

II. SCOPE

As defined in the Preamble, this MOU covers therapeutic products. The Participants intend to develop specific procedures for the sharing and exchange of regulatory, emergency management, and public health information related to these products. The types of information that may be shared include, but are not limited to, the following:

- A. Drafts of pending laws, regulations, guidance documents, policies, procedures, and other technical documents available to the individual Participants that are related to such therapeutic products for which the Participants have responsibility.
- B. Post-marketing data and information that could have an impact on the public health, such as pharmacovigilance data or information about impending regulatory actions including proposed market withdrawals and product recalls.
- C. Information on quality defects or product recalls of therapeutic products known by the USFDA to have been manufactured or distributed in Canada, and products known by Canada HPFB to have been manufactured or distributed in the United States.
- D. Information contained in clinical trials or related to marketing or investigational applications for therapeutic products, including the various discipline reviews. This also includes information on maximum residue levels of animal drugs in tissues of animals intended for human consumption.
- E. Information related to orphan drug designations.
- F. Inspection reports and product sample test results such as those describing the conformity of therapeutic products, or of a facility that manufactures, distributes, wholesales, tests, or imports these products, with applicable regulatory requirements.
- G. Information on facilities registered or authorized in each Participant's country that then market product to the other Participant's country, including facilities that only export their products.
- H. Information related to import refusals for reasons related to the safety, quality, or integrity of the shipment.
- I. Information on activities that feature major public involvement.
- J. Information on technology (e.g. information systems, database systems, and other related computer applications) that support the evaluation/review of the safety, quality, and efficacy of therapeutic products.