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EU GMP Annex 21

Changes in importation guidelines will bring challenges to Regulatory, Tax, and Legal

Up to now, the methods of importation for pharmaceutical products into the European Economic Area (EEA) could vary from country to country for a pharmaceutical manufacturer. As importation is defined differently across the EEA countries, it affects how the importation structure is set-up for a pharmaceutical company's products.

Importation requires a Manufacturing and Importation Authorisation (MIA) by the importing organisation providing a full Quality Management System including a Qualified Person for that purpose. Since 2013, the Belgium health authority (FHMAP) has defined that the change of ownership of a product from a non-EEA organisation to an organisation within the EEA represents an import of the product, even if the product has not been physically moved. Which means that any previous quality certifications will no longer be valid to allow the release of the product within the EEA. In addition, some health authorities also state that the Qualified Person has to be locally employed by the importing entity.

With EU GMP Annex 21, which is applicable for all EEA countries not only the EU, importation rules will be standardised throughout the EEA. It is expected that the view of the Belgian health authority will be adapted by all EEA countries, which will lead to changes in the supply chain and impact on regulatory requirements, tax and legal issues.

Currently, for tax purposes, many pharmaceutical companies distribute their products via a non-EEA subsidiary until they are sold to a local distributor within the EEA. According to the Belgian authority's importation definition, the change of ownership through the direct sale of the product from the non-EEA organisation to the local entity will represent an import of the product into the EEA.

Pharmaceutical companies need to start planning for those changes now.

Importation

Legal implications

In the EEA countries, importation of pharmaceutical products falls under local legislations which are not standardised. In the interest of free product flow and distribution within the EEA, any importation into the EEA allows the product owner to distribute the product into every other country of the EEA zone.

Based on directives by the EU, local legislation shall now be aligned and standardised in all EEA countries. A transition period, usually around three years, will be allowed to change local laws and for affected companies to align to the new regulation.

For the distribution of pharmaceutical products, the following licenses are necessary based on EU regulations:

- **The Manufacturing and Importation Authorisation (MIA).** The MIA allows a producer or importer of pharmaceutical products to supply products to EU markets. The producer or importer falls under EU GMP regulations.
- **A Wholesaler Distribution Authorisation (WDA).** The WDA allows a producer or importer to ship pharmaceutical products and to distribute them to other distributors or end customers following GDP guidelines.
- **A Market Authorisation (MA, given to an organisation to sell the drug known as Market Authorisation Holder (MAH)).** The MA allows a pharmaceutical company to supply their product to the local market for a particular pharmaceutical product. With the Market Authorisation, the suppliers of the product must be identified and their compliance to EU GMP regulations must be certified.

European Economic Area (EEA)

All EU countries (Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden), Norway, Iceland, and Liechtenstein. Switzerland is not a member of EEA; the status of the UK is open.

Tax implications

Many pharmaceutical and BioTech companies operating in the EEA are structured under a principal model with a non-EEA affiliate as the central entrepreneur with local limited risk distributors. Accordingly, the non-EEA affiliate owns their products when it sold to the local entity, i.e. the flow of goods do not follow the invoicing of the products.

The supply chain and the related management functions are the basis for the allocation of the taxable profit to the different entities in the different jurisdictions. Furthermore, the supply chain has VAT and customs implications.

Regulatory and quality implications

Depending on the licence owned by the supplier of the pharmaceutical product, quality certifications performed by a Qualified Person (QP) for GMP or verifications of transport conditions and product identity based on GDP are required. At any point of importation, GMP certification is needed according to the new definitions of EU GMP Annex 16 (Certification by a Qualified Person and Batch Release). Local laws on the implementation of QP certification by person and location can vary.

In the case of Switzerland (and limited for Canada, Australia, New Zealand, and Israel), a Mutual Recognition Agreement on GMP is in place. This agreement allows GMP activities in the EEA or Switzerland to be recognised as compliant to the standards of the importing country of the EEA or Switzerland, thus limiting the risks and reducing the depth of the quality measures to be taken for the acceptance of a pharmaceutical product. This does not replace or abolish the quality measures carried out by the MIA holder.

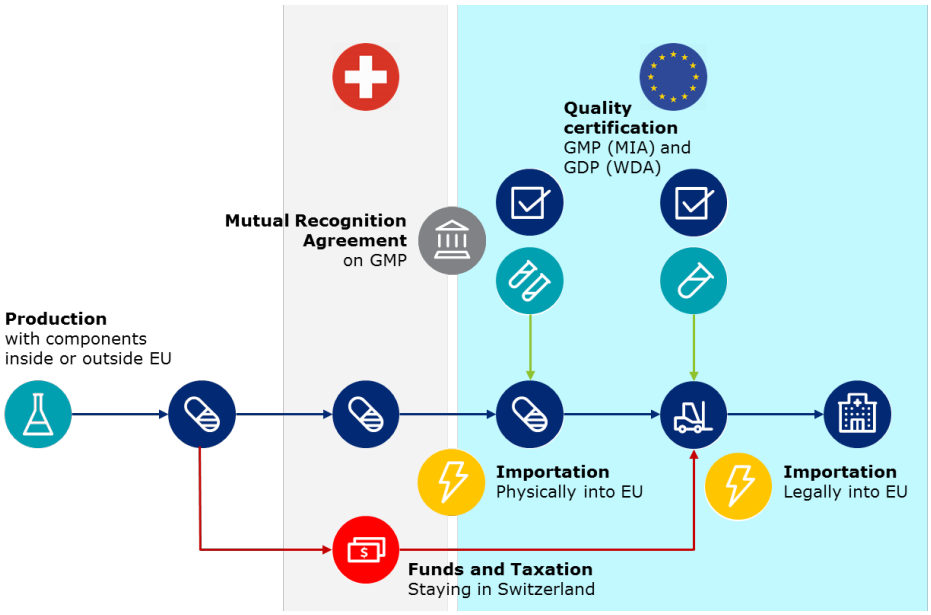
With EU GMP Annex 21, settling the importation guidelines, QP certifications based on EU GMP Annex 16 might become necessary where there were none or different operational structures before, leading to substantial costs and changes in the organisational and operational structures. Local laws might request specific set-ups which will render QP certifications at different locations or through people not employed by the local entity difficult.

GMP – Good Manufacturing Practice: standards and requirements for the production of pharmaceutical products

GDP – Good Distribution Practice: standards and requirements for the transportation and storage of pharmaceutical products

EU GMP regulations: also known as Eudralex Volume 4, those contain GMP and GDP regulations as defined by the EU valid for the EEA

Sample flow for a product going via Switzerland as the non-EEA



Preparing for Annex 21

With the physical flow of the product being separated from the legal and financial flows, the change of ownership from a non-EEA owner to an owner within the EEA will represent an importation and consequently require the receiving owner to have a MIA in place.

According to the new regulation, an importation will occur when a change of ownership occurs, even at country level. In case of multiple countries, multiple MIAs may be required. This may impact the management and performance of the supply chain. Changing the supply chain may have significant impact on the tax model including the allocation of profit between the countries in the supply chain as well as VAT and customs implications. The goal will be to find the optimal balance of quality requirements with minimal tax impact while also covering all legal requirements.

Without even a draft version available, it is widely expected that the EU GMP Annex 21 will follow the importation definition articulated by the Belgian authorities. In preparation for the change, several options can be considered for importation scenarios in the future.

The potential solutions must cover all possible product manufacturing and distribution flows: products being manufactured in a non-EEA country, being distributed from there while being produced inside or outside of the country, or just owned by a non-EEA organisation but never being physically with that organisation.

It is important to acknowledge that there is no one size fits all solution. Different organisations have different fund flows, markets, and licences. All of which have to be considered to develop the optimal solution – optimised in terms of product flow, quality certification steps, flows of funds and taxes, financial reporting, as well as legal implications covering specific country rulings across the EEA.

EU regulations will impact country laws and health authorities' positions

How Deloitte can support you

We have the right mix of experts from regulatory in pharmaceuticals, technology and taxes available to perform a qualified analysis for your specific situation. With our industry knowledge, we can translate your requirements into solutions suitable for your organisation and provide advice on how to optimally set up physical and legal product flows versus financial flows.

There is no one size fits all solution – there is a significant potential to re-shape your organisation to optimally supply products to all markets in the EEA whilst considering every factors.

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