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Amendments and completions regarding the method of calculation and the procedure for the approval of the maximum prices of medicinal products for human use

By **Order of the Minister of Health no. 407 of 30th of March 2018 (the "Order")** published in the Official Gazette no. 288 of 30th of March 2018, it has been approved the amendment and completion of the **Order of the Minister of Health no. 368/2017 approving the Norms regarding the method of calculation and the procedure for the approval of the maximum prices of medicinal products for human use** (the "**Norms**").

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The Order of the Minister of Health no. 407 entered into force on 30th of March 2018.

The new **Order** amends, completes and clarifies the Norms mainly in relation with the following aspects:

- As of the entry into force of the Order, the maximum prices and the reference prices approved in Canamed remain valid until the publication of the order approving the prices calculated following the annual correction, but not later than 1 October 2018.
- The annual update of the prices in „lei" shall be made by applying the medium exchange rate „leu/ euro" of the National Bank of Romania for the first quarter of the year when the update is performed. According to the previous provisions, such update was performed by applying the exchange rate for the third quarter of the previous year in which the update is performed.
- For the year 2018, the documentation for the approval of producer prices for the purpose of correction shall be filed by the holder of the APP/the representative starting with 30 April 2018 until 31 May 2018.
- For the price files that were filed and not approved as of the date of publication of the Order, as well as for the ones filed until 30 June 2018, the calculation of the producer prices from other foreign currency in „lei" shall be made by considering the medium foreign exchange rates of the National Bank of Romania for the third quarter of 2017. For the price files filed after 1 July 2018, the calculation of the producer prices from other foreign currency in „lei" shall be made by considering the medium foreign exchange rates of the National Bank of Romania for the first quarter of 2018.
- The definition for „**medicines derived from blood or human plasma**" is included, such being considered innovative medicines for the purposes of the Norms.
- The definition for "**Single Electronic Contact Point**" is included, representing the platform for integrating eGovernment services into the National Electronic System, managed and operated by the Agency for the Digital Agenda of Romania. Through the platform it may be submitted the documentation for approval of prices.
- A new article is included (art.5^1) which provides, by way of exception from art. 5 regarding the documentation for requesting price approval, in the case of medicines that have a price approved by the order of the Minister of Health, the necessary documentation to be submitted by the applicant to the specialized structure of the Minister of Health, in the case of changing the CIM code of the medicinal product, in the same pack size (number of therapeutic units) and also at the same price:
  - A standard application according to annex no.5 of the **Norms**;
  - Copy of APP;
  - Copy of APP annexes or of the authorization to supply special need medicines;

- An extract <<Medication Details>> from the ANMDM website.

The Order for the approval of the price of the medicinal product shall be issued within 30 days from the receipt of the application-form and the complete documentation submitted by the holder of the APP or by the representative, in accordance with the norms provisions.

The price of the approved medicine is valid until the next correction.

Until the stocks in the trading circuit run out, the product price with the old CIM code will remain in Canamed. If until the next correction the stock in the trading circuit with the old CIM code has not been run out, the new APP holder may submit the documentation for the correction also for the old CIM.

- The Order includes clarifications with respect to the procedure by which the Ministry of Health may approve the proposed price for the validity period of the authorization regarding the supply of the medicines for special needs.
- A new article (art.20^1) is included, which expressly provides that **the pharmacy mark-up for medicinal products for human use and the distribution mark-up provided by the Norm are set only for the calculation of the maximum wholesale prices, respectively the maximum retail prices of medicinal products for human use.**

For further questions regarding the aspects mentioned in this alert, please contact us.

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