



ISSUE OF CERTIFICATE OF REQUEST FOR SUBSIDISATION OF THE PRICE OF MEDICINES

In its judgment of 19 January 2012 (case no. 08332/11), the Southern Central Administrative Court, decided that INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I.P. (the national authority for medicines and healthcare products), is obliged to issue a certificate of subsidisation of the price of a medicine even when the person requesting the issue of the certificate was not the person who applied for the subsidy.

The certificate must include (i) the request for subsidisation and the documents that accompany it, (ii) the pharmaco-economic evaluation study, (iii) any complementary information that has been requested, (iv) the final decision, including the grounds on which it was made and, if one has been concluded, (v) the subsidisation agreement. The certificate must also include the information on sale of medicines after being placed on the market that has been communicated and/or requested in entering into the said agreement in respect of market monitoring, the use and the economic impact of the subsidisation of the medicine in question.

The Southern Central Administrative Court, following closely the opinions of the Commission for Access to Administrative Documents (CADA) numbered 336/2009, 381/2010 and 382/2010, based its decision on the fact that, unlike the situation the documents relating to a request for introduction of a medicine to the market, the documents relating to a request for subsidisation are not likely to reveal secret commercial or industrial

information or secret information on the internal workings of a company.

Finally, the Southern Central Administrative Court decided that article 188 of Decree-Law 176/2006 of 30 August, in the wording introduced by Law 62/2011 of 12 December - under which any information or documents presented to INFARMED are confidential and presumes that all or any information or documents are classified or are likely to reveal a commercial, industrial or professional secret or a secret relating to a literary, artistic or scientific property right, except if the management body of INFARMED decides to the contrary - applies to requests for introduction of a medicine to the market. However, the court also held that the said article does not apply requests for subsidisation of the price of medicines as the system for subsidisation of the price of medicines is regulated specifically by its own piece of legislation (Decree-Law 48-/2010 of 13 May).

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