

ARTICLE VIII

Confidentiality

1. A Party shall not be required to disclose confidential proprietary information to the other Party except where such disclosure would be necessary for the Party to demonstrate the competence of its Regulatory Authority to conduct GMP Inspection and GMP Compliance Program activities.
2. A Party shall, in accordance with its applicable laws, protect the confidentiality of any proprietary information disclosed to it in connection with GMP Inspection and GMP Compliance Program activities.
3. Subject to paragraphs 1 and 2 of this Article, each Party reserves the right to make public the results of any GMP Inspection, including the conclusions of GMP Inspection reports provided by the other Party, in situations in which public health and safety may be affected.

ARTICLE IX

Safeguards

1. Each Party retains all authority under its laws to interpret and implement its Mandatory GMP Requirements.
2. This Agreement does not limit the authority of a Party to determine the level of protection it considers necessary with regard to health, safety and the environment.
3. This Agreement does not limit the authority of a Party to take all appropriate measures whenever it ascertains that Medicines may not conform with its Mandatory GMP Requirements. Such measures may include withdrawing Medicines from the market, prohibiting their placement on the market, restricting their free movement, initiating a Medicine recall, and initiating legal proceedings or otherwise preventing the recurrence of such problems, including through a prohibition on imports. If a Party takes such measures, it shall notify the other Party within 15 calendar days of taking the measures, providing its reasons.