MINISTRY OF HEALTH

ORDER no. 1359 of 13 November 2013 on amendment of Order of the Minister of Health No. 716/2009 on approval of the National Agency for Medicines and Medical Devices fees and fee for maintenance of marketing authorisation

PUBLISHED IN: THE OFFICIAL GAZETTE OF ROMANIA no. 708 of 19 November 2013

On seeing the Approval report No. E.N. 11.463/2013 of the Pharmaceutical and Medical Devices Directorate,

Taking into account provisions of Article 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 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. – Order of the Minister of Health no. 716/2009 on approval of fees of the National Agency for Medicines and Medical Devices and marketing authorisation maintenance fee, published in the Official Gazette of Romania, Part I, no. 422 of 19 June 2009, as amended, is hereby amended as follows:

1. Article 2 is amended and reads as follows:

"Article 2 - The marketing authorisation maintenance fee is 230 euro/year and shall be paid to the National Agency for Medicines and Medical Devices every year before the 31 December of the following year."

2. A new article, 4^1, is introduced after Article 4, which reads as follows:

"Article 4^1 – The administrative procedure for the handling of fees received by the National Agency for Medicines and Medical Devices in case of discontinuation of the procedure for clinical trial evaluation, authorisation and amendment is as follows:

a) For notification by applicants on withdrawal of their application for authorisation of a clinical trial on a medicinal product for human use after payment of fee for clinical trial authorisation procedure, the trial authorisation fee paid by applicants according to Annex 3 provisions shall be managed as follows:

(i) For applications for discontinuation of the authorisation procedure concerning a clinical trial on a medicinal product for human use submitted prior to validation of the application, depending on applicant’s request, the respective

fee may be returned/directed for payment of a different fee due to the National Agency for Medicines and Medical Devices by the respective applicant;

(ii) For applications for discontinuation of the authorisation procedure concerning a clinical trial on a medicinal product for human use submitted after validation of the application for authorisation, but no later than 25 calendar days as of procedure onset, depending on applicant's request, 90% of the fee may be returned/ directed for payment of a different fee due by the applicant in question to the National Agency for Medicines and Medical Devices;

(iii) For applications for discontinuation of the authorisation procedure concerning a clinical trial on a medicinal product for human use submitted after day 25 as of procedure onset, the fee paid shall be retained by the National Agency for Medicines and Medical Devices and may no longer be returned;

b) If the application for authorisation of a clinical trial on a medicinal product for human use is rejected following the validation procedure, 90% of the fee may be returned/directed for payment of a different fee due by the applicant in question to the National Agency for Medicines and Medical Devices;

Notification by applicants on withdrawal of the application for approval of a substantial amendment to a clinical trial on a medicinal product for human use after payment of fees for the procedure for approval of a clinical trial amendment, the fee for evaluation of the clinical trial amendment, as paid by applicants according to Annex 3 provisions, shall be managed as follows:

(i) For applications for discontinuation of the clinical trial amendment approval procedure submitted prior to validation of the application, depending on applicant's request, the respective amount may be returned/directed for payment of a different fee due by the applicant in question to the National Agency for Medicines and Medical Devices;

(ii) For applications for discontinuation of the clinical trial amendment approval procedure submitted after validation of the application, but no later than 15 calendar days as of procedure onset, 90% of the fee may be returned/ directed for payment of a different fee due by the applicant in question to the National Agency for Medicines and Medical Devices;

(iii) For applications for discontinuation of the authorisation procedure to the National Agency for Medicines and Medical Devices submitted after day 15 as of procedure onset, the amount paid shall be retained by the National Agency for Medicines and Medical Devices and may not be returned;

d) If the application for authorisation of a clinical trial on a medicinal product for human use is rejected following the validation procedure, depending on applicant's request , 90% of the fee may be returned/directed for payment of a different fee due by the applicant in question to the National Agency for Medicines and Medical Devices;"

3. Letter C of Annex 3 is amended and reads as follows:

"C.	Authorisation of clinical trials, approval of substantial amendments and approval of advertising material
28.	Authorisation of clinical trials for investigational medicinal products not authorised on a global scale
	(new substances). Phases I - III
29.| Authorisation of clinical trials for investigational	1.000	medicinal products not authorised in Romania, but
	authorised in other countries or having a marketing authorisation
	(MA), (known substances), not used however in the respective
	clinical trial in accordance with conditions mentioned in the
	Summary of Product Characteristics (SmPC) in force
	(as regards indications, dose, route of administration,
	method of treatment, population group).
	Phases I - IV
30.	Authorisation of clinical trials for products authorised and
410	used in accordance with the SmPC in force in Romania. Phase IV
31.	Authorisation of clinical trials for bioequivalence
600	
32.	Approval of substantial amendments (mentioned in
200	Scientific Council Decision no. 22/2010 of the National Agency for
	Medicines and Medical Devices)
33.	Approval of advertising material for over-the-counter medicinal products
550	(OTCs)
34.	Approval of educational material for medicinal products
350 | for human use |

NOTE:
Fees established under section 33 and 34 refer to approvals valid 6 months as of issuing date."

4. A new letter, F, is introduced after letter E in Annex 3, which shall read as follows:

"F.	Assessment of dossier for scientific advice, respectively

| | of amendment of scientific advice on ancillary active substances | |
| incorporated in a medical device |
_____	_____	_____
55.	Scientific advice of ancillary active substances
2.660	incorporated in a medical device for substances not previously assessed
	by the National Agency for Medicines and Medical Devices (NAMMD)
_____	_____	_____
56.	Scientific advice on ancillary active substances
1.330	incorporated in a medical device for substances not
	previously assessed by the NAMMD with a different manufacturer
_____	_____
57.	Scientific advice on ancillary active substances
535	incorporated in a medical device for substances not
	previously assessed by the NAMMD with a different manufacturer
_____	_____	_____
58.	Amendment of scientific advice of ancillary active substances
665	incorporated in a medical device for substances
	not previously assessed by the NAMMD
_____	_____	_____
59.	Amendment of the scientific advice on ancillary active
335	substances incorporated in a medical device	
for substances previously assessed by the NAMMD with a different manufacturer
	_____	_____	_____
60.	Amendment of the scientific advice on ancillary active
250"	substances incorporated in a medical device
	for substances previously assessed by the NAMMD with the same manufacturer
_____	_____	_____

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

Minister of health,
Gheorghe-Eugen Nicolăescu

Bucharest, 13 November 2013.
No. 1.359.