MINISTRY OF PUBLIC HEALTH

ORDER
on approval of the Norms for implementation of provisions of Article 699 (1) of Law No. 95/2006 on healthcare reform concerning medicinal products for special needs

Taking into account the provisions of Article 699 (1) of Law 95/2006 on healthcare reform, as amended;

On seeing the Approval report of the Pharmaceutical Directorate No. E.N. 2.730/2006,

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

the **minister of public health** hereby issues the following order:

Art. 1. - The Norms for implementation of provisions of Article 699 (1) of Law No. 95/2006 on healthcare reform concerning medicinal products for special needs are approved, as provided in the Annex, which is integral part of this Order.

Art. 2. - This Order is to be published in the Official Gazette of Romania, Part I.

Minister of Public Health,
Ervin Zoltan Szekely,
Secretary of state

Bucharest, 1 August 2006.
No. 962.

ANNEX

NORMS FOR IMPLEMENTATION of provisions of Article 699 (1) of Law No. 95/2006 on healthcare reform concerning medicinal products for special needs

Art. 1. - (1) Article 1. - (1) These Norms refer to medicinal products without valid marketing authorisation in Romania as per Article 700 of Law 95/2006, required for resolution of special needs in line with Article 699(1) of the same Law.

(2) These Norms do not refer to other medicinal products exempted from the marketing authorisation, in accordance with Art. 699 of Law 95/2006.

(3) Medicinal products subject to a clinical trial performed in Romania and off-label prescription of a medicinal product are not subject to these Norms.

Art. 2. – The prescription of certain medicinal products for special needs should comply with the following conditions:

a) The responsibility for the decision whether a patient has special needs which cannot be met by medicinal products authorised for marketing should belong to the concerned patient's physician; this physician prescribes the medicinal product;

b) A medicinal product which is the pharmaceutical equivalent of an already authorised product shall not be considered a medicinal product for special needs; in line with this paragraph, a medicinal product is considered a pharmaceutical equivalent if it meets all the following requirements:

- it contains the same amount of active substance(s) or the same strength, for liquid pharmaceutical forms;
- it has the same pharmaceutical form;
- it meets the same/equivalent standards as regards the patient's clinical needs at the moment of product administration.

c) As an interim solution, a medicinal product authorised for marketing may be considered for special needs in case it cannot be obtained via the regular distribution chains in reasonable time; this does not justify long-term supply; supply under such circumstances must be discontinued as soon as availability of the authorised medicinal product in the regular distribution chains is re-established.

d) Medicinal products for special needs have to be authorised in at least one EEA Member State or in a third country.

Art. 3. - A medicinal product for special needs may be supplied in accordance with these Norms, if the following requirements are met:

- there is a bona fide unsolicited order (on behalf of the supplier, initiated by the physician, with the patient's consent);
- the product is prescribed by a physician;
- the product is meant for one/several patient(s) under the respective physician's direct responsibility.
- the product is supplied in accordance with the conditions specified in this Order.

Art. 4. - Everyone involved in the supply circuit must be informed that the respective product does not have a valid marketing authorisation in Romania.

Art. 5. - The authorisation for supply of medicinal products for special needs can only be granted to wholesale distributors authorised by the Ministry of Public Health, in accordance with Annex 2.

Art. 6. - (1) The applicant submits to the Ministry of Public Health a dossier containing:

- a standard application form, in accordance with Annex 1;
- medical justification;
- Summary of Product Characteristics.

(2) The authorisation is granted for the amount specified in the prescription, without exceeding the necessary for 12 months use.

Art. 7. - The wholesale distributor of medicinal products for special needs has the following obligations:

a) to immediately inform the National Agency for Medicines and the Ministry of Health about safety/quality concerns, of which the distributor has been informed;

b) not to advertise the medicinal product or its effects;

c) to retain specific records about its supply, including the products' manufacturing batches;

d) to notify the Ministry of Public Health about the actual imported amount of the medicinal product for special needs as well as any other issue related to its supply.

Art. 8. - The records mentioned under Article 7 c) are to be retained for at least 5 years from the date of the issuance of the authorisation and include the following information:

a) the external supplier of the medicinal product;

b) the date and beneficiary of the medicinal product;

c) the amount of each delivery;

d) the number of the product manufacturing batch;

e) details about any adverse reaction as known to the supplier.

ANNEX 1
to the Norms

MINISTRY OF PUBLIC HEALTH
THE PHARMACEUTICAL AND MEDICAL EQUIPMENT GENERAL DIRECTORATE

FORM
Application for authorisation of supply of medicinal products for special needs,

1. Prescriber information

Name and surname:	Number of the free practice document:	Stamp code:
Medical unit:		
Address:	Telephone number: Fax number:	Mobile phone number: E-mail address:
I hereby declare that I take the responsibility for use of ....., in accordance with the attached medical explanatory document, full aware that this is not authorised for marketing in Romania, in accordance with the law. Date ..... Signature and stamp		

2. Patient information

Name and surname:		Identity document:	PIN:
Address:		Telephone number: Fax number:	Mobile phone number: E-mail address:
Age:	Diagnosis:		
I hereby declare that I have been informed that ..... does not have a marketing authorisation in Romania, in accordance with the law, and duly agree with the treatment. I have been informed about the potential adverse reactions as well as the manner of their reporting and undertake the charges for the product. Date ..... Signature			

3. Information about the medicinal product for special needs

Trade name:
Active substance (INN):
Pharmaceutical form and strength:
Manufacturer and country of origin:
Quantity required *):
Indications on administration (dosage):
Adverse reactions and cautions related to the administration:

4. Information about the supplier

Name of the wholesale distributor:	
Address:	
Number of the wholesale distribution authorisation:	
Qualified person (contact data):	
Telephone number:	Mobile phone number:
Fax number:	E-mail address:
We hereby apply for grant of an authorisation for supply of the aforementioned product according to the quantity required. We hereby declare compliance with legal provisions on supply of medicinal products for special needs without a marketing authorisation in Romania, in accordance with Article 699 (1) of Law 95/2006 on healthcare reform. Date	Signature and stamp .....

NOTE:

This application form is available only if accompanied by:

- medical justification for prescription of the concerned medicinal product, in accordance with the criteria mentioned in this Order;
- the Summary of Product Characteristics.

This application form is available only if accompanied by all documents mentioned under Article 14 (1) of the Norms for implementation of provisions of Article 699 points (1) and (2) of Law 95/2006 on healthcare reform concerning medicinal products for special needs, approved through Order of the Minister of Health No. 85/2013.

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*) Quantity prescribed for one year at most.

ANNEX 2
to the Norms

MINISTRY OF PUBLIC HEALTH
THE PHARMACEUTICAL AND MEDICAL EQUIPMENT GENERAL DIRECTORATE

AUTHORISATION

for supply of medicinal products for special needs

No. ..... of .....

Date

.....

Taking into account Application No..... of ....., submitted to the Ministry of Public Health, and approval report no. .....,

Distributor:

..... is authorised to supply.....,

(Trade name, pharmaceutical form and strength), containing ....., quantity:....., in response to the prescription issued by Dr. …… (International Non-proprietary Name)

for .....

This authorisation is valid for .....

Minister of public health,

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