Letter of Intent for the pilot project of relying on pharmaceutical GMP inspections results between Anvisa and Swissmedic

The Brazilian Health Surveillance Agency (Anvisa) and the Swiss Agency for Therapeutic Products (Swissmedic) acting for and on behalf of the Federal Department of Home Affairs of the Swiss Confederation (FDHA) (hereinafter referred to as "the Participants") agree to operate under the Memorandum of Understanding (MOU) between the Participants a pilot project of relying on pharmaceutical GMP inspections results.

The Participants note that their GMP control system and GMP enforcement will be deemed equivalent to the PIC/S standards for GMP inspectorates, once Anvisa has concluded its accession process to PIC/S (expected in 2020). Until then, the equivalence of Anvisa's GMP control system and GMP enforcement to the PIC/S Standards is based on a self-assessment. With a view to agree on the mutual reliance of GMP certificates, the Participants agree on the following:

1. The pilot project shall apply to all medicinal products including active pharmaceutical ingredients, investigational medicinal products, pharmaceuticals (medicinal products), biopharmaceuticals (including biologicals), and herbal medicinal products.

2. The pilot project shall be run based on the Decision Tree (attachment 1).

3. The Participants shall strive for signing the mutual reliance agreement as soon as possible based on the results of the pilot project, and unless there is any other notice, this pilot project shall remain to be run until the signing of the mutual reliance agreement. The participants agree that the signing of the mutual reliance agreement will only be possible after Anvisa has officially become a PIC/S Participating Authority.

The Letter of Intent will come into effect on the day of its signature.

Rome, Italy, October 29, 2019

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Attachment 1. Decision Tree

Attachment 1: Decision tree