



HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS

Authorisation and review of prices of medicines

Criteria to be in force in 2024

Ministerial Order 39-C/2024 of 2 February was published in order to define the reference countries to be taken into account in 2024 and the exceptional criteria to be applied in the review of the prices of medicines.

Reference countries for new prices and for the annual price revision

In 2024, the reference countries for the approval of new prices and the annual price review of medicines (outpatient and hospital market) will be maintained: Spain, France, Italy and Slovenia.

Exceptional criteria to be observed in the Annual Review of Medicine Prices (APR) 2024

Outpatient market

MAXIMUM RETAIL PRICE OF THE MEDICINE	REVIEW CRITERIA
€10 or less (generic and non-generic)	Increase of 3.5% over the maximum retail price in force on 26 January 2023
Above €10 and up to €16 (non-generic)	Exempt from the APR
Above €10 and up to €16 (non-generic)	The APR cannot result in a reduction of more than 5% in relation to the maximum retail price in force
Above €30 (non-generic)	The APR cannot result in a reduction of more than 10% in relation to the maximum retail price in force

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Hospital market (non-generic and non-biosimilar)

MAXIMUM PRICE FOR ACQUISITION BY NHS ESTABLISHMENTS AND DEPARTMENTS	REVIEW CRITERIA
Non-generic and non-biosimilar medicines with a maximum price of no more than €15	Exempt from the APR
Non-generic medicines with a maximum price of more than €15	The APR cannot result in a reduction of more than 5% in relation to the maximum retail price in force

Outpatient¹ and hospital market (generic and biosimilar)

All generic and biosimilar medicines are exempt from the APR, except for generic medicines with a maximum price of €16 or more and which is higher than the maximum price of the reference medicine resulting from the 2024 APR or the 3.5% increase (if applicable). In this case, the maximum price of the generic medicine cannot exceed the maximum price of the reference medicine.

Deadlines for marketing authorisation holders or their legal representatives to submit the prices to be applied in 2024:

Annual review of the maximum retail price of non-generic medicines:

By 15 February 2024, with prices taking effect on the following 1 March.

Annual review of maximum retail price for generic medicines:

By 29 February 2024, with prices taking effect on the following 1 March. ■

¹ Generic medicines on the outpatient market, with a price of €10 or less, can increase by up to 3.5% compared to the maximum retail price in force on 2 February 2024.