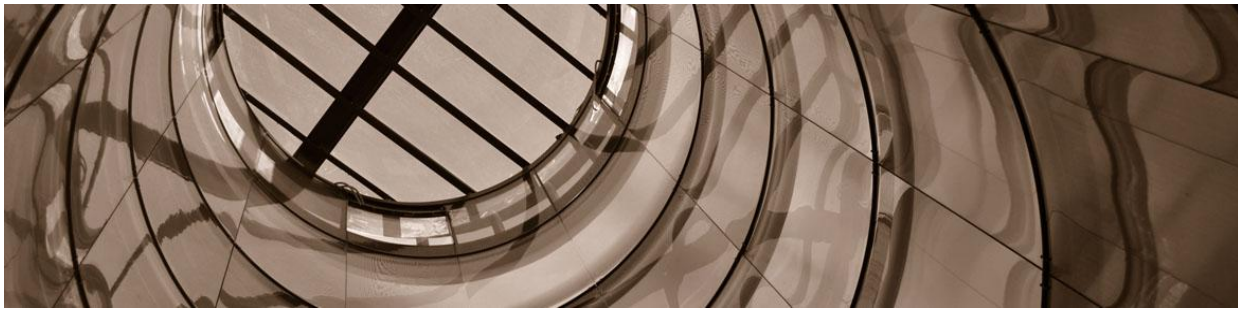

LEGAL FLASH | HEALTH LAW

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AMENDMENT TO THE REIMBURSEMENT REGIME AND TO THE MEDICINAL PRODUCTS PRICE REGIME

The general scheme of reimbursement by the State in the price of medicinal products, approved by the Decree-Law No. 48-A/2010, of 13th May ("Reimbursement Regime"), and the system of pricing of medicinal products subject to prescription and medicinal products non subject to prescription but reimbursed, approved by the Decree-Law No. 112/2011, of 29th November ("Medicinal Products Price Regime"), were today amended by Decree-Law No. 19/2014 of 5th February ("DL 19/2014"), published today on the Official Public Gazette ("Diário da República").

The main changes introduced by DL 19/2014, regarding the Reimbursement Regime are the following:

- The main objective of the legislator was to improve the existent regime, by introducing some mechanisms which enable to "understand the real plus of such medicinal products that justify the reimbursement by the Portuguese State". In this respect, the main changes to this legal regime are related to the evaluation proceedings of the medicinal products, either on the phase regarding the grant of the reimbursement, or in the evaluation phase of the reimbursement;

- Regarding the proceeding to obtain the reimbursement on the evaluation phase of the medicinal products, the new regime states expressly that the MAH shall demonstrate the efficiency and/or the relative effectiveness and the higher or equal therapeutic

comparative value, presenting to Infarmed the evidence that is now listed in an annex to the Contribution Regime. This annex identifies the criteria which shall be observed either on evaluation or in the revaluation of the medicinal products, which are not only technical and scientific, but also related to the demonstration of an economic benefit, being the evaluation always realized in a comparative way, which means, with reference to characteristics of alternative therapeutic made available.

-Also, under the evaluation proceedings of reimbursement revaluation, the new legal regime establishes that the MAH, whenever it is required, shall prove that the medicinal product continue to satisfy the reimbursement requirements, by demonstrating the efficiency and/or the relative effectiveness and the higher or equal therapeutic comparative value, presenting to Infarmed the evidence that is listed in the annex to the Contribution Regime;

- Another relevant change is that the exclusion of the reimbursement of a medicinal product is automatic whenever a pharmaceutical group or sub-group that is excluded from the reimbursable medicinal products list, established under the Ordinance No. 924-A/2010, of 17th September, in its actual version.

- Finally, the diploma establishes a limit to the price to the public of the generic medicinal products reimbursable, by establishing that, for purposes of assessment of the economic benefit of the generic, which is achieved by setting a price to the public that is 5% lower than the maximum price of the generic whose request for reimbursement is immediately previous to the one at stake, may not result in setting a price that is 20% lower than the reference medicinal product considered for the pricing regime of generic medical products.

We shall now analyze the main changes introduced in the Medicinal Products Price Regime:

- Under the annual review of pricing procedure, such of the reference medicinal products, as of the generics, incorrect updating of prices by the MAH having regard to the rules applicable to annual review implies for the MAH the obligation to transfer to the NHS budget authority the amount equivalent to the difference between the price reported by those entities and the price fixed by Infarmed, for all packages which have been marketed within the NHS with an incorrect price value;

- However, the main novelty of Decree-Law No 19/2014 of 5 February, and perhaps the most controversial one, is the change to the marketing margins of medicinal products by wholesalers and pharmacies. As the Government had already announced at the end of the year 2013, upon approval by the Council of Ministers of the changes to these legal regimes, it is intended "a greater appreciation of the fixed component over the variable component." Indeed, all levels of prices of the medicinal products foreseen in article 11 of the Medicinal Products Price Regime shall now be composed by a fixed component and the variable component was subjected to a substantial reduction. With the new legal

regime, variable components of wholesale margins suffer, on average, a decrease of eight percentage points, and pharmacies suffer, on average, a reduction of 20 percentage points.

- Finally, and although it is not yet regulated, it is expected the implementation of measures to encourage the supply generics through an additional remuneration to the pharmacies.

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