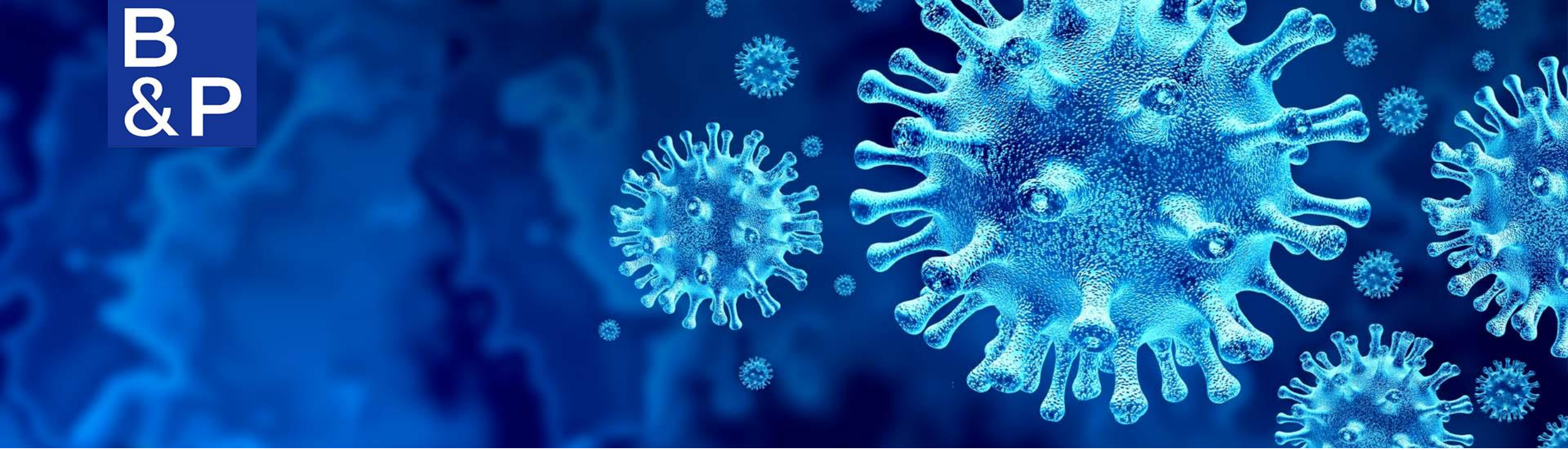

COVID-19: Regulatory and Privacy Considerations

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MEDICAL DEVICES - Definition

Section 2 of the *Food and Drugs Act* defines a device as any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in:

a. diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physical state, or any of their symptoms, in human beings or animals;

b. restoring, modifying or correcting the body structure of human beings or animals or the functioning of any part of the bodies of human beings or animals;

c. diagnosing pregnancy in human beings or animals;

d. caring for human beings or animals during pregnancy or at or after the birth of the offspring, including caring for the offspring; and

e. preventing conception in human beings or animals.

Excludes: an article, etc. that does any of the actions referred to in paragraphs a. to e. solely by pharmacological, immunological or metabolic means or solely by chemical means in or on the body of a human being or animal.

MEDICAL DEVICES - OVERVIEW

The Medical Devices Directorate ("MDD") is Canada's regulator of medical devices.

The MDD monitors and evaluates the safety, efficacy and quality of diagnostic and therapeutic medical devices in accordance with the *Food and Drugs Act* and the *Medical Device Regulations*.

A combination of:

- pre-market approval (licensing),
- post-approval surveillance (e.g. mandatory problem reporting, recall procedures and complaint handling) and
- quality systems in the manufacturing process.

MEDICAL DEVICES - Classification

Medical Devices Regulations -a risk-based approach

Medical devices are classified into one of Classes I to IV by means of the classification rules set out in Schedule 1 of the *Medical Device Regulations*.

Class I represents the lowest risk and Class IV represents the highest risk.

Canadian device classification system – harmonized with European Union's Council Directive 93/42/EEC

Set of risk classification rules to determine how to classify a device.

MEDICAL DEVICES - Classification

The risk classification scheme was developed to categorize medical devices according to the hazard a particular device presents and not the probability that harm will occur.

The following risk indicators posed by a device were used to create the Canadian classification rules:

- degree of invasiveness (i.e. comes into contact with the surface of the eye or penetrate the body, either through a body orifice / body surface),
- duration of contact (i.e. short term or long term = 30 or more days of continuous use),
- body system affected, and
- local versus systemic effects.

MEDICAL DEVICES - Classification

- Intended use of device primarily determines the Class.
- Classification must be consistent with the claims that appear on the label (incl. brochures, operating manuals, and the directions for use). If use not specified, then deemed to be that accepted in general medical practice.
- Manufacturer must take into consideration all of the rules to establish proper classification.
- Device may fall under more than one rule, however, final classification will be determined by the rule which assigns the higher risk.
- If discrepancy between the manufacturer and Health Canada regarding the classification, final decision rests with Health Canada.

ACTIVITIES RELATED TO MEDICAL DEVICES

Manufacturer

A person who sells a medical device under their own name, or under a trademark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf.

Distributor (Seller)

A person (other than a manufacturer, an importer or a retailer) who sells a medical device in Canada for the purpose of resale or use, other than for personal use. A person outside of Canada selling medical devices into Canada is also considered to be a distributor.

Importer

A person in Canada (other than the manufacturer of a medical device) who is responsible for the medical device being brought into Canada for sale.

Sell

As defined in section 2 of the Food and Drugs Act - Includes:

- offer for sale, expose for sale or have in possession for sale, or distribute to one or more persons, whether or not the distribution is made for consideration; and
- lease, offer for lease, expose for lease or have in possession for lease.

LICENSES REQUIRED FOR ACTIVITIES

Health Canada issues two types of licences:

Medical Device Licence (MDL) - issued for the device itself

- Class II, III or IV devices must have MDLs
- Prior to selling or importing, manufacturers of Class II, III or IV medical devices in Canada must obtain MDLs
- Class I devices do not require a MDL (they are monitored through establishment licenses)

LICENSES REQUIRED FOR ACTIVITIES

Medical Device Establishment Licence (MDEL) - issued to an "establishment" i.e. the entity manufacturing, importing, distributing

- Required by manufacturers of Class I devices
- Required by importers or distributors of all four device classes to permit importation or distribution (sale) of a medical device in Canada.

An MDEL permits importers, distributors, and manufacturers of Class I devices who do not sell their products through a licenced importer or distributor, to operate in Canada.

EXEMPT FROM MDEL

Manufacturers of Class II, III or IV medical devices for which they hold a valid Medical Device Licence (MDL).

Manufacturers of Class I medical devices who import or distribute solely through a person that holds an Medical Device Establishment License (MDEL)*.

* to be exempt, the manufacturer cannot import or sell medical devices manufactured by other companies.

APPLICATION FOR MDL

Medical Device Licence Application

Application fee

Amount of information which must be submitted regarding safety and efficacy varies depending on the class of the device.

Health Canada reviews the application.

If the information provided meets the requirements of the *Medical Devices Regulations*, a MDL is issued.

Review time varies on Class of device, but targets:

- Class II - 15 calendar days
- Class III – 75 calendar days
- Class IV – 90 calendar days

APPLICATION FOR MDEL

Medical Device Establishment Licence Application

Health Canada screens the application for completeness. Applicant given two opportunities to correct any deficiencies.

If application is complete, Health Canada issues an invoice for the application fee (no refunds).

30 days to pay fee; review of application begins after payment.

Review time varies on Class of device, but target for review decision is 120 calendar days from the day the MDEL application is complete.

APPLICATION FOR MDEL

The application must list all activities that apply:

- **Class I Manufacturer:** if your company name is the only company listed on the label or if your company is identified on the label as the manufacturer of a **Class I Device**. Class I manufacturers may or may not be located in Canada.
- **Importer:** if you are a company **in Canada** responsible for bringing medical devices into Canada.
- **Distributor:** if you are selling medical devices received from a manufacturer or supplier **in Canada** or if you are a company **located outside of Canada** selling medical devices in Canada other than the devices for which you are not the legal manufacturer.

APPLICATION FOR MDEL

Establishment Licencing ensures that Health Canada is aware of the identity of establishments that are selling or manufacturing devices.

The application requires attestation from a senior official of an establishment that:

a) medical devices sold or imported into Canada meet the safety requirements set out in the *Medical Devices Regulations*, and

b) regulatory procedures related to post-production activities are in place to protect Canadians, should a problem arise.

Issued by Health Canada based on the attestation that the establishment meets all of Health Canada's MDEL regulatory requirements.

During an inspection, MDEL holders must demonstrate they meet the regulatory requirements (e.g. documented procedures) they attested to having in place.

HEALTH CANADA'S RESPONSE TO THE PANDEMIC

Health Canada is speeding up the importation and sale of "COVID-19 medical devices" i.e. device that is manufactured, sold or represented for use in relation to severe acute respiratory coronavirus 2 (SARS-COV-2)

On March 18, 2020, the Minister of Health approved an interim order (IO) (*Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19*) to expedite the review of COVID-19 medical devices to authorize their importation and sale.

An interim order is one of the fastest mechanisms available to address large-scale public health emergencies.

Goal is for Health Canada to review all COVID-19 related applications quickly without compromising patient safety.

HEALTH CANADA'S RESPONSE TO THE PANDEMIC

Under the IO, to remove impediments for manufacturers:

- there is (generally) an exemption from the requirements of Part I of the *Medical Device Regulations*;
- manufacturers need only submit an abbreviated application to support safety, efficacy and quality of their medical device;
- fees associated with the application process are waived; and
- manufacturers need not hold a Medical Device Single Audit Program (MDSAP) prior to submitting the abbreviated application. (A MDSAP is a way that medical device manufacturers can be audited once for compliance with the standard and regulatory requirements of up to five different medical device markets: Australia, Brazil, Canada, Japan and the United States.)

HEALTH CANADA'S RESPONSE TO THE PANDEMIC

The IO provides an expedited authorization pathway for:

- new COVID-19-medical devices that are not yet licensed in Canada or other jurisdictions,
- for COVID-19-related uses for existing devices licensed under the *Medical Device Regulations*, or under this Interim Order, and
- for COVID-19 medical devices that leverage an authorization of a device from a trusted foreign regulatory authority.

ABBREVIATED APPLICATION FOR AUTHORIZATION

Application

4(1) An application for the authorization of importation or sale of a COVID-19 medical device must contain sufficient information and material to enable the Minister to determine whether to issue the authorization and must include the following:

a) the name of the device;

b) the class of the device;

c) the identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;

d) the name and address of the manufacturer as it appears on the device label;

e) the address where the device is manufactured, if different from the one referred to in paragraph (d);

f) the diagnosis, treatment, mitigation or prevention for which the device is required;

g) the known information in relation to the quality, safety and effectiveness of the device;

h) the directions for use, unless directions are not required, for the device to be used safely and effectively;

i) an attestation by the applicant that documented procedures are in place in respect of distribution records, complaint handling, incident reporting and recalls; and

j) a copy of the label of the device.

ABBREVIATED APPLICATION FOR AUTHORIZATION

Class III and IV devices

4(2) An application in respect of a Class III or IV COVID-19 medical device must contain, in addition to the information and material referred to in subsection (1), the following:

a) a description of the materials used in the manufacture and packaging of the device; and

b) a list of the countries, other than Canada, where the device has been sold, the total number of units sold in those countries and a summary of any reported problems with the device and any recalls of the device in those countries.

The application need not contain the information in RED if the applicant demonstrates the sale of the COVID-19 medical device is authorized by a “foreign regulatory” authority and has not been suspended.

A “foreign regulatory authority”

> a government agency outside Canada that has a legal right to control the manufacturing, use or sale of medical devices within its jurisdiction and that may take enforcement action to ensure that medical devices marketed within its jurisdiction comply with the applicable legal requirements.

ABBREVIATED APPLICATION FOR AUTHORIZATION

IMPORTANT: Attestation of Post Market Oversight. Requires the applicant to attest that documented procedures are in place in respect of:

- distribution records
- complaint handling
- incident reporting
- recalls

Health Canada may request additional information, including samples, if the information provided is deemed insufficient to render a decision on whether to grant authorization.

AUTHORIZATION UNDER IO

An authorization will only be granted if Health Canada:

- determines that there is a public health need for the importation and sale of the COVID-19 medical device.
- has assessed the submitted information and concluded that the applicant provided sufficient evidence to support the benefits of the COVID-19 medical device and those benefits > risks.

If authorization granted, the manufacturer may import or sell their COVID-19 medical device in Canada.

Each shipment of the COVID-19 medical device imported into Canada must be accompanied with a copy of the authorization.

The authorization is only as valid for as long as the IO is in effect (i.e. one year but subject to renewal depending on public health need).

Review is approximately 5 to 20 business days.

POST-AUTHORIZATION UNDER IO

Due to the nature of the application and expedited authorization, Health Canada may:

- Impose terms and conditions on the authorization
- Cancel the authorization
  - Benefits no longer > risks
  - Foreign authority cancels or suspends authorization

Holder of the authorization must report to Health Canada within 10 days of Canadian incidents relating to: failure of device, deterioration of its quality or effectiveness, any inadequacy in its labelling or in its directions of use.

Any device authorized under the IO is subject to mandatory recall provisions of the *Food and Drugs Act*.

CLEANERS, DISINFECTANTS, SANITIZERS - OVERVIEW

Chemical products used on environmental surfaces and inanimate objects are regulated according to their represented use or purpose.

To determine regulatory framework applicable, must consider:

- the intended use as represented by the expressed or implied claims on its label; and
- the type of surface or object to which it is intended to be applied.

CLEANERS, DISINFECTANTS, SANITIZERS - OVERVIEW

- **Cleaner**: A substance, or mixture of substances, that physically removes foreign material from surfaces and objects due to the detergent or enzymatic properties of the formulation
- **Disinfectant**: A substance, or mixture of substances, capable of destroying or inactivating pathogenic microorganisms present on surfaces and objects due to the antimicrobial action of the active ingredient(s)
- **Sanitizer:** A substance, or mixture of substances, that reduces the bacterial population on surfaces and objects due to the antimicrobial action of the active ingredient(s)

DISINFECTANTS

- Disinfectant drugs are classified as non-prescription drugs.
- Disinfectant drugs require a pre-market assessment and assignment of a drug identification number (DIN) prior to being sold in Canada.
- Pre-market assessment may require evaluation of:
  - Efficacy
  - Safety
  - Quality
- Market authorization requires draft labelling which complies with the *Food and Drugs Act* and *Regulations.*
- For a DIN to be issued for a disinfectant regulated as a drug, the product must be established by the Natural and Non-prescription Health Products Directorate to be safe and effective for its intended use.

DISINFECTANTS CONTINUED…

- A drug establishment licence (DEL) is required for any person in Canada who is: fabricating, packaging, labelling, testing, importing, distributing, or wholesaling a drug
- The holder of an establishment licence must ensure that the licensable activities are being conducted in compliance with Good Manufacturing Practices (GMP) requirements
- Compliance with GMP includes:
  - mandatory declaration of the manufacturing process of a drug
  - record keeping regarding history of a production batch of the drug
  - drug's expiration date (i.e., shelf-life)
  - continuing stability program

HARD SUFRACE DISINFECTANTS - DEL EXEMPTION

- Fabricators, packagers/labellers, distributors, importers and testers of disinfectants for use on non-critical medical devices, environmental surfaces and inanimate objects **are not required** to obtain an establishment licence or meet GMP compliance requirements
- They are still expected to meet the provisions of section 8 of the *Food and Drugs Act*:

> 8. No person shall sell any drug that
>
> (a) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions; or
>
> (b) is adulterated.

- Health Canada provides a voluntary standard guidance to meet requirements of Section 8

HAND SANITZIERS (ALCOHOL-BASED)

Alcohol-based hand sanitizers containing the following ingredients are natural health products (NHPs) in Canada:

  - Ethanol
  - Isopropanol

- A product licence, represented by a Natural Product Number (or NPN), is required to legally distribute the product
- A site licence (SL) is required to manufacture, package, label and/or import an NHP hand sanitizer in Canada
- The holder of SL must ensure that the licensable activities are being conducted in compliance with GMP

HEALTH CANADA'S INTERIM INITIATIVES - EXPEDITED LICENSING

- Domestic companies that do not currently have a DEL or SL to conduct activities related to hand sanitizers and disinfectants may submit an application for expedited review to Health Canada
- Domestic companies that do not currently have a DIN or NPN for a disinfectant or hand sanitizer may submit an application for expedited review to Health Canada

EXPEDITED LICENSING – ALCOHOL-BASED HAND SANITIZERS

- The interim approach applies to products that strictly comply with Health Canada's Antiseptic Skin Cleansers (Personal Domestic Use) monograph
- This monograph sets out pre-cleared information about an ingredient or product, including acceptable uses, and supports the licensing of certain NHPs
- Applications that go beyond the parameters of the monograph are not eligible for the expedited licensing process

EXPEDITED LICENSING – ALCOHOL-BASED HAND SANITIZERS CONTINUED…

- SL Application:
  - Certain GMP requirements are waived:
    - Stability testing is not required
    - Quality assurance report is not required
    - For products containing more than 50% alcohol, finished product testing for microbiological contaminants is not required
- PL Application:
  - Upon notifying Health Canada, PL for hand sanitizers (for personal use) can also be expanded for distribution to healthcare and commercial settings

LABELLING REQUIREMENTS – ALCOHOL-BASED HAND SANITIZERS

- As per *Food and Drugs Act*, it is illegal to label, sell or advertise a product, including hand sanitizers, in a false, misleading or deceptive manner
- Labelling must be compliant with the product licence (consistent with Antiseptic Skin Cleansers monograph)
    - Authorization under this monograph **does not** permit any specific references to "COVID-19", "SARS-CoV-2" or "coronavirus"
- The requirement for bilingual labelling is waived
    - still required for distribution in bilingual regions

GRADE - ALCOHOL-BASED HAND SANITIZERS

- Health Canada will no longer limit manufacturers to using food grade ethanol for production of hand sanitizers
- Temporary authorized use of technical-grade ethanol:
  - Technical - grade ethanol has more impurities, including acetaldehyde

GRADE - ALCOHOL-BASED HAND SANITIZERS

- Manufacturers that use technical-grade ethanol must provide additional information on their product labels:
  - Indicate that technical-grade ethanol is included as an ingredient;
  - specific directions for use and warnings that these products are intended for adult use only, that they should not be used on broken or damaged skin, that they should not be used by women who are pregnant or breastfeeding, and that they should not be inhaled; and,
  - information on how to report any adverse reactions to Health Canada

CLAIMS - HARD SURFACE DISINFECTANTS

- Manufacturers and distributors of hard surface disinfectants can make claims for the virus that causes COVID-19 (SARS-CoV-2), if these authorized products are already:
  - labelled as a broad-spectrum virucide
  - carry a specific claim against non-enveloped viruses of the picornaviridae, caliciviridae, astroviridae, reoviridae, or papillomaviridae families or
  - carry a specific claim against a specific coronavirus, such as
    - MERS-CoV
    - SARS-CoV
    - human coronavirus strain 229E

PRIVACY CONSIDERATIONS - OVERVIEW

- “Personal information” is generally defined in federal and provincial law as “information about an identifiable individual”
- Properly aggregated or anonymized data does not contain personal information - not subject to privacy legislation
- De-identifying data = general term for the process of removing personal information from a record or data set (helps protect privacy of individuals)
- Importance of consent, consider whether an exception applies

OPC “A Framework for the Government of Canada to Assess Privacy-Impactful Initiatives in Response to COVID-19”

- Framework is intended assist government institutions and help “guide the development of privacy impactful initiatives that seek to alleviate the effects of the pandemic”
- “Flexible and contextual” application of privacy laws, but principles still apply (e.g., necessity, purpose limitation, proportionality)

OPC “A Framework for the Government of Canada to Assess Privacy-Impactful Initiatives in Response to COVID-19”

- Key Privacy Considerations:
  - Legal Authority
  - Necessity and Proportionality
  - Purpose Limitation
  - De-identification and other safeguarding measures
  - Vulnerable Populations
  - Openness and Transparency
  - Open Data
  - Oversight & Accountability
  - Time Limitation

POSITION OF REGULATORS

- Generally, organizations are required to obtain consent and to collect, use and disclose information only for purposes a reasonable person would consider appropriate in the circumstances
- Privacy laws are not a barrier to appropriate information sharing during a pandemic
  - Legislation typically includes collection, use or disclosure in emergency circumstances or when necessary to protect the health of an individual

PIPEDA –

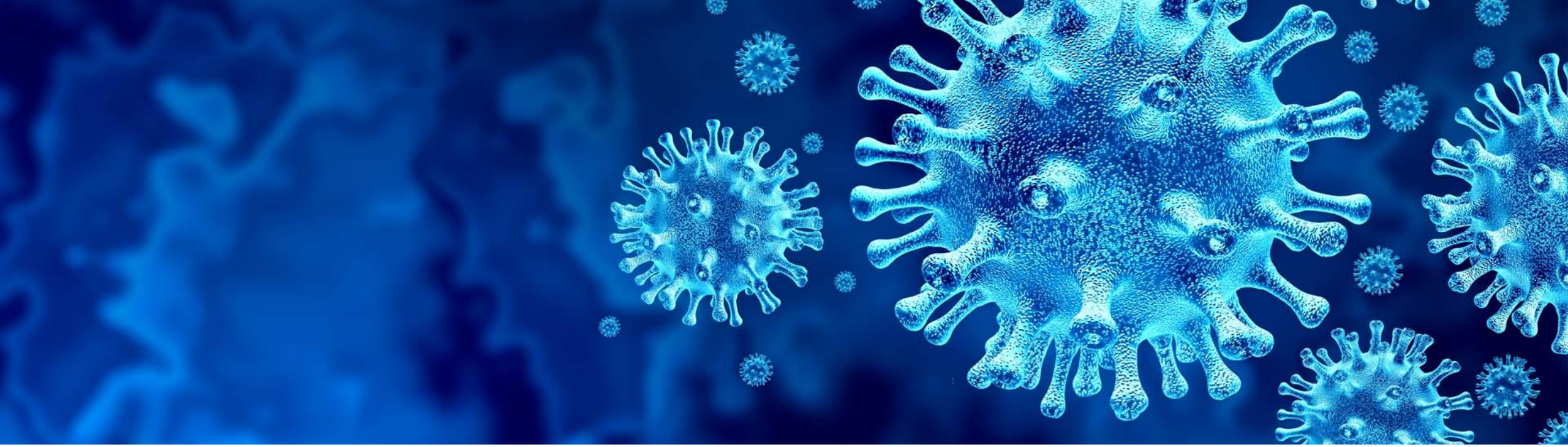
- If the collection is clearly in the interests of the individual and consent cannot be obtained in a timely way (paragraph 7(1)(a)), such as if an individual is critically ill or in a particularly dangerous situation, and needs help.
- If the collection and use is for the purpose of making a disclosure required by law (paragraphs 7(1)(e), 7(2)(d) and 7(3)(i)). For instance, this would include where a public health authority has the legislative authority to require the disclosure.

COVID 19, PRIVACY INITIATIVES

- PANTHR (Ontario government and Office of the Information and Privacy Commissioner of Ontario)
  - “Pandemic Threat Response” – platform that will hold secure health data (de-identified) to allow researchers to better support health system planning and responsiveness, including immediate need to analyze current COVID-19 outbreak
- Google & Apple Contact Tracing initiative
  - Privacy, transparency and consent are of “utmost importance in this effort”
  - Privacy by Design / Default

INDIVIDUALS – VIDEO CONFERENCING

- Movement to more remote working and videoconferencing
- OPC blog on videoconferencing
  - Follow news stories on technology (privacy/security vulnerabilities)
  - Review Privacy Policy & Terms of Use
  - New account = new password
  - Make meeting private/locked/accessible only to invitees & password protected
  - Consider where you are sitting / background objects
  - Ensure videoconferencing app is up to date
  - Be mindful of your surroundings and any personal information shared during a call



Thank you

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