

PUBLIC
LAW

Simplified
procedure of
parallel trade
of medicines

PARALLEL TRADE OF MEDICINES

On August 7, Decree-Law 182/2009 was published, which significantly amended the **procedure of parallel trade of medicines**, set out in “*Estatuto do Medicamento*” (which contains the legal framework of medicines in Portugal), approved by Decree-Law 176/2006, August 30.

The parallel trade of medicines is a mechanism which allows for a medicine that has a valid marketing authorization (MA) in a Member State of the European Union, including Portugal, **to be imported and commercialized in Portugal**, during a period of time, **without having to apply for a new MA**.

As a general rule, the commercialization of medicines in national territory is subject to an authorization procedure by the highest body of INFARMED (National Authority of Medicines and Health Products). The procedure for the introduction of a medicine subject to direct trade, in the national market, may and should be **a simplified procedure in view of the fact that its safety, efficacy and quality has already been verified by the regulatory agency from the member state of provenance**.

Given the reduced practical application of this mechanism, until today, which was also justified by the complexity of the procedure then established, **the new decree-law simplifies the procedure related to parallel trade**, devoting a legal presumption that the medicine subject to parallel trade, in relation to the medicine considered, has the same qualitative and quantitative arrangements in active substances, the same pharmaceutical form, the same therapeutic indications and that the authorization for parallel trade is not a risk for public health.

However, the legal presumption mentioned above only operates, in the event : *i*) the medicine to be imported has a **common origin** - this expression means the manufacture of the medicine in other Member State of the European Union by a company contractually connected to the holder company of the MA in Portugal or with one

Legal presumption only operates under certain requirements

of its affiliates; or if *ii*) the holder company of the MA in Portugal manufactures and commercializes the medicine in Portugal pursuant to **an agreement entered into with a company contractually connected to the holder company of the MA in the member state of provenance.**

Moreover, while in the previous legislation, the petitioner had to prove that any differences in the excipients - the neutral substances that join the active principles of a medicine - did not affect their therapeutic value or endangered public health, the new Decree-Law only requires a **statement** in that sense. (see new paragraph i), number 3, of article 83).

Other procedural requirements were simplified in order to allow that parallel trade of medicines becomes a reality in Portugal.

According to a source in INFARMED, the simplification of the procedures for the parallel trade would result in a greater and cheaper availability of medicines, enhancing further competition.

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