MINISTRY OF PUBLIC HEALTH

ORDER
on approval of simplified authorisation procedure for certain homeopathic medicinal products

Taking into account:

- provisions of Title XVII – The medicinal product of Law No. 95/2006 on healthcare reform, as amended;

- 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,

on seeing the Approval Report of the Pharmaceutical Sector No. E.N. 4889/2007

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

the Minister of Public Health hereby issues the following order:

Article 1. – The simplified procedure for authorisation for certain homeopathic medicinal products shall be approved, in compliance with the Annex which is integral part of the present order.

Article 2. - On this order coming into force, any other contrary dispositions shall be repealed.

Article 3. – The present order shall be published in the Official Gazette of Romania, Part I.

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Minister of Public Health,
Gheorghe Eugen Nicolăescu

Bucharest, 10 May 2007.
No. 816.

ANNEX

PROCEDURE
on simplified authorisation for certain homeopathic medicinal products

Article 1. - (1) The present procedure refers to specific rules concerning the simplified authorisation for homeopathic medicinal products which meet the demands of Article 711 (1) of Law No. 95/2006 on healthcare reform, as amended.

(2) Within the present procedure, the term *homeopathic medicinal product* has the same meaning as under Article 695 (4) of Law No. 95/2006, as amended.

Article 2. - (1) In view of initiating a simplified authorisation procedure for a medicinal product or batch of medicinal products derived from the same homeopathic source which meets the demands of Article 711 (1) of Law No. 95/2006, as amended, the applicant must submit to the National Medicines Agency an application in the same format as in Annex 2 on regulations concerning the marketing authorisation and supervision of medicinal products for human use, approved through Minister of Public Health Order No. 895/2006.

(2) The application must be accompanied by the following information or documents:

a) name and address, or, as required, name and site of the applicant;

b) name and address or, as required, name and site of the manufacturers of the homeopathic medicinal product, as well as the production sites involved in various manufacturing stages, including those belonging to the manufacturer of the finished product and to the manufacturers of the homeopathic source(s);

c) documents and information under Article 712 (2) of Law No. 95/2006, as amended.

(3) If the application does not meet the demands under (2), the National Medicines Agency 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.

Article 3. - (1) According to the provision under paragraph (2), the National Medicines Agency shall take the necessary measures in order to complete the simplified authorisation procedure in maximum 120 days from the submission of the application.

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

Article 4. – The National Medicines Agency refuses the authorisation through simplified procedure in the following situations:

a) The respective homeopathic medicinal product does not fulfil one or more demands of Article 711 (1) of Law No. 95/2006, as amended;

b) following the check-up of documents and data submitted at the same time with the application under Article 2, the medicinal product proves to be harmful under normal circumstances;

c) qualitative or quantitative composition of the medicinal product differs from the one previously declared.

Article 5. - (1) Marketing authorisation issued by the National Medicines Agency for a homeopathic medicinal product based on the present procedure may be renewed in 5 years, on Holder′s demand, submitted at least three months prior to the expiry date of the period of validity, if the holder attests that no modification has interfered with elements which have determined the authorisation application through simplified procedure.

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

Article 6. - (1) Modifications (variations) which have shown up in the information or documents which were the basis of simplified authorisation according to Article 2 (2) are submitted for approval to the National Medicines Agency based on adequate justifying documents and data.

(2) National Medicines Agency shall give its verdict upon variation applications, 60 days as of the application registration.

(3) In the absence of a reply coming from the National Medicines Agency within 60 days from the registration of the application, this shall be considered approved.

Article 7**. –** Tariffs for authorisation through simplified procedure, as well as for the renewal of this authorisation in case the application refers to a single homeopathic medicinal product or to a batch of medicinal products derived from the same homeopathic source(s), each dilution having the same pharmaceutical form, are stipulated in the Minister of Public Health Order in force on approval of tariffs for the activities performed by the National Medicines Agency.

Article 8. **–** The present procedure shall be supplemented with provisions of Regulations on marketing authorisation and supervision of medicinal products for human use, approved through Minister of Public Health Order No. 895/2006.

NOTE:

In accordance with Article 711 (2) of Law No. 95/2006, as amended, "Procedural criteria and rules provided in Article 722 (1), Article 727-732, Article 824, 828 and 842 are applicable by analogy to a special simplified authorisation procedure for homeopathic medicinal products, excepting the proof of the therapeutic efficacy". In order to avoid legislative redundancy, the content of these provisions has not been included in the present procedure.