MINISTRY OF HEALTH

ORDER
on amendment of Order of the Minister of Health No. 716/2009 on approval of tariffs and amount of marketing authorisation maintenance fee required by the National Medicines Agency

(Published in the Official Gazette of Romania, Part I, No. 667 of 24/09/2012)

On seeing the Approval report of the Pharmaceutical and medical devices direction No. C.V. 3.786/7 September 2012,

taking into account provisions of Art. 10 (d) 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 Art. 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:

Art. I. – The Order of the Minister of Health No. 716/2009 on approval of tariffs and amount of marketing authorisation maintenance fee required by the National Medicines Agency, published in the Official Gazette of Romania, Part I, No. 422 of 19 June 2009, is amended as follows:

1. "National Medicines Agency" (NMA) shall be replaced by "National Agency for Medicines and Medical Devices" (NAMMD).

2. Under Annex 2, "Tariffs due for various inspections and related activities", a new item is inserted after item 25, namely 26, which reads as follows:

Crt. No.	Performance	Tariff - euro - ***	Fixed component*	Variable component**
"26.	Inspection for accreditation of readability testing providers	750	750	-"

3. Under Annex 3 "Tariffs for assessment of documentation in view of marketing authorisation/marketing authorisation renewal of medicinal products for human use and development of marketing authorisation related activities", section B "Assessment of documentation in view of marketing authorisation/marketing authorisation renewal through European procedures", a new item is inserted, namely item 27.a), which reads as follows:

Crt. No.	Performance	Tariff - euro -
"27.a)	Marketing authorisation renewal of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State	4.305"

4. Under Annex 3, section D, "Approval of variations" is amended and shall read as follows:

Crt. No.	Performance	Tariff - euro -
D.	Approval of variations	
35.	Approval of Type IA variations and Type IA variations defining the group for medicinal products authorised through national procedure	300
36.	Approval of Type IB variations and Type IB variations defining the group for medicinal products authorised through national procedure	500
37.	Approval of Type II variations and Type II variations defining the group for medicinal products authorised through national procedure	1.600
38.	Approval of Type IA variations included in the group for medicinal products authorised through national procedure	200
39.	Approval of Type IB variations included in the group for medicinal products authorised through national procedure	340
40.	Approval of Type II variations included in the group for medicinal products authorised through national procedure	1.070
41.	Approval of Type IA variations for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Reference Member State	460
43.		
44.	Approval of Type IA variations for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State	300

45.	Approval of Type IB variations for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State	500
46.	Approval of Type II variations for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State	1.600
47.	Approval of Type IA variation included in the group, other than the variation defining the group, for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Reference Member State	375
47.a)	Approval of Type IB variation included in the group, other than the variation defining the group, for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Reference Member State	750
47.b)	Approval of Type II variation included in the group, other than the variation defining the group, for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Reference Member State	2.400
48.	Approval of Type IA variation included in the group, other than the variation defining the group, for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State	165
48.a)	Approval of Type IB variation included in the group, other than the variation defining the group, for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State	225
48.b)	Approval of Type II variation included in the group, other than the variation defining the group, for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State	825

NOTE: 1. As far as grouped variations are concerned, the tariff will be calculated for each marketing authorisation, by summing up the tariff for the variation defining the group and the tariff for the grouped variation which applies to each variation in the group, other than the variation defining the group.

2. The tariff for the variation defining the group is the one for the variation to the marketing authorisation.

5. Under Annex 3, section E "Other marketing authorisation related activities", a new item in inserted, which reads as follows:

Crt. No.	Performance	Tariff - euro -
"54.	Approval of parallel import authorisations	250"

Art. II. - This order is to be published in the Official Gazette of Romania, Part I.

Minister of health,

Vasile Cepoi

Bucharest, 7 September 2012.
No. 868