MINISTRY OF HEALTH

ORDER
on approval of Norms concerning donations of medicinal products, medical supplies, medical devices, vaccines, sera and related supplies

On seeing the joint report for approval no. Cs. A. 6739/2011 of the Healthcare Directorate, the Medicinal Product Policy Directorate, the Public Health Directorate and Public Health Control and of the General Economic Directorate of the Ministry of Health,

Taking into account the provisions of Law No. 95/2006 on healthcare reform, as amended,

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

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

Article 1. - The Norms concerning donations of medicinal products, medical supplies, medical devices, vaccines, sera and related supplies are approved as listed in the Annex which is integral part of this Order.

Article 2. - The National Agency for Medicines and Medical Devices, the specialised directorates of the Ministry of Health and donation beneficiary units shall carry out the provisions of this Order.

Article 3. - This order is to be published in the Official Gazette of Romania, Part I.

Article 4. - On publication of this Order in the Official Gazette of Romania, Part I, any contrary provisions is repealed.

Minister of Health,
Cseke Attila

Bucharest, 14 June 2011.
No. 1.032.

ANNEX 1

NORMS
concerning donations of medicinal products, medical supplies, medical devices, vaccines, sera and related supplies

CHAPTER I
General provisions

Article 1. – These Norms regulate donations of medicinal products, medical supplies, medical devices, vaccines, sera and related supplies in Romania.

Article 2. – All donations stipulated in Article 1 shall be based on medical necessity.

Article 3. – Donations shall not be made without the recipient's approval.

Article 4. - The donation recipient must be a medical unit provided with closed circuit pharmacy, a social welfare unit or a nongovernmental organisation employing authorised medical staff, i.e. physician or pharmacist, in accordance with the law.

Article 5. - Only products meeting quality and safety legal requirements in force may be received as donations.

Article 6. - Before donation dispatch, the donor must apply for approval of the donation by the National Agency of Medicines and Medical Devices (NAMMD) with respect to medicinal products and medical devices, and respectively the Ministry of Health, for vaccines.

Article 7. – (1) The NAMMD and the Ministry of Health approvals for donation are granted in accordance with the following documentation:

a) the donor's intent for donating, in accordance with the application form for approval of donation provided in Annex 1;

b) the recipient's approval of the donation, in accordance with the form provided in Annex 2;

c) the donor's act of donation;

d) the list of medicinal products / medical devices / vaccines to be donated; the quantity and the manner of packaging and transportation and identification data are specified for each product in accordance with the guidelines for establishment of the list of medical products for donation provided in Annex 3.

(2) Provision of the approval for donation is free of charge.

Article 8.- (1) The donor is responsible for ensuring proper storage conditions for medicinal products, healthcare material, medical devices, vaccines, sera and related supplies specified by the manufacturer, during transportation to the recipient.

(2) The NAMMD and the Ministry of Health do not grant approvals for donations that are not compliant with these Norms.

CHAPTER II
Provisions on medicinal product donations

Article 9. - Only medicinal products authorised for marketing in the European Economic Area or the United States of America are accepted for donation.

Article 10. – Medicinal products containing psychotropic substances and narcotics are not accepted for donation.

Article 11. – The shelf life of the donated medicinal products shall be no shorter than 8 months as of the application for the grant of the approval of donation.

Article 12 - (1) Donations of medicinal products shall be submitted in sealed original packaging.

(2) Medicinal products returned by patients to pharmacies are not accepted for donation.

Article 13. - The identification data of each donated medicinal product shall be imprinted in accordance with regulations in force.

Article 14. - After accepting the donation and signing the delivery-receipt donation protocol, the recipient is responsible for ensuring the conditions related to the storage, release and administration of the respective medicinal products.

Article 15. - (1) Medicinal products shall be accompanied by a leaflet written in Romanian; these must comply with regulations in force and shall be approved by the NAMMD before release of the approval for donation. These are the key means for physician and patient information.

(2) Translation of the leaflet into Romanian is the responsibility of the donation recipient.

Article 16. - (1) Medicinal products shall be packed individually.

(2) Medicinal products received as donations are included in the regular medicinal product circuit from the recipient unit and are distributed to patients for free, depending on their therapeutic needs.

(3) The recipient shall keep strict record of donated medicinal products.

CHAPTER III
Provisions relating to donations of vaccines and sera and related supplies

Article 17. - Only vaccines and sera authorised for marketing in the European Economic Area or the United States of America are accepted as donations.

Article 18. - (1) The shelf-life of donated medicinal products shall be no shorter than eight months as of the date of donation entry into the country.

(2) Exceptionally, in case of special epidemiological situations, calamities, natural disasters, vaccines and sera may be accepted as donations of shorter shelf life than 8 months as of the date of application for the approval for donation.

Article 19. - (1) Donations consisting of sera and associated supplies (syringes) shall be presented in sealed original packaging.

(2) Vaccines, sera and related consumables whose compliance with storage and manufacturer to recipient transportation conditions cannot be proved shall not be accepted as donations.

Article 20. - Identification data of each donated serum and vaccine shall be imprinted in accordance with regulations in force.

Article 21. – Following acceptance of the donation and signing the delivery-receipt donation protocol, the recipient is responsible for ensuring proper storage, release and administration conditions for sera and vaccines.

Article 22 - (1) Vaccines and sera should be accompanied by a leaflet written in Romanian.

(2) The recipient of the donation is responsible for the translation of the leaflets into Romanian.

CHAPTER IV
Provisions on donations of medical devices

Article 23. - As far as medical devices are concerned, the approval for donation shall be granted for both new and second-hand medical devices, as issued by the NAMMD.

Article 24. - Only EC-marked medical devices submitted for assessment prior to their placement on the market in accordance with European regulations on medical devices are accepted as donations.

Article 25. - For second-hand medical devices, used endurance of donated medical devices shall be at least 3 years shorter than the normal operation life established by legislation in force (affidavit of the donor).

Article 26. - Only medical devices containing all the accessories n their needed for their use in accordance with their manufacturer established intended purpose, are in working order and do not display deviations from the functional performance and security requirements are accepted as donations (affidavit of the donor).

Article 27. - Donated medical devices shall be accompanied by instructions for use, on a case-by-case basis.

Article 28. - The labels of donated medical devices shall contain the information stipulated by the regulations in force.

Article 29. - Donated second-hand medical devices are to be made operational and used following NAMMD assessment of their performances and based on its own approval of donation.

Article 30. - In accordance with Article 14 of the Order of the Minister of Health no. 253/2010 on registration of medical devices, the NAMMD approval for customs issued for donated medical devices shall be issued in accordance with provisions of this chapter.

Article 31. - Annexes 1-3 are integral part of these Norms.

ANNEX 1
to the Norms

MINISTRY OF HEALTH

APPLICATION FORM
for donation approval

Information about the donor

Name of donor:
Address:
Wholesale distribution authorisation number:
Contact person:
Telephone number: | Mobile phone number:
Fax number: | E-mail address:

We hereby request issuance of a letter of approval for donation of the products listed in the Annex.

We also hereby declare that:

- the products meet quality and safety requirements stipulated by legislation in force;
- we ensure storage conditions during transportation to the recipient as required by the manufacturer;
- provision of donated products are to be performed in accordance with legislation in force.

Date: Signature and stamp:

ANNEX 2
to the Norms

MINISTRY OF HEALTH

DECLARATION
on donation acceptance

Information about the recipient

Name of recipient:	
Address:	
Contact person:	
Telephone number:	Mobile phone number:
Fax number:	E-mail address:

We hereby declare that the present donation meets the medical requirements established by our unit.

We undertake to accept the donation specified in the Annex, to ensure proper storage conditions during the storage period as required by the manufacturer and we guarantee that the destination of these products shall remain the same.

Date:	Signature and stamp:

ANNEX 3
to the Norms

Guideline
on setup of the list of medical supplies to be donated

1. Each category of donated products is to be included in a separate list as follows:

A. Medicinal products other than vaccines;

B. Vaccines;

C. Medical devices;

D. Other products that do not fall into the aforementioned categories but are used in medical treatments.

2. The list of medicinal products / vaccines contains the following information:

- trade name, INN, strength, pharmaceutical form, packaging size, MA number, amount (and means of transportation), shelf life.

3. The list of medical devices includes the amount, the means of packaging and transportation as well as the identification data for each product.