MINISTRY OF HEALTH

ORDER
on approval of the Norms for implementation of provisions of Article 699 (1) and (2) of Law No. 95/2006 on healthcare reform concerning medicinal products for special needs

On seeing the Approval report of the Pharmaceutical and Medical Devices Directorate No. E.N. 996/2013,

taking into account:

- provisions of Article 699 (2) of Law 95/2006 on healthcare reform, as amended;

- provisions of Article 12 (9) of Government Decision No. 734/2010 on the set up, organisation and operation of the National Agency for Medicines and Medical Devices, as amended,

based on Article 7 (4) of Government Decision No. 144/2010 on the organisation and operation of the Ministry of Health, as amended,

the minister of health hereby issues the following order:

Article 1. – The Norms for implementation of provisions of Article 699 (1) and (2) 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.

Article 2**. –** On this Order coming into force, Order of the Minister of Public Health No. 962/2006 on approval of the Norms for implementation of provisions of Article 699 (1) of Law 95/2006 on healthcare reform, concerning medicinal products for special needs, published in the Official Gazette of Romania, Part I, No. 701 of 16 August 2006, is repealed.

Article 3. **–** This Order is to be published in the Official Gazette of Romania, Part I.

Minister of Health,
Gheorghe-Eugen Nicolăescu

Bucharest, 7 February 2013.
No. 85.

(Published in the Official Gazette of Romania, Part I, No. 93/14/II/2013)

ANNEX

NORMS
for implementation of provisions of Article 699 (1) and (2) of Law 95/2006 on healthcare reform concerning medicinal products for special needs

CHAPTER I
Norms for implementation of provisions of Article 699 (1) of Law 95/2006 on healthcare reform concerning medicinal products for special needs

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

(2) These Norms do not apply to medicinal products subject to a clinical trial performed in Romania and off-label use of a medicinal product.

Article 2. - (1) The decision on whether or not a patient has special needs which cannot be met by medicinal products authorised for marketing lies with the respective patient's physician; prescription of the medicinal product for special needs must comply with the therapeutic indications for which the product has been authorised; the medical prescription must be accompanied by an explanatory document.

(2) 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.

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

(4) 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:

a) it contains the same active substance(s);

b) it contains the same amount of active substance(s) or the same strength, for liquid pharmaceutical forms;

c) it has the same pharmaceutical form;

d) it meets the same/equivalent standards as regards the patient's clinical needs at the moment of product administration.

Article 3. – The National Agency for Medicines and Medical Devices grants the authorisation for supply of medicinal products for special needs, in

accordance with Article 699 (1) of Law 95/2006, as amended, if the following requirements are met:

a) there is a bona fide unsolicited order (on behalf of the supplier, initiated by the physician, with the patient's consent);

b) the product is prescribed by a physician, who provides justification for the respective request;

c) the product is meant for one/several patient(s) under the respective physician's direct responsibility.

Article 4. – In accordance with Article 699 (1) of Law 95/2006, as amended, the wholesale distributor, holder of an authorisation for supply of medicinal products for special needs, must inform everyone involved in the supply circuit that the respective product does not have a valid marketing authorisation in Romania.

Article 5. – The authorisation for supply of medicinal products for special needs can only be granted to wholesale distributors authorised by the National Agency for Medicines and Medical Devices, in accordance with Annex 3.

Article 6. - (1) The applicant submits to the National Agency for Medicines and Medical Devices a dossier containing:

a) a standard application form, in accordance with Annex 1;

b) a medical explanatory document signed by the prescribing physician;

c) the product quality specifications, quality/compliance/Good Manufacturing Practice certificates, as required;

d) a marketing authorisation in one of the EEA states or in the third country where the product has been authorised;

e) The Summary of Product Characteristics and package leaflet in the language of the country where the product has been authorised, as well as the Romanian version thereof;

f) proof of the existence of pharmacovigilance responsible staff and the means required for notification of the National Agency for Medicines and Medical Devices about all suspected adverse reactions, reported in Romania or another Member State.

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

(3) The authorisation may be suspended or withdrawn when the conditions for its grant have not been met. The suspension remains in force until remedy of deficiencies found, without extending the period of the validity of the authorisation.

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

a) to immediately inform the National Agency for Medicines and Medical Devices about safety/quality concerns, including those determined by a potential counterfeit, of which the distributor has been informed;

b) not to advertise the medicinal product;

c) to retain specific records about its supply, in accordance with Article 8 provisions;

d) to notify the National Agency for Medicines and Medical Devices about the actual imported/marketed amount of the medicinal product for special needs as well as any other issue related to its supply.

Article 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) the product storage/shipping conditions;

f) details about any adverse reaction as known to the supplier;

g) details about any potential report on counterfeiting of the medicinal product as known to the supplier.

Article 9. – The National Agency for Medicines and Medical Devices may at any time require evidence from the wholesale distributor of records mentioned under Article 8 and may impose any measure concerning the quality/safety/efficacy of the medicinal product authorised for special needs, in accordance with Article 699 (1) of Law 95/2006, as amended, meant to reduce the potential risk for the patient's health.

CHAPTER II
Norms on implementation of provisions of Article 699 (2) of Law 95/2006 on healthcare reform concerning medicinal products for special needs

Article 10. - (1) These Norms refer to medicinal products without valid marketing authorisation in Romania in accordance with Article 700 of Law 95/2006, as amended, required for special needs in accordance with Article 699 of the same Law (1).

(2) Medicinal products subject to a clinical trial performed in Romania and off-label prescription of a medicinal product without are not subject to these Norms.

Article 11. – (1) The National Agency for Medicines and Medical Devices grants the authorisation for supply of medicinal products for special needs, in accordance with Article 699 (1) of Law 95/2006, as amended, if the following requirements are met:

a) there is an explanatory document in place on the respective medicinal product designation as special needs which cannot be met by medicinal products already authorised for marketing in Romania at the time of the request, as granted by specialised Ministry of Health commissions/directorates;

b) there is a bona fide requested order (on behalf of the supplier, initiated by the specialised Ministry of Health commissions/directorates), for circumstances provided for in Article 699 (2) of Law 95/2006, as amended;

c) the product is authorised in at least one EEA or third country;

(2) 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.

(3) 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:

a) it contains the same active substance(s);

b) it contains the same amount of active substance(s) or the same strength, for liquid pharmaceutical forms;

c) it has the same pharmaceutical form;

d) it meets the same/equivalent standards as regards the patient's clinical needs at the moment of product administration.

Article 12. - (1) In accordance with Article 699 (2) of Law 95/2006, as amended, the wholesale distributor, holder of an authorisation for supply of medicinal products for special needs, must inform everyone involved in the supply circuit that the respective medicinal product does not have a valid marketing authorisation in Romania.

(2) In accordance with Article 699 (2) of Law 95/2006, as amended, for each delivery to the beneficiary, the wholesale distributor, holder of an authorisation for supply of medicinal products for special needs, attaches the Summary of Product Characteristics and the leaflet, both translated into Romania.

Article 13. – In accordance with Article 699 (2) of Law 95/2006, as amended, the authorisation for supply of medicinal products for special needs can only be granted to wholesale distributors authorised by the National Agency for Medicines and Medical Devices, in accordance with Annex 4.

Article 14. - (1) The applicant submits to the National Agency for Medicines and Medical Devices a dossier containing:

a) the standard application form, in accordance with Annex 2;

b) the medical explanatory document and quantity required by the specialised Ministry of Health commission/directorate;

c) the marketing authorisation in one of the EEA states or third country where it has been authorised;

d) the medicinal product quality specifications, summary of batch protocol, the quality/compliance certificate, GMP certificate, as required;

e) the Summary of Product Characteristics and the leaflet in the language of the country where it is authorised as well as the Romanian version thereof;

f) proof of the existence of pharmacovigilance responsible staff and the means required for notification of the National Agency for Medicines and Medical Devices about all suspected adverse reactions, reported in Romania or another Member State.

(2) The authorisation is granted for the amount established by the specialised Ministry of Health commission/directorate, without exceeding the necessary for 12 months use.

(3) The authorisation may be suspended or withdrawn when the conditions for its grant have not been met. The suspension remains in force until remedy of deficiencies found, without extending the period of the validity of the authorisation.

(4) After having obtained the authorisation for supply of medicinal products for special needs, in accordance with Article 699 (2) of Law 95/2006, as amended, the wholesale distributor submits to the National Agency for Medicines and Medical Devices a request for exemption from legal provisions in force concerning the packaging/labelling of medicinal products authorised for marketing, other than those mentioned in the Norms on the procedure for grant of exemption of specific medicinal products labelling and package leaflet from the obligation that certain particulars should appear and that the leaflet are written in Romanian, when the product is not intended to be delivered to the patient for self-administration, approved through Order of the Minister of Public Health No. 872/2006.

Article 15. – The wholesale distributor of medicinal products for special needs has the following obligations:

a) to immediately inform the National Agency for Medicines and Medical Devices about safety and quality concerns, including those determined by a potential counterfeit, of which the distributor has been informed;

b) to not advertise the medicinal product;

c) to retain specific records of its supply, in accordance with Article 7 provisions;

d) to notify the National Agency for Medicines and Medical Devices on the actual imported/marketed quantity of the respective medicinal product for special needs at each supply/release as well as about any other issue related to its supply;

e) to ensure that the medicinal product for which a special needs authorisation has been granted is used on Romanian territory only.

Article 16. – The records mentioned under Article 15 c) are stored for at least 5 years from issuance of the authorisation and contain the following information:

a) the external supplier of the product;

b) the date and list of the product beneficiaries;

c) the quantity of each supply;

d) the product manufacturing batch;

e) the product storage/shipping conditions;

f) details about all adverse reactions known to the supplier;

g) details about any potential report of product counterfeiting known to the supplier.

Art.17. – The National Agency for Medicines and Medical Devices may at any time require evidence from the wholesale distributor of records mentioned under Article 16 and may impose any measure concerning the quality/safety/efficacy of the medicinal product authorised for special needs, in accordance with Article 699 (1) of Law 95/2006, as amended, meant to reduce the potential risk for the patient's health.

Article 18. – Annexes 1-4 are integral part of these Norms.

ANNEX 1
to the Norms

THE NATIONAL AGENCY FOR MEDICINES
AND MEDICAL DEVICES

FORM
Application for authorisation of supply of medicinal products for special needs, in accordance with Article 699 (1) of Law No. 95/2006 on healthcare reform

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.

Prescriber,
.....
(Signature and stamp)
Date .....

2. Patient information
Name and surname:
Identity document:
PIN:
Address:
Telephone number:
Fax number:
Mobile phone number:
E-mail address:
Date of birth:
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.
Patient,
.....
(signature)

Date .....
3. Information about the medicinal product for special needs
Trade name:
Active substance (INN):
Strength:
Pharmaceutical form:
Manufacturer and country of origin:
Quantity required*)
Indications on administration (dosage):
Adverse reactions and cautions related to the administration:

_____
***)** Please specify quantity for one year at most

4. Information about the applicant:
Name of the wholesale distributor:
Address:
Number of the wholesale distribution authorisation:
Qualified person (contact data):
Telephone 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, as amended.

Applicant,
.....
(signature and stamp)

Date .....

NOTE:
This application form is available only if accompanied by all documents mentioned under Article 6 (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.

ANNEX 2
to Norms

THE NATIONAL AGENCY FOR MEDICINES
AND MEDICAL DEVICES

APPLICATION FORM
concerning authorisation for supply of medicinal products for special needs, in accordance with Article 699 (2) of Law 95/2006 on healthcare reform

1. Information about the medicinal product for special needs:
Trade name:
Active substance (INN):
Strength:
Pharmaceutical form:
Manufacturer and country of origin:
Quantity required*):
Indication for administration:
Adverse reactions and warning for administration:

_____
***)** Specify quantity for one year at most

2. Information about the applicant:
Name of the wholesale distributor:
Address:
Number of the wholesale distribution authorisation:
Qualified person (contact data):
Telephone number:
Fax number:
E-mail address:
We hereby require the supply of the aforementioned product in the specified quantity.
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, as amended.

Applicant,

.....

(signature and stamp)

Date .....

NOTE:
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.

ANNEX 3
to Norms

THE NATIONAL AGENCY FOR MEDICINES
AND MEDICAL DEVICES

AUTHORISATION

for supply of medicinal products for special needs

in accordance with Article 699 (1) of Law 95/2006 on healthcare reform

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

Taking into account Application No. ..... of ....., submitted to the National Agency for Medicines and Medical Devices,.....
……..…….. is authorised to supply
….....,
(Trade name, pharmaceutical form and strength), containing.....
…….....
(International Non-proprietary Name)
quantity: ....., in response to the prescription issued by Dr. ..... for ..... .

This authorisation is valid for 1 year.

President,
.....
(Name and surname, signature and stamp of the institution)

ANNEX 4
to Norms

THE NATIONAL AGENCY FOR MEDICINES
AND MEDICAL DEVICES

AUTHORISATION

for supply of medicinal products for special needs in accordance with Article 699 (1) of Law 95/2006 on healthcare reform

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

Taking into account Application No. ..... of ....., submitted to the National Agency for Medicines and Medical Devices, ……..…….. is authorised to supply …....., (Trade name, pharmaceutical form and strength) containing …….....
(International Non-proprietary Name)
quantity: ....., in response to the application submitted by the commission ...../directorate ..... of the
(name of specialised commission/direction)
Ministry of Health.

This authorisation is valid for 1 year.
President,
.....
(Name and surname, signature and stamp of the institution)