MINISTRY OF PUBLIC HEALTH

ORDER
on approval of the procedure on simplified authorisation for traditional herbal medicinal products

On seeing the Approval Report of the Pharmaceutical Sector No. E.N. 2.295 of 9 March 2008,

Taking into account provisions of Title XVII – The medicinal product of Law No. 95/2006 on healthcare reform, as amended, and Government Ordinance No. 125/1998 related to the set up, organisation and functioning of the National Medicines Agency, approved as amended through Law No. 594/2002, as amended,

based on Government Decision No. 862/2006 on the organisation and functioning of the Ministry of Public Health, as amended

the Minister of Public Health hereby issues the following order:

Art. 1. – The procedure on simplified authorisation for traditional herbal medicinal products is approved, in compliance with the Annex which is integral part of the present order.

Art. 2. – The present order shall be published in the Official Gazette of Romania, Part I.

Minister of Public Health,

Gheorghe Eugen Nicolăescu

Bucharest, 11 March 2008.
No. 297.

ANNEX

PROCEDURE
on simplified authorisation for traditional herbal medicinal products

Art. 1.- (1) The present procedure refers to specific rules concerning the simplified authorisation for traditional herbal medicinal products meeting the demands of Article 714 (1) of Law No. 95/2006, Title XVII "The medicinal product" on healthcare reform, as amended.

(2) Within the present procedure, the term *traditional herbal medicinal product* has the same meaning as under Article 695 (30) of Law No. 95/2006, as amended.

Art. 2. - (1) In view of initiating a simplified authorisation procedure, the applicant must submit to the National Medicines Agency (NMA) an application in the same format as in Article 716 of Law No. 95/2006, as amended.

(2) If the application does not meet the demands under (1), the NMA requires the completion of the application form or elucidations concerning the attached documents; in this case, provisions of Article 724 (c) of Law No. 95/2006, as amended, shall be applied.

(3) When preparing the authorisation dossier, the guidelines and the other documents issued by the EMEA Committee on Herbal Medicinal Products should be taken into consideration.

Art. 3. - (1) According to the provision under paragraph (2), the NMA shall take the necessary measures in order to complete the simplified authorisation procedure in maximum 120 days as of submission of the valid application.

(2) The time limit mentioned under (1) may be extended by another 90 days, provided that the applicant is informed about this prior to the expiry of the 120 days.

(3) In case of enforcing provisions of Art. 717 of Law No. 95/2006, as amended, the procedure should is finalised compliant with the terms under Art. 736 of the same Law.

Art. 4. - (1) The marketing authorisation may be renewed after 5 years, by issuance of a new authorisation, on Holder's application, submitted at least three months prior to the expiry date of the period of validity, if the Holder certifies that no change has been made to elements underlying the authorisation application through simplified procedure.

(2) In the absence of any NMA decision or of an application requesting data or supplementary information addressed to the applicant before the expiry date of the authorisation, the authorisation shall be considered renewed on that date.

Art. 5. - (1) Changes in the information or documents underlying simplified authorisation are submitted for NMA approval based on adequate justifying documents and data.

(2) The NMA shall give its verdict upon variation applications, within the timeframe imposed by the variations regulations in force.

Art. 6. - Tariffs for authorisation through simplified procedure and renewal of this authorisation, respectively, are stipulated in the Order of the Minister of Public Health in force on approval of tariffs for NMA activities.

Art. 7. - The present procedure shall be supplemented with provisions of Regulations on marketing authorisation and surveillance of medicinal products for human use, approved through Order of the Minister of Public Health No. 895/2006, as amended, and of the norms on the NMA administrative procedure for handling variations, approved through Order of the Minister of Public Health No. 874/2006.

NOTICE

In accordance with Art. 720 (1) of Title XVII – "The medicinal product" of Law No. 95/2006, "Art. 697 a) and b), Art. 700 (1), Art. 709, Art. 722 (1), Art. 724, 725, 728, 730, 731, 748 – 761, 780 – 796, 812 – 820, 823 (1) and (3), Art. 824, 828 – 830, 839, 840, 842, 843 (2) and Art. 846 of the present title, as well as with the Principles and Guidelines of Good Manufacturing Practice for medicinal products for human use and for investigational medicinal products, approved through Order of the Minister of Public Health, shall apply by analogy to authorisations of traditional herbal medicinal products issued based on the provisions of this section". In order to avoid legislative redundancy, the content of these provisions and of section 3.3., title XVII – „The medicinal product" of Law No. 95/2006 have not been included in the present procedure.