

II. SCOPE

The products covered under this MOU include (as defined in the Preamble): pharmaceutical products for human use; pharmaceutical products for animal use; and, medical devices. The Participants intend to develop specific procedures for the exchange of regulatory (including enforcement) 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, procedures, and other technical documents available to the individual Participants that are related to such pharmaceutical and medical device products.
- 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.
- C. Information on quality defects or product recalls of human or animal pharmaceutical products or medical devices known by the FDA/HHS to have been manufactured or distributed in Switzerland, and products known by Swissmedic to have been manufactured or distributed in the United States of America.
- D. Information contained in or related to marketing or investigational applications for human or animal pharmaceutical products or medical devices, 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. Inspection reports and product sample test results such as those describing the conformity of a human or animal pharmaceutical product or medical device, or a facility that manufactures these products, with applicable regulatory requirements.
- F. Information on facilities registered or authorised in each Participant's country that then market product to the other Participant's country.
- G. Information related to import refusals for reasons related to the safety, quality, or integrity of the shipment.

Such information shall not be used for purposes other than those envisaged by this MOU.