Frequently Asked Questions for Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19

## Questions

## Q1. How is Health Canada adapting to make therapeutic products available to treat or prevent COVID-19 for Canadians?

**A.** It is up to a manufacturer to initiate studies on therapeutic products or to seek market authorization of therapeutic products in Canada. To allow products on the market, Health Canada requires studies to confirm that the benefits of the product outweigh its risks when used properly. In this crisis however, studies are ongoing globally and information is limited. In response, Health Canada has developed special regulatory measures for therapeutic products similar to those recently put in place to speed up the authorization of medical devices that diagnose, treat, mitigate or prevent COVID-19 as well as for clinical trials for medical devices and drugs relating to COVID-19.

Typically, for a drug to receive market authorization for the treatment of a specific indication, like COVID-19, manufacturers are required to submit a drug submission under Division 8 of the *Food and Drug Regulations* (FDR) for Health Canada review. These submissions must contain sufficient evidence to show how their drug meets the safety, efficacy and quality requirements of the FDR.

The Interim Order introduces three alternative mechanisms for the Minister of Health to expedite the availability of COVID-19 drugs in Canada:

(1) authorizing a brand new drug with a modified set of application requirements (with the potential for a "rolling" submission of information as it becomes available)
(2) authorizing a drug based on certain elements being approved by a foreign regulatory authority
(3) expanding the indication for an already approved drug

To help ensure timely access to COVID-19 drugs, the Interim Order also introduces a mechanism for the Minister of Health to allow the importation of drugs that show promise for treating or preventing COVID-19 into Canada for placement in Canadian facilities prior to their authorization, referred to as "pre-positioning". Promising COVID-19 drugs to be pre-positioned must not have been issued an authorisation under the FDR or the Interim Order, and are those for which the Government of Canada has entered into a contract with the manufacturer for their procurement.

## Q2. What drugs and indications fall within the scope of the Interim Order?

**A:** A new drug must treat, prevent, mitigate or manage the key clinical manifestations caused by COVID-19.

A person may file an application for an authorization in respect of a COVID-19 drug under the Interim Order on the basis of a direct or indirect comparison to another drug only if that other drug is not available on the Canadian market in sufficient quantities to address the urgent public need related to COVID-19.

## Q3. How does the Interim Order authorization pathway differ from the Division 8 of the *Food and Drug Regulations* pathway?

**A.** Compared to the Division 8 of the FDR, the Interim Order is more adaptable regarding information required in an application. It also has the ability to rely more on post-market surveillance to manage safety and effectiveness through terms and conditions that can be imposed on an authorization. Agilities include:

- Specific exemptions granted from certain provisions of the FDR*;*
- Information can be submitted in an application in a rolling fashion by providing some requirements at time of filing and including a plan outlining how and when the sponsor will provide the outstanding information or data until the package is complete;
- Comparisons to foreign approved drugs can be the basis for issuing these expedited approvals;
- the Minister can expand indications for new drugs that are already approved; and
- Establishment licences can be issued in relation to COVID-19 drugs with certain flexibilities, and modified good manufacturing practices requirements.

An authorization or expanded indication that is issued or published under the Interim Order is valid until the Interim Order expires. Interim Orders, once approved by the Governor-in-Council, will cease to have effect one year after the Minister signs them

### Q4. How does the Interim Order compare to the Access to Drugs in Exceptional Circumstances pathway?

**A:** The Access to Drugs in Exceptional Circumstances regulation and its *List of Drugs for an Urgent Public Health Need* (UPHN) is a mechanism that enables an establishment to import a drug that is not authorized for sale in Canada, to address an urgent public health need. The Interim Order is a regulation that creates agile requirements that allow a manufacturer to apply for a Canadian market authorization in respect of a COVID-19 drug that demonstrates promising evidence. Both regulations are designed to address an urgent public health need, however, the Interim Order is specific to COVID-19 drugs only, and is a regulatory pathway used by manufacturers that want to obtain market authorisation for their product in Canada. This is different from the UPHN which is a regulatory mechanism used to import drugs that are not authorized in Canada for use by public health officials.

Under the *Access to Drugs in Exceptional Circumstances Regulations*, a federal, provincial, or territorial Chief Public Health Officer (CPHO) must notify Health Canada of an urgent public health need for a specified immediate use of a drug. Drugs eligible for listing on the UPHN List must have received market authorization in either:

- Europe
- Switzerland
- United States of America

Once listed, these drugs may be imported for immediate use in Canada, within the jurisdiction of the CPHO.

While the UPHN enables a drug that is unauthorized to be made available in Canada, Health Canada's preference is for products to receive Canadian market authorization. The Interim Order was developed to allow more agility to manufacturers filing an application for market authorization of a COVID-19 drug in Canada. One of these elements is the use of a foreign decision as the basis for issuing an expedited authorization. Under this pathway of the Interim Order, a sponsor can use an authorization for sale in a broad list of foreign jurisdictions to streamline their application, such as:

- Australia (Therapeutic Goods Administration)
- Europe (European Medicines Agency)
- Japan (Ministry of Health, Labor, and Welfare/Pharmaceuticals and Medical Devices Agency)
- Singapore (Health Sciences Authority)
- Switzerland (Swissmedic)
- United Kingdom (Medicines and Healthcare products Regulatory Agency)
- United States of America (US Food and Drug Administration)

Many of the regulatory authorities are the same as those in the UPHN. In the case where there is overlap in the foreign regulatory decision authority, the drug may be imported for immediate use under the UPHN and a manufacturer may use the foreign decision of the drug that is listed on the UPHN to file an application under the Interim Order. Once a drug product is reviewed and authorized through the Interim Order, access to products through the UPHN pathway would no longer be need as the products would have a market authorisation and be available for sale on the Canadian market.

### Q5. What are the benefits and agilities of the Interim Order for manufacturers?

**A:** The Interim Order offers key benefits and agilities intended to expedite access to COVID-19 drugs:

*Amount of evidence and rolling applications.*

The Interim Order requires the sponsor to submit the information that is known regarding the quality, safety, and effectiveness of a drug. In order to expedite the review process under the Interim Order, flexibility has been included to allow an applicant to submit the required information throughout the course of the review as it becomes available. When using this element, the applicant must submit a plan outlining how and when they will provide the Minister with the required information or data that is outstanding.

For example, Health Canada may accept a rolling drug application for a drug that has promising evidence and for which clinical trials are ongoing. This means that Health Canada will begin its assessment using the information submitted by the manufacturer and accept new evidence as it becomes available from clinical trials, until the examination of the application is completed, while ensuring that the review maintains an appropriate evidence bar for safety, efficacy and quality. A similar approach was taken to approve the H1N1 vaccine in 2009.

This element aligns with strategies in use by European Medicines Agency and United States Food and Drug Administration for COVID-19 drugs. However, in some instances there may be difference as well as potential for greater agility.

*Use of a foreign regulatory approval*

The Minister can add a foreign approved drug to the *List of Foreign Drugs in Relation to the COVID-19 Pandemic* (*List of Foreign Drugs*) if it is deemed necessary or is shown to have a benefit in the context of the COVID-19 pandemic, and it has received an authorization for sale in a foreign jurisdiction such as:

- Australia (Therapeutic Goods Administration)
- Europe (European Medicines Agency)
- Japan (Ministry of Health, Labor, and Welfare/Pharmaceuticals and Medical Devices Agency)
- Singapore (Health Sciences Authority)
- Switzerland (Swissmedic)
- United Kingdom (Medicines and Healthcare products Regulatory Agency)
- United States of America (US Food and Drug Administration)

Health Canada may become aware of such drugs through interactions with international counterparts or environmental scanning including dialogues with health care providers or potential drug applicants.

Sponsors can also submit an application for a drug on the foreign regulatory approvals list with fewer application requirements, based on the approval received from the foreign regulatory authority. This drug is not a copy or generic version of that drug, but is the same drug.

However, if a foreign jurisdiction waives pre-market submission and evaluation requirements, this would not be considered a foreign regulatory authorization for the purposes of the Interim Order. Pathways that involve reduced filing requirements may not be acceptable under this provision, however, may be considered on a case-by-case basis with additional supplementary information requirements.

*New COVID-19 indication for authorized drugs.*

The new indication must be relevant to the urgent public health need related to COVID-19 and there needs to be evidence that the benefits associated with the new indication outweigh the risks. This can happen through an application from a manufacturer or without an application from the manufacturer using the Minister's power to expand an indication under the Interim Order.

*Importing promising COVID-19 drugs in advance of a Canadian authorization*

Drugs that show promise for treating or preventing COVID-19 may be imported into Canada to be pre-positioned for immediate distribution upon authorization.

The CPHO of the Public Health Agency of Canada may use this pre-positioning mechanism to identify to the Minister of Health promising COVID-19 drugs to be pre-positioned. Promising COVID-19 drugs to be pre-positioned must be the subject of a contract between the Government of Canada and manufacturer for their procurement. The importer of COVID-19 drugs to be pre-positioned must be a Canadian establishment licence holder.

### Q6. Are there any changes to establishment licences requirements under the Interim Order?

**A:** An establishment licence is required to fabricate, package, label, test, import, distribute or wholesale a drug in Canada, and these activities must be conducted following the principles of good manufacturing practices. The Interim Order introduces an optional application pathway for a new establishment licence for applicants who intend to conduct activities solely on COVID-19 drugs. Existing establishment licences issued under the FDR can also use this optional application pathway for activities related to COVID-19 drugs conducted under the Interim Order. Terms and conditions may be used to allow an agile approach to factor public health needs into the decision-making process.

### Q7. Are there any changes to good manufacturing practices requirements under the Interim Order?

**A:** The Interim Order modifies certain good manufacturing practices requirements, balancing the need for agility, while still protecting the health and safety of Canadians who will use these COVID-19 drugs. For example:

- Importers and distributors will be exempt from confirmatory testing.
- Importers do not need to have master production documents or other manufacturing or packaging batch documents available on-site and may rely on a batch certificate or certificate of manufacture and certificate of analysis to release product.
- Importers do not need to have stability evidence available. The shelf life must still be established in accordance with quality information submitted in the application.
- Reduction in record keeping requirements for importers.

### Q8. Can terms and conditions be imposed by Health Canada under the Interim Order?

**A:** Terms and conditions can be imposed on a COVID-19 drug authorization holder or establishment licence holder. Terms and conditions are a tool that can be used in the post-market to ensure post-authorization considerations can be managed and to mitigate certain risks based on the authorization of drugs with limited clinical information. They also allow the Minister to act quickly to gather important safety information or mitigate risk.

### Q9. Will there be review timelines with respect to the Interim Order?

**A:** There are no performance standards that apply to the Interim Order. However, applications will be prioritized and reviewed immediately. The time that it will take to complete the review will depend on the application, the volume of data to be assessed and the number of applications received.

### Q10. Are drug and establishment licence applications made under the Interim Order subject to cost recovery or fees?

**A:** Fees will not be charged for the review of drug authorization applications filed under the Interim Order. Nor will fees be charged for establishment licence applications submitted under the Interim Order if the application meets the conditions specified in the *Establishment Licence Fees Remission Order (Indication of an activity in respect of a COVID-19 Drug).*

### Q11. What will happen when the Interim Order expires?

**A:** Product authorizations issued under this Interim Order are only valid while the Interim Order is in effect. Health Canada is developing transition measures to avoid disruptions for the ongoing authorization of drugs upon the expiry of the Interim Order. Transition measures will ensure products maintain their legal status as long as there is a public health need and afford sufficient time for manufacturers to convert these authorizations into Notice of Compliances (NOCs).

Transition measures will also ensure activities authorized through an establishment licence issued under the Interim Order can continue after the Interim Order expires.

The key objectives of the transition measures will be to ensure that:

- products authorized under the Interim Order are allowed to continue after the 1-year expiration
- activities authorized through an establishment license issued under the Interim Order are allowed to continue after the 1-year expiration any regulatory obligations or other requirements set out in the Interim Order would continue after the 1-year expiration, as needed
- authorization holders under the Interim Order have sufficient time to transition products into one of the existing regulatory pathways

### Q12. Can the Minister expand the indication of a product to include age groups or populations not included in a Notice of Compliance or Interim Order authorization?

**A:** Yes, it is possible to expanded the indication of the new drug if it is necessary to address the urgent public health need related to COVID-19 and there is sufficient evidence of benefit outweighing risks. However, Health Canada will examine each instance on a case-by-case basis to ensure that patients have access to the safe and effective drugs they need to fight COVID-19.

### Q13. Will manufacturers be notified that their product has been granted an expanded indication by the Minister?

**A:** The expanded indication will be published on a *List of New Drugs for Expanded Indication*. It is Health Canada's intent to notify sponsor(s) to ensure an efficient response and access to the product by Canadians. However, there is no requirement in the Interim Order to do so.

### Q14. What is being done to ensure clarity and transparency with regards to the Interim Order?

**A:** A Guidance Document and Notice have been posted to assist manufacturers who file a drug authorization application explaining the information that must be included in the application or in an establishment licence application.

The Interim Order requires the Minister to publish information in the form of two Incorporated by Reference lists:

- List of new drugs for expanded indication in relation to the COVID-19 pandemic
- List of foreign drugs in relation to the COVID-19 pandemic

Health Canada will publish two additional lists:

- List of applications received for drugs for use in COVID-19
- List of drugs that have been authorized for use in COVID-19

In addition, Health Canada will publish summaries of the rationales for various decisions related to the interim order, including the decision to authorize a product and to add a product to one of the Incorporated by Reference lists. Drugs that are issued an authorization under the Interim Order will also be listed on the Drug Product Database (DPD).

Health Canada will also make publicly available safety and efficacy evidence relied upon to issue a market authorization under the Interim Order respecting market authorization of drugs in relation to

COVID-19. Clinical information will be released for non-commercial purposes and will have all personal information and confidential business information protected prior to publication on the portal.

### Q15. There are several other Interim Orders with respect to Health Canada's response to COVID-19, what are they and how are they linked?

**A:** Three other Interim Orders have been published under the FDA to address COVID-19. These orders, along with the Drugs Licensing Interim Order, work together to ensure flexible, safe and efficient pathways are available for key areas that may be or are impacted by the exceptional situation of the COVID-19 pandemic. These Interim orders are designed to protect the health and safety of Canadians by ensuring timely access to the drugs, medical devices, and foods for special dietary purposes.

1. *Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19*

There is an unprecedented demand and urgent need for access to medical devices during the COVID-19 pandemic. On March 18, 2020, the Minister of Health signed the *Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19.*

This Interim Order allows the expedited authorization of medical devices indicated to diagnose, treat, mitigate or prevent COVID-19 that may not fully meet regulatory requirements to be imported and sold.

2. *Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in relation to COVID-19*

On March 30, 2020, the Minister of Health signed the *Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in relation to COVID-19*. These measures for drugs, medical devices, and foods for special dietary purposes are necessary to help prevent or alleviate the effects of shortages directly or indirectly related to COVID-19.

This Interim Order allows the Minister to permit the exceptional importation and sale of drugs, medical devices, and foods for special dietary purposes that do not fully comply with Canadian requirements, but are manufactured according to comparable standards. Additionally, this Interim Order introduces a mandatory mechanism for the Minister to be notified of shortages of medical devices considered to be critical during the COVID-19 pandemic. Finally, this Interim Order modifies certain application requirements to allow for the expedited authorization of biocide drugs, such as hard surface disinfectants and hand sanitizers.

*3. Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19*

On May 23, 2020, the Minister of Health signed an *Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19*. This Interim Order is a response to the need for urgent COVID-19 diagnosis, treatment, mitigation or prevention options.

This Interim Order introduces an alternate pathway to facilitate clinical trials for potential COVID-19 drugs and medical devices, while upholding strong patient safety requirements and validity of trial data. This Interim Order does not apply to radiopharmaceutical drugs, natural health products and Class I medical devices.

### Q16. Do applications for COVID-19 drugs have to be made under the Interim Order?

**A:** Applicants can choose the regulatory pathway they want to use for market authorization: a drug submission under Division 8 of the FDR or an application under the Interim Order.

### Q17. Will pre-positioning be available for promising COVID-19 drugs?

**A:** When the Government of Canada has entered into a contract to procure a COVID-19 drug pending its approval under this Interim Order or the FDR the CPHO can notify the regulator that the drug is to be pre-positioned so that it can be stored for distribution upon its approval.

### Q18. What is required for the pre-positioning of a promising COVID-19 drug?

**A:** Drugs that are in queue for approval may be imported into Canada prior to the drug receiving a Canadian market authorization or NOC so that they can be pre-positioned for immediate distribution upon authorization. These drugs may be imported and pre-positioned by the holder of a Canadian establishment licence.

To be eligible to import a COVID-19 drug for pre-positioning, several conditions must be met.

The CPHO must provide the Minister of Health with a description of the drug, which includes the following:

- the drug's proposed indication, that is, its intended use or purpose
- the drug's brand name, if any,
- either its proper name, common name and chemical name, or
- its identifying name, code, number or mark

The CPHO must also indicate that the manufacturer of the drug has filed an application or submission for the drug's authorization in Canada, or abroad with a foreign regulatory authority. In cases where the manufacturer has filed an application for market authorization in a foreign regulatory authority, the COVID-19 drug to be pre-positioned must be identical in its chemistry and manufacturing to the foreign drug for which the application was filed.

The CPHO must provide the name and contact information of the drug's manufacturer and the civic address of the facilities where the COVID-19 drug will be stored once imported, and the name and contact information of the Canadian establishment licence holder who will import the drug. The quantity of drug to be imported and pre-positioned in Canada must be provided.

Once all the conditions have been met, the Minister of Health will send a Letter of Acknowledgement to the Chief Public Health Official that will specify the COVID-19 drug to be pre-positioned.

If the conditions for pre-positioning are met, the importer specified by the CPHO may import the COVID-19 drug for pre-positioning purposes. The importer of the drug must always hold an establishment licence, and the Minister must be provided with evidence demonstrating compliance with good

manufacturing practices for foreign facilities involved in the fabrication, packaging, labelling, and testing of the drug. The importer must also follow certain good manufacturing practices requirements related to the storage and distribution of the drug.

The drug cannot be sold until a Canadian market authorization has been issued. It can, however, be moved to an alternate storage facility, as long as the Minister has been notified by the CPHO of the civic address of that facility.

**PMPRB Price Regulation of Drugs Authorized for Use in COVID-19**

Q19. Does the Patented Medicine Prices Review Board (PMPRB) give special consideration to COVID-19 related products?

**A:** The PMPRB intends for the price of medicines appearing on the *List of Drugs for Exceptional Importation and Sale* or those approved via the *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19* and on the *List of drugs that have been authorized for use in COVID-19* to only be subject to review or investigation following a specific complaint from the Minister of Health or any of her provincial or territorial counterparts during the term of the Interim Order. Upon the expiry or repeal of the Interim Orders, absent a pre-existing complaint, price reviews for these medicines will be based on the prevailing domestic and international list prices, and not on the prices at introduction.

The PMPRB will continue to monitor the evolving situation regarding the COVID-19 virus in Canada, and will assess the feasibility and appropriateness of its approach.

Q20. How do I know a patented medicine is under PMPRB jurisdiction and subject to special consideration as a COVID-19 related product?

**A:** If a patented medicine is on the list(s) set out by the Department of Health under the Interim Order(s), it will be subject to the special consideration measures.

Q21. Are patented COVID-19 vaccines subject to special consideration as a COVID-19 related product?

**A:** Yes.

**Comparative Submissions**

Q22. Will a manufacturer of a generic or biosimilar product be prohibited from applying for an Interim Order authorization for the same drug that the innovator manufacturer has been granted an Interim Order authorization or an approval under the Food and Drug Regulations?

**A:** The Interim Order is generally limited in scope to the filing of applications from manufacturers of innovator COVID-19 drugs. A manufacturer of a generic or biosimilar may only submit an application for an authorization in respect of a COVID-19 drug on the basis of a direct or indirect comparison to another

drug if the manufacturer notifies the Minister of their intention to submit the application and provides information to the Minister to establish that the following requirements are met:

- a notice of compliance or authorization is issued in respect of the other drug, and
- the other drug is not offered for sale in Canada or is offered for sale in Canada but not in sufficient quantities to address the urgent public health need related to COVID-19

A generic or biosimilar manufacturer is required to provide information demonstrating that the innovator's drug is not available in sufficient quantity to supply the Canadian market. The Minister must then notify the innovator, to allow them to make representations respecting their ability to supply the Canadian market, before making a determination of insufficient supply and accepting the generic or biosimilar manufacturer's submission.

Any authorization issued under the Interim Order must have an indication related to COVID-19 and is only valid while the Interim Order is in force, which is one year from the time the Interim Order is signed. The potential need to issue authorizations for generic and biosimilar products will be limited to products used to treat COVID-19, as each vaccine is considered to be unique and can only be provided by innovators.

### Q23. What happens if supply shortage ends, will generics or biosimilars that were authorized be allowed to continue sale?

**A:** The use of the parameter of "sufficient quantities" of a drug is about setting a gate for when Health Canada would accept the generic application. Once an authorization under the Interim Order is issued, it would not be revoked.

### Q24. Under the Interim Order, will a generic or biosimilar manufacturer need to comply with the full requirements of the *Patented Medicines (Notice of Compliance) Regulations*?

**A:** A generic or biosimilar drug application that meets the eligibility criteria for authorization under the Interim Order would not trigger the *Patented Medicines (Notice of Compliance)* (PM(NOC)) *Regulations*.

### Q25. Will a manufacturer be allowed to file a submission for a Notice of Compliance under Division 8 of the *Food and Drug Regulations* based on a direct or indirect comparison to a drug that is issued an authorization under the Interim Order?

**A:** No. Under the Interim Order, a manufacturer cannot file a submission for a NOC under Division 8 of the FDR based on a direct or indirect comparison to a drug that is issued an authorization under the Interim Order. This will prevent a generic or biosimilar company from blocking a manufacturer of an innovative drug from obtaining data protection for their innovative product by attempting to file an application for their generic or biosimilar product first under Division 8 of the FDR.

**Intellectual Property Rights**

### Q26. Will data protection or protection under the *Patented Medicines (Notice of Compliance) Regulations* be provided for products authorized under the Interim Order?

**A:** Authorizations made under the Interim Order are not provided data protection under the FDR or protection under the *PM(NOC) Regulations*. This is because the Interim Order does not permit an application for an authorization based on a comparison to another drug, unless the other drug is either, not offered for sale in Canada or, is not offered for sale in Canada in sufficient quantities to address the urgent public health need related to COVID-19. In other words, a generic or biosimilar drug application will only be considered for authorization if the innovative drug is not sold in Canada, or the manufacturer of the innovative drug is unable to produce the drug in sufficient quantity to address the urgent health crisis. These criteria have been put in place to ensure that the filing of applications under the Interim Order is limited, for the most part, to manufacturers of innovative COVID-19 drugs.

Furthermore, the filing of an application for an authorization under this regulation will not affect a manufacturer's ability to later secure data protection under the FDR if its drug is later approved under the FDR.

### Q27. Are products authorized under the Interim Order subject to the *Patent Act*?

**A:** The Interim Order has no impact on the rights under the *Patent Act.*

### Q28. Without specific data protection provisions in the Interim Order, how will Health Canada protect innovative drug manufacturers?

**A:** Drugs authorized under the Interim Order cannot be used as a Canadian Reference Product for the purposes of an application made under the FDR in which a drug compares itself to a drug authorized under the Interim Order. This will prevent a generic company from blocking data protection for an innovative product by attempting to file their application first under Division 8 of the FDR. Additionally, generic applications will only be considered for authorization through the Interim Order if the innovative drug is unable to be produced in sufficient quantity to meet the Canadian demand.

**Transition**

### Q29. Will my product remain authorized once the Interim Order expires?

**A:** No. Authorizations expire with the Interim Order. However, transition measures will be put into place to permit a product authorized under the Interim Order to remain authorized following its expiry. These transition measures are being developed based on feedback received from stakeholders. Health Canada

intends to consult further with stakeholders as these transition measures are developed. It is anticipated these consultations would begin in early Fall 2020.

### Q30. What are the main objectives of the transition measures?

**A:** The main objectives of the transition measures will be to:

- enable products that have been authorized under the Interim Order to have continued market access beyond the time of expiry of the Interim Order;
- enable the review of applications and issuance of authorizations for any COVID-19 drug application that had been filed under the Interim Order, but for which the review had not yet been completed prior to the expiry of the Interim Order;
- retain terms and conditions to ensure that on-market requirements issued under the Interim Order continue to apply following the expiry of the Interim Order;
- allow for amendments to authorizations; and
- include measures that will enable companies to more easily transition their products to a NOC authorization under the FDR.

Transition measures will be in place before the Interim Order expires.

### Q31. Will intellectual property protections be provided to innovative products under the transition measures?

**A:** Measures to address intellectual property, and more specifically, the patent linkage under the *PM(NOC) Regulations* and supplementary patent protection (CSP), will be addressed as part of the transition measures. As part of transition measures, a product containing a new medicinal ingredient will also be eligible to apply for data protection.

Transition measures will be developed in collaboration with Innovation, Science and Economic Development Canada and in consultation with industry and other stakeholders.

### Q32. Will more information on safety, efficacy and quality be required to receive a Notice of Compliance under the *Food and Drug Regulations*?

**A:** Health Canada intends to offer the ability to submit an abbreviated application to companies wishing to convert the authorization received under the Interim Order into a NOC under the FDR.

This approach will prevent duplication of information previously submitted and reviewed by Health Canada and will ensure that all application requirements under Division 8 of the FDR are met. With a NOC, data protection and patent linkage would be available based on the FDR and *PM(NOC) Regulations.*

**Alternative Authorization Pathway**

### Q33. Are there alternative authorization pathways for seeking authorization of COVID-19 drugs?

**A:** Yes, instead of seeking an authorization under the drug Interim Order, a manufacturer of an innovative product has the option of pursuing a NOC under the NOC with conditions (NOC/c) policy. This option could provide the manufacturer with an authorization to market their product in Canada with the condition that they undertake additional studies to verify the clinical benefit of their innovative product. It is not anticipated that vaccines would utilize the NOC/c pathway but may still qualify for priority review if a full data package is filed.

The NOC, qualifying under the NOC/c policy, is issued under section C.08.004 of the FDR and as such, would trigger data protection and *the PM(NOC) regime*. However, the requirements under the NOC or NOC/c are limited to what is spelled out currently in Division 8 of the FDR, and do not include flexibilities such as the use of foreign decisions or rolling reviews. Submissions that are made under Division 8 of the FDR are also subject to cost recovery fees.