pbbr SOCIEDADE DE ADVOGADOS, SP, RL

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Annual price review of medicines for 2025

The recent Administrative Ruling no. 293/2024/1, of November 15 established the regime for the annual price review of medicines purchased by services of the National Health System (SNS) and medicines delivered within the scope of the OTC market, including generic and biosimilar medicines, for the year 2025.

The approval of this Administrative Ruling falls within the regime applicable to the pricing of medicines under Decree-Law no. 97/2015, of June 1, as amended, which governs the National Health Technologies Assessment System, and establishes that the annual price review of medicines is based on a comparison with the prices practiced in the countries identified as reference countries.

We would like to highlight the following aspects regarding the price revision of medicines for 2025:

1. Reference countries
The reference countries for 2025 will be Spain, France, Italy and Belgium.

2. Annual price review criteria
2.1. Medicines in the OTC market
*All medicines with a **maximum public sale price (PVP) of less than or equal to €16 can be increased by 2.6%**, in line with the nominal inflation rate for 2024, and will be exempt from the application of the annual price review regime established in Administrative Ruling no 195 C/2015 of June 30*

*An exceptional price review criteria is also established, which includes a price reduction **brake mechanism** for cases where the comparison with the average prices practiced in the reference countries results in a reduction of the public sale price of medicines.*

In these cases, the reduction in the PVP of the medicines in question may not exceed:
*(i) **5%** for medicines with a **maximum PVP greater than €16 and up to €30**; and*
*(ii) **10%** for medicines with a **maximum PVP greater than €30**.*

2.2. Medicines in the hospital market
Non-generic and non-biosimilar medicines*, which maximum acquisition price for SNS services is* ***less than or equal to €75, are exempt from the application of the annual price review regime*** *provided for in Administrative Ruling no. 195-C/2015, of June 30.*

With regard to medicines in the hospital market with a ***maximum price greater than €75****, a price reduction* ***brake mechanism*** *is also established.*

Thus, if the rules set out in Article 20 of Administrative Ruling no. 195-C/2015, of June 30, which stipulate that the price of non-generic hospital medicines may not exceed the lowest PVP in force in the reference countries, result in a price reduction, such ***reduction may not exceed 5% of the price****.*

2.3. Generic and biosimilar medicines
With respect to generic and biosimilar medicines, ***they are exempt from the annual price review regime*** *established in Administrative Ruling no. 195-C/2015, of June 30. Those with a* ***maximum price of €16 or less may be increased by 2.6%****, according to the nominal inflation rate for 2024.*

The exemption from the application of the rules for reviewing the prices of generic and biosimilar medicines, as set forth in Administrative Ruling no. 195-C/2015, of June 30, does not apply to generic medicines priced at or above €16, where the price exceeds the maximum price of the respective reference medicine following the annual price review for 2025, or the increase resulting from the application of the 2.6% inflation rate.

It should be noted that, in any case, the annual price review of generic medicines is limited to the maximum price of the respective reference medicine.

3. Deadlines
Holders of marketing authorization (MA) or their legal representatives for ***non-generic medicines*** *have to submit the maximum prices of medicines by* ***December 15, 2024****, which will come into force on January 1, 2025.*

For ***generic and biosimilar medicines****, the respective MA holders or their legal representatives have to submit the maximum prices of medicines by* ***January 15, 2025****, to take effect on February 1, 2025.*

If you have any doubts or questions on this matter, please do not hesitate to contact the Health Law team at pbbr - Sociedade de Advogados, SP, RL.

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