INFORMATIVE NOTE

INDUSTRIAL PROPERTY

INDUSTRIAL PROPERTY DISPUTES: REFERENCE AND GENERIC MEDICINES

The aim of Law 62/2011 of 12 December is to create a system for settlement of disputes relating to industrial property rights when reference medicines and generic medicines are at issue. The new law also changes the rules on reimbursements of the costs of medicines by the State.

THE CREATION OF A COMPULSORY ARBITRATION SYSTEM

The Law provides that conflicts arising from disputes over innovation in industrial property rights, including interim injunctions, related to reference medicines and generic medicines, are subject to compulsory arbitration, whether institutionalised or not.

The Law establishes that the use of arbitration is compulsory regardless of whether process, product or utility patents, or supplementary protection certificates are at issue.

Within 30 days of the publication of a request for Market Authorisation ("MA") for generic medicines on the INFARMED website, any interested party that wishes to exercise their industrial property right may do so at the institutionalised arbitral tribunal or make a request for the dispute to be submitted to non-institutionalised arbitration.

After notification from the arbitral tribunal, the MA applicant must present a defence within 30 days, failing which the applicant will be at risk of being banned from beginning the industrial or commercial exploitation of the generic medicine as long as the industrial property rights invoked remain in force. The means that the Law includes an effective threat against the applicant for - or holder of - the MA.

The documentary evidence will be presented together with the pleadings and the hearing for production of evidence, which must be presented orally, will take place within 60 days of the presentation of the defence.

The decision of the arbitral tribunal can be appealed to the appropriate Appeal Court (*Tribunal da Relação*). The appeal does not stay the arbitral proceedings or, in other words, it does not suspend the decision of the arbitral tribunal.

To sum up the changes, the Commercial Court (*Tribunal de Comércio*) no longer has jurisdiction to hear disputes over industrial property rights related to reference medicines and generic medicines, and the parties are obliged to settle any disputes through arbitration.

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SOCIEDADE DE ADVOGADOS, RL

A.M.PEREIRA, SÁRAGGA LEAL, OLIVEIRA MARTINS, JÚDICE E ASSOCIADOS

Thus, the Law makes it very clear that application for an MA, an RSP and reimbursement of the price of the medicine cannot be rejected on the grounds of the possible existence of industrial property rights.

THE NON-INFRINGEMENT OF INDUSTRIAL PROPERTY RIGHTS BY THE GRANT OF MAs, RSPs OR REIMBURSEMENTS

The new Law seeks to draw a line under the controversy that has been raging in the academic community and in the courts for many years. It does so by making it clear that the acts of granting the MA, RSP (Retail Sale Price) or reimbursement of the price of the medicine are not contrary to the rights relating to the patents or supplementary certificates.

Thus, the Law makes it very clear that application for an MA, an RSP and reimbursement of the price of the medicine cannot be rejected on the grounds of the possible existence of industrial property rights. Equally, these same grounds cannot be used as a basis to alter, suspend or revoke the grant, authorisation or registration of MAs, RSPs or reimbursements.

Article 9 of the Law provides that these rules are interpretative in nature which means they will be integrated into the interpreted law and, as a consequence, they will take effect in pending legal cases even if these cases were brought before the date of entry into force of this Law. However, it should be noted that under article 13 of the Civil Code, the effects of existing final judgments which cannot be appealed will be safeguarded

OTHER PROVISIONS

Another innovation under this legislation is the publication on the INFARMED website of all MA applications regardless of the procedure they are following. This publication occurs within five days of INFARMED having checked that the presentation of the application is in order and includes the name of the applicant, the date of the application, the substance, dosage and pharmaceutical form of the medicine and the identification of the reference medicine (new article 15-A of the Medicine Statute).

This legislation also makes changes to article 188 of the Medicine Statute by strengthening the duties of confidentiality and secrecy and introducing a presumption that all elements or documents presented to INFARMED or are passed on to it are classified, or are capable of disclosing commercial or industrial secrets. This presumption can be overturned by the management of INFARMED.

Finally, the new Law establishes that the RSP of generic medicines to be marketed in Portugal should be at least 50% lower than the RSP of the reference medicine with the same dosage and the same pharmaceutical form, without prejudice to the specific provisions in the legislation on the establishment of the prices of medicines.