Health Canada Santé Canada

Guide to authorities under the Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)

Canada

Health Canada is responsible for helping Canadians maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks.

Également disponible en français sous le titre :
Lignes directrices provisoires pour l'application des pouvoirs en vertu de la Loi visant à protéger les Canadiens contre les drogues dangereuses (Loi de Vanessa)

To obtain additional information, please contact:

Health Canada
Address Locator 0900C2
Ottawa, ON K1A 0K9
Tel.: 613-957-2991
Toll free: 1-866-225-0709
Fax: 613-941-5366
TTY: 1-800-465-7735
E-mail: hc.publications-publications.sc@canada.ca

Publication date: August 2023

Cat.: H164-355/2023E-PDF
ISBN: 978-0-660-67777-4
Pub.: 230356

Table of contents

Overview

Objective

Authorities came into force for drugs (other than natural health products) and medical devices upon Royal Assent of Bill C-17 (41-2), the *Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)*, on November 6, 2014.

The authorities conferred by the *Protecting Canadians from Unsafe Drugs Act* were extended to natural health products upon Royal Assent of Bill C-47 (44-1) on June 22, 2023.

This guide will:

- help Health Canada apply the authorities fairly, consistently and effectively
- support the development of operational tools for the authorities (for example, standing operating procedures, guidance documents, process maps and templates)
- guide the development of potential future regulations related to the authorities

Background

Bill C-17 (41-2) and subsequently Bill C-47 (44-1) amended the *Food and Drugs Act* (Act) regarding therapeutic products with a goal to improve safety. These authorities:

- strengthen the safety oversight of therapeutic products throughout their lifecycle
- mandate certain health care institutions to report serious adverse drug reactions (ADRs) and medical device incidents (MDIs)
- promote greater confidence in the oversight of therapeutic products by increasing transparency, for example
    - allowing for regulations to require therapeutic product authorization holders to register clinical trials
    - requiring the Minister to make orders publicly available
    - allowing for regulations to require decisions under certain authorities, along with the reasons for those decisions, be made public
- set out increased penalties and fines for non-compliance

These authorities allow the Minister of Health to act when a safety issue is identified. Actions include the ability to order a company to carry out a mandatory product recall or perform additional tests or studies on a therapeutic product.

With the enactment of Bill C-17 (41-2) and Bill C-47 (44-1), certain authorities came into force immediately. These included the ability of the Minister to:

- require a person to provide information
- disclose confidential business information in certain circumstances
- order a change to a label or a modification to a package
- order a recall

Other authorities were subject to regulations and came into force when those regulations were included under the *Food and Drugs Regulations* and the *Medical Devices Regulations*. For natural health products, those other authorities would require supporting regulations to be made under the *Natural Health Products Regulations* before they are brought into force.

About this guide

This guide sets out principles, policies and standards that should typically be followed when Health Canada identifies situations where it may be appropriate for the Minister to exercise the power to:

- require a person to provide information
- disclose confidential business information in certain circumstances
- order a change to a label or a modification to a package
- order a recall
- require an assessment
- require tests or studies

Specifically, it:

- sets out guiding principles, policies and standards that should govern decisions made by Health Canada as a regulatory decision-maker
- covers "what" triggers the Minister's ability to make use of these powers and explains to "whom" the powers apply
- strives to ensure that Health Canada applies the authorities consistently

The overall goal is to improve both compliance and the quality of regulatory decision-making.

This guide is intended to help Health Canada staff implement their mandates and objectives fairly, consistently and effectively. It is an administrative instrument, not a legal instrument.

This document should be read along with the relevant parts of other applicable guidance documents.

Role of the regulator

Health Canada's role as a health regulator stems from the federal government's constitutional law-making power over criminal law. Criminal law is the basis for the Act. This legislation aims to protect the health and safety of the public through the control of possible hazards from food, drugs, natural health products, cosmetics and medical devices.

The Act and its regulations give the Minister and Health Canada the authority to regulate food, drugs (including natural health products), medical devices and cosmetics. As a therapeutic product regulator, Health Canada's role is to verify that regulatory requirements for the safety, quality and efficacy of therapeutic products are met through the following activities:

- scientific assessments
- product market authorization
- site and establishment licensing
- monitoring and surveillance
- compliance and enforcement

Scope and application

These authorities apply to therapeutic products. They give the Minister an improved ability to identify, assess and take action when a therapeutic product presents a risk of injury to the public.

In addition to prescription and non-prescription drugs, therapeutic products include:

- vaccines
- medical devices
- tissues and organs
- cell and gene therapies
- natural health products
- blood and blood products

Principles

Although the Act sets out the powers available to the Minister, the administration of legislation in Canada is subject to generally applicable legal principles. These principles require that administrative powers be exercised fairly, reasonably and in accordance with the powers that have been conferred on the body exercising them.

The following principles should guide the application of the powers in the Act by the Minister and Health Canada. These administrative law principles ensure that the process by which the laws are administered and enforced is accessible, fair and efficient.

- **Principle 1:** The regulator should exercise a statutory power of decision reasonably and in a procedurally fair manner that's free from bias or the appearance of bias.
- **Principle 2:** The regulator should exercise statutory powers of decision based on evidence, taking account only those considerations that are relevant to the exercise of the power. Decisions should be documented.
- **Principle 3:** Statutory powers of decision should be exercised in a transparent manner. Decisions and reasons for them should be expressed in a logical and understandable narrative.

Applying the law

Elements of the law

When deciding whether to exercise a power, the Minister (or an official acting on the Minister's behalf) first determines whether the elements of the law have been met.

There are 5 elements in a power:

1) who can use the power
2) to whom the power applies
3) to what the power applies
4) the threshold or considerations that need to be met to exercise the power
5) the scope of the power

The following example for the authority that confers a power on the Minister to require information (subsection 21.1(1) of the Act) shows how these elements can be broken down:

- If the Minister **(1)** believes that a therapeutic product **(3)** may present a serious risk of injury to human health **(4)**, the Minister may order a person **(2)** to provide the Minister with information that is in the person's control **(5)** and that the Minister believes is necessary to determine whether the product presents such a risk **(4)**.

Interpreting the elements

When determining whether the elements of the law have been met, the Minister relies on the recommendations of Health Canada. Experts analyze the scientific information, taking into account any limitations in methodology as well as perceived risk.

Openness and transparency

In addition to transparency measures that are required by regulation, administrative law principles hold that the Minister should disclose and explain the scientific evidence and reasoning used to support decisions. Increased transparency around regulatory decision-making helps regulated parties and the public better understand how decisions are made. This also enhances the integrity of the regulator.

Designation of authority

The powers give the Minister of Health the authority to use them. As a general rule, the *Interpretation Act* makes it clear that the term "Minister" includes officials in the department who act in a capacity appropriate to the exercise of the power.

Health Canada may designate officials to carry out the various regulatory functions. These designated officials and their superiors up to and including the Deputy Minister and Minister become capable of issuing Orders. Throughout this guide, "Minister" includes the "Minister" or "Minister's designate."

Consequence of contravening an Order

A person who contravenes an order made under the Act in relation to therapeutic products is guilty of a criminal offence. They may be liable for fines and penalties set out in section 31.2 or 31.4 of the Act.

To deal proactively with cases of potential or continued non-compliance with the Act, the Minister may apply to a court for an injunction (refer to section 21.5 of the Act). An injunction allows the courts to direct a person to refrain from an action that contravenes the Act or to do something to prevent a contravention of the Act.

The person named in the application is given 48 hours' notice before an injunction is issued. The person is not notified in advance if the situation is urgent and notice would not be in the public interest.

Power to require and disclose information

Power to require information: serious risk

If the Minister of Health believes a therapeutic product may present a serious risk of injury to human health, the Minister may order a person to provide information that is in their control. To do so, the Minister must believe this information is necessary to determine whether the product presents such a risk. The authority to do so is outlined in subsection 21.1(1) of the *Food and Drugs Act* (Act).

Who can use this power?

Only the Minister or designate can exercise this power. The regulator's decision to exercise the power relies upon the scientific evaluation and recommendation of Heath Canada.

To whom does it apply?

The Order applies to the person who controls the information that the Minister believes is necessary to determine whether a therapeutic product presents a serious risk of injury to human health. A "person" can be an individual, a research institution, a corporation or an authorization holder.

To what does it apply?

This power applies to therapeutic products only (refer to the description in the Overview page).

Threshold

There are 2 components to the threshold that must be met for the Minister to use this power. The Minister must believe that:

1) the therapeutic product may present a serious risk of injury to human health and
2) a person has within their control information that the Minister believes is necessary to determine whether the product presents such a risk

For the first component, information that a therapeutic product may present a serious risk of injury to human health may come from a number of sources, including:

- a pre-market scientific assessment of a clinical trial application
- a post-market scientific assessment based on sources like:
    - additional studies submitted as part of terms and conditions placed on a market authorization
    - information received as part of a routine safety update
    - information received as part of an application for a new indication
- a recommendation based on post-market safety signal
- information from other international regulatory agencies
- reports published in the medical or scientific literature
- an inspection by Health Canada or another regulator

The Act does not contain a definition of "serious risk," to allow for flexibility in its application. For further discussion about "serious risk," refer to Annex A.

The second component of the threshold is largely a question of judgment. Officials or subject matter experts will recommend to the Minister to request further information to determine whether a therapeutic product presents a serious risk of injury to human health. The recommendation must be reasonable, factual and based on the information at hand.

Scope of the power

This power allows the Minister to order a person to provide the Minister with information that is in that person's control. The power may only be used to obtain existing information and not to order a person to create new information. In other words, it can't be used to require a person to conduct new analysis or studies.

The Order must also be made against the person in control of the information. It can't be used to seek out information from another person outside the scope of the power.

Before issuing an Order

Notification and opportunity to respond

Before issuing an Order under subsection 21.1(1), the Minister may notify the person about information in their control that the Minister believes is necessary to determine whether a therapeutic product presents a serious risk to human health. The notification would set out the facts upon which the Minister is basing this belief.

The notification would also provide the affected person with a reasonable opportunity to respond in the following ways that include:

- correct an error in fact
- dispute the proposed exercise of the power
- comply voluntarily with the potential order

An Order should specify the timeframe in which the person must respond. The severity and immediacy of risk presented by the product would inform the response time. For example, it can be 12 hours, 2 business days, 90 days and so on.

The issuance, or not, of a notification does not in any way limit or prevent the exercise of the power of the Minister to issue an Order. In general, a notice would be provided because the Orders may adversely impact the regulated persons. However, in urgent or exceptional circumstances, the notice may not be provided or may be dispensed with. For further discussion of sufficient notification, refer to Annex B.

What an Order looks like

An **Order** is instructions, decisions or directions given by the Minister that are authorized by the legislation.

An Order issued by the Minister to the person in accordance with subsection 21.1(1) of the Act should include:

a) the person(s) to whom it applies
b) the legislative provision being relied upon
c) the therapeutic product in question
d) a description of the information that's in the person's control that the Minister believes is necessary to determine whether the product presents a serious risk
e) the timeframe for providing or disclosing the information
f) the consequences for contravening the Order

In accordance with subsection 21.4(2), the Order is to be made public.

Orders issued by the Minister should be accompanied by **reasoned decisions**. They should clearly communicate both the decision and the evidence used to make that decision so the affected party understands how the result was reached.

Reasoned decisions accompanying the Order should be unbiased and include:

- the legislative power being relied upon
- the decision
- an explanation of the basis for the decision and how it was reached, which may include:
    - a narrative and chronological review of the facts
    - the scientific evidence considered
    - any findings on important questions of fact and the accompanying analysis applying the facts of the law
    - any relevant criteria considered as part of the threshold determination
    - an explanation of how the evidence satisfies the threshold

Regulatory outcomes

Health Canada should evaluate the information obtained by the Minister under subsection 21.1(1). The evaluation should result in 1 of the following 3 outcomes:

1) information insufficient for the purposes of evaluation
2) no further action needed
3) additional regulatory action needed

Power to disclose information: serious risk

As outlined in subsection 21.1(2), the Minister may disclose confidential business information about a therapeutic product if the Minister believes the product may present a serious risk of injury to human health. The Minister does not need to notify the person to whose business or affairs the information relates or obtain their consent.

Who can use this power

Only the Minister of Health or the Minister's designate can exercise the power. The regulator's decision to exercise the power relies upon the scientific evaluation and recommendation of Health Canada.

What it applies to

As part of its normal regulatory functions, the regulator may obtain confidential business information (CBI) about a therapeutic product (for example, CBI that supports pre-market authorization or post-authorization). As long as the threshold is met, the Minister may disclose the CBI to any person.

This power is through the Act and applies to therapeutic products whether licensed or unlicensed (refer to the description in the Overview page).

Threshold

To use this power, the Minister must have reasonable grounds to believe that the therapeutic product may present a serious risk of injury to human health. There must be documented evidence that the therapeutic product could pose such a risk.

The Act does not contain a definition of serious risk of injury to human health. For further discussion about "serious risk," refer to Annex A.

Scope of the power

This power allows the Minister to disclose CBI about the therapeutic product. The Act sets out 3 conditions that must be met for information to be considered CBI:

"confidential business information," in respect of a person to whose business or affairs the information relates, means, subject to the regulations, business information

a) that is not publicly available
b) in respect of which the person has taken measures that are reasonable in the circumstances to ensure that it remains not publicly available and
c) that has actual or potential economic value to the person or their competitors because it is not publicly available and its disclosure would result in a material financial loss to the person or a material financial gain to their competitors

Under this provision, CBI should only be disclosed when it's necessary to mitigate the serious risk of injury to human health.

Note: Any disclosure of CBI on new chemical entities must comply with Canada's international treaty obligations, including those under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and Canada-United States-Mexico Agreement (CUSMA).

Power to disclose information: health and safety

Subsection 21.1(3) gives the Minister the power to disclose CBI about a therapeutic product without notifying the person to whose business or affairs the information relates. The Minister does not need to get their consent to disclose this information.

The CBI must concern the protection or promotion of human health or the safety of the public. Disclosure is only to certain individuals (refer to the following section on scope of power).

Who can use this power

Only the Minister or Minister's designate can exercise the power. The regulator's decision to exercise the power relies upon the scientific evaluation and recommendation of Health Canada.

What it applies to

This power applies to CBI collected about a therapeutic product. The regulator has obtained this information as part of its normal regulatory functions. For example, it was submitted to support pre-market authorization or post-authorization.

While subsection 21.1(2) allows CBI to be disclosed to anyone, subsection 21.1(3) only allows the CBI to be disclosed to certain individuals. The threshold for disclosure is lower.

Threshold

The Minister may use this power if the purpose for disclosing the CBI concerns the protection or promotion of human health or the safety of the public. The purpose speaks to the various regulatory activities that Health Canada conducts to help evaluate and monitor the safety, effectiveness, efficacy and quality of therapeutic products before and after they're marketed.

The "protection or promotion of human health" is intended to allow Health Canada to disclose CBI for 2 purposes:

1) protecting patients from safety risks or
2) promoting the safe use of therapeutic products

"Promotion" is interpreted narrowly, in keeping with Health Canada's role as a health regulator and its mandate to promote and protect the health of Canadians. In this context, the disclosure of CBI could be for the purpose of determining the appropriate prescribing of therapeutic products to optimize their use.

Scope of the power

The Minister can only disclose CBI for this purpose to the following entities or persons:

- a government
- a person from whom the Minister seeks advice
- a person who carries out functions relating to the protection or promotion of human health or the safety of the public

"Government" is defined in subsection 21.1(4) to include:

- a federal, provincial, territorial, municipal and foreign government
- an Aboriginal government as defined in the *Access to Information Act*
- a corporation named in Schedule III of the *Financial Administration Act*
- an international organization of states

This power establishes the Minister's authority to disclose CBI on a therapeutic product with the following:

- regulatory counterparts
- other federal departments and agencies
- provinces and territories
- scientific and medical experts
- members of departmental advisory bodies
- any other person who carries out functions related to protecting or promoting the health and safety of the public

Amendments concerning certain information on therapeutic products were made to the *Food and Drug Regulations* and *Medical Devices Regulations* on February 28, 2019. The amendments indicate that clinical information in drug submissions and medical device applications is no longer "confidential" once a final regulatory decision is made. Health Canada may then make this information public. Other information in therapeutic product submissions/applications may be eligible for disclosure under this authority.

Note: Any disclosure of CBI under this section concerning new chemical entities must comply with Canada's international treaty obligations under TRIPS and CUSMA.

Power to order a label change or package modification

Under section 21.2 of the *Food and Drugs Act* (Act), the Minister of Health may order the holder of a therapeutic product authorization to modify the product's label or replace or modify its packaging if it's believed that doing so is necessary to prevent injury to health.

Who can use this power

Only the Minister or designate can exercise this power. The regulator's decision to exercise the power relies upon Health Canada's scientific evaluation and recommendation.

Who it applies to

The Order applies to the holder of an authorization that authorizes the import or sale of the therapeutic product. This includes therapeutic products used in clinical trials or medical device investigational testing.

What it applies to

This power applies to therapeutic products (refer to description in the Overview page).

Threshold

The Minister may order the holder of a therapeutic product authorization to change a label or modify a package. The Minister must believe that doing so is necessary to prevent injury to health.

Health Canada assesses therapeutic products before they're available for sale in Canada.

However, new information about the risk/harms associated with the use of the product may become available following a clinical trial or once the product is on the market. The label may not adequately reflect this new information.

Confusion over similar brand names or product packaging also has the potential to cause harm.

New information about a product comes from a number of sources:

- before a product is marketed, for example:
    - during a clinical trial
- after a product is in the marketplace, for example:
    - additional studies submitted as part of terms and conditions placed on a market authorization
    - information received as part of a routine safety update
    - information received as part of an application for a new indication

This information may also come from:

- post-market safety signal detection by a manufacturer
- report from a patient or health care facility
- information shared by other international regulatory agencies
- reports published in medical and scientific literature
- an inspection or investigation performed by Health Canada or another regulator

These or other relevant sources are used to form the basis for a reasonable belief that a label change or package modification is needed to prevent injury to health.

Scope of the power

This power allows the Minister to order a therapeutic product authorization holder to change the label or modify a package. For example, the Minister may require that:

- a label be revised to include new safety information (for example, new warning)
- the brand-name or packaging be revised to prevent confusion and medication error

This power also permits the Minister to order label or package changes to therapeutic products used in clinical trials or medical device investigational testing.

Before issuing an Order

Notification and opportunity to respond

Before issuing an Order under section 21.2, the Minister may notify the therapeutic product authorization holder who sells or imports the product that they believe the product label or package requires modification to prevent injury to health. This notification sets out the facts and the relevant criteria upon which the Minister is basing this belief.

The notification also gives the authorization holder a reasonable opportunity to respond in a number of ways, such as:

- correct an error in fact
- dispute the proposed exercise of power
- comply voluntarily with the potential order

The notification should specify a reasonable timeframe in which the holder must respond. The severity and immediacy of risk presented by the product would inform the response time. For example, it can be 12 hours, 2 business days, 90 days and so on.

Issuing a notification does not limit or prevent the Minister from exercising the power to issue an Order. In general, a notice would be provided because the Orders may adversely impact the regulated persons. However, in urgent or exceptional circumstances, the notice may not be provided or may be dispensed with. For more information on sufficient notification, please refer to Annex B.

What an Order looks like

An Order is instructions, decisions or directions given by the Minister that are authorized by the legislation.

An **Order** issued by the Minister to the holder of a therapeutic product authorization in accordance with section 21.2 of the Act should include:

a) the therapeutic product holder(s) to which it applies
b) the legislative provision being relied upon
c) the therapeutic product in question
d) the risk of injury to be mitigated by changing the label or packaging (if known, the areas of the label to modify)
e) the timeframe for completing the ordered changes or modifications
f) the consequences for contravening the Order

In accordance with subsection 21.4(2), the Order is to be made public.

Orders issued by the Minister should be accompanied by **reasoned decisions**. The Order should clearly communicate the decision and the evidence used to make that decision so that the affected party understands how the result was reached. This allows for transparent decision-making.

Reasoned decisions accompanying the Order should be unbiased and include:

a) the legislative power being relied upon
b) the decision
c) an explanation of the basis for the decision and how it was reached, which may include:
    - a narrative and chronological review of the facts
    - the scientific evidence considered
    - any findings on important questions of fact and the accompanying analysis applying the facts to the law
    - any relevant criteria considered as part of the threshold determination
    - an explanation of how the evidence satisfies the threshold

Supporting regulations may be developed later with input from internal and external stakeholders.

Power to recall or require assessments, tests and studies

Power to recall (section 21.3)

Minister's powers: risk of injury to health (subsection 1)

If it's believed that a therapeutic product presents a serious or imminent risk of injury to health, the Minister may order a person who sells the product to:

- recall the product or
- send the product, or cause it to be sent, to a place specified in the Order

Recall Order: corrective action (subsection 2)

If it's believed that corrective action can deal effectively with the risk, instead of requesting the product's return, the Order may allow corrective action to be taken in respect of the product.

Prohibition: selling (subsection 3)

Subject to subsection (5), no person shall sell a therapeutic product that the Minister orders them, or another person, to recall.

Power to authorize sale (subsection 4)

The Minister may authorize a person to sell a therapeutic product, with or without conditions, even if the Minister has ordered them, or another person, to recall it.

Exception (subsection 5)

A person does not contravene subsection (3) if they sell a therapeutic product that they've been authorized to sell under subsection (4). However, they must sell it in accordance with any conditions that the Minister establishes.

Contravention of unpublished Order (subsection 6)

No person shall be convicted of an offence for contravening subsection (3), unless it's proved that at the time of the alleged contravention:

- the person had been notified of the recall order or
- reasonable steps had been taken to bring the purpose of the recall order to the notice of those persons likely to be affected by it

Who can use the power

Only the Minister or designate can exercise this power. The regulator's decision to exercise the power relies upon Health Canada's scientific evaluation and recommendation.

Who it applies to

The Order applies to the person who sells the therapeutic product. Under the Act, seller includes:

- anyone offering a therapeutic product for sale, such as a pharmacy
- a person distributing a therapeutic product, such as a drug sample in a doctor's office
- a person distributing blood from a blood establishment

What it applies to

This power applies to therapeutic products only (refer to the description in the Overview page).

Provisions relating to voluntary recall in the regulations continue to operate.

Threshold

If it's believed that the therapeutic product presents a serious or imminent risk to health, the Minister may order a person selling the product to recall it or have it sent to a place that the Minister specifies.

The *Food and Drugs Act* (Act) does not define "serious risk". This allows for flexibility in its interpretation. For more information about "serious risk", please refer to Annex A.

For the purposes of this section, "imminent" can be interpreted as "ready to take place" or "close at hand".

Scope of the power

The Minister uses this power to order the recall of a therapeutic product that's believed to present a serious or imminent risk of injury to health.

Subsection 21.3(1) allows the Minister to order a seller to remove a therapeutic product from the marketplace. This would typically involve the return of a therapeutic product to the seller. It may also include an Order to send the product to a particular place (for example, a warehouse for examination or quarantine).

Under subsection 21.3(2), the Minister may also order the seller to take corrective action. Generally, this is for cases involving large medical devices (for example, MRIs) where correcting the product is an effective means of dealing with the risk.

When a recall has been ordered, subsection 21.3(4) lets the Minister authorize a person to sell a therapeutic product that's subject to a recall to be sold with or without conditions. In this case, recalling the product would pose a greater risk to health than the reason for the recall. An example is a permitted sale of a life-saving drug not compliant with good manufacturing practices, to a group of patients for whom no alternative is available due to a drug shortage.

Before issuing an Order

Notification and opportunity to respond

Before issuing an Order under subsection 21.3(1), the Minister may notify the seller that the therapeutic product may pose a serious or imminent risk of injury to health and that the product will be subject to a recall Order. The notification would set out the facts and the relevant criteria used to form the basis of this decision.

Unless circumstances warrant otherwise, the notification would also provide the seller with a reasonable opportunity to:

- correct an error in fact
- dispute the proposed exercise of the power
- voluntarily comply with the potential order

The notification should specify the timeframe in which the seller must respond. The severity and immediacy of risk that the product presents would inform the timeframe. For example, it can be 12 hours, 2 business days, 90 days and so on.

Issuing a notification does not limit or prevent the Minister from exercising the power to issue an Order. For more information on sufficient notification, please refer to Annex B.

The Minister considers the nature of the risk posed by the product before deciding to issue an Order without prior notice.

What an Order looks like

An Order is instructions, decisions or directions given by the Minister that are authorized by the legislation.

An **Order** issued by the Minister to the seller in accordance with subsection 21.3(1) of the Act should include:

a) the person(s) to whom it applies
b) the legislative provision being relied upon
c) the therapeutic product subject to the Order (including lot number, manufacturing site and so on)
d) the requirement for the person to provide a recall plan satisfactory to the Minister
e) other instructions for conducting the recall (such as taking corrective action, performing effectiveness checks), including if necessary, the site to which the recalled product will need to be sent
f) the timeframe for conducting the above activities
g) the consequences for contravening the Order

In accordance with subsection 21.4(2), the Order is to be made public.

Orders issued by the Minister should be accompanied by **reasoned decisions**. They should clearly communicate the decision taken and the evidence used to make that decision so that the affected party understands how the result was reached. This allows for transparent decision-making.

Reasoned decisions accompanying the Order should be unbiased and include:

a) the legislative power being relied upon
b) the decision
c) an explanation of the basis for the decision and how it was reached, which may include:
    - a narrative and chronological review of the facts
    - the scientific evidence considered
    - any findings on important questions of fact and the accompanying analysis applying the facts to the law
    - any relevant criteria considered as part of the threshold determination
    - an explanation of how the evidence satisfies the threshold

Supporting regulations may be developed later with input from internal and external stakeholders.

Power to require an assessment (section 21.31)

Subject to the regulations, the Minister may order the holder of a therapeutic product authorization to conduct an assessment of the product in question. The holder must then provide the Minister with the results of the assessment.

This power is to be read in conjunction with its supporting regulations under section C.01.052 of the *Food and Drug Regulations* and section 62.1 of the *Medical Devices Regulations*.

Supporting regulations under the *Natural Health Products Regulations* may be developed at a later date with input from stakeholders.

Who can use the power

Only the Minister or designate can exercise the power. The regulator's decision to exercise the power is based on Health Canada's scientific evaluation and recommendation.

Who it applies to

The Order applies to the holder of one or more of the following therapeutic product authorizations:

- a drug identification number (DIN) that's been assigned under subsection C.01.014.2(1) of the *Food and Drug Regulations*
- a drug establishment licence (DEL) that's been issued under subsection C.01A.008(1) of the *Food and Drug Regulations*
- a notice of compliance (NOC) that's been issued under section C.08.004 or C.08.004.1 of the *Food and Drug Regulations*
- a medical device licence that's been issued under section 36 of the *Medical Devices Regulations*

What it applies to

This power applies to therapeutic products only (refer to the description in the Overview page). However, it will not apply to natural health products until section 21.31 is brought into force by an Order in Council.

Threshold

The Minister may order an authorization holder to conduct an assessment of the relevant therapeutic product and provide the results of the assessment, if the Minister has reasonable grounds to believe as follows:

1) The benefits or risk of injury to health associated with the therapeutic product are "significantly different" than they were when the authorization or licence was issued
2) Establishment licence (EL) holder (for drugs) who is an importer: the manner in which the drug is imported or the manner in which the drug is fabricated, packaged/labelled or tested outside of Canada may pose a risk of injury to health
3) EL holder (for drugs) other than an importer: the manner in which the holder conducts an authorized activity may pose a risk of injury to health

Scope of the power

The Minister may issue an assessment Order if new information indicates the benefits of or risks associated with a therapeutic product have changed since the previous authorization was issued. The Minister can only order the authorization holder to assess information that is currently available.

The power to order a test and study under section 21.32 gives the Minister the ability to obtain additional information about the product's effects on health or safety.

Before issuing an Order

Notification and opportunity to respond

Before issuing an Order under section 21.31, the Minister may notify the authorization holder that the threshold for issuing an assessment order has been reached. The Minister may not order the holder to conduct an assessment solely on information that had been previously provided to support an application for market authorization or to license an establishment.

The notification sets out the facts and the relevant criteria upon which the Minister is basing this Minister's belief.

The notification also provides the holder with a reasonable opportunity to:

- correct an error in fact
- dispute the proposed exercise of the power
- discuss compliance with the potential order

An Order should specify the timeframe in which the holder must respond. The severity and immediacy of risk that the product presents would inform the timeframe. For example, it can be 12 hours, 2 business days, 90 days and so on.

Issuing a notification does not limit or prevent the Minister from exercising the power to issue an Order. In general, a notice would be provided because the Orders may adversely impact the regulated persons. However, in urgent or exceptional circumstances, the notice may not be provided or may be dispensed with. For more information on sufficient notification, please refer to Annex B.

What an Order looks like

An Order is instructions, decisions or directions given by the Minister that are authorized by the legislation.

An **Order** issued by the Minister to the authorization holder in accordance with section 21.31 of the Act should include:

1) the person(s) to whom it applies
2) the legislative provision being relied upon
3) the therapeutic product and relevant authorization subject to the Order (including lot number, manufacturing site)
4) the rationale as to why the Minister now believes that the benefits or risks associated with the therapeutic product are different than when the authorization was issued or amended
5) the timeframe for responding to the Order and providing the Minister with the results of the assessment
6) the consequences for contravening the Order

In accordance with subsection 21.4(2) of the Act, the Order is to be made public.

Orders issued by the Minister should be accompanied by **reasoned decisions**. They should clearly communicate both the decision and the evidence used to make that decision so that the affected party understands how the result was reached. This allows for transparent decision-making.

Reasoned decisions accompanying the Order should be unbiased and include:

- the legislative power being relied upon
- the decision
- an explanation of the basis for the decision and how it was reached, which may include:
    - a narrative and chronological review of the facts
    - the scientific or other new evidence considered
    - any findings on important questions of fact and the accompanying analysis applying the facts to the law
    - any relevant criteria considered as part of the threshold determination
    - an explanation of how the evidence satisfies the threshold

The results of an assessment and steps taken

After examining the results of an assessment, the Minister will:

- provide the authorization holder with the results of the examination
- publish a summary of the results of the examination
- publish a description of any steps the Minister has taken or may take as a consequence of the examination

If the benefits or risks associated with the therapeutic product are not significantly different from when the authorization was issued or amended, the Minister may take no further action.

If, however, there is sufficient information to determine that the benefits or risks associated with the therapeutic product are significantly different from when the authorization was issued or amended, the Minister may take regulatory action. This may include cancelling a DIN or suspending an NOC, a DEL or a medical device licence.

Under subsections C.01.014.6(3) and C.08.006(3) of the *Food and Drug Regulations*, the Minister may cancel the assignment of a DIN or suspend an NOC if:

- the authorization holder has failed to comply with the Order
- the Minister determines the results of the assessment are not sufficient to establish that the benefits associated with the drug outweigh the risks of injury to health

Under section C.01A.017.1 of the *Food and Drug Regulations*, the Minister may suspend a DEL if:

- the licensee has not complied with the Order
- the Minister determines the results of the assessment are not sufficient to establish that the licensing requirements in paragraph C.01A.005(l), subparagraph C.01A.005(m)(ii) or (iii) or paragraph C.01A.005(o) continue to be met

Under section 41.1 of the *Medical Devices Regulations*, the Minister may suspend a medical device licence if:

- the licensee has not complied with the Order
- the Minister determines the results of the assessment are not sufficient to establish that the benefits associated with the device outweigh the risks to health or safety

Before taking this type of action, the Minister considers whether there are other more appropriate means to reduce the risks. The Minister may give the authorization holder an opportunity to demonstrate how these means will be implemented.

Power to require tests, studies or other activities (section 21.32)

To obtain more information about a therapeutic product's effects on health or safety, the Minister may order the holder of a therapeutic product authorization to:

- compile information, conduct tests or studies, or monitor users' experiences with the product
- provide the Minister with the information or results of tests, studies or monitoring

This power must be read in conjunction with its supporting regulations under section C.01.053 of the *Food and Drug Regulations* and section 62.2 of the *Medical Devices Regulations*.

Supporting regulations under the *Natural Health Products Regulations* may be developed later with input from stakeholders.

Who can use the power

Only the Minister or designate can exercise this power. The regulator's decision to exercise the power relies upon Health Canada's scientific evaluation and recommendation.

Who it applies to

The Order is made against the holder of one or more of the following therapeutic product authorizations:

- a DIN that's been assigned under subsection C.01.014.2(1) of the *Food and Drug Regulations*
- a DEL that's been issued under subsection C.01A.008(1) of the *Food and Drug Regulations*
- a NOC that's been issued under section C.08.004 or C.08.004.1 of the *Food and Drug Regulations*
- a medical device licence that's been issued under section 36 of the *Medical Devices Regulations*

What it applies to

The Order applies to therapeutic products only (refer to the description in the Overview page). However, it will not apply to natural health products until section 21.32 is brought into force by an Order in Council.

Threshold

The Minister may issue an Order under section 21.32 of the Act if there are reasonable grounds to believe as follows:

- for drug DIN or NOC holder: there are significant uncertainties relating to the benefits or harms associated with the drug
- for drug EL holder: the manner in which the holder conducts an activity has introduced significant uncertainties relating to the benefits or harms associated with the drug
- for medical device licence holder: there are significant uncertainties relating to the benefits or adverse effects associated with the device
- authorization holder: is unable to provide the Minister with information sufficient to manage those uncertainties
- the applicable requirements in the regulations, along with any terms and conditions that have been imposed on the authorization, do not allow for sufficient information to be obtained to manage those uncertainties

The Minister must consider whether:

- the activities the holder will be ordered are feasible
- there are less burdensome ways of obtaining additional information about the therapeutic product's effects on health or safety

The Minister should be satisfied about 2 things:

- the holder will be able to conduct the activities in a timely manner without undue burden
- information produced as a result of the activities will likely resolve the uncertainties

Scope of the power

This power allows the Minister to order a test or study, compile information or monitor user experience that the Minister considers necessary to assess uncertainties associated with the therapeutic product.

The Minister reserves this power for cases where a lack of knowledge could negatively impact human health and safety. For example, there may be cases where information supporting the safety of a therapeutic product is determined to be invalid. Deficiencies in the test methods used to obtain the information failed to detect harms associated with the product.

Before issuing an Order

Notification and opportunity to respond

Before issuing an Order under section 21.32, the Minister may notify the authorization holder that based on new information, the Minister believes the threshold for issuing such an Order has been reached. The notification sets out the facts and relevant criteria upon which the Minister is basing this belief.

The notification also provides information demonstrating that the Minister considered whether:

- the activities the holder will be ordered to undertake are feasible
- there are less burdensome ways of obtaining additional information about the therapeutic product's effects on health or safety

The notification also provides the authorization holder with a reasonable opportunity to:

- correct an error in fact
- dispute the proposed exercise of the power
- discuss compliance with the potential Order

The Order should specify the timeframe in which the holder must respond. The severity and immediacy of risk the product presents would inform the timeframe. For example, it can be 12 hours, 2 business days, 90 days and so on.

Issuing a notification does not limit or prevent the Minister from exercising the power to issue an Order. For further information on sufficient notification, refer to Annex B.

What an Order looks like

An **Order** is instructions, decisions or directions given by the Minister that are authorized by the legislation.

An Order issued by the Minister to the authorization holder in accordance with section 21.32 of the Act should include:

a) the person(s) it applies to
b) the legislative provision being relied upon
c) the therapeutic product and relevant authorization subject to the Order (including any applicable details such as lot number, manufacturing site)
d) a description of the uncertainties and the activities ordered by the Minister intended to resolve them
e) an explanation of how the Minister assessed the feasibility of the activity and whether other less burdensome means of obtaining the information were considered
f) the timeframe for responding to the Order and providing the Minister with the results of the activity
g) the consequences for contravening the Order

In accordance with subsection 21.4(2) of the Act, the Order is to be made public.

Orders issued by the Minister should be accompanied by **reasoned decisions**. They should clearly communicate both the decision and the evidence used to make that decision so the affected party understands how the result was reached. This allows for transparent decision-making.

Reasoned decisions accompanying the Order should be unbiased and include:

- the legislative power being relied upon
- the decision
- an explanation of the basis for the decision and how it was reached, which may include:
    - a narrative and chronological review of the facts
    - the scientific or other new evidence considered
    - any findings on important questions of fact and the accompanying analysis applying the facts to the law
    - any relevant criteria considered as part of the threshold determination
    - an explanation of how the evidence satisfies the threshold

The results of an examination and steps taken

The Minister may decide to take further action if they are not satisfied that the uncertainties have been resolved or adequately managed.

Key elements for consideration about serious risk (Annex A)

This annex sets out the considerations to be used to determine whether a therapeutic product presents a serious risk of injury to human health. Determining this is complex and is conducted on a case-by-case basis when new information becomes available.

The following non-exhaustive list of elements are used as the starting point for determining serious risk:

a) **The seriousness of the adverse health consequence.** A serious adverse health consequence includes any untoward occurrence that:
   - results in death
   - is life-threatening
   - requires inpatient hospitalization or prolongs existing hospitalization
   - results in persistent or significant disability/incapacity
   - is a congenital anomaly/birth defect (this is given the most weight when determining serious risk)

Examples of the seriousness of the adverse health consequence include:

   - a change in the nature or frequency of a serious adverse health consequence posed by the therapeutic product
   - the probability of the serious adverse health consequence upon exposure to the therapeutic product

b) **Whether the patient population and/or sub-population** exposed to the particular therapeutic product is at higher risk of any potential adverse health consequences. Such populations may include children, the elderly, pregnant and lactating persons, and immunocompromised patients.

c) **The extent of the population's exposure to the therapeutic product** and the potential public health impact of the exposure.

Each element may have a different influence or "weight" on the determination of serious risk. When determining serious risk, Health Canada will also consider other contextual elements not listed above that are pertinent to the assessment of a particular risk incident. These elements include:

- public health considerations
- international regulatory actions
- chronology of events and previous regulatory actions taken
- past-history of the therapeutic product or its manufacturer

Sufficient notice (Annex B)

Affected parties may benefit from receiving notice of the Minister's intention to issue an Order against them so that they have an opportunity to be heard. For the purposes of procedural fairness, a notice should contain the following elements, depending on the circumstances:

- a reference to the section of the *Food and Drugs Act* (Act) by which the Minister derives the ability to issue the Order
- the therapeutic product subject to the notice
- scientific evidence that relates to the issue that needs to be addressed (such as a summary of the history and facts that the regulator intends to rely upon to issue the Order)
- the criteria that the regulator will use to determine the threshold has been met, including any relevant findings on important questions of fact, and the analysis used to form the basis for the conclusions reached
- the proposed necessary action the party should take to resolve the issue
- a specified reasonable timeframe for the affected party to take action to resolve the issue (this may vary depending upon the immediacy of risk that the product presents: 12 hours, 2 business days, 90 days and so on)
- a specified reasonable timeframe proposed for the affected party to respond to the notification should they want to make representations (this may vary depending upon the severity and immediacy of the risk that the product presents: 12 hours, 2 business days, 90 days and so on)
- a statement that the Minister reserves the right to extend the timeframe for the therapeutic product authorization holder to take action

Issuing a notification does not limit or prevent the Minister from exercising the power to issue an Order. In general, a notice would be provided because the Orders may adversely impact the regulated persons. However, in urgent or exceptional circumstances, the notice may not be provided or may be dispensed with.