



## Office of Global Policy and Strategy

### OGPS STATEMENT

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#### FDA Mutual Recognition Agreement with Swissmedic Enters Into Force

Starting today, the U.S. and Switzerland can begin to rely on each other's factual findings from a good manufacturing practice (GMP) inspection of a pharmaceutical manufacturing facility.

The FDA, the U.S. Office of the Trade Representative, and the Swiss Confederation signed an [Agreement on Mutual Recognition \(MRA\)](#) on January 12, opening the door for the FDA and the Swiss Agency for Therapeutic Products (Swissmedic) to utilize each other's GMP inspections. But the agreement couldn't enter into force, i.e., become operational, until the FDA had determined that Swissmedic is capable of conducting inspections that meet U.S. requirements, and Swissmedic had made a similar determination with respect to the FDA.

Both agencies have now completed those determinations based on the criteria and procedures outlined in the MRA and recognized each other under the MRA.

In addition to covering good manufacturing practice inspections of facilities making human drugs, the MRA with Swissmedic also includes veterinary drugs.

The MRA with Swissmedic becomes the third operational MRA to enter into force. MRAs are also in effect with the European Union and the United Kingdom.

"MRAs are an effective tool in today's global pharmaceutical market, allowing the FDA to work more efficiently and maximize its resources" said Mark Abdoo, FDA's Associate Commissioner for Global Policy and Strategy.

Over 250 pharmaceutical companies are based in Switzerland, ranging from start-ups all the way to multinationals, according to Swissmedic, which has issued manufacturing licenses to approximately 370 sites across the country.

"Sharing information will help the FDA and Swissmedic avoid the duplication of drug inspections, lower inspection costs and enable regulators to devote more resources to other parts of the world," Abdoo said.

For additional information:

[Frequently Asked Questions: Mutual Recognition Agreements](#)  
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