HEALTH CANADA RELEASE ASSESSMENT

Title of Guidance, Policy, or Changes to Act/Regulations:	CANADA AND EUROPEAN UNION (EU) - RECOGNITION OF GOOD MANUFACTURING PRACTICES (GMP) EXTRA-JURISDICTIONAL INSPECTION OUTCOMES
Release Date:	22 APRIL 2021
Effective Date:	22 APRIL 2021
Assess By:	3 JUNE 2021 (note: Updates post this date have been made and are detailed below)
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Discussed With:	YANNIE MELETOPOULOS

TOPLINE:

The scope of the existing Mutual Recognition Agreement (MRA) between Health Canada (HC) and European Medicines Agency (EMA) has been expanded. In addition to the mutual recognition of the outcomes of the GMP inspections conducted within HC and EMA jurisdictions, the scope of the mutual recognition has now expanded to include GMP inspections conducted by HC or the EMA outside of HC and EMA jurisdictions.

Gilead Sciences Canada, Inc. (GSCI) may benefit from the Recognition of GMP Extra-Jurisdictional Inspection Outcomes if the most recent GMP inspection of a foreign building is conducted by HC or equivalent EU Regulatory Authority. GSCI can maintain or add foreign buildings to their Drug Establishment Licence (DEL) by requesting HC to obtain the extra-jurisdictional CoC from the equivalent EU Regulatory Authority that conducted the inspection. In such case, GSCI would not need to submit full GMP evidence to Health Canada for review, which would shorten the time required to prepare a DEL application.

Further details on significant revisions (only) are provided below.

HISTORY:

- The prior guidance or policy was entitled:
  - *MRA (September 1998).*
  - *The Comprehensive Economic and Trade Agreement (CETA) - Protocol on the mutual recognition of the compliance and enforcement programme regarding GMP for pharmaceutical products replaced the Canada-EU 1998 MRA Annex (September 2017)*
- This is a new guidance or policy:
  - *Recognition of GMP extra-jurisdictional inspection outcomes (1 April 2021) under The Comprehensive Economic and Trade Agreement (CETA) - Protocol on the mutual recognition of the compliance and enforcement programme regarding GMP for pharmaceutical products replaced the Canada-EU 1998 MRA Annex (September 2017).*
  - *DEL Bulletin No. 111 Canada and the European Union's - Recognition of Good Manufacturing Practices Extra-Jurisdictional Inspection Outcomes (April 22, 2021)*
  - *Update: DEL Bulletin No. 116 Canada and the European Union's - Recognition of Good Manufacturing Practices Extra-Jurisdictional Inspection Outcomes – Additional*

information with regards to the date from which Canada and the EU will start recognizing GMP Extra-Jurisdictional Inspection Outcomes (July 7, 2021)

ASSESSMENT:

Revised Guidance or Policy:

- **Key Change(s):**
  - Canada and the EU will officially recognize GMP inspections conducted by HC or the EMA outside of their respective jurisdictions (i.e. extra-jurisdictional inspections). On April 22, 2021, Health Canada communicated in DEL Bulletin No. 111 that this notice is applicable for the inspections conducted on or after April 1, 2021. However, on July 7, 2021, Health Canada communicated in DEL Bulletin No. 116 that Canada and the EU will also recognize the outcomes of extra-jurisdictional inspections conducted prior to April 1, 2021 as long as the Certificate of GMP Compliance (CoC) is within the period of validity.
  - The expanded scope will enhance cooperation and regulatory alignment between HC and the EMA. In addition, it will reduce the regulatory burden for Canadian importers as the GMP evidence will be exchanged directly between HC and the equivalent EU Regulatory Authority.
  - Certificates of GMP Compliance (CoC), i.e. certificates issued by a regulatory authority attesting the compliance of a facility with the GMP requirements, will continue to be exchanged directly between HC and the equivalent EU regulatory authorities.

- **Potential Impact:**
  - GSCI may benefit from the Recognition of GMP Extra-Jurisdictional Inspection Outcomes. GSCI can maintain or add foreign buildings to their (DEL) by requesting HC to obtain the extra-jurisdictional CoC from the equivalent EU Regulatory Authority that conducted the extra-jurisdictional inspection. In such case, GSCI would not need to submit full GMP evidence to Health Canada for review, which would shorten the time required to prepare a DEL application.

  - RA Canada requested the clarification of this release from Health Canada and learned that the following condition must be met for GSCI to benefit from the Recognition of GMP Extra-Jurisdictional Inspection Outcomes:
    - The most recent GMP inspection of a foreign building is conducted by HC or equivalent EU Regulatory Authority. For example, if the most recent GMP inspection is conducted by US FDA or any regulatory authority other than HC or EU authority, GSCI must submit full GMP evidence to maintain or add a foreign building to the DEL

NEXT STEPS:

- RA Canada shared with QA Canada this release and the received Health Canada's clarification.
- RA Canada to circulate this release assessment to the QA Canada teams who we work with on the DEL.
- RA Canada to circulate this release assessment to the RA CMC group for their awareness.