



Price revision regime of medicines for the year 2023

Ministerial Order no. 35/2023 on the price revision of medicines for the year 2023 was published in the Official Gazette.

This Order, framed within the legal regime on the setting and review of medicine prices, sets out the criteria to be applied in 2023 and includes exceptional review criteria aimed to address the risk of supply shortages arising from the existence of very low prices. Given the current national and international economic situation, exceptional criteria are introduced to allow for an increase in the prices of cheaper medicaments, in order to accommodate increases in production and supply costs.

The main measures adopted in this Order are set out below:

1) Reference countries

The reference countries for the purposes of determining the new prices of medicines to be authorised during 2023 and the annual review of the prices of medicines purchased by National Health Service (NHS) establishments and services and dispensed on the outpatient market are maintained, being **Spain, France, Italy and Slovenia**

2) Exceptional price revision criteria in the outpatient market

- All medicines with a maximum retail price of less than 10 euros are increased by 5% in relation to their current maximum retail price;
- All medicines with a maximum retail price between 10 and 15 euros are increased by 2% in comparison with their current maximum retail price;
- For medicines with a maximum retail price of more than € 15, the application of the annual price revision regime based on a comparison with the average prices charged in the reference countries and other rules laid down in Article 16 of Ministerial Order 195-C/2015 of 30 June, as amended ("Ministerial Order 195-C/2015") may not result in a reduction of more than 5% in relation to the maximum retail price in force.

3) Annual Price Review of Generic Medicines

Without prejudice to the application of the exceptional price revision regime referred to in point 2) above, the suspension of the application of article 17 of Ministerial Order no.195-C/2015 to generic medicines priced above €15, and of article 20 of the same Ministerial Order in relation to the price revision of generic medicines acquired by NHS establishments and services, shall be maintained in 2023.

This suspension does not apply to generic medicines whose maximum revised price is higher than that of the respective reference medicine resulting from the price review of 2023. In these cases, the maximum price resulting from the price revision of these generic medicines cannot exceed the maximum price resulting from the annual revision of the respective reference medicine.

4) Submission of information to Infarmed

The lists of the new prices to be practised in 2023 must be sent to Infarmed by Marketing Authorization Holder or representatives until,

- (i) **15.02.2023**, in respect of non-generic medicines, to come into force on 01.03.2023; and
- (ii) until **15.03.2023**, in respect of generic medicines, to come into force on 01.04.2023.

5) List of Essential Medicines

The Ministerial Order also foresees INFARMED's obligation to draw up a list of essential medicines within a maximum period of 90 days, whose critical nature may lead to the application of specific measures so as to avoid ruptures in availability. The measures to be applied may consist of increasing the maximum price of these medicines.

6) Excessive Cost

The prices of medicines may also be extraordinarily reviewed by decision of the Minister of Health on the grounds of their excessive cost to the NHS, namely when this results from a high and unexpected growth rate and share in NHS expenditure.

The criteria for determining the excessive cost shall be defined by order of the Minister of Health and shall take into consideration, namely:

- a) the average cost of daily treatment per patient for the NHS; and
- b) The maximum price of medicines with the same active substance, pharmaceutical form, dosage and presentation, which in the previous year had at least a 10% market share for the NHS.

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