Ministry of Health - MH – Order no. 272/2017 of 14 March 2017

Order of the Minister of Health no. 272/2017 of 14 March 2017 on amendment and supplementation of Rules for implementation of provisions of articles 703 (1) and (2) of Law 95/2006 on healthcare reform on medicinal products for special needs, approved through Order of the Minister of Health no. 85/2013

In force since 15 March 2017
Published in the Official Gazette of Romania, Part I, no. 183 of 15 March 2017.
There are no amendments until 17 March 2017.

On seeing the Approval report of the Medicinal Product Policy and Medical Devices Directorate No. 2.195/2017 and NAMMD notification no. 57.679E/2014, registered at the Ministry of Health with no. 69.569/2014,

taking into account provisions of Article 703 of Law 95/2006 on healthcare reform, republished, as amended,

provisions of Article 4 (2) a) of Government Decision No. 734/2010 on the set up, organisation and operation of the National Agency for Medicines and Medical Devices, as amended,

based on Article 7 (4) of Government Decision No. 144/2010 on the organisation and operation of the Ministry of Health, as amended,

the minister of health hereby issues the following order:

Article 1. – The Rules for implementation of provisions of articles 703 (1) and (2) of Law No. 95/2006 on healthcare reform on medicinal products for special needs, approved through Order of the Minister of Health no. 85/2013, published in the Official Gazette of Romania, Part I, no. 93 of 14 February 2013, as amended, are amended as follows:

1. Article 5 is amended and will read as follows:

“Art. 5. - (1) The authorisation for supply of medicinal products for special needs can only be granted to wholesale distributors authorised by the National Agency for Medicines and Medical Devices, in accordance with Annex 3.

(2) For issuance and inclusion of the authorisation for supply of medicinal products for special needs in the Index of medicinal products for human use, no fees are required, in line with Article 896 of Law 95/2006, republished, as amended."

2. Under Article 11, three new paragraphs are introduced after (2), namely (2^1) - (2^3), reading as follows:

“(2^1) In cases under (2), the National Agency for Medicines and Medical Devices shall notify the specialised directorate of the Ministry of Health on

termination of marketing of the respective product, 60 days before expiry of the MAH's duty to ensure adequate and undisrupted supply.

(2^2) Within 3 working days after receipt of the notification mentioned in Article (2^1), the Ministry of Health, via its specialised directorate, shall require the specialist commission/the National Health Insurance House, as necessary, for transmission of stocks for 12-months use.

(2^3) The specialist commission/the National Health Insurance House shall notify the Ministry of Health about the stocks for 12-months use within 5 days from receipt of the request. The Ministry of Health, via its specialised directorate, shall notify the applicant about the stocks for 12-months use received from the specialist commission/the National Health Insurance House within 3 days after receipt."

3. Under Article 14, a new paragraph is introduced after (2), namely (2^1), reading as follows:

"(2^1) Should a medicinal product not require grant of a new authorisation for supply of medicinal products for special needs, in case the amount specified in (2) is not used up until expiry of authorisation validity, the holder may require the NAMMD to extend the authorisation validity until depletion of the respective amount, but no longer than 6 months after expiry of its validity."

4. Article 21 (2) is amended and will read as follows:

"(2) Documentation mentioned in (1) shall be submitted in writing."

5. Under Article 22, two new paragraphs are introduced after (4), namely (5) and (6), reading as follows:

"(5) In the case mentioned in Article 2 (2) of these Rules, the price of the medicinal product for special needs shall be less than or equal to the price approved in the National Index of Prices for On-Prescription Medicinal Products for Human Use (CaNaMed) for the medicinal product authorised for marketing but temporarily unavailable by the regular distribution channels.

(6) In case of special needs medicinal product price not compliant with these Rules, the Ministry of Health can temporarily approve the price proposed for the period of validity of the special needs authorisation."

6. Article 26 is hereby repealed.

7. Article 31 is hereby repealed.

8. Article 32 is hereby repealed.

Art. II. - This Order shall be published in the Official Gazette of Romania, Part I

Minister of Health,
Florian-Dorel Bodog

Bucharest, 14 March 2017.
No. 272.