

ORDER

on amendment of Minister of Public Health Order No. 1038/2008 on approval of tariffs and amount of marketing authorisation maintenance fee required by the National Medicines Agency

On seeing Approval Report No. EN 12.410 of 2 December 2008 of the Pharmaceutical Directorate of the Ministry of Health,

taking into account provisions of Art. 8(e) of Government Ordinance No. 125/1998 on the set up, organisation and functioning of the National Medicines Agency, approved with changes and completions through Law no. 594/2002, with further amendments and supplementations,

based on Government Decision no. 826/2006 on organisation and functioning of the Ministry of Public Health, with further amendments and supplementations,

the Minister of Public Health hereby issues the following order:

Art. I. – Minister of Public Health Order No. 1.038/2008 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. 419 of 4 June 2008, with further completions, shall read as follows:

1. **Paragraph (3) of Art. 3 is removed.**

2. **A new Art. is introduced after Art. 5, namely Art. 5¹, which reads as follows:**

"Art. 5¹. - In case of discontinuation of marketing authorisation/marketing authorisation (MA) renewal and variations approval procedures, the administrative procedure for management of amounts entered into National Medicines Agency accounts is as follows:

a) In case of notification by applicants on withdrawal of MA/MA renewal application after payment of dues for MA/MA renewal procedure, the National Medicines Agency shall transfer to the state budget the marketing authorisation/marketing authorisation renewal fee paid by applicants according to Art. 854 of Law 95/2006 on healthcare reform, with further amendments and supplementations on submission of the marketing authorisation/marketing authorisation renewal application;

b) In case of notification by applicants on withdrawal of MA/MA renewal application after payment of dues for MA/MA renewal procedure, the marketing authorisation/marketing authorisation renewal tariff paid by applicants according to Annex 1a) provisions shall be managed as follows:

(i) Should the applicant submit an application for discontinuation of the marketing authorisation/marketing authorisation renewal procedure prior to validation of the marketing authorisation/marketing authorisation renewal application, on applicant's request, the respective amount may be returned/directed to a different payment due by the applicant in question to the National Medicines Agency;

(ii) Should the applicant submit an application for discontinuation of the marketing authorisation/marketing authorisation renewal procedure after validation of the marketing authorisation/marketing authorisation renewal application but prior to start of the mutual recognition or decentralised procedure, or no later than 90 calendar days as of payment in case of national procedure, respectively, on applicant's request, 90% of the tariff may be returned/directed to a different payment due by the applicant in question to the National Medicines Agency;

(iii) Should the applicant submit an application for discontinuation of the marketing authorisation/marketing authorisation renewal procedure after start of the mutual recognition or decentralised procedure, or after 90 calendar days as of payment in case of national procedure, respectively, the paid amount shall be retained by the National Medicines Agency and may not be returned;

c) In case of notification by applicants on withdrawal of the application for variation approval after payment of dues for variation approval procedure and after validation of the application for variation approval but prior to request for additional information by the National Medicines Agency, on applicant's request, 90% of the tariff may be returned/directed to a different payment due by the applicant in question to the National Medicines Agency;

d) In case of notification by applicants on withdrawal of the application for variation approval after request for additional information by the National Medicines Agency, the paid amount shall be retained by the National Medicines Agency and may not be returned.

3. Art. 6 is modified and shall read as follows:

"Art. 6 – On the date of this Order coming into force, Minister of Public Health Order No. 407/2005 on the approval of tariffs and emergency tariffs for activities performed by the National Medicines Agency, as well as for the maintenance fee of the marketing authorisation, published in the Official Gazette of Romania, Part I, No. 461 of 31 May 2005; Minister of Public Health Order No. 1.454/2005 on the approval of tariffs for the activities carried out by the National Medicines Agency, published in the Official Gazette of Romania, Part I, No. 25 of 11 January 2006; Order of Minister of Public Health Order No. 876/2006 on approval of the tariffs for certain activities carried out by the National Medicines Agency, published in the Official Gazette of Romania, Part I, No. 641 of 25 July 2006; Minister of Public Health Order No. 1.247/2006 on the approval of the tariff in view of the release by the National Medicines Agency of the certificate attesting the status of qualified person, published in the Official Gazette of Romania, Part I, No. 868 of 24 October 2006; Minister of Public Health Order No. 1.767/2006 on the approval of the administrative handling procedure of the amounts of fees in the National Medicines Agency's accounts, in case of discontinuation of the Marketing Authorisation Procedure, published in the Official Gazette of Romania, Part I, No. 58 of 24 January 2007; Minister of Public Health Order No. 1.779/2006 on the approval of tariffs for the activities performed by the Evaluation-Authorisation Department for products authorised through the mutual recognition/decentralised procedure and in view of the release of the authorisation for parallel import, published in the Official Gazette of Romania, Part I, No. 9 of 8 January 2007; Minister of Public Health Order No. 1.335/2007 on the approval of tariffs for activities performed by the NMA Evaluation-Authorisation Department for products authorised through the mutual recognition/decentralised procedure, published in the Official Gazette of Romania, Part I, No. 552 of 13 August 2007."

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

Minister of Public Health,
Gheorghe Eugen Nicolăescu

Bucharest, 2 December 2008.
No. 1.961.

(Published in the Official Gazette of Romania, Part I., No. 836 of 11 December 2008)