

MINISTRY OF PUBLIC HEALTH

ORDER

Norms on the procedure for grant of exemption of specific medicinal products label and package leaflet from the obligation that certain particulars shall appear and that the leaflet must be in Romanian, when the product is not intended to be delivered to the patient for self-administration

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

on seeing Approval Report of the General Pharmaceutical and Medical Devices Directorate No. EN 2.141 din 17 July 2006,

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

the minister of public health hereby issues the following order:

Article 1. - Approval of Norms on the procedure for grant of exemption of specific medicinal products label and package leaflet from the obligation that certain particulars shall appear and that the leaflet must be in Romanian, when the product is not intended to be delivered to the patient for self-administration, provided in the Annex which is integral part of this order.

Article 2. – Repeal of Order of the minister of public health No. 1.178/2004 on approval of approval of Norms for application of provisions of Emergency Ordinance No. 152/1999 on medicinal products for human use, approved with changes and completions through Law No. 336/2002, with further changes and completions, on grant of exemption of imported medicinal products from the obligation that the leaflet must be in Romanian, published in the Official Gazette of Romania, Part I, No. 870 din 23 September 2004 on the date of this order coming into force.

Article 3. - Provisions of this order come into force on 28 July 2006.

Article 4. - The present order is to be published in the Official Gazette of Romania, Part I.

The minister of public health,
Gheorghe Eugen Nicolăescu

Bucharest, 17 July 2006.
No. 872

Norms on the procedure for grant of exemption of specific medicinal products label and package leaflet from the obligation that certain particulars shall appear and that the leaflet must be in Romanian, when the product is not intended to be delivered to the patient for self-administration

Article 1. - (1) According to article 773 of Law No. 95/2006 on healthcare reform, Title XVII, The medicinal product, the application for grant of exemption of specific medicinal products label and package leaflet from the obligation that certain particulars shall appear and that the leaflet must be in Romanian, is submitted to the National Medicines Agency either at the same time with the application for marketing authorisation or during the authorisation procedure and is processed at the same time with the application for authorisation..

(2) The application must specify what label and package leaflet particulars applying for exception and the reasons for the specific request and should be accompanied by relevant supporting documents.

(3) The National Medicines Agency decides on the grant of exception based foremost on the interest of patients.

Article 2. – According to Order of the minister of public health No. 1126/08.12.2003 on resolution of applications for changes in package design and inscription and changes in package leaflet other than those due to Type IA, IB and II variations, on condition of clear presentation of request for exception and reasons underlying the request, the application specified under 1 (1) may also be submitted after submission of the application for authorisation.

Article 3. - (1) When exception is granted from the obligation that the leaflet must be in Romanian, the leaflet should be in English and/or French; for solid reasons, another, preferably Romance, official language of the European Union may also be accepted.

(2) When exception is granted from the obligation that the leaflet must be in Romanian, exception from the obligation that the label must be in Romanian may also be granted.