

MINISTRY OF PUBLIC HEALTH

ORDER

on supplementation of Order of the Minister of Public Health no. 1.038/2008 on approval of tariffs and amount of marketing authorisation maintenance fee required by the National Medicines Agency

Taking into account provisions of Art. 8(e) of Government Ordinance No. 125/1998 on the set up, organisation and operation of the National Medicines Agency, approved as amended through Law no. 594/2002, as amended,

On seeing Approval Report No. EN 7.215 of 6 July 2008 of the Pharmaceutical Directorate of the Ministry of Health,

Based on Government Decision no. 826/2006 on organisation and operation of the Ministry of Public Health, as amended,

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 be supplemented as follows:

- A new paragraph is introduced after Article 3 (2), namely paragraph (3), which reads as follows:

"(3) In case of discontinuation by the applicant of procedures related to marketing authorisation, marketing authorisation renewal, variation submitted through national/decentralised/mutual recognition procedure, after approval of the submitted documentation by the National Medicines Agency, 10% of the tariff shall be retained."

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

Minister of Public Health,
Gheorghe Eugen Nicolăescu

Bucharest, 7 July 2008.
No. 1.255.

(Published in the Official Gazette of Romania, no. 527 of 14 July 2008)