

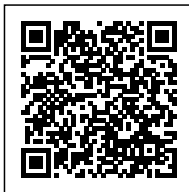
NEW RULES OPEN PORTUGAL TO PARALLEL IMPORTS - MLGTS

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António Pinto Leite

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The enactment of new legislation relating to the parallel import of medicines into Portugal has dramatically simplified the obligations of applicants and the duties of the Portuguese medicines regulator INFARMED, say António Pinto Leite and Tomás Vaz Pinto of Morais Leitão, Galvão Teles, Soares da Silva & Associados in Lisbon.

The previous administrative parallel trade procedures were overly-complex and had no practical application, says Pinto Leite. 'The new legal regime has significantly simplified this and takes into consideration that the safety, efficacy and quality of the medicine subject to parallel trade has already been assessed by the competent authority of another EU Member State.'

The new rules came into force in August amending the 2006 Medicines Statute, with the main impact being that there is now a legal presumption that a medicine subject to parallel trade has the

same qualitative and quantitative composition, pharmaceutical form and indications, and that it does not represent a risk to public health.

'This presumption is applicable when the medicine to be imported has a common origin or where there is a connection between the companies that hold the marketing authorisation in Portugal and in the Member State of origin,' explains Vaz Pinto.

La entrada en vigor de la nueva legislación relativa a la importación paralela de medicamentos en Portugal ha simplificado drásticamente las obligaciones de los solicitantes y las obligaciones del regulador de los medicamentos portugueses, dice António Pinto Leite de MLGTS.

The outcome is that an applicant now only has to declare, not demonstrate, that any differences in any inactive carrier substances (excipients) does not affect the medicines therapeutic value or endanger public health.

'Applicants are also no longer obliged to file specific documents relating to the medicine and a prior notification is no longer required from the holder of the Portuguese marketing authorisation, instead a notification is made while the procedure is already running and there is a reduction in the time available for the Portuguese holder to respond,' adds Pinto Leite.

The result being that the previous redundant legal regime – no parallel trade application had ever been received by INFARMED – has been done away with, which is in itself a positive development, they say.

'According to INFARMED itself, the new regime is expected to result in a greater and cheaper availability of medicines and to increase competition,' concludes Vaz Pinto.