

Calculation methodology of maximal prices for medicinal products

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In brief

GD 800/2016 repealed (i) Health Minister Order no. 75/2009 approving the Norms on the calculation prices for medicinal products for human use, and (ii) Health Minister Order no. 245/2012 regarding the approval of prices for human medicines included in the National Catalogue of prices for such medicines authorised for marketing in Romania ("**Canamed**")

In detail

The new methodology introduces the following amendments:

1. Art. 6 para. (5) introduces a new method for calculating prices for essential medicines listed by the World Health Organization ("**WHO**"), for which the costs are fully met by the Romanian authorities.

According to the new methodology for calculating price proposed by the owner of the marketing authorisation ("**MA owner**") must be the lowest price between the price approved in Canamed for the innovative medicine whose generic is and the average of the lowest three prices given the same product from the list of the comparison states.

2. Art. 6 para. (9) introduces the new method for price calculation for medicinal products resulting from human blood / plasma or immunological products

included in the WHO-recommended list of essential medicines, for situations where the medicine has a recorded price in less than two countries on the list of comparison states.

Thus, if this medicine has a price registered in only two countries on the list, the price provided by the MA owner must be equal to or lower than the average prices in that states.

If the medicine has a registered price in only one country on the list or, where applicable, only in the state of origin, the price proposed by the MA owner must be equal to or lower than the price registered in that state.

If the medicine has no registered price, the price proposed by the MA owner will be approved by the Romanian authorities.

3. Art. 9 establishes the calculation method

applicable if a different amount of medicine is to be sold in a packet.

Where a medicine's price is registered in another country for a different amount of medicine in the packet, the price in Romania is calculated in proportion to the price set for that other content amount. The registered packaging size must be in a range of 2.5 times lower or higher than the packaging size for which the approval of price is requested..

4. The new methodology modifies the maximum rates of commercial margins to be applied to one maximum manufacturer price.

The calculation method includes a variable quota and a fixed quota, depending on the maximum price set by the medicine producer or on the wholesale price.

The methodology provides the maximum commercial margins for the establishment of the

Tax and Legal Alert

maximum price for both pharmacies and distributors.

Quotas applicable for distributors:

Price of medicine (RON)	Maximum Variable quota	Fixed quota (RON)
0 - 25	5%	1
25 -50	4%	5
50 -100	2.5%	9
100 -300	2%	11
over 300	RON 30	

Quotas applicable for pharmacies:

Price of medicine (RON)	Maximum Variable quota	Fixed quota (RON)
0 - 25	14%	2
25 -50	12%	4
50 -100	8%	9
100 -300	6%	10
over 300	RON 35	

5. The methodology provides the criteria for achieving annual corrections applicable to prices of innovative medicines and biological medicines.

These are new criteria.

According to the provisions of the methodology, the price correction will be performed over a period of three consecutive years, taking into account the reference price for the generic medicine or biosimilar.

Original patented medicine prices will be set based on the price for generic medicine, as follows:

Year 1	1.3826 GM
Year 2	1.2307 GM
Year 3	GM

*GM = price for generic medicine

Biological medicine prices will be set based on the biosimilar medicine price, as follows:

Year 1	1.3826 MBsim
Year 2	1.2307 MBsim
Year 3	MBsim

MBsim = price for biosimilar medicine

6. Files on new prices have to be submitted to the relevant authorities within 30 days as of the adoption of the methodology.

The price correction procedure will be finalised on 1 March

2017 and enter into force on 1 April 2017.

The takeaway

A new methodology has been introduced regarding the calculation method and procedure for notice and approval of the maximum prices of medicinal products with marketing authorisation in Romania. It modifies the medicine price calculation method for manufacturers / distributors and pharmacies.

This methodology introduces a fixed rate quota for the first time. The previous version provided only the possibility for a variable maximum quota.

Within 30 days as of the methodology's publication in the Official Gazette, all MA holders for medicines price-approved in Canamed have to submit to the Ministry of Health the documentation necessary for executing the annual price correction procedure.

[Source: Government Decision no. 800 dated 26 October 2016 concerning the Methodology and procedure on calculation for notification and approval of the maximal prices for medicinal products with marketing authorisation in Romania]

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Let's talk

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