Changes to Good Manufacturing Practices Guide for Drug Products (GUI-0001)

Jul 2020
Drug GMPs

OVERVIEW

- On July 1, 2020, Health Canada published an updated GUI-0001 Good Manufacturing Practices Guide for Drug Products, replacing the previously effective 2018 edition.
- This QuickNote focuses on the key updates made to the regulations, with an emphasis on the regulatory amendments to Finished Product Testing.

WHO DOES THIS APPLY TO?

- Importers
- Distributors
- Fabricators
- Packagers
- Labellers
- Wholesalers
- Testers

2550 Argentia Rd., Suite 119
Mississauga, Ontario, Canada
L5N 5R1
TOLL FREE: 1 (877) 877-5152
PHONE: (905) 363-1182
FAX: (905) 542-7981
www.qualityandcompliance.com

KEY POINTS

C.02.008 Sanitation

- Added expectation that the medical examinations for communicable diseases on staff who have access to any area where a drug is exposed are to be performed by qualified healthcare professionals who are authorized under their professional practice.

C.02.012 Manufacturing Control - Agreement

- New contact email for notifying Health Canada of any important information from foreign regulatory authority:

  hc.foreign.site-etranger.sc@canada.ca

C02.019 Finished Product Testing

Drugs not subject to certain testing requirements

- A distributor or importer of a non-prescription drug that is fabricated, packaged/labelled and tested in a recognized country is **not** required to **perform finished product testing** and **identity testing**, if all of the following conditions are met:
  - The drug belongs to a class of drugs listed below:
    - Mouthwashes
    - Personal care use antiseptic skin cleansers
    - Sunscreens
    - Anti-dandruff products
    - Diaper rash products
    - Medicated skin care products
    - Acne therapy products
    - Throat lozenges

2550 Argentia Rd., Suite 119
Mississauga, Ontario, Canada
L5N 5R1
TOLL FREE: 1 (877) 877-5152
PHONE: (905) 363-1182
FAX: (905) 542-7981
www.qualityandcompliance.com

- Athlete's foot products

  - The drug aligns with the health claims, strengths, routes of administration, and active ingredient amounts set out in the List of Non-Prescription Drugs Not Subject to Certain Testing Requirements.
  - The drug is fabricated in Canada or in a recognized country or region[1].
  - The drug is packaged/labelled in Canada or in a recognized country or region.
  - The drug is tested in a recognized country or region.

- A drug that satisfies the above conditions may be shipped directly to a person other than an importer if:

  - Prior to importing, the importer receives a document that demonstrates that the drug complies with applicable specifications (e.g. CofA, CofM, Batch Certificate).
  - The importer and distributor have measures in place to ensure that all respective importation requirements are met (e.g. Quality Agreements).

Additional Identity Testing exemptions for Drugs from non-MRA country that are not covered by the List

  - Identity testing is not required for multiple shipments of the same finished product lot (from non-MRA countries) where both primary and secondary packaging/ labelling of the entire batch has been completely processed as a single batch (not as partial packaging of the same bulk). However, storage and transportation conditions must be evaluated for each shipment.

2550 Argentia Rd., Suite 119
Mississauga, Ontario, Canada
L5N 5R1
TOLL FREE: 1 (877) 877-5152
PHONE: (905) 363-1182
FAX: (905) 542-7981
www.qualityandcompliance.com

[1] The following countries are notable exclusions and are not part of the Recognized Countries and Regions list: China (mainland), India, Latin America (with exception of Argentina)

Periodic Confirmatory Testing for Drugs from non-MRA country that are not covered by the List

- Additional explanations have been added to clarify types of periodic confirmatory testing and when they should be performed.
  - A confirmatory testing is to be performed annually on at least one strength of a drug.
  - Each strength of a drug is to be tested at least once every 5 years.

Additional information for relying on foreign manufacturer's testing

- A third-party audit that focuses on a foreign manufacturer's integrity in laboratory testing provides added oversight beyond the inspections that regulatory authorities conduct.

C.02.024.1 Records

- A suggestion has been added to have a site master file available on-site to help satisfy the requirement to maintain detailed plans and specifications of each building in Canada.

  Explanatory notes for drug establishments on the preparation of a site master file (GUI-0005) can be used as reference when preparing a site master file.

Terms

- Batch Certificate
  - Update to include the application of its use to non-MRA drugs that are referred to under the List of Non-Prescription Drugs Not Subject to Certain Testing Requirements.
- Wholesaler
  - Addition of "selling drug containing cannabis as defined in subsection 2(1) of the Cannabis Act (C.01A.001(1))".

2550 Argentia Rd., Suite 119
Mississauga, Ontario, Canada
L5N 5R1
TOLL FREE: 1 (877) 877-5152
PHONE: (905) 363-1182
FAX: (905) 542-7981
www.qualityandcompliance.com

Guidance Title Changes

- GUI-0002 Guidance on Drug Establishment Licences
- GUI-0023 Risk classification guide for drug good manufacturing practices observations
- GUI-0029 Guide to validation – drugs and supporting activities
- GUI-0039 Drug and natural health products recall guide
- GUI-0066 Annex 7 to the Good manufacturing practices guide – Selected non-prescription drugs
- GUI-0069 Guidelines for environmental control of drugs during storage and transportation
- GUI-0071 Annex 3B to the Good Manufacturing Practices Guidelines – Positron Emitting Radiopharmaceuticals (PER's)
- POL-0016 Recall policy for health products

WHAT DO I NEED TO DO?

- If you are an importer or distributor of products from a non-MRA country:
    - Assess the applicable products to determine if they fall under the List of Non-Prescription Drugs Not Subject to Certain Testing Requirements.

      If the given criteria are met, update your Finished Product Testing and Identity Testing processes and procedures for these products.
    - Consider whether direct shipment of applicable products to customers would benefit your business.
- Prepare a site master file using the Guideline GUI-0005.

2550 Argentia Rd., Suite 119
Mississauga, Ontario, Canada
L5N 5R1
TOLL FREE: 1 (877) 877-5152
PHONE: (905) 363-1182
FAX: (905) 542-7981
www.qualityandcompliance.com

DEFINITIONS

MRA	Mutual Recognition Agreement
Recognized Country or Region	A country or region that is set out in the document entitled List of Foreign Countries or Regions and Their Regulatory Authorities for the Application of Subsection C.02.019(5) of the Food and Drug Regulations, published by the Government of Canada on its website, as amended from time to time

RELATED DOCUMENTS

- Good Manufacturing Practices (GUI-0001)
- Explanatory notes for drug establishments on the preparation of a site master file (GUI-0005)
- Annex 7 to the Good manufacturing practices guide – Selected non-prescription drugs (GUI-0066)
- List of Non-prescription Drugs for Which the Testing Requirements Set Out in Subsections C.02.019 (1) and (2) of the Food and Drug Regulations Do Not Apply
- List of Foreign Countries or Regions and Their Regulatory Authorities for the Application of Subsection C.02.019(5) of the Food and Drug Regulations

2550 Argentia Rd., Suite 119
Mississauga, Ontario, Canada
L5N 5R1
TOLL FREE: 1 (877) 877-5152
PHONE: (905) 363-1182
FAX: (905) 542-7981
www.qualityandcompliance.com

Quick NOTES

Jul 2020
Drug GMPs

FAQ

1. What do the Finished Product Testing regulatory amendments mean?

a. Canadian importers and distributors are now exempt from performing confirmatory and identity testing as part of release process on certain non-prescription products imported from recognized countries or regions prior to being sold in Canada.

These tests are duplicative as the qualified imported products have already been tested in foreign jurisdictions with GMP requirements and compliance programs comparable to Canada's.

b. Importers are now permitted to ship finished products that are exempt from confirmatory testing directly to Canadian retailers, distributors, and wholesalers.

2. Do these amendments impact the release and oversight for products shipped directly to Canadian retailers, distributors, and wholesalers?

No. Importers and distributors remain responsible for the safety, efficacy, and quality of the finished products and for ensuring the product is GMP compliant and meets finished product specifications, regardless of any arrangement made for direct shipping.

3. How do importers ensure importation requirement are met in case of direct shipment?

a. Importers perform full release activities prior to shipping of the product by reviewing all applicable documentation and testing results.

b. Importers and distributors are to retain a copy of the batch certificate for the drug they import. Where Batch Certificate is not available, Certificate of Analysis (CofA) and Certificate of Manufacture (CofM) are acceptable if they contain all the information that would be found on a Batch Certificate.

c. Importers and distributors are responsible for having the appropriate quality agreements, identifying roles and responsibilities, between all the parties involved.

2550 Argentia Rd., Suite 119
Mississauga, Ontario, Canada
L5N 5R1
TOLL FREE: 1 (877) 877-5152
PHONE: (905) 363-1182
FAX: (905) 542-7981
www.qualityandcompliance.com

4. How do the Regulatory Finished Product Testing amendments impact Canadian Importers participating in the Expanded Sunscreen Pilot?

The Expanded Sunscreen Pilot is cancelled since the new amendments incorporate the flexibilities allowed under the Pilot. As such, all applications currently in queue will not be reviewed. Canadian importers that participate in the Expanded Sunscreen Pilot are required to follow the amended Regulations and update all their documents to reflect the amendments. They are also required to maintain all records pertaining to the Expanded Sunscreen Pilot in accordance with the Food and Drug Regulations requirements.

5. Are the lists of products and countries impacted by these regulatory amendments subject to change?

Changes to both lists (of products and of countries) could arise as a result of ongoing initiatives. The lists are published on Health Canada's website and could be amended from time to time by the Minister.

6. What sort of implementation activities are expected to support these regulations?

Given that the Finished Product Testing regulatory amendments are removing existing requirements, implementation activities such as staff training and compliance promotion are minimal.

7. What is the source of the amendments?

The amendments pertaining to certain non-prescription drugs from recognized countries or regions have been made as part of the Canada - United States - Mexico Agreement (CUSMA).

8. Will Q&C be updating the Blue Book?

Yes. Please contact us for further information and to place pre-orders. Online booklet ordering is available here.

2550 Argentia Rd., Suite 119
Mississauga, Ontario, Canada
L5N 5R1
TOLL FREE: 1 (877) 877-5152
PHONE: (905) 363-1182
FAX: (905) 542-7981
www.qualityandcompliance.com