022. As well a webpage was launch on October 26, 2022 dedicated to the analgesic shortage.

In addition to discussions with suppliers, on November 2, 2022, the Honourable Jean-Yves Duclos, Minister of Health, hosted a roundtable discussion on the pediatric and children's analgesics shortage in Canada. In attendance were 18 external participants representing manufacturers, distributors, pharmacists, children's hospitals, and pediatricians. The objective of the roundtable was to highlight actions to date and provide participants with an opportunity to share perspectives on the shortage, measures taken, and ongoing challenges, while underscoring the need for all stakeholders to continue taking measures to end this shortage as soon as possible.

REGULATING PEDIATRIC MEDICINES

ISSUE

- Access to medicines for children in Canada has been a long-standing issue, and is a global challenge. Health Canada is working with national and international partners to improve both access to and the regulation of medicines for children.

KEY FACTS

- Health Canada is responsible for regulating all therapeutic products, including medicines for children.
- Health Canada has mechanisms in place to prioritize the review of medicines addressing unmet needs for children.
- During the pandemic, Health Canada expedited the review of several vaccines and treatments for COVID-19, some of them for use in children.
- Providing access to drugs for children remains a priority for Health Canada. Currently, the majority of drugs prescribed to children are used off-label, meaning outside of the approved use of the drug.
- Health Canada has an action plan in place to increase access to needed drugs, including appropriate formulations that were specifically developed and studied in children.

KEY MESSAGES

Access to Drugs for Children

- Health Canada prioritizes the review of drugs addressing unmet needs, including drugs for children, with a target review time of 180 days compared to the regular timeframe of 300 days.
- In 2020 and 2021, Health Canada authorized 17 new drugs for use in children in 2020 and 10 additional new drugs in 2021. Health Canada recognizes that more needs to be done to increase access to safe and effective medicines for children, and is working with key stakeholders to make this happen.
- In June 2021, Health Canada launched a Pediatric Drug Action Plan, with the ultimate vision that children in Canada have access to the medicines they need in age-appropriate formulations. A number of policy and regulatory actions are currently being implemented.

Rare Diseases and Children

- Rare diseases are life-threatening, seriously debilitating and sometimes chronic in nature. Approximately 50% of people affected by rare diseases are children, and 70% of rare diseases with a genetic basis start in childhood.
- Canada's national strategy for drugs for rare diseases, led by Health Canada, which will be launched later this year, would help to ensure patients have improved access to effective rare disease drugs, leading to better health outcomes.

IF PRESSED ON ACCESS TO MEDICINES FOR CHILDREN …

- Health Canada is committed to increasing access to drugs for children by implementing regulatory measures similar to those that exist in other jurisdictions. For example, Health Canada is looking to compel pharmaceutical companies to conduct pediatric studies on medicines that are expected to be used in pediatric populations, and to submit those data to Health Canada for approval. A pilot to implement the pediatric regulation in late 2023 is currently under development.
- Health Canada is also working closely with the Canadian pediatric medical community to develop a draft list of priority medicines to include in Canada's first National Priority List of Pediatric

Drugs. , Once finalized, this list will help to notify industry stakeholders of the areas of urgent need for pediatric patients in Canada and will help to encourage increased drug submissions and development.

BACKGROUND

Health Canada Initiatives to Increase Overall Access to Drugs for Children:

- Access to medicines for children in Canada has been a long-standing challenge. Up to 80% of drugs prescribed to children in Canada is done off-label (i.e. without safety or efficacy data in the pediatric population) because pharmaceutical developers tend not to focus their research on children.

- To address this gap, the Department has developed a Pediatric Drug Action Plan (PDAP) with the ultimate vision that children and youth (0-17 years) in Canada have access to the medicines they need in age appropriate formulations. There are a number of specific actions within the plan that are tied to the its 3 main goals:
  - Increasing the development of pediatric medicines and formulations;
  - Improving access to pediatric medicines and formulations; and
  - Providing more information to Canadians.

- Pediatric stakeholders across the country (i.e., academics, clinicians, patient organizations, Health Technology Assessment organizations and industry) were consulted regularly throughout the development of the PDAP, and continue to be engaged through early implementation. The pediatric stakeholder community are broadly supportive of the goals and focus areas of the PDAP.

- Implementation of various activities within the PDAP has begun, and will continue over the next 5 or more years. Current priorities include:
  - Developing a "pediatric regulation" (pediatric provisions within the Food and Drug Regulations) that will bring Health Canada into alignment with other jurisdictions in requiring pediatric studies to be completed and submitted when it is expected that a drug will be used in the pediatric population;
  - Assessing the impact of our current pediatric incentive (see below), and exploring other incentive models to bring more pediatric products to Canada; and
  - Working with pediatricians across Canada to develop a National Priority List of Pediatric Drugs that are needed for the pediatric population. Health Canada will identify the regulatory pathways and flexibilities that can be offered to bring these products to Canada.

- Health Canada is looking to include the new "pediatric regulation" in the Food and Drug Regulations as part of its Agile Licensing Framework expected to move forward in 2024-2025. These new pediatric provisions will be tested via a policy pilot scheduled for launch in 2023.

- Current Pediatric Incentive: Under the current regulations, all manufacturers of innovative drugs are provided with a guaranteed minimum period of eight years of market exclusivity. If a sponsor provides clinical trial data that increases the knowledge about the use of the drug in pediatric populations, regardless of whether the data results in a pediatric indication, an additional six months may be added to this period of market exclusivity if the data is found to be acceptable by Health Canada. The sponsor may submit this information at any point during the first five years of the eight year period of market exclusivity in order to obtain the six month extension.

- National Priority List of Pediatric Drugs (NPLPD): The purpose of the list will be to highlight the pediatric therapies most urgently needed in Canada, and to work with industry stakeholders to support the submission and approval of these products. The NPLPD will be developed by Health Canada based on the expert advice from the pediatric medical community.
- Because improving access to medicines for pediatric populations is a global and multi-faceted issue, in order to address the challenges and barriers, Health Canada will work across the health and other government departments, and with our external national and global partners, on key initiatives. This collaborative approach will take time, but is already underway through, for example:
  - Regulatory Cooperation Forum: the European Medicines Agency and Health Canada are working together on a pediatric workplan that aims to align regulatory approaches to pediatric medicines in both jurisdictions
  - World Health Organization – Paediatric Regulatory Network: brings together regulators from across the world to address global issues of access to medicines for children. Health Canada is the co-chair of this network.

DRUGS FOR RARE DISEASES

- Patients with rare diseases generally have few treatment options, resulting in unmet clinical need. Accordingly, treatments are in high demand and can command high prices. The pharmaceutical treatments for rare diseases are often referred to as orphan drugs, or expensive drugs for rare diseases, or drugs for rare diseases.
- High prices are often attributed to factors such as the high cost of research, limited number of patients, small market size, and lack of competitors.
- The Government of Canada is working with provinces and territories as an active member of the pan-Canadian Pharmaceutical Alliance (pCPA) to combine the governments' collective buying power to negotiate lower prices on brand name drugs for all public plans, including drugs for rare diseases.
- Budget 2019 proposed to invest up to $1 billion over two years, starting in 2022-2023, with up to $500 million per year ongoing, to help Canadians with rare diseases access the drugs they need. We are working with provinces, territories and other partners willing to move forward to develop a national strategy for drugs for rare diseases to be launched in 2022.

SPECIFIC CHALLENGES FOR CHILDREN WITH RARE DISEASES

- The four main challenges that are exacerbated for Canadian children with rare diseases and their families are: (1) the inadequate receipt of pediatric data, particularly in comparison to counterparts in the US and Europe; (2) barriers to pediatric clinical trials; (3) economic challenges associated with developing, marketing, and maintaining a stable pediatric drug supply; and (4) current widespread use of off-label medications in children.
- Economic, ethical, regulatory, and infrastructure considerations associated with the conduct of child health research have limited the numbers of clinical trials conducted with children. There are several challenges specific to conducting clinical trials with a pediatric population with rare conditions that have contributed to current gaps in the evidence base on medicines for children. These challenges include the difficulty to obtain a sufficient sample size to design and execute a well-powered clinical trial, and the lack of special methodological and analytic expertise required to conduct innovative and adaptive study types.
- Despite these challenges, there is growing recognition of the undesired consequences of the vast gap in knowledge, such as a lack of information to guide dosing, inappropriate formulations, less than optimal clinical and patient-oriented outcomes, and issues related to transitioning into adulthood.

HEALTH PRODUCT SHORTAGES

ISSUE

- Health product shortages pose a risk to the health of Canadians. The COVID-19 pandemic further exposed vulnerabilities in the health product supply chain that impacted supplies of products required to treat patients with COVID-19 and other health conditions.
- The need for vigilance in maintaining the national health product supply continues. Health Canada is continuing its surveillance activities and engagement with provinces and territories, key supply chain players and patient groups to mitigate impacts and move towards prevention of shortages where possible.

KEY FACTS

- Canada is a small market that relies heavily on imported products, making it vulnerable to shortages. During the pandemic, global supply challenges and unprecedented demand further contributed to shortages in Canada.
- Lessons learned from the pandemic informed the development of new regulations that provide new tools to address health product shortages.
- As of November 1, 2022, 61 drug shortages were de-escalated from critical status, out of a total of 83 that were deemed in critical shortage since the onset of the pandemic.
- As of November 1, 2022, 321 of the 439 medical device shortages reported through the mandatory framework are now resolved.

KEY MESSAGES

- Ensuring that Canadians have access to needed health products is a top priority for this Government.
- Health product supply disruptions are a complex global challenge. I share the concern of Canadians when important health products we rely on are in shortage and understand the stress it can create for patients and health care professionals.
- You can be assured that the Government of Canada will continue to do everything within its power to ensure people in Canada have access to the health products they need.
- In 2021, the Government put in place new regulations that provide tools to help prevent and alleviate health product shortages to safeguard the supply.
- Resolving shortages is a multi-stakeholder responsibility. The Government continues to work with provinces and territories, industry, healthcare and patient groups, as well as international partners to closely monitor the supply of health products, as we work collectively to take necessary actions to help prevent and minimize the impact of shortages.

IF PRESSED ON [WHAT TOOLS DOES THE GOVERNMENT HAVE AVAILABLE?]

- The regulations allow for the exceptional importation of drugs and medical devices to address shortages, or those that may be anticipated.
- They also include a requirement for manufacturers and importers of specified medical devices to report shortages to the Department to help monitor the market, building on a similar reporting requirement for drugs, introduced in 2017.
- In order to prevent the exacerbation of a shortage, Health Canada also put in place a prohibition to prevent the distribution of certain drugs intended for the Canadian market for use outside of Canada.

BACKGROUND

Shortages in Canada

Health product shortages are an increasingly common, global issue. Canada is particularly vulnerable to shortages due to its small market share and reliance on imported products. 68% of Canadian drugs are imported from outside of Canada and 83% of activities related to drug production (e.g., manufacturing, packaging, labeling) are performed outside of Canada. Similarly, the majority of medical devices on the Canadian market are imported. Further, Canada holds only 2% of the global market share for drug sales and 1.8% of the global market share for medical devices.

Health Canada's Role

Health product shortages can have a significant impact on patients and health care professionals.

Addressing the complex issue of health product shortages is a multi-stakeholder responsibility requiring federal leadership and collaborative action from provinces and territories, manufacturers, distributors, and practitioners. When national shortages occur, Health Canada works with provinces and territories and stakeholders across the supply chain to identify mitigation strategies and to explore access to alternative products available in other jurisdictions, which may require regulatory measures.

Several factors are taken into account to determine both the potential impact of a shortage of health products and the actions required by Health Canada. Factors such as whether the shortage is national in scope, whether alternative supplies are available and whether the product is considered medically necessary are all considered in determining the potential impact.

New tools to address shortages

The pandemic has had major impacts on drugs and medical devices in Canada and globally. The number of national/critical shortages increased significantly throughout the pandemic. As well, secondary effects from the pandemic are expected to persist in the medium to long term, such as fluctuating demand, supply chain challenges and healthcare system recovery.

The department built on time-limited regulatory instruments (Interim Orders) introduced early in the pandemic to develop permanent regulatory tools to help address these challenges. New authorities were added in the Food and Drug Regulations and the Medical Devices Regulations, which allow the Minister to:

- Permit the exceptional importation of drugs and medical devices to address a shortage or an anticipated shortage. Imported products in this case do not need to fully meet Canadian regulatory requirements but must be manufactured to comparable quality standards.
- Require manufacturers and importers of specified medical devices to report shortages and discontinuances that could lead to a shortage.
- If required, request that drug establishment licence holders and medical device manufacturers, importers, and distributors provide information needed to assess, prevent, or alleviate a shortage.

The regulations also respond to risks posed by bulk importation frameworks, such as the one established by the United States. A prohibition was put in place on drug establishment licence holders from distributing certain drugs intended for the Canadian market for use outside of Canada if that distribution could cause or exacerbate a shortage. This serves to ensure that bulk importation frameworks, do not cause or exacerbate a drug shortage in Canada.

With these tools in place, Health Canada is now better equipped to help address shortages of health products.

Engagement with Provinces and Territories in Managing Health Product Shortages
Over the last number of years, capacity has been built up across governments, leading to a more coordinated and effective approach to mitigate the impacts of shortages.

Health Canada has strengthened existing mechanisms to manage health product shortages, and has leveraged existing FPT infrastructure and increased cooperation with multiple partners to identify shortage signals earlier, especially for critical products required for COVID-19. For example, through FPT collaboration, a process for the allocation of imported critical drugs is now in place to facilitate the distribution of critical products. The process allows companies the opportunity to work with Health Canada and provincial and territorial governments in allocating supply where it is needed most. This has also been effective in managing limited supplies of therapies being used to treat COVID-19 (e.g., Tocilizumab, Remdesivir) as well as drugs that are in high global demand upon authorization by Health Canada (e.g., Paxlovid).

Working with provinces and territories, Health Canada established a COVID-19 Critical Drug Reserve in 2020 that complemented other drug shortage mitigation efforts. It included 12 drugs used to support patients with COVID-19 that were in high demand or in shortage, including sedatives, pain relievers, antibiotics, muscle relaxants, and inhalers. The Critical Drug Reserve served as a backstop for Canada's existing supply, complemented the current drug shortage management systems, and mitigated critical drug shortages, which relieved pressures on provincial and territorial health care systems through several pandemic waves. This pandemic initiative ended on June 30, 2022.

During the pandemic, Health Canada began to ramp up its work with FPT and supply chain partners to address medical device shortages. Work continues to formalize FPT collaboration and strengthen relationships in the medical devices sector, building on Health Canada's experience in leading responses to drug shortages.

Health Canada officials continue to work with the provinces and territories, international regulators and industry stakeholders to closely monitor Canada's health product supply so that timely action can be taken to ensure Canadians have access to the health products they need.

INFANT FORMULA SHORTAGE

ISSUE

- The Abbott manufacturing facility in Sturgis, Michigan was closed on February 17 due to possible bacterial contamination and has been gradually resuming production since July 1. The supply of specialized formulas, including dietary products for people with rare metabolic diseases and formulas for infants with food allergies, will remain limited until this facility returns to its full production capacity. In addition, the supply of regular infant formula seems increasingly affected as the situation persists.

KEY FACTS

- The Abbott manufacturing plant in Sturgis, Michigan is an important supplier and its closure in February affected the availability of infant formula in Canada and elsewhere.
- In Canada, this resulted in a shortage of specialized products for people with rare metabolic diseases and for infants with food allergies.
- Health Canada published an interim policy on March 10 to facilitate the importation of equivalent products from other countries. To date, the importation of 46 specialized products has been authorized pursuant to the interim policy and the list is updated regularly. The interim policy is in effect until December 30, 2022 and will be extended until December 31, 2023.
- Health Canada has mitigated the impact of the shortage by permitting the importation of products from countries with similar regulatory requirements, convening regular stakeholder (provinces, territories, manufacturers, distributors, health professionals, non-governmental organizations) meetings, developing communication materials for the public and for the healthcare community, monitoring supply, and assisting with equitable distribution.
- The supply of formulas for infants with allergies reached a low point in June. Since that time the shortage has largely subsided and is now replaced by a limited but stable supply.
- Since the spring, formulas for infants with allergies could only be accessed at the pharmacy counter to help manage the supply. Certain manufacturers have decided to return some of their products to shelves at pharmacies and retailers as of late October. It is anticipated that the current supply will continue meeting the needs of Canadian families for the coming months.
- Metabolic products are not available to the general public. Their supply is very limited and is managed by specialized distributors in close collaboration with healthcare professionals caring for patients with metabolic disorders.
- Abbott's Sturgis plant reopened on July 1. Production will gradually increase over the coming months, initially prioritizing specialized products.
- Health Canada has been receiving signals in October that the supply of regular infant formula is now more sensitive than it was earlier in the year. The extension of the interim policy will help bolster the supply of regular infant formula to help mitigate a potential shortage of these types of formulas in early 2023.

KEY MESSAGES

- Our government has taken necessary actions to address the shortage.
- Health Canada published an interim policy to facilitate the temporary importation of products to mitigate the shortage.
- Health Canada has issued a range of relevant information to the public, healthcare professionals and pharmacists to help them navigate the shortage.
- Health Canada engaged with manufacturers on an ongoing basis. Although limited, the supply should remain stable for the coming months.

- Health Canada will continue collaborating with various stakeholders to manage the limited supply until the situation has fully stabilized.

IF PRESSED ON THE DURATION OF THE SHORTAGE…

- Abbott's Sturgis plant had resumed production on June 4. However, operations were halted again on June 15 after severe thunderstorms caused flooding in the plant. The plant reopened on July 1. It is estimated that it will take several months before the plant is back to its regular production capacity.
- The Department is working with manufacturers to maintain a continued supply of specialized products for Canadian families over the coming months. Health Canada will continue coordinating the supply with manufacturers and our provincial and territorial counterparts until the situation has fully stabilized.

IF PRESSED ON ADDITIONAL ACTIONS THE GOVERNMENT SHOULD TAKE…

- Given the serious nature of this situation, we have been working closely with stakeholders to proactively resolve barriers that could compromise access to products as the situation evolves.

BACKGROUND

Recall of Abbott products and plant closure

A recall of certain Abbott brand powdered infant formula was issued on February 17, 2022, after cases of infant illness caused by Cronobacter and Salmonella bacteria were reported to the U.S. Food and Drug Administration (FDA) between September 2021 and January 2022, including one fatal case associate with Cronobacter sakazakii. Another fatal case linked to this bacterium was reported about a week after the recall. No cases of illness linked to the recalled formulas were reported in Canada.

- Cronobacter is not commonly linked to human disease. In rare instances, it is associated with severe intestinal infection (necrotizing enterocolitis) and blood poisoning (septicemia), especially in newborns.
- Salmonella usually causes short-term symptoms such as fever, headache, vomiting, nausea, abdominal pain and diarrhea. However, young children, pregnant women, the elderly and people with weakened immune systems can develop more severe and sometimes fatal symptoms.

Recalled products were from the Abbott manufacturing facility in Sturgis, Michigan. Although five strains of Cronobacter were found in the production plant, none of them was an exact match for the patient samples.

The recall includes regular and specialized infant formulas including metabolic and hypoallergenic products. Only powdered formulas were affected by the recall. Liquid ready-to-feed formulas and liquid concentrate have not been recalled and are safe.

The Sturgis facility in Michigan is a key supplier for many countries including the United States (US) and Canada. Most of its production was destined for the US market and the rest to more than 30 countries. Its closure is creating a global shortage of these products, although the North American market appears to be most affected. Other manufacturers have increased their production capacity, but it is not possible to fully compensate the volume usually produced at the Abbott Sturgis facility. There are currently no facilities manufacturing infant formula in Canada.

Abbott's Sturgis plant had reopened on June 4 but closed again on June 16 due to flooding from a severe storm. The plant resumed production again on July 1. Production will gradually increase, focusing initially on specialized formulations. It is anticipated that it will take several more months for this plant to return to its full production capacity.

Specialized formula

The shortage of specialized formula is concerning because it affects a more vulnerable population who depend on them. Specialized products include metabolic products for people with rare metabolic disorders and hypoallergenic formula for babies with allergies.

Metabolic products:

- Metabolic products are used for the treatment of inborn errors of metabolism that result in the inability to metabolize specific amino acids, carbohydrates or fatty acids.
- Approximately 2000 Canadian patients (infants, children and adults) currently require metabolic products; while the incidence of metabolic disorders is relatively low (1 in 30,000 to 1 in 200,000 newborn babies, depending on the disorder), these products are essential to the survival of affected individuals.
- Metabolic products are used only under medical supervision and are not available at retail. In Canada, they are obtained through the National Food Distribution Centre, a non-profit organization solely dedicated to the distribution of metabolic products. They work in close collaboration with registered dietitians and health care professionals and apply just-in-time inventory management for the whole country.
- Patients using metabolic products are particularly affected by the shortage, because there are few or no equivalent products, and switching metabolic formulas can cause problems with palatability and gastrointestinal intolerance.

Hypoallergenic products:

- Regular infant formula will typically contain intact proteins, although some products may also contain partially hydrolyzed proteins for babies with intolerances and gastrointestinal discomfort. Hypoallergenic formulas contain extensively hydrolyzed proteins (for mild allergies) or are amino acid based (for severe or multiple allergies). Symptoms of allergy include digestive disturbances that may affect infant growth. Cases of severe allergy can result in an anaphylactic shock.
- Up to 2-2.5% of infants have food allergies, with an estimated 1.2% suffering from allergies to milk protein. Considering the birth rate and the breastfeeding rate in Canada, it is estimated that this represents between 3,000 and 6,000 Canadian infants potentially using hypoallergenic formula.
- However, product usage is believed to be much higher for a variety of reasons. For instance, extensively hydrolyzed products are readily accessible and may be preferred over regular formulas by parents of infants with colic or other mild digestive problems. Other factors include the reimbursement of some extensively hydrolyzed formula in some provinces, noting that an allergy diagnosis may be challenging (there may be self-diagnosis supported by a subsequent medical opinion based on reported symptoms).
- With the closure of the Abbott Sturgis plant, a popular Abbott formulation (Similac Alimentum) has been sold out since April 20, which has significantly increased the demand for hypoallergenic formulas from other manufacturers.
- The supply of hypoallergenic formula reached a low point in June. Since that time the shortage has largely subsided and is now replaced by a limited but stable supply.

- Health Canada has recommended that hypoallergenic formula be accessed only at the pharmacy counter during the shortage to help manage the supply and to facilitate the distribution of products imported under the Interim Policy.
- Certain manufacturers informed us of their intention to return some of their products to shelves in pharmacy and retailers starting in late October. Only formulas that have bilingual labelling may return on store shelves, at the discretion of the manufacturer. Some products imported during the shortage under the Health Canada Interim Policy do not meet bilingual labelling requirements; these will continue to be available for order at the pharmacy counter while supplies last, even after the policy expires at the end of December 2022. Bilingual labels are available on Health Canada's website and from the pharmacist.

Regular formula

- Regular infant formula continued to be available on shelves during the shortage. While individual products may sometimes be out of stock, alternate formats or comparable products from other brands are usually available.
- Health Canada has been receiving signals in October that the supply of regular infant formula is now more sensitive than it was earlier in the year. Some manufacturers are indicating that they are having difficulty meeting the current demand. The extension of the interim policy will help bolster the supply of regular infant formula to help mitigate a potential shortage of these types of formulas in early 2023.

Additional pressures

The closure of the Abbott Sturgis facility has occurred in a context where manufacturers were already facing supply issues for certain ingredients due to the pandemic, including a shortage for some of the materials needed to make the plastic components of their packaging.

More recently, sunflower oil (a key ingredient in many infant formulas) is in short supply due to the conflict between the Russia and Ukraine, which are the largest exporters for this commodity. One manufacturer producing infant formula for the Canadian market indicates that the supply of sunflower oil cannot be guaranteed beyond this summer and the oil blends in their products must be modified as a result. An ingredient substitution is considered a major change and it must undergo pre-market assessment as per Division 25 of the Food and Drug Regulations. Health Canada is currently working with manufacturers to accelerate the pre-market assessments for more than thirty (30) products.

Health Canada actions to mitigate the shortage:

Health Canada has been taking strong action in two key areas: supply and distribution as well as communications.

Supply and distribution

- Health Canada implemented an interim policy on March 10 to facilitate the importation of equivalent infant formula from countries with similar regulatory standards to Canada. The list of products suitable for importation is included in the interim policy and is updated regularly. Our experts conduct a safety assessment of each product before adding them to the list. These products are safe to use, even if they differ from products available on the Canadian market in terms of labelling or composition. Bilingual labelling provisions continue to apply.

- The Department is monitoring the situation very closely, for both metabolic products and hypoallergenic formulas to understand the status in terms of product availability across the country. We are gathering information from distributors (for hypoallergenic and regular formula) and from the National Food Distribution Centre (for metabolic products).

Communication

- The Department has proactively taken on a facilitator role to promote information sharing since the beginning of the shortage. This includes sending targeted information to the healthcare community and caregivers as well as the development of several communication products for the public, healthcare professionals and pharmacists to help them navigate the shortage. In addition, we have contacted various associations to raise awareness and explore ways to reduce or eliminate barriers to providing rapid and fair access to product.
- Many communication materials were developed by Health Canada:
  - Information for the public include a public advisory and a detailed fact sheet for families, with two separate social media campaigns to further emphasize key messages and reach a broader audience. In addition, information about the shortage was posted on Service Canada screens across the country between July 1 and August 31.
  - Information for healthcare professionals include a clinical decision tree jointly developed by a broad community of healthcare stakeholders to guide treatment decisions and help families make appropriate choices while rationing the use of specialized infant formulas.
  - Information for pharmacists were developed to help them order hypoallergenic formula during the shortage and answer questions from the public.

The situation in the United States

On May 12, President Biden directed his administration to work urgently to ensure that infant formula continues to be safe and available during the Abbott recall. He recommended the simplification of product offerings to increase the speed and scale of production, the cracking down on any price gouging or unfair market practices related to sales of infant formula, and increased supply through importation. The United States Congress also investigated the shortage.

On May 18, President Biden invoked the Defense Production Act (DPA). On June 2, Health Canada met with officials from the Office of the Assistant Secretary for Preparedness and Response (ASPR), U.S. Department of Health and Human Services, which is responsible for administering the DPA. ASPR confirmed that the DPA was being used to prioritize the acquisition of additional raw material to infant formula manufacturers to bolster capacity. ASPR is not directing where the infant formula is going and there were no indications that the measures under the DPA would result in a cessation of U.S. infant formula exports to Canada. Both Health Canada and ASPR have committed to keeping each other abreast of developments as the shortage evolves.

Media presence

The shortage has been receiving media attention in the United States since early May. In Canada, coverage has been sporadic. Media focused initially on understanding measures taken domestically to alleviate the effects of the shortage, including efforts to import products to Canada, and questioning the absence of domestic production of infant formula (see section on Canada Royal Milk, below). This summer, Canadian news stories were around the challenges faced by families when trying to access specialized formula. Some media reports were positive and reiterated key information published by

Health Canada. More recently, stories have focused on the frustrations experienced by parents who must often switch regular formula as more popular products are out of stock.

Canada Royal Milk

Canada Royal Milk (CRM) owns a production plant in Kingston, Ontario, that manufactures fortified cow milk powder, whole goat milk powder and skim goat milk powder that may be used in fortified milk products for adults and for infant formula production. These products are not for the Canadian market and are exported to other countries including China. Contrary to certain media reports, CRM does not produce infant formula.

CRM cannot sell infant formula on the Canadian market until the company receives pre-market approval from Health Canada. The company met with Health Canada to discuss information requirements to support a pre-market submission to produce and sell infant formula in Canada.

Summary of Children Pain Medication Debates in Parliament and Parliamentary Committee
Updated November 15, 2022

November 14 – Question Period

Hon. Pierre Poilievre (Leader of the Opposition, CPC):
Mr. Speaker, Canadian children are in pain and there is no medication available. Mark Parrish, the president of a drug distribution association that represents 19 countries, says that Canada is the only country that has a shortage of essential drugs. Parents are even having to go to the United States to buy these drugs, because although we do not have them here in Canada, they are abundant south of the border.
Why is it that children in other countries have these drugs, but Canadian children do not?

Hon. Jean-Yves Duclos (Minister of Health, Lib.):
Mr. Speaker, I think we can thank our colleague for asking that question and addressing the stress that families and children are under.
There are two pieces of good news. The first is that Canadian production of these drugs has increased substantially in the last few weeks. The second is that just a few hours ago, we were able to announce an agreement with a company to provide Canadians with several months' worth of additional pain medication for children.

Hon. Pierre Poilievre (Leader of the Opposition, CPC):
Mr. Speaker, it does not answer the question.
I will quote from the Wall Street Journal, which had an article about Canada's shortage of children's medication. Mark Parrish, president of the International Federation of Pharmaceutical Wholesalers, a trade association with members from 19 countries, says that no other country is experiencing similar shortages as Canada is.
That forces our parents to drive south of the border and buy the medications in the United States, where they are abundant and in supply, and bring them back here. Many people are actually hawking them with a profit back in our country.
Again, why are these medications available abroad but not here at home?

Hon. Jean-Yves Duclos (Minister of Health, Lib.):
Mr. Speaker, I am pleased to repeat the answer in English this time.
The question is right. The stress that families and children are going through is real. That is why we were pleased with the collaboration with other producers and partners in the last few weeks to see a substantial increase in production, home production, of analgesics for children. More important, just a few hours ago, we announced an important importation of a few months additional supply of analgesics for children, which will make a big difference in the ability for children to be cared for in Canada.

Mr. Don Davies (Vancouver Kingsway, NDP):
Mr. Speaker, parents do not want to hear excuses; they want to know their kids will be taken care of when they get sick.
Across Canada there are shortages of children's Tylenol and Advil, and now hospitals are dealing with a lack of pediatric antibiotics. It is a scary time to be a parent, and there are things the government can do now.
Instead of giving vague promises and pointing fingers, the Liberals must ensure our kids get the medicine they need. Parents are desperate for help. Where is the plan to care for our children?

Hon. Jean-Yves Duclos (Minister of Health, Lib.):
Mr. Speaker, families and children are indeed living through stressful times, and that is why we were pleased to announce just a few hours ago that there will be a special importation of additional analgesics, the equivalent of several months' of normal supply, in addition to the increased domestic production of these analgesics, so that children and their families can have access to those drugs in a very short time. We will keep working on longer term solutions to these shortages.

November 3 HESA – Motion to invite Health Canada officials

Laila Goodridge (CPC) I mean no disrespect in this, but one of the issues that has been very top of mind for me....I'm a young mom. Through the course of this study, and through the course of the last few months, I have—on numerous occasions—brought up the real, serious concerns that have been brought to me by a lot of parents—moms and dads, regular people, grandparents all across the country—who are struggling to find children's pain medication. We're at a crisis level. We're at a space where it's on the shelves in the U.S. in abundance, you can even pick your flavour, but in Canada you can't find it anywhere. This is especially troubling in rural, remote and isolated communities such as the ones that I live in. We're a long ways away from a children's hospital, if something does go bad.
With that, I'd like to move a motion:
That, the committee hold a meeting on Tuesday, November 15th to discuss the ongoing shortages of children's pain medications to include an hour of officials from Health Canada and the second hour to include one witness from each political party represented on the committee.

Don Davies (NDP) It's my understanding that the shortage of children's pain medication is a global matter. I'm not sure I can say it is for every country but almost every country is experiencing this. Second, I want to talk to industry a little bit. I happened to have a meeting this morning with a Canadian pharmaceutical manufacturer, in fact the largest domestic manufacturer of pharmaceuticals in the country, and he had some interesting information about this as well. It would be nice to have a broad array of witnesses in that second hour so that we can get a fulsome picture to find out what are the potential solutions for this. That's where I'll conclude. My interest in this matter is understanding what the problem is, but, more important, seeing what solutions may exist, not in politically attacking the government on this but rather working practically to see what we can do to help.

Laila Goodridge (CPC): I appreciate the support I've received from my colleagues on this issue. I think it's critically important. One anecdote I'd like to share, because I think it's important, is the number of, particularly, young moms who have reached out to me since yesterday when this was brought up in question period. This isn't about politicizing this issue. They wrote to me and said, "Thank you. I thought that I was crazy. I have felt like I was alone in this. I have been struggling. I didn't realize that this was more than just my problem or my community's problem." It really made them feel heard. I haven't personally seen any children's pain medication on the shelves in my northern Alberta community since early this summer. This is something that's hugely concerning. We're five hours from a children's hospital.

Don Davies (NDP): I just think it's an appropriate moment to make one observation. This is an opportunity to think of young parents. Mrs. Goodridge has been very passionate, effective and brave in sharing her own experience with her child that had pain from teething and couldn't get pain medication and bringing up young parents across this country who can't get pain medication for their children. I think it's appropriate to point out the policy symmetry between this issue and lack of dental care because there are millions of children and parents in this country who go to bed every night with pain

because they can't get access to dental care. Whether you're a parent who has got a teething child and you can't get pain medication or whether you're a parent with an adolescent child who's going to bed at night with the same pain because he can't get dental care, it's the same parental pain—it's the same frustration—and I think it's the same health need. I just think it's an opportunity to remind all of us as parliamentarians about consistency and I'm hoping that this can serve as a good example for all of us around this table, from all parties, to work constructively to address this problem, not only for the temporary issue of pain medication but also for the structural opportunity to fix the problem of ensuring that all children get access to oral health care in this country.

Emergency Debate Request - November 2 (Pierre Poilievre):
Mr. Speaker, I think all parents would agree that the matter I am about to raise is indeed an emergency. Across this country, there have been shortages of medications required for pain relief by small infants and babies. Children's Tylenol, ibuprofen and other medicines are necessary to relieve the often intense pain that young children feel during sickness, teething or other conditions. It has come to be expected that one could go to a local drug store to get these medications. Unfortunately, in Canada, that has not been the case. There have been shortages right across the country. We raised this matter a month ago. The good news is that in the United States, they do not appear to have this problem. We did check online today and found it was easy to order these medicines, but an American address is needed to get them. The American shelves are stocked, but here in Canada the shelves are empty.
I want to thank the hon. member for Fort McMurray—Cold Lake who brought this to my attention. She was the one who first alerted me to this crisis. She is a young parent. I am a parent, although not a young one. We were lucky last night. My little one needed children's Tylenol. We had a few pills left, but I cannot imagine what kind of night it would have been for her and us if we had run out.
On behalf of parents right across the country, Conservatives are seeking an emergency debate on how Canada could restore its supply chains and supply parents and children with these necessary medications that are available in other countries, but for some reason that the Prime Minister still cannot explain are not available here in Canada.

Request for an Emergency Debate was denied by the Speaker.

Question Period – November 2

Pierre Poilievre:
Mr. Speaker, a month ago, the Conservatives warned the Prime Minister that there was a shortage of pain medication for children. This medication is widely available in the United States, but here in Canada parents are scrambling to find it. Widely available in drugstores in the United States, pain medication for small children cannot be found here in Canada, leaving mothers and fathers scrambling to help their suffering children. The Prime Minister has had a month since we warned him about this problem. He said he would fix the supply chain issues in our medical system. Why has he not solved this problem?

Prime Minister's Response:
Mr. Speaker, we have heard from parents who are struggling to get pain medication for their kids. They are heartbreaking stories, and that is why Health Canada is taking concrete action to accelerate the flow of pain medication for children.
We are working closely with provinces and territories as they work to support and resupply as well. We know this is something that is part of the global disruptions we are facing because of climate change, and the pandemic has left…

Mrs. Laila Goodridge (Fort McMurray—Cold Lake, CPC):
Mr. Speaker, a parent's worst nightmare is a sick child. A shortage of infant and children's Tylenol, Motrin and Advil from earlier this summer is turning into a full-blown crisis. Parents are now having to choose between taking their sick kids to an overcrowded emergency room and crossing the border to the U.S., where there are no shortages on these drugs, just to get basic medicine to bring down their kid's fever and relieve pain.
When does the Prime Minister intend to do something about this crisis?
Prime Minister's Response:

Mr. Speaker, we hear the concerns from parents on the supply of children's pain and fever meds. As a parent, I can completely understand. That is why we are committed to ensuring all families have access to the essential medicines their children need. Health Canada has been in communication with manufacturers, pharmacists and provinces and territories to ensure mitigation measures are in place. Our main priority will always be the health and safety of Canadians, and all options are on the table.

Mr. Luc Berthold (Mégantic—L'Érable, CPC):
Mr. Speaker, we advised the Prime Minister of this situation one month ago, but the Prime Minister always has a ready-made excuse to justify his inability to take action. As a grandfather, I get upset thinking about young children who are ill.
One month ago, he asked Health Canada to do something so that mothers and fathers can access medication for their children, medication that children will want to take.
Why is the Prime Minister once again making excuses to avoid providing the medications that sick children need?

Prime Minister's Response:
Mr. Speaker, we are all hearing the concerns of parents about the supply of children's pain and fever medication. We will continue to ensure that all families have access to the essential medications that their children need. We will deal with this shortage.
Health Canada is in communication with manufacturers, pharmacists and the provinces and territories to ensure mitigation measures are in place. Our main priority will always be the health and safety of Canadians. All options are on the table.

October 6 – HESA debated children's pain medication shortages and issued their fourth Report:

Over-the-Counter Paediatric Medication
That, due to nationwide shortages of over-the-counter paediatric medication, the committee report to the House its support for the Government of Canada continuing to allow the importation and sale of foreign language labelled products of the same drug formulation to address the shortage, as is already allowed under the Food and Drug Regulations; and, to ensure that patients and caregivers understand what medication they are consuming, work must also be done in partnership with providers to add information to the label in both official languages.

October 6 – Debate on HESA's 4th Report

Michael Barrett (CPC – Introduction of the Motion):
Colleagues will be aware from media reports and, in my case and the case of some members of the committee, personal experience that there is a nationwide shortage of pediatric medicines available. This is causing a lot of grief for moms and dads right across the country.

I'd like to move a motion and seek the support of members for it.
That, due to nationwide shortages of over-the-counter paediatric medication, the committee report to the House its recommendation that the Government of Canada allow the importation and sale of foreign language labelled products of the same drug formulation to address the shortage.

Sonia Sidhu (Lib.):
Mr. Chair, I agree with my colleague. The shortage is having a real impact on patients and families.
My understanding is that we already do this, but I would propose an amendment. I will read it as amended: "That, due to nationwide shortages of over-the-counter paediatric medication, the committee report to the House its support for the Government of Canada continuing to allow the importation and sale of foreign language labelled products of the same drug formulation to address the shortage, as is already allowed under the Food and Drug Regulations. To ensure that patients and caregivers understand what medication they are consuming, work should also be done in partnership with providers to add information to the label in both official languages."

Laila Goodridge (CPC):
I want to stress the fact that this is something that's critically important. As a young mom who hangs out with a lot of other young parents, I know that this is a top-of-mind issue. This is something that I hear about every single day. I hear every single day without fail about the shortages and the consequences they're having.
I think it's an important piece for this committee to study and for the government to be aware of, showing parents that we're listening to them, that we understand their concerns and that we're doing what we can.
Frankly, I don't think they saw that when it came to formula shortages. I think we can and must do better to make sure we're protecting some of the youngest and most vulnerable people in our society, and those are our infants and our children.

Don Davies (NDP) (Importation of Medication, Labelling Requirements):
I'm going to first express that I'm deeply concerned by and empathic with the situation Canadians find themselves in by not getting access to essential medication. This is just the most recent example of this need for parents in this country who are unable to access things like over-the-counter pediatric Tylenol for their children who are suffering and in pain. We've heard evidence at this committee that there's a shortage of pediatric formulations of medication generally.
A few years ago, colleagues will remember that we had a national EpiPen shortage, which actually presented a danger to the lives of people who rely on EpiPens to not go into anaphylactic shock, and that can be a life-threatening illness.
I think it gives us a chance to pause for a moment and ask ourselves how it is that a G7 country, one of the wealthiest countries on earth, is not self-sufficient in essential medication for our people, especially when we're talking about our children. How is it that we're in a situation where parents who have children in pain are going to pharmacies and they can't even get basic over-the-counter pain medication, never mind prescription medicine? How is it that our country requires doctors and pharmacists to have to MacGyver adult formulations of medication to try to turn it into something that maybe they can give to children? That's unacceptable.
The fact that the motion calls for us to import medication that we need here from other countries implies that those other countries have done a much better job than we have. They actually have surplus medicine to send to a country like Canada, so their good planning is lucky for us because it will cover up our poor planning. The truth is Canada is not self-sufficient in essential medicines or vaccines.

I have to say that I find it passingly ironic that this motion comes from the Conservatives because it was a Conservative government, the Mulroney government that sold off Connaught Labs some decades ago. It was a publicly owned drug manufacturing facility in this country. It manufactured things like insulin and other life-saving medications to make sure that Canadians always had access to essential life-saving medication that was at an affordable cost.

That was not only a profoundly short-sighted and incorrect policy decision, but make no mistake that it's decisions like that which have led to the situation we are in today. We didn't just find ourselves in a situation today where parents can't get pain medication for their children. That's the result of decades of bad policy decisions by successive federal governments, frankly, of both Liberal and Conservative view.

The fact that we have to pass an emergency resolution to ask the government to get medication that's not even in English and French to be sold in Canada as an emergency stopgap measure should give us pause and make us start thinking about deeper policy responses.

Now, to this motion, I have concerns about this motion. We have a regulatory system in this country around medication for a reason. The reason is consumers' protection and safety. We also have official languages legislation, by the way, which is not something that can be dispensed with easily.

It has been said by the Liberals in the amendment that Health Canada already does this now. I'm having trouble actually finding out the extent to which that really happens. I know during COVID there was some emergency acquisition of equipment in foreign languages, not in English or French, but they were things like gloves and personal protective equipment, and I think we have done it with a few other devices, but I'm not sure how prevalent this practice is with respect to medication. I'm prepared to acknowledge that it might happen to some degree.

I'm concerned about slapping on a label. Most medication, in fact, all medication I'm aware of, comes in a box with very detailed consumer protection information, including warnings. How else does a parent or an informed consumer make an informed choice about the medication they are getting?

I'm unclear on this. Are we just going to be getting medication and putting a sticker on the outside of it to say that it's pediatric Tylenol? Are we going to dispense with the requirement for translating the consumer information inside the box? By doing so, we're essentially saying that's not important, and I have concerns about that. I also am aware that when Health Canada does permit the importation of medication of the same compound that's not in English or French, very often there's a requirement that it be administered under the supervision of a medical professional.

I'm not sure that's the case here, because we're talking about over-the-counter medication. We could have parents going into a pharmacy, accessing medication made in a different country without the consumer protection or warnings inside, and giving it to their children, our most precious resource, without necessarily having the supervision of a medical practitioner. I recognize that some of these medications are relatively benign, but Tylenol can kill.

I also want to ask about the countries. I was talking with a colleague earlier, who said, “We don't really have a problem if Tylenol coming from Germany is sold here.” I probably don't either, but what if it's coming from China? What if it's coming from Vietnam or Peru? I don't know where it's coming from.

My final point on this is going to be about the amendment that we just received. I'm concerned about this last statement:

To ensure that patients and caregivers understand what medication they are consuming, work should also be done in partnership with providers to add information to the label in both official languages.

Right off the bat, there should be no “should” about it. It should be “must”. It should be an absolute requirement that information for the label for this medication is added in both official languages.

I recognize the extent of the problem. I am fully prepared to look for solutions. I think there is one here, but let's not allow such a stopgap measure as this to be an acceptable solution to the fact that

Canadians and Canadian parents and patients should never be in a position where we have to import medication that is skirting Health Canada normative regulations.

Marcus Powlowski (Lib.) (Labelling and Packaging):
I don't have a problem with the motion and the amendment, but I did want to point out that I was tempted to want to add to the motion a proviso that "as long as these medications continue to comply with other existing regulations regarding packaging". I wanted to point out that perhaps a big part of the problem in getting medications isn't so much the translation in the language, but the packaging.
Laila and Michael will know that you can't buy pediatric Tempra, Tylenol or Advil in a big container. My understanding is that there is a requirement that you can't sell larger packages because, as Don has pointed out, Tylenol is toxic if you take it in enough quantities. They make it sweet, so that way, you can't give a large package of Tylenol to kids. I'm not sure if that's the case in other countries, so for anything that's brought in, I would assume it would still meet that requirement.
Another thing—and I'm probably violating the rules of Parliament by showing this as a prop—is that most medications like Tylenol and Advil sold in Canada have a top that's childproof. You have to line up the two little arrows. On Aleve, there's another one that you have to do. It's childproof.
However, I would note—and this is of real concern to me—that the other day I turned around and my two-year-old was sitting at the kitchen table with this big bottle of adult Tylenol, which has a very nice top that looks like one of the tires off one of his toy cars. It's very easy to take off, even for a two-year-old. He dumped the Tylenol all over the table, and I didn't know how many he had taken.
In terms of the toxic dose of extra-strength Tylenol, probably four of those is within the toxic range for him. You have to take him to the hospital. You have to do four-hour acetaminophen levels. You have to give him charcoal, and you have to give him Mucomyst if he's in the toxic level.
I would just point out to the opposition and to people with concern about this issue that I think a big problem is not so much the language, but the other packaging requirements, which are there in order to protect the Canadian public.

Laila Goodridge (CPC):
My family is currently rationing baby pain medication for my son who is teething with molars because we do not have adequate access to this critical medication. Parents with brand new babies can't even find it on the shelves. It's not even in stock. They're going to the emergency room, because they have no other option.
This is something that government needs to address. Perhaps the wording of this motion isn't perfect, but I would suggest to each and every member of this committee that now is not the time to find perfect. Now is the time to find solutions. We have the power to find a solution. Vote in favour of this motion.

Adam van Koeverden (Lib.) (Importation of Drugs):
I would like to get on the record that we aren't in a situation where we need to pass an emergency resolution, not because this isn't urgent—this is very urgent—but the food and drug regulations already allow for this. We aren't in a situation where we need to ask for anything new. This happens regularly due to shortages across supply chains, to address these sorts of things. The Food and Drug Regulations include a framework for the exceptional importation and sale of drugs that are not otherwise licensed in Canada. The intention of that framework is to help ensure that Canadians have access to critical drugs when there is a shortage due to supply or demand issues. In critical shortage situations, Health Canada will never hesitate to accept foreign products as long as they meet Canada's very high health and safety requirements.

Jean-Denis Garon (BQ) (Generic drug industry in Quebec and bilingual labelling requirements)
There used to be a generic drug industry in Quebec, in the Laval region, on the north shore near Montreal. That industry used to produce these kinds of drugs, but it was obliterated over time, in part by federal government policies like the supercluster. Under that policy, the federal government, with its "we-know-best" attitude, decides where to send this or that industry, and it makes investments accordingly.
The life sciences cluster, which is currently located in Manitoba, is working on GMOs, while the Standing Committee on Health is wondering where we will get Tylenol for Quebec and Canadian children. This is absolutely disgraceful, Mr. Chair.
Now, at the risk of repeating myself, which I try to do as little as possible, I would argue that the issue of French is fundamental. I completely agree that we must ensure the safety of medicines and enforce the existing regulations for all imported medicines. However, labelling in both official languages is fundamental to ensuring the safety of medicines.
There are two official languages in Canada and one in Quebec. Foreign companies often don't bother taking into account the language that Quebeckers speak and read when those companies are labelling the products they import. This includes everything from children's toys to food products to medicines. However, Quebeckers need to understand the information on these labels in order to protect their children and ensure their safety.
I would even go so far as to quote Bill C-13, which will unfortunately be passed. Our bill on Quebec's official language was rejected. Bill C-13 states very explicitly that urgency does not justify a failure to comply with official language obligations. We cannot trade one problem for another. We cannot trade the danger of not having medication for the danger of having francophone parents in Quebec, and outside Quebec, who can't read the instructions in order to protect their children. Since I'm not a member of the "bloc canadien" I will narrow my comments somewhat.
This is a fundamental and non-negotiable issue. It should be worded even more clearly than in the amendment. There must be no compromise on this whatsoever. None.

Michael Barrett: (Bilingual Labelling)
With regard to Mr. Davies' question, the "Guide to the exceptional importation and sale of drugs in response to drug shortages", dated March 2022, says:
Before a designated drug can be sold in Canada, risk communications to support its safe use must be finalized and available in both English and French.
The regulation that we're appealing for the government to use says, "must be finalized and available in both English and French." My comments prior to this committee indicated that Canadians should be able to access these drugs in the official language of their choice.
With regard to Mr. Powlowski's example with Tylenol, when I buy that exact product at the pharmacy, I take it to the pharmacist, who repackages it and labels it in the official language of my choice with a safe lid for children. They have the capacity to do it. The regulation requires that it must be available in English and French, which ensures the safety, and all of the information that they provide must be approved by Health Canada in advance before it can be dispensed in Canada.