U.S.–Swiss Mutual Recognition Agreement on Good Manufacturing Practices

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On 12 January 2023, the United States of America and Swiss Confederation (Switzerland) signed a mutual recognition agreement (MRA) relating to Pharmaceutical Good Manufacturing Practices (GMP). The MRA will allow the U.S. Food and Drug Administration (USFDA) and the Swiss Agency for Therapeutic Products (Swissmedic) to rely upon each other's GMP inspections of pharmaceutical manufacturing facilities, avoiding the need for duplication of effort. This will enhance efficiency at USFDA and Swissmedic by allowing each agency to exercise *their respective regulatory discretion and to reallocate resources to where they are most needed.* In addition to covering GMP inspections of facilities making human drugs, the MRA includes inspections of facilities manufacturing veterinary drugs.

1. Mutual Reliance Initiatives

"Reliance" is a buzzword in the world of national competent authorities (NCAs) for enforcing pharmaceutical regulations. The more NCAs work together and are able to rely on one another's assessments, evaluations, and inspections, the more they can streamline procedures and decisions and lessen the burden on their resources. The willingness to rely on work results produced by foreign NCAs has increased in the past 10 years. The USFDA already has an MRA in place with the European Union (EU) and one with the United Kingdom, while Switzerland has already concluded MRAs on GMP with the EU, the UK, and South Korea. There also has been collaboration in non-GMP spaces such as the ACCESS consortium and the USFDA-led Project Orbis.

As a result of globalization, facilities manufacturing products for multiple markets are in place and need regulatory oversight by each jurisdiction. A seamless partnership that enables such regulatory authorities, as trusted partners, to rely on, coordinate with, and leverage one another's work, data, and actions to meet their public health goals benefits both the regulators and industry. NCAs benefit by efficiently and proactively learning about a manufacturer's current state, while manufacturers benefit by not having multiple inspections.

Additionally, bilateral agreements such as memoranda of understanding (MoUs) and confidentiality commitments (CCs) allow for cooperation between NCAs.

2. The New U.S.–Swiss MRA on GMP

On 12 January 2023, the United States and Swiss Federation signed a bilateral treaty on GMP inspections that, once implemented, will allow USFDA and Swissmedic to rely on each other's GMP inspections of pharmaceutical manufacturing facilities for human and veterinary drugs.

a. Current Policies

According to U.S. and Swiss regulations, the manufacturing of medicinal products must be carried out in accordance with, among other things, current GMP. Compliance with these regulations is assessed during inspections by the USFDA and Swissmedic (or accredited Swiss regional inspectorates on behalf of Swissmedic).

In the absence of an MRA, manufacturing facilities for medicinal products are inspected not only by the NCA of the state where the manufacturing takes place but also by the NCAs of countries that import the medicinal products. Inspections of NCAs on foreign soil are relatively expensive and oftentimes have to comply with specific requests of national law regarding activities of foreign agencies on the respective territory.

Switzerland, for example, restricts such activities by foreign administrations. A foreign NCA is allowed to carry out an inspection only if the concerned manufacturer gives its consent. Further, the foreign NCA must notify Swissmedic in advance of their intention to perform an inspection and provide Swissmedic with a copy of the inspection report after they have done so. Swiss companies and foreign NCAs, therefore, need to make arrangements for inspections with each other. Swissmedic will notify establishments in good time if it intends to accompany the inspectors from the foreign NCA.

b. Background for the MRA

Over the past few years, the United States and Switzerland have become important partners in trade and investments. Regarding trade alone, two-thirds of all exports from Switzerland to the United States are pharmaceuticals, worth over 30 billion Swiss francs (conversely, products worth only 4 billion Swiss francs are imported). With this, the United States has become the first export market for pharmaceuticals from Switzerland globally. These close trades require the regular performance of inspections by USFDA. Currently, GMP compliance of manufacturers in Switzerland for sites manufacturing for the U.S. is audited twice for the same products, once by the USFDA and once by Swissmedic.

c. Facilitations Provided by the MRA in General

The MRA provides Swiss and U.S. companies with important facilitations. Once the agreement enters into force, the USFDA and Swissmedic will in principle rely on GMP certifications issued and inspections performed by the other authority. Therefore, the NCA of the importing country need not inspect the manufacturing sites in the exporting country.

Thus, the agreement facilitates trade between the two countries by reducing nontariff barriers and the associated financial and administrative burden: The inspection of a facility ties up considerable human and financial resources of a company; such inspections can take several days and quickly cost more than 1 million Swiss francs.

However, the MRA reserves the rights of USFDA and Swissmedic to decide not to accept an official GMP document issued for a manufacturing site in their respective territories in specific circumstances, *inter alia,* if the document shows inconsistencies or inadequacies.

Further, a safeguard clause (Art. 8 of the MRA) guarantees both parties' right to, in exceptional circumstances, conduct inspections in the other's territory in the future. Regarding such USFDA inspections in Switzerland, it will be interesting to see whether the MRA takes precedent over Article 64a paragraph 1 letter b of the Swiss Act on Therapeutic Products (what we would expect, as the MRA is an international treaty), that is, whether USFDA, after informing Swissmedic accordingly, will be allowed to inspect manufacturing establishments in Switzerland without needing the prior consent of the concerned company.

d. Entry Into Force

Before the MRA becomes effective, the two concerned agencies have to mutually assess and align their respective criteria and procedures for assessments under the agreement according to Annex 3 of the MRA. They then have to notify each other as soon as the assessment has been completed and, based on this assessment, the agency of the other party has been positively recognized. The day after the second notification, the MRA will become effective. This is expected for mid-2023.