Game changing new pharma regulatory rules for non EU/EEA companies selling drugs in the EU

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Europe at a glance

Based on internet search in 2022

Pharmaceuticals market size

$296.3bn

Avg. health care expenditure in Europe

8% of GDP

44 Total European countries

of which

27 EU Member States

Pharmaceutical market projected growth *(until 2028)*

+5.4%

European Population

746.4m

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Game changing pharma regulatory developments in the EU 1/2

Have you heard and already considered the impact?

Are you planning or already have a clinical trial / commercial pharma supply chain in the world's 2nd largest pharmaceutical market, i.e. Europe?

→ **YES?** Then you should pay attention to the recent developments in the pharma regulatory landscape, when planning **a new pharma supply chain**.

Existing pharma supply chains might have to be double checked / reviewed for full compliance (incl. toll & contract manufacturer) with the newest EU pharma regulatory developments, otherwise this might lead to supply chain disruptions.

Game changing pharma regulatory developments in the EU 2/2

What happened in short:

- Based on recently changed local legislation in the EU as well as a published court decision (as an example see Appendix), basically a non EU/EEA established pharmaceutical company is only allowed to sell products to companies holding an appropriate authorization granted from one of the European Health Authorities.

What does it mean?

- A non-EU established pharma company will not be granted with a required EU authorization, i.e. it cannot sell / distribute pharmaceuticals in the EU anymore.
- In practice this leads to a **business critical** supply chain stop if necessary authorisations are not in place.

Who is affected by these developments?

Any Non-EU / EEA pharmaceutical company that **manufactures, sells (import, exports, local distribution) and stores** pharmaceuticals, API, IMP in the European Union (EU).

How to prevent a business critical supply chain stop?

PwC's Cluster of Excellence via a global collaboration has developed and assisted in implementing straightforward and tailored solutions that can be easily implemented in practice by multinationals, SMEs and start-ups.

A holistic 360 degree picture with added value

Additionally to addressing all regulatory licensing requirements, each of our solution offers a holistic view over the global and local tax implications (Corporate Tax, Transfer Pricing, Indirect Tax, Environmental Taxes) as well as corporate legal, ERP, accounting and supply chain aspects. This ensures full compliance with the EU regulatory requirements and a highly optimized tax setup.

Credentials

Non EU pharma multinational and start-up

The credential from a multinational market player:

The issue PwC helped to address

PwC supported the pharma company in developing a new target operating model for the launch of a new product in the EU and incorporation of it in the existing supply chain.

This included mapping out the required pharma regulatory licenses and approvals from various local health authorities in the EU in order to be able to buy, sell (import, export, distribute) store and produce drugs in a compliant and lean way.

How PwC collaborated to achieve the objectives

- PwC network team prepared a feasibility study with local EU specific advise for various member states on tax, pharma licensing and accounting topics.
- Tailored study for the countries under discussion (e.g. at the time for **EU 27** different jurisdictions).
- This study included the information about what kind of licensing / approvals from the health authorities were required in order to go live with the envisaged supply chain.
- Project duration: It takes up to 12 months from Feasibility Study to execution / launch.

The value PwC helped to create

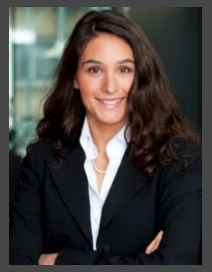
- Overview of all required pharma licensing approvals and marketing authorization requirements relevant for our client in order for them to successfully have the envisaged new supply chain adopted. Providing the respective advise on tax, ERP (Financial and QMS), accounting and corporate legal impact.
- Leverage of our practical know-how to implement the solution

“We recently had a business critical project requiring a very time sensitive and reliable feasibility study, covering the clarification of extensive international regulatory and tax components.

We wanted to have a single point of contact and be sure that all our requirements were met on time and with much less effort from our side. We decided to engage with PwC Switzerland and so far they have managed to meet all our expectations and requirements, which created a trusted relationship we continue to rely on.”

Credential from a pharma start-up

Your Contacts



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Appendix

The EU-Regulatory Gamechanger

The German Federal Administrative Court decision regarding pharmaceuticals purchased from Non-EU / EEA companies (BVerwG 3 C 1.20, dated 25.02.2021)

In a nutshell – management summary

German pharmaceutical wholesalers are only allowed to purchase respective products from companies holding an appropriate authorization granted in one of the EU Member States.

An equivalent authorization (e.g. a whole sale distribution license “WDA”) from a third party Non-EU / EAA country is not sufficient in order to sell medicinal products in Germany and/or to the German / EU market.

The issue:

- A non-EU established pharma company will not be granted with a respective EU authorization.
- One year after implementation more and more EU Member States have implemented similar regulations on a local basis.
- In practice this will lead to a **business critical** supply chain stop if necessary authorisations are not in place.

The solution:

- PwC has developed and tested straightforward solutions that can be easily implemented ➔ tailored based on the requirements and needs of the pharmaceutical companies (we have a solution for every company - from small start-up to big pharma players)