

PUBLIC
LAW

NEW MEDICINES LEGISLATIVE PACKAGE

AMENDMENT TO THE PORTUGUESE REIMBURSEMENT SYSTEM

On May 13th, the Decree-law no. 48-A/2010 was published setting out the **reimbursement system by the Portuguese State on the price of medicines** and the **system for price reference applicable to the above mentioned reimbursement**, thus amending Decree-laws no. 195/2006 of October 3¹ and no. 65/2007 of March 14².

This new legal regime will **come into force on June 1st**.

With regard to the reimbursement by the Portuguese State on the price of medicines, this new Decree-law, apart from setting the **general system for reimbursement**, also contains provisions relating to **special rules according to the beneficiaries and to the diseases or according to special groups of users**, as well as specific rules for the reimbursement of **generic and handled medicines**.

The most significant provisions foreseen in this new Decree-law are the following:

- i) **100% reimbursement for all echelons, for pensioners whose annual income does not exceed 14 times the minimum monthly wage guaranteed in the past civil year**, for medicines whose retail prices are equivalent to one of five cheaper prices to their respective homogeneous group, and if they are equal or less to the reference price for that group (article 19, no. 2);
- ii) **Shortening by 15 days of the deadline for a decision on the request to the reimbursement** by the Portuguese State in the price of **generic medicines** (article 11);
- iii) **New rules for determining the price of each new generic medicine to enter into homogenous group**, which must be **less than 5% on the retail price of the cheaper generic medicine**, with at least 5% of the market share of generic medicine on their homogenous group (article 26, no. 1);
- iv) With regard to the system for price reference, the Decree-Law establishes the rule of **reimbursement by reference price** (retail price of the more expensive generic medicine on the market), regardless of the value of the medicine, except when this is lower than the value of such reimbursement;

¹ The Decree-Law no. 195/2006 of October 3 establishes rules for the preliminary evaluation of medicines exclusively reserved for hospital treatment and other medicines subject to restricted medical prescription, for purposes of its acquisition by hospitals of the National Health System, regardless of their legal statute.

² The Decree-Law no. 65/2007 of March 14 establishes the pricing system for human medicines subject to medical prescription or not subject to medical prescription but reimbursed.

*Sales margins
at the existing levels
in 2005*

v) Clarifies rules about the notification for the start of sales, by establishing that **the notice of the date of the start of sales of reimbursed medicines** to INFARMED shall be done **by electronic means**, and these medicines **necessarily must be available at pharmacies in the date indicated** by the marketing authorization (AIM) holder.

Moreover, this new Decree-law has set the **sales margins for medicines reimbursed and not-reimbursed to the existing levels in 2005**. This without implying any change in retail prices approved through the amendment to article 12 of the Decree-law no. 65/2007 of March 14, setting out the **wholesale margin in 8% and 20% for pharmacies**, both to be calculated on the retail price, after deduction of VAT.

Another amendment, now revealed, concerns to the **end of the stability of the original final price of the medicines for three years**. The new article 7 of the Decree-law no. 65/2007 of March 14, sets the **annual review** of the medicines prices calculated under this law, based on comparison with the average of prices, in the reference member states, in January 1st of each year. The Government explained that this principle has been revoked for that medicines prices could be revised (downwards).

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