

LEGISLATION ON MEDICINES REVISED NEW AMENDMENT TO THE PORTUGUESE PRICE AND REIMBURSEMENT SYSTEM

PUBLIC LAW

Only a few months after the entry into force of Decree-Law no. 48-A/2010, 13 May – setting out **the reimbursement system by the Portuguese State on the price of medicine and the system for price reference applicable to the above mentioned reimbursement** – on 1 October the Government published Decree-Law no. 106-A/2006 which significantly amends the aforementioned diploma, introducing as well

*New rules on the system
for price reference*

amendments to Decree-Law no. 176/2006, 30 August¹, Decree-Law no. 242-B/2006, 29 December², and Decree-Law no. 65/2007, 14 March³.

The diploma now published, which came into force on the day following its publication, aims mainly at rationalizing public expenses regarding medicine and the sustainability of the National Health System (SNS), introducing innovative measures, among which the legislation highlights the following:

- i) Amendment of the rules on the system for price reference, whereby it is established that, for the purpose of reimbursement by the State, **the calculation of the price reference shall correspond to the average of the five least expensive medicines on the market** and not, as established up until now, correspond to the generic medicine with the highest retail price (amendment to article 25 of Decree-Law no. 48-A/2010);
- ii) **Reduction from 95% to 90%** with regard to the reimbursement set out for echelon A in the normal regime (amendment to article 5 of Decree-Law no. 48-A/2010);

¹ Decree-Law no. 176/2006, 30 August, sets out the “Estatuto do Medicamento” which contains the legal framework of medicine in Portugal.

² Decree-Law no. 242-B/2006, 29 December, establishes the manner of payment to pharmacies for the reimbursement by the State on the retail price (RP) of medicine provided to beneficiaries of the SNS which are not encompassed by any subsystem.

³ Decree-Law no. 65/2007, 14 March, sets out the legal regime on prices of medicine for human use subject to medical prescription and of those which are reimbursable and not subject to medical prescription.

- iii) Within the special reimbursement systems, **reduction to 95% from the previously established reimbursement of 100% for all echelons**, for pensioners whose annual income does not exceed 14 times the minimum monthly wage guaranteed in the past calendar year or 14 times the value of the index of the social benefits in force, when the latter value exceeds the former (amendment to article 19 of Decree-law no. 48-A/2010); and further,
- iv) Establishment that, in case of proven abuse, the pensioner at stake **loses the benefit for a period of 24 months**, after the fact of the abuse becomes known (amendment to article 19 of Decree-law no. 48-A/2010);
- v) Finally, the legislation points out measures to incentivize the **electronic prescription of medicine, which will be mandatory from 1 March 2011** (article 10 of the new diploma) and to allow the removal of the retail price (RP) from the package, only with regard to the medicine subject to medical prescription, when the users benefit from the reimbursement (amendment to article 105 of the “Estatuto do Medicamento” which contains the legal framework for medicine in Portugal).

In addition to the underlined measures, the diploma at hand introduces amendments to the **legal procedure for the reimbursement of medicine**, set out in the said Decree-Law no. 48-A/2010. In particular, we highlight **the cumulative nature of the conditions for the reimbursement of medicine** – therapeutic and economic – set forth in article 4, paragraph 1 (amendment to article 4 of Decree-Law no. 48-A/2010). On the other hand, the legislation amended the **legal criteria for the exclusion from reimbursement**, introducing as a ground for exclusion, for example, the fact that medicine is priced 20% higher than the non- generic reimbursable therapeutic alternatives, used with the same therapeutic aim (amendment to article 17 of Decree-Law no. 48-A/2010).

*Deduction of 6%
over the prices*

Finally, we underline the publication of **Order no. 1041-A/2010**, 7 October, which came into force on 15 October. For reasons of public interest concerning the sustainability of the State's expenses for medicine, this Order establishes a deduction of 6% over the maximum RP allowed for medicine for human use. Also it amends Order no. 312-A/2010, 11 June¹, #4, establishing a rule according to which, from the moment the new prices come into force, the industry must not place on wholesale distributors or pharmacies, medicine at prices different from those which result from the Order or the law.

It should be noted that Order no. 1041-A/2010 was further regulated by a Joint Information Circular by INFARMED and the Directorate General for Economic Activities (DGAC) concerning the instructions for the application of the Order at stake. The Circular is dated 13/10/2010 and available at www.infarmed.pt.

¹ Order no. 312-A/2010, 11 June 11, regulates the regime for the formation of prices of medicine set out in the above mentioned Decree-Law no. 65/2007.

Contact
Fernanda Matoso | fmatoso@mlgts.pt

MORAIS LEITÃO, GALVÃO TELES, SOARES DA SILVA

& ASSOCIADOS
SOCIEDADE DE
ADVOGADOS

www.mlgts.pt

LISBON

Rua Castilho, 165
1070-050 Lisbon
Telephone: (+351) 213 817 400
Fax: (+351) 213 817 499
mlgtslisboa@mlgts.pt

OPORTO

Av. da Boavista, 3265 - 5.2
Edifício Oceanvs – 4100-137 Oporto
Telephone: (+351) 226 166 950
Fax: (+351) 226 163 810
mlgtsporto@mlgts.pt

MADEIRA

Avenida Arriaga, Edifício Marina Club, 73, 2º
Sala 212 – 9000-060 Funchal
Telephone: (+351) 291 200 040
Fax: (+351) 291 200 049
mlgtsmadeira@mlgts.pt

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