

**ORDER No. 355 of 24 March 2015**  
**for supplementation of Order of the Minister of Health No. 888/2014 on approval of fees payable to the National Agency for Medicines and Medical Devices for services related to medicinal products for human use**

ISSUED: THE MINISTRY OF HEALTH

PUBLISHED IN: THE OFFICIAL GAZETTE OF ROMANIA, NO. 212 of 30 March 2015

On seeing the Approval report no. N. B. 2. 859/2015 drafted by the Directorate for Medicinal Product and Medical Devices Policies of the Ministry of Health and the proposal of the National Agency for Medicines and Medical Devices no. 4. 580/2015,

Taking into account provisions of article 10 d) of Government Decision no. 734/2010 on the 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 I

Order of the Minister of Health no. 888/2014 on approval of fees payable to the National Agency for Medicines and Medical Devices for services related to medicinal products for human use, published in the Official Gazette of Romania, no. 572 of 31 July 2014, is hereby supplemented as follows:

- Under point III of the Annex, "Assessment of documentation for marketing authorisation/marketing authorisation renewal for medicinal products for human use and conduct of other activities", letter B "Assessment of documentation for marketing authorisation/marketing authorisation renewal through European procedures", a new item, 26<sup>1</sup>, shall be introduced item 26. b), reading as follows:

No.	Activity	Fee -Euro-
26 <sup>1</sup>	Marketing authorisation of traditional herbal medicinal products [art. 16(a) of Directive 2001/83/EC or art. 714 of Law no. 95/2006, as amended] authorisation by simplified procedure	1. 925

	– European procedures	
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## Article II

This Order is to be published in the Official Gazette of Romania, Part I.

p. Minister of Health,  
Gabriel Florin Pușcău,  
Secretary General 2

Bucharest, 24 March 2015.  
No. 355.