Health Canada Santé Canada

Canada

Inspection & Licensing of Health Products during COVID-19

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YOUR HEALTH AND SAFETY... OUR PRIORITY.

Overview

Health Canada continues to work closely with the Public Health Agency of Canada to monitor and respond to this evolving situation.

Health Canada recognises the need for flexibilities to ensure a balance is maintained between rapid access to imported and domestic products and assuring appropriate product quality oversight.

- Key challenges – GMP and DELs
- Need to adapt to the evolving context
- Alternative approaches being explored
- On-site inspections

Key challenges – GMP and DELs:

Main challenges raised by stakeholders:

- Higher product demands
- Global supply chain – patient access to medicines
- Need for expedited innovation and development of drugs and devices
- Maintenance of product quality standards with limited access to staff and resources

A need to adapt to the evolving context

1 Interim Order

- **Exceptional importation**
- Products medically necessary / important to mitigate the risks of COVID-19

2 Flexibilities

- **Interim approaches**
- Extensions, new forms of evidence

Access to high quality drugs

3 New Approach

- Electronic licensing
- Remote Evaluations

A need to adapt to the evolving context

1 Interim Order (IO)

The IO Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in relation to COVID-19

- ✓ Allows 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

- ✓ Rapid market access to the health products deemed medically necessary and important to mitigate the risks of COVID-19

A need to adapt to the evolving context

2 Flexibilities

Regulatory & Guidance

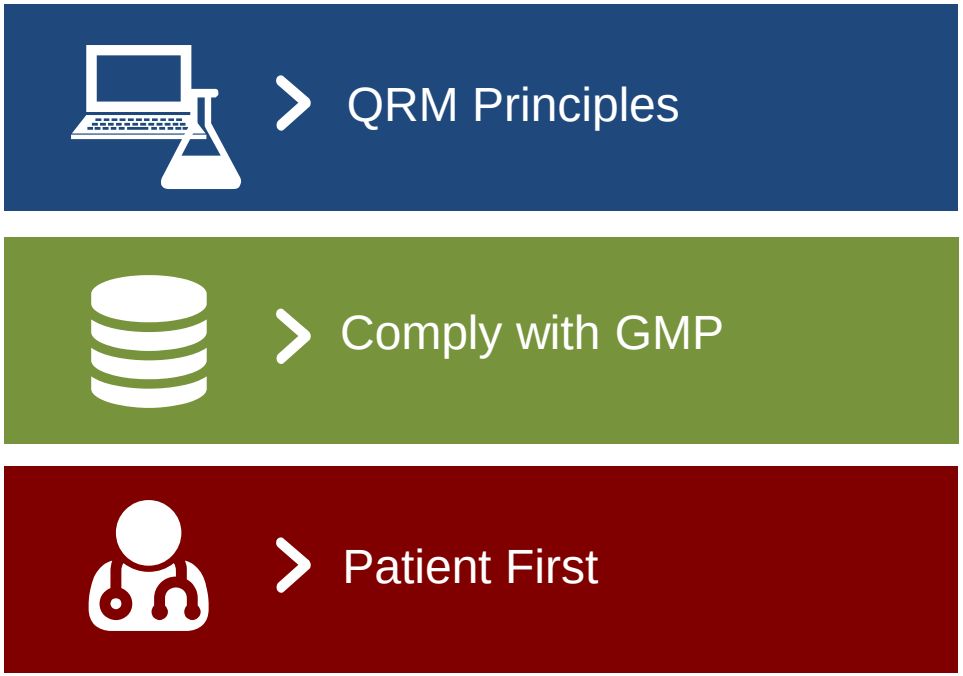
- Ensure a balance is maintained between rapid access to imported and domestic products and assuring appropriate product quality oversight
- Flexibilities have been communicating via a series of DEL Bulletins
- Health Canada will continue to monitor the context during the pandemic, and adapt as necessary

For more information or to access all DEL Bulletins, you can register at GCCollab.

A need to adapt to the evolving context

DEL Bulletin 84 – Business Impact Mitigation/Relief

The following overarching principles should be taken into account when adapting to the current context:



A need to adapt to the evolving context

DEL Bulletins 75 & 84 – Business Impact Mitigation/Relief

Due to restrictions on travel, Health Canada has modified the requirements of GMP evidence for foreign buildings:

- Extension of the New Evidence Required By (NERBY) dates for foreign building evidence
- Extension of the acceptable "age" of inspection reports to demonstrate GMP compliance of foreign buildings (from 3 years to 5 years)
- Acceptance of corporate/consultant audit reports to demonstrate GMP compliance of foreign buildings
- Extension of acceptable "age" of evidence of Foreign Building compliance for Table A

A need to adapt to the evolving context

DEL Bulletins 76 & 77 – Product Testing Relief

Due to challenges of the global supply chain, limited availability of contract service providers and of in house staff, Health Canada is allowing:

- Modified approach to ID testing of imported Rx drugs
- Deferral of confirmatory testing of Rx drugs
- Shipment in quarantine
- No ID or confirmatory testing required for certain non-Rx drugs coming from a site in an eligible PIC/s country
- Direct shipment to retailers of certain non-Rx drugs if released prior to receipt in Canada

A need to adapt to the evolving context

3 New Approach

Assessing GMP Compliance

- As part of the overall strategy to continue the flow of critical drugs to the Canadian market and support industry moving forward, assessments of GMP compliance continue to be done

- Holistic and flexible approach to assessing the GMP compliance

- Alternative approaches to on-site inspections – Protecting the health and safety of all.

What alternative approaches are being explored?

Domestic – Remote GMP evaluations:

- Based on documentation/information requested and received via email/e-post
- No on-site portion, off-line review of documentation

Eligibility

- Lower risk activity (wholesale, distribute, import, initial testing)
- Priority given to new or amended DEL applications

Exclusions

- High risk activities (Fabrication, packaging/labeling, sterile)

What about On-Site Inspections?

Foreign Inspections

- All foreign on-site inspections are postponed until further notice
- Aligns with trusted regulatory partners.
- Working in close collaboration with its trusted regulatory partners in exploring alternative means to assess GMP compliance of foreign sites.

Resources:

Health Canada is committed to maintaining on-going and transparent dialogue with stakeholders.

To ensure COVID-19 questions are addressed appropriately, please direct all inquiries to the following email addresses:

- For drug establishment licensing:
  hc.del.questions-leppp.sc@canada.ca
- For domestic GMP inspections:
  hc.drug.gmp.questions-bpf.medicaments.sc@canada.ca
- For foreign GMP inspections:
  hc.foreign.site-etranger.sc@canada.ca