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4 Questions on the Import of Medicinal Products and APIs

Excerpt from the GMP Compliance Adviser, Chapter 0.F

by Simone Ferrante

GMP or GDP – Which applies for importation?

Although the import of medicinal products is an act related to distribution and logistics, this activity is considered GMP relevant in the EU and is therefore subject to GMP requirements. The publication of Annex 21 to the EU GMP Guide makes this unambiguously clear.

As a result, the same requirements regarding the pharmaceutical quality system must be met for import as for pharmaceutical manufacturing. There is no differentiation between manufacturing and import in this context. Thus, the presence of the key GMP responsible personnel is also required for the import of medicinal products.

For the import of medicinal products and active substances subject to authorisation from outside the EEA, the site of physical importation must have a *Manufacturing and Importation Authorisation (MIA)* in accordance with Annex 21.

The Manufacturing and Importation Authorisation described in the EU GMP Guideline in Annex 16 and Annex 21 is a document divided into two parts:

- Part I Manufacturing Authorisation
- Part II Importation Authorisation

Within the scope of an MIA, a company can hold either

- only a manufacturing authorisation

OR

- only an importation authorisation

OR

- both a manufacturing and an importation authorisation.

Do these requirements apply for wholesalers?

The answer is "yes": if a wholesaler wishes to import finished medicinal products from a third country for placing on the market in the EEA, he must also have an authorisation that includes QP certification of the imported batch. The sole wholesale distribution authorisation is not sufficient.

This is justified by the fact that it is always necessary to have an EU batch release by a qualified person (QP) in the EU or EEA in accordance with Article 20 of Directive 2001/83/EC in order to place the product on the market in the EEA. This activity is understood as the last step of pharmaceutical manufacturing or import.

What difficulties may occur as a result?

Within the drug supervisory agencies, different departments may be responsible for GMP and GDP monitoring. In such a case, a wholesaler would be supervised by a different department of the supervisory authority than a manufacturer or importer. He will therefore have to coordinate with both agency departments with regard to the importation and the application for the required authorisation.

What evidence can be used prove the GMP compliance of the third-country manufacturer?

Within the EEA, documented compliance with the European GMP standard for medicinal products and active pharmaceutical ingredients must be ensured. This applies both to the manufacture of the products and to their storage and transport. Therefore, the warehouse where the products are imported must be covered by a MIA.

But the manufacturer in the third country must also be able to prove that he has followed the EU GMP Guide. This may not be easy, as he will have basically followed the national guidelines of the respective third country and not the EU standards. Therefore, for all active substances for the manufacture of medicinal products for human use that are imported into the EU/EEA a so called "written confirmation" is required. The competent authority of the exporting third country hereby confirms that the GMP standards of the respective site are at least equivalent to the EU standards.

GMP compliance can of course also be certified by an official EU inspection. If the GMP inspection is successful, the manufacturer will be issued a GMP certificate. This will be filed in the EUDRA GMDP database.

In order to reduce the inspection effort for European inspectorates, there are Mutual Recognition Agreements (MRAs) in place.

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