JUN. 23

INFORMATIVE NOTE

HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS

New list of reimbursed compounded medicines

Ministerial Order 160/2023 of 12 June, which enters into force today, establishes the new list of reimbursed compounded medicines, with the addition of new reimbursed medicines to the list in force until now. This Ministerial Order also establishes the prescription and dispensing conditions on which the reimbursement of these medicines depends, as well as the conditions for the inclusion of new compounded medicines and the exclusion of compounded medicines from the reimbursement system.

Compounded medicines are classified as (i) magistral formulae if they are prepared in accordance with a medical prescription specifying the patient for whom the medicine is intended, or (ii) officinal formulae in the case of medicines prepared in accordance with the compendial indications of a pharmacopoeia or formulary. The list of reimbursed compounded medicines is approved by a ministerial order issued by the member of the government responsible for health. The order also establishes the reimbursement percentage.

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Ministerial Order 160/2023 of 12 June stipulates that the reimbursement rate for compounded medicines included in the list published in the annex to the Ministerial Order is 30% of their price. This price is determined in accordance with the legislation in force[1]. Access to the reimbursement also depends on compliance with the following prescription and dispensing conditions:

i) Prescriptions submitted electronically in accordance with the law must include the name of the compounded medicine and state the active ingredient and the pharmaceutical form in accordance with the annex to the above-mentioned Ministerial Order. They must also include the dosage, route of administration and quantity. The prescription may also contain a list of the excipients to be used and any other information necessary for the correct preparation of the compounded medicine. However, reimbursement is excluded if the prescription refers to brands of medicines, health products or other products.

ii) Compounded medicines are dispensed in compounding pharmacies.

1 Currently, Ministerial Order 769/2004 of 1 July stipulates that the calculation of the retail price of compounded medicines by pharmacies is based on the preparation fee, the cost of raw materials and the cost of packaging materials.

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The inclusion of new medicines in the reimbursement system or the exclusion of existing medicines from the system must be approved by the member of the government responsible for health. The approval must then be recorded in a decision of the Board of INFARMED.

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i) Absence on the market of a medicinal product with the same active substance in the intended pharmaceutical form;

ii) The existence of a therapeutic gap in relation to industrially manufactured medicinal products;

iii) The need to adapt dosages or pharmaceutical forms to the therapeutic needs of specific groups, such as paediatric and geriatric patients.

Finally, the authorisation for exceptional reimbursement of medicines for the treatment of hyperphenylalaninemia (HFA) in patients with phenylketonuria (PKU) and in patients with tetrahydrobiopterin (BH4) deficiency, approved by Ministerial Order 3/2022 of 3 January, remains in force. ■