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National Agency for Medicines and Medical Devices

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DECISIONS OF THE NAMMD SCIENTIFIC COUNCIL

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 common report for approval No. Cs. A. 6739/2011 of the Medical Assistance 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 Art. 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:

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

Art. 2. - The National Agency for Medicines and Medical Devices, the special directions of the Ministry of Health and the units benefiting from donations shall carry out the provisions of this Order.

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

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 - On the publication of this Order in the Official Gazette of Romania, Part I, any contrary disposition is repealed.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

Art. 1. – These Norms settle the donations of medicinal products, medical supplies, medical devices, vaccines, sera and related supplies in Romania.

Art. 2. – All donations stipulated in Art. 1 should be based on medical necessity.

Art. 3. – Donations should not be sent without the recipient's approval.

Art. 4. - The recipient of donation must be a medical unit with closed circuit pharmacy, social work unit or a nongovernmental organization that has authorised medical staff i.e. physician or pharmacist, in accordance with the law.

Art. 5. - Only products that meet quality and safety requirements of compliant with the legislation in force are considered donations.

Art. 6.- Before sending the donation, the donor must obtain the notification for donation issued by the National Agency of Medicines and Medical Devices (NAMMD) for medicinal products and medical devices, namely the Ministry of Health, for vaccines.

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

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

b) the recipient's approval for donation, in accordance with the draft 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 the establishment of the list of medical products for donation provided in Annex 3.

(2) The provision of the notification for donation is free of charge.

Art. 8.- (1) The donor is responsible for ensuring the proper storage conditions for medicinal products, sanitary materials, 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 notifications for donations that are not compliant with these Norms.

CHAPTER II
Provisions on medicinal product donations

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

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

Art. 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 notification of donation.

Art. 12. - (1) Donations of medicinal products must be submitted in sealed original packagings.

(2) Medicinal products returned by patients to pharmacies are not accepted in view of donation.

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

Art. 14. - After accepting the donation and signing the minute of submission-receipt of the donation, the recipient is responsible for ensuring the conditions related to the storage, release and administration of medicinal products.

Art. 15. - (1) Medicinal products must be accompanied by a leaflet written in Romanian; they must comply with the regulations in force and shall be approved by the NAMMD before releasing the notification for donation. These represent the essential means of information of physicians and patients.

(2) The translations of the leaflet into Romanian are the responsibility of the recipient of the donation.

Art. 16. - (1) Medicinal products should be packed individually.

(2) Medicinal products received as donations are included in the common circuit of the medicinal products from the recipient unit and are distributed to patients at no cost, depending on their therapeutic needs.

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

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

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

Art. 18. - (1) The validity of donated medicinal products shall be no shorter than eight months as of the date of entry of donations in the country.

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

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

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

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

Art. 21. - After accepting the donation and signing the minute of grant-receipt of the donation, the recipient is responsible for ensuring proper storage, release and administration conditions for sera and vaccines.

Art. 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

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

Art. 24. - Only medical devices imprinted in accordance with EC regulations, which have been submitted in view of assessment prior to their placement on the market, in accordance with the European regulations concerning medical devices are accepted as donations.

Art. 25. - For second-hand medical devices, consumed the life of donated medical devices will be smaller by at least 3 years than during normal operation established by the legislation in force (affidavit of the donor).

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

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

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

Art. 29. - Donated second-hand medical devices are put to use and are used following the assessment of their performances conducted by the NAMMD, based on the notice released by the latter.

Art. 30. - The customs approval issued by the NAMMD for donated medical devices, in accordance with Art. 14 of the Order of the Minister of Health no. 253/2010 on the registration of medical devices, is issued in accordance with the

provisions of this chapter.

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

ANNEX 1
to the Norms

MINISTRY OF HEALTH

APPLICATION FORM
for notification for donation

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 the issuance of a notification for donation for the products listed in the Annex.

We also declare that:

- the products meet quality and safety requirements stipulated by the legislation in force;
- We undertake to ensure storage conditions during transportation to the recipient imposed by the manufacturer;
- the provision of donated products shall be performed in accordance with the legislation in force.

Date: Signature and stamp:

ANNEX 2
to the Norms

MINISTRY OF HEALTH

DECLARATION
on approval of the donation

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 are committed to accept the donation specified in the Annex, to ensure proper storage conditions during the storage period imposed 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 the setup of the list of medical supplies to be donated

1. Each category of donated products will 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 shall contain the following information: - common name, INN, strength, pharmaceutical form, packaging size, MA number, amount (and means of transportation), validity.

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

ORDIN
on the modification of the Norms concerning donations of medicinal products, medical supplies, medical devices, vaccines, sera and related supplies, approved through Minister of Health Order No. 1.032/2011

On seeing the common report for approval No. Cs. A. 9410 of 11 August 2011 of the Medicinal Product Policy Directorate

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

Based on Art. 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:

Art. I – Art. 11 of the Norms concerning donations of medicinal products, medical supplies, medical devices, vaccines, sera and related supplies, approved through Order of the Minister of Health No. 1032/2011, published in the Official Gazette of Romania, Part I, No. 436 of 22 June 2011, is modified as follows:

"Art. 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 notification of donation; exception: the medicinal products whose shelf life is shorter than 2 years, whose shelf life may at least equal the third part of the shelf life as of the import of the respective product."

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

Minister of health,

Cseke Attila

Bucharest, 12 August 2011.
No. 1.252.

DECISION

No. 17/06.07.2011

on extension of term provided in Art. 4 of NAMMD Scientific Council Decision No.5/22.02.2011 on compulsory monthly reporting of placement on the market in Romania, i.e. of sales of medicinal products for human use by authorised wholesale distributors

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 1123/18.08.2010, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 06.07.2011, in accordance with Art. 12(5) of Government Decision No. 734/2010 on establishment, organization and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following:

DECISION

Sole Art. - The extension of term provided in Art. 4 of NAMMD Scientific Council Decision No. 5/22.02.2011, on compulsory monthly reporting of placement on the market in Romania, i.e. of sales of medicinal products for human use by authorised wholesale distributors, is approved for 01.11.2011.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,

Acad. Prof. Dr. Leonida Gherasim

DECISION

No. 18/06.07.2011

on approval of the Community format of the Good Manufacturing Practice (GMP)

The Scientific Council of the National Medicines Agency,
set up based on Order of the Minister of Public Health No. 1123/18.08.2010, reunited on summons of the NAMMD President in the ordinary meeting of 06.07.2011, in accordance with Art. 12 (5) of Government Ordinance No. 734/2010 related to the set up, organisation and functioning of the National Agency for Medicines and Medical Devices, as amended, hereby adopts the following

DECISION

Art. 1. – The Community format of the Good Manufacturing Practice (GMP) inspection report is approved, according to the Annex which is integral part of this Decision.

Art. 2. – On this decision coming into force, SCD No. 2/27.03.2009 is repealed.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,

Acad. Prof. Dr. Leonida Gherasim

ANNEX

COMMUNITY FORMAT OF THE GOOD MANUFACTURING PRACTICE (GMP) INSPECTION REPORT

CHAPTER I
Introduction

Art. 1. – This form is a translation into Romanian and an adaptation of document EMA/INS/GMP/459921/2010 Rev 12 on the community format of the Inspection Report set up by the European Medicines Agency (EMA).

CHAPTER II
Inspection Report

Art. 2. - The Community format for a GMP Inspection report is as follows:

Inspection Report Reference no. (code):				
Name of product(s) and pharmaceutical form(s):	*Essential for inspections requested by EMEA otherwise only necessary for product specific inspections.*			
Inspected site(s):	*Name and full address of the inspected site, including exact location/designation of the production facilities inspected* *EudraGMP reference number* *DUNS number*			
Activities carried out:		*Human use*	*Veterinary use*	*Investigational medicinal products (IMPs)*
	Manufacture of finished medicinal products	☐	☐	☐
	Sterile	☐	☐	☐
	Non-Sterile	☐	☐	☐
	Biologicals			
	Sterilisation of excipient, active substance or medicinal product	☐	☐	☐
	Primary Packaging	☐	☐	☐
	Secondary Packaging	☐	☐	☐
	Quality control testing	☐	☐	☐
	Importing	☐	☐	☐
	Batch certification	☐	☐	☐
	Storage and distribution	☐	☐	☐

	Manufacture of active substance ☐ ☐ ☐ *Other* ☐ ☐ ☐ _____
Inspection date(s):	*Date(s), month, year*
Inspector(s) and expert(s):	*Name(s) of the inspector(s).* *Name(s) of expert/assessor (if applicable).* *Name(s) of the Competent Authority(ies)*
References:	*Reference number of Marketing and/or Manufacturing Authorisations* *EMEA reference number(s).(If the inspection is an EMEA inspection)*
Introduction:	*Short description of the company and the activities of the company.* *For inspections in non-EEA countries, it should be stated whether the Competent Authority of the country, where the inspection took place, was informed of the inspection and whether the Competent Authority took part in the inspection.* *Date of previous inspection.* *Name(s) of Inspector(s) involved in previous inspection.* *Major changes since the previous inspection.*
Brief report of the inspection activities undertaken: **Scope of Inspection:** **Inspected area(s) and main steps/history of the inspection:**	 *Short description of the inspection (Product related, process related inspection and/or General GMP inspection, reference to specific dosage forms where appropriate). The reason for the inspection should be specified (e.g. new marketing application, routine, investigation of product defect).* *Each inspected area should be specified.*
Activities not inspected:	*Where necessary, attention should be drawn to areas or activities not subject to inspection on this occasion.*
Personnel met during the inspection:	*The names and titles of key personnel met should be specified (listed in annex).*
Inspectors' findings and observations relevant to the inspection; and deficiencies:	*Relevant headings from Order of the Minister of Public Health OMSP no. 905/2006 on approval of Good Manufacturing Practice principles and guidelines for medicinal products for human use, investigational medicinal products (IMP) included and Scientific Council Decision no. 38/2006 on approval of the Guideline on Good Manufacturing Practice for medicinal products for human use (basic requirements, relevant to the inspection purpose).* *This section can link the findings to the deficiencies and be used to explain classification* *The detail in the narrative of this section of the report may be reduced where a Site Master File acceptable to*

	the National Medicines Agency – The Pharmaceutical inspection department.
…….	**……** Overview of inspection findings from last inspection and the corrective action taken.
Headings to be used *New headings may be introduced when relevant*	Quality management Personnel Premises and equipment Documentation Production Quality control Contract Manufacture and Analysis Complaints and Product Recall Self inspection
Distribution and shipment:	e.g. Compliance with Good Distribution Practice
Questions raised relating to the assessment of a marketing application:	e.g. Pre-authorisation Inspections e.g. Relevant future changes announced by company
Other specific issues identified: *Standard Master File*	Assessment of SMF if any; date of SMF
Miscellaneous: Samples taken **Annexes attached:**	*List of any annexes attached.*
List of Deficiencies classified into critical, major and others:	*All deficiencies should be listed and the relevant reference to the EU GMP Guide and other relevant EU Guidelines should be mentioned.* *All deficiencies found should be listed even if corrective action has taken place straight away.* *If the deficiencies are related to the assessment of the marketing application it should be clearly stated.* *The company should be asked to inform the Inspectorate about the proposed time schedule for corrections and on progress.*
List of deficiencies and observations which may affect product safety or efficacy:	*Deficiencies listed above can be referred to in this section*
Inspectors' comments on the manufacturer's response to the inspection findings:	*i.e. whether the responses are acceptable*

Inspectors' comments on the questions/issues raised by the rapporteurs in the assessment report	
Recommendations for further actions (if any):	*To the Committee requesting the inspection or to the Competent/Enforcement Authority for the site inspected.*
Summary and conclusions:	*The Inspector(s) should state whether, within the scope of the inspection, the company operates in accordance with Order of the Minister of Public Health No. on approval of the Principles and guidelines for good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use and, where relevant, that appropriate corrective actions are implemented and mention any other item to alert requesting authority.* *Reference may be made to conclusions recorded in other documents, such as the close-out letter, depending on national procedures.* *For inspections requested by the CHMP/CVMP a clear conclusion on whether the manufacturer operates in general compliance with the requirements of Directive(s) 2003/94/EC and/or 91/356/EEC, or not, and whether the manufacturer is acceptable for the medicinal products in question. (This would apply to situations where there is a degree of non-compliance but where a corrective action plan has been agreed and the inspector has no reason to believe that it will not be implemented and where there is no immediate threat to public health)*
Name(s): **Signature(s):** **Organisation(s):** **Date:**	*The inspection report should be signed and dated by all inspector(s)/assessors having participated in the inspection*
Distribution of Report:	*For CHMP/CVMP inspections, the inspection report should be forwarded to the EMEA.*

DEFINITIONS OF THE DEFICIENCIES REFERRED TO IN THE GMP INSPECTION REPORT

1. CRITICAL DEFICIENCY

A deficiency which has produced, or leads to a significant risk of producing a product which is harmful to the human patient.

2. MAJOR DEFICIENCY

Non-critical deficiency:

a deficiency which has produced or may produce a product, which does not comply with its marketing authorisation;

or

a deficiency which indicates a major deviation from EU Good Manufacturing Practice;

or

(within the EU) a deficiency which indicates a major deviation from the terms of the manufacturing authorisation;

or

a deficiency which indicates a failure to carry out satisfactory procedures for release of batches or (within the EU) a failure of the Qualified Person to fulfil his legal duties;

or

a combination of several "other" deficiencies, none of which on their own may be major, but which may together represent a major deficiency and should be explained and reported as such.

3. OTHER

A deficiency, which cannot be classified as either critical or major, but which indicates a departure from good manufacturing practice.

(A deficiency may be "other" either because it is judged as minor, or because there is insufficient information to classify it as a major or critical).

DECISION

No. 19/06.07.2011

on repeal of Decision No. 24/22.05.2006 on approval of drafts for assessment reports related to the enforcement of Good Manufacturing Practice provisions concerning the manufacturing/quality control of medicinal products

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 1123/18.08.2010, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 06.07.2011, in accordance with Art. 12(5) of Government Decision No. 734/2010 on establishment, organization and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following:

DECISION

Sole Art. - SCD No. 24/22.05.2006 is repealed on the approval of drafts for assessment reports related to the enforcement of Good Manufacturing Practice provisions concerning the manufacturing/quality control of medicinal products.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,

Acad. Prof. Dr. Leonida Gherasim

DECISION

No. 20/06.07.2011

on approval of the Guideline on the use of investigational medicinal products (IMPs) and noninvestigational medicinal products (NIMPs) in clinical trials

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 1123/18.08.2010, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 06.07.2011, in accordance with Art. 12(5) of Government Decision No. 734/2010 on establishment, organization and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following:

DECISION

Art. 1. – The Guideline on the use of investigational medicinal products (IMPs) and noninvestigational medicinal products (NIMPs) in clinical trials is approved, in accordance with the Annex which is integral part of this Decision.

Art. 2. – On this Decision coming into force, SCD No. 7/26.06.2009 is repealed.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,

Acad. Prof. Dr. Leonida Gherasim

ANNEX

Guideline
on the use of investigational medicinal products (IMPs) and noninvestigational medicinal products (NIMPs) in clinical trials

CHAPTER I
Introduction and legal basis

Art. 1. – This Guideline is a translation into Romanian and a transposition of the Guidance on Investigational Medicinal Products (IMPs) and Noninvestigational Medicinal Products (NIMPs) of Eudralex, Volume 10 – Clinical trials, updated version – 1 March 2011.

Art. 2. - To facilitate the conduct of clinical trials in the Member States of the European Union (EU)[1], especially multi-centre clinical trials carried out in more than one Member State it is necessary to have a common understanding of the definition of an investigational medicinal product ('IMP').

Art. 3. - This document intends to clarify and provide additional guidance on the definition of IMP and to provide specific guidance about the use of non-investigational medicinal products (NIMPs), in accordance with the applicable EU legislation.

Art. 4. - This document complements the "Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial in Romania, a transposition of the European Commission release (EC) (2010/C 82/01)[1], approved through Scientific Council Decision (SCD) No. 22/2010 and the "Detailed guidance on the application format and documentation to be submitted in an application for an Ethics Committee opinion on the clinical trial on medicinal products for human use in Romania", transposition of the CT-2 Guideline of the European Commission[2], approved through SCD No. 50/2006.

CHAPTER II

Medicinal products intended for research and clinical trials and investigational medicinal products (IMPs)

Art. 5. - Art. 697 c) of Law No. 95/2006 on healthcare reform, Title XVII – The medicinal product, transposing Directive 2001/83/EC on the Community code relating to medicinal products for human use, excludes "*medicinal products intended for research and development trials*" from its scope of application.

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[1] http://ec.europa.eu/health/files/eudralex/vol-10/2010_c82_01/2010_c82_01_en.pdf, 30.3.2010
[2] http://ec.europa.eu/health/files/eudralex/vol-10/imp_03-2011.pdf - EudraLex, Volume 10

Art. 6. - Order of the Minister of Health No. 904/2006 defines in Art. 21 (d) an IMP as "a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorization but used or assembled (formulated or packaged) in a way different from the authorised form, or when used for an unauthorised indication, or when used to gain further information about the authorised form." (Art. 21 (d) of Order of the Minister of Health No. 904/2006 transposes Art. 2 (d) of Directive 2001/20/EC).

Art. 7. – It follows that medicinal products with a marketing authorisation (MA) are IMPs when they are to be used as the test substance, reference substance or comparator in a clinical trial, provided they are either used or presented (formulated or packaged) in a way different from the authorised pharmaceutical form, or used in view of an unauthorised indication or to obtain additional information about the authorised pharmaceutical form.

CHAPTER III

Non-investigational medicinal products (NIMPs)

III.1. What is an NIMP?

Art. 8. - (1) Noninvestigational Medicinal Products (NIMPs) are medicinal products that fall within Art. 697 c) of Law No. 95/2006 on healthcare reform, Title XVII – The medicinal product (transposing Art. 3(3) of Directive 2001/83/EC on the Community code relating to medicinal products for human use), while not falling within the definition of IMP as defined in Art. 21 (d) of Minister of Health Order No. 904/2006, transposing Art. 2 (d) of Directive 2001/20/EC.

(2) For instance, some clinical trial protocols require the use of medicinal products such as concomitant or rescue/escape medication for preventive, diagnostic or therapeutic reasons and/or to ensure that adequate medical care is provided for the subject.

(3) Investigational medicinal products may also be used in accordance with the protocol to induce a physiological response.

(4) A list of types of NIMPs, with examples, is contained in Annex 1.

Art. 9. – Medicinal products that do not have a marketing authorisation, but prepared in accordance with a magistral formula, i.e. prepared in a pharmacy in accordance with a medical prescription for an individual patient, and medicinal products prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia[3] and intended to be supplied directly to the patients served by the pharmacy in question, i.e. officinal formula, as mentioned under Art. 697 (a) and (b) of Law No. 95/2006 on healthcare reform, Title XVII – The medicinal product, as amended (hereinafter called Law No. 95/2006) transposing Art. 3(1) and (2) of Directive 2001/83/EC may also be an NIMP.

III.2. Requirements for non-investigational medicinal products (NIMPs)

Art. 10. - The manufacturing of NIMPs *per se* does not fall within:

- The rules for manufacturing of medicinal products, as set out in Chapter IV, "Manufacturing and import", of Law No. 95/2006 on healthcare reform, Title XVII – The medicinal product[3], transposing Title IV of Directive 2001/83/EC, or
- The rules for manufacturing of investigational medicinal products, according to Chapter XIV, „Manufacturing and import of Investigational Medicinal Products (IMPs)" of the Order of the Minister of Public Health Order No. 904/25.07.2006 [transposing Art. 13 of Directive 2001/20/EC], Chapter IV, „The marketing/import authorisation", of the Order of the Minister of Public Health No. 903/25.07.2006 on approval of the Principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products [transposing Art. 9 of Directive 2005/28/EC] and to Order of the Minister of Public Health No. 905/25.07.2006 on approval of the Principles and guidelines for good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use [transposing Directive 2003/94/EC][4].

Art. 11. – (1) However, the safeguarding of the clinical trial subject, in accordance with the provisions of Chapter V of the Order of the Minister of Public Health No. 904/2006 (transposing Art. 3 of Directive 2001/20/EC) and the objectives of the Directive has to ensured inter alia by guaranteeing the quality and safety of the products and substances used in the trial.

(2) Therefore, the main rules for the choice of IMPs are mentioned in the Detailed guideline on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, notification of substantial amendments and declaration of the end of the clinical trial in Romania, approved through Scientific Council Decision (SCD) No. 22/2010.

Art. 12. - (1) When NIMPs do not have a marketing authorization in the EU, appropriate GMP requirements foreseen for the safety of the patients should still be applied and the sponsor should ensure that NIMPs are of appropriate quality for the purposes of the trial, taking into account, among other things, the source of the raw materials and any repackaging.

(2) To meet the requirements of Art. 23 and as referred to in Art. 28 (3) of the Order of the Minister of Public Health No. 904/2006, transposing Art. 3 (2) and 6 (3) of Directive 2001/20/EC relating to protection of the trial subject, the same level of quality and safety should be ensured for the NIMPs as for the IMPs used in the trials.

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[3] According to Art. 697 c) of law No. 95/2006 on healthcare reform, Title XVII – The medicinal product

[4] Since a NIMP is not the same as an IMP, in accordance with the definition in Art. 21 d) of the Order of the Minister of Public Health No. 904/25.07.2006

2 OJ C82, 30.3.2010, p. 1.

3 EudraLex, Volume 10.

Art. 13. - This requirement will be fulfilled by applying for these NIMPs the same requirements as provided for the IMPs, in particular, the standards as provided for in Section 4 of Title XVII of Law No. 95/2006, transposing Title IV of Directive 2001/83/EC and the requirements established under Art. 50 and Chapter XVI of the Order of the Minister of Health No. 904/2006, transposing Art. 13 (3) and 15 of Directive 2001/20/EC should be applied.

Art. 14. - (1) The sponsor is responsible for implementing a system to ensure that the trial is conducted and data are generated in accordance with the principles of Good Clinical Practice.

(2) To comply with these principles, a trial has to be conducted according to the protocol and all clinical trial information should be recorded, handled and stored in such a way that it can be accurately reported, interpreted and verified.

(3) In this context, traceability of medicinal products which allows adequate reconstruction of NIMP movements and administration should be ensured taking into account the purpose of the trial and trial subjects' safety.

(4) It has at least to include a procedure to record which patients received which NIMPs during the trial with an evaluation of the compliance, where necessary.

Art. 15. - NIMPs may be supplied by the sponsor or by the investigator site.

III.3 Information related to IMPs to be provided to the competent authority

Art. 16. – (1) As a general rule, the documentation requirements in the application dossier for IMPs[7] also apply to NIMPs.

(2) However, there are possibilities for simplified documentation requirements ('simplified dossier') depending on the extent of knowledge of the NIMP. Annex 2 sets out those simplified documentation requirements.

Art. 17. - Regarding language requirements for the documentation in the dossier, reference is made to the Detailed guideline on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, notification of substantial amendments and declaration of the end of the clinical trial in Romania, approved through SCD No. 22/2010[5].

Art. 18. – (1) Within each document, the amount of data might differ.

(2) A risk-based approach will be applied in determining the type and amount of data required for each specific case.

(3) Existing voluntary cooperation mechanisms between national competent authorities should be used to ensure harmonised application of a risk-based approach on each specific case.

[5] Section 2.1.6.

III.4 Adverse reactions related to NIMPs

Art. 19. - Regarding safety reporting related to NIMPs, reference is made to the Detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use (‘CT-3’) published in Chapter II of EudraLex, Volume 10.

ANNEX 1

Types of NIMPs with examples

This section provides guidance on some categories of medicinal products which are normally used in clinical trials as non-investigational medicinal products (NIMPs).

1. Rescue medication

Description

Rescue medications are medicines identified in the protocol as those that may be administered to the patients when the efficacy of the IMP is not satisfactory, or the effect of the IMP is too great and is likely to cause a hazard to the patient, or to manage an emergency situation.

Rescue medication allows patients to receive effective treatment, e.g. placebo controlled clinical trials where a standard treatment is available or dose response studies where lower doses might be ineffective. Rescue medications are sometimes called 'Escape medications' in protocols. Usually these NIMPs have a MA in the given MS and are used according to the authorised conditions.

Examples:

Ineffective treatment

In case of a repeated-dose, randomised, double-blind, placebo-controlled, three-parallel group study performed to evaluate the analgesic efficacy and safety profile of intravenous acetaminophen as compared with its prodrug (propacetamol) and placebo in patients suffering mild to moderate pain after an orthopaedic surgical operation, patients were allowed "rescue" patient-controlled intravenous morphine for pain.

Anticipated adverse reactions

A phase III clinical trial trying to assess the efficacy of a new anti-neoplasic IMP; all patients receive a corticoid /antihistamine treatment in order to minimise the appearance of expected adverse reactions;

Anticipated emergency situation

A clinical trial where a new biotechnology product is to be given for the first time to humans; the protocol requires the validity of appropriate medicinal products needed for the treatment of anaphylactic shock.

2. Challenge agents

Description

Challenge agents are usually given to trial subjects to produce a physiological

response that is necessary before the pharmacological action of the IMP can be assessed. They may be substances without a MA, however some have a long tradition of clinical use.

Examples:

Skin prick test

Skin prick tests may be used to identify subjects with allergic responses to specific allergens. Dilute solutions are manufactured from extracts of allergens such as pollens, house dust, animal dander and foods. In the skin prick test, a drop of each solution is placed on the person's skin, which is then pricked with a needle. If the person is allergic to one or more substances, he/she has a wheal and flare reaction. This test may be used as part of the inclusion criteria for a clinical trial of a new medicine to control or prevent symptoms from allergic reactions.

Blood pressure

Open-label sensitivity test of blood pressure response to oral tyramine following treatment with an IMP (new MAO inhibitor) in healthy volunteers.

3. Medicinal products used to assess end-points in the clinical trial

Description:

This type of NIMP is given to the subject as a tool to assess a relevant clinical trial endpoint; it is not being tested or used as a reference in the clinical trial.

Examples:

Organ function(s):

PET (positron emission tomography) radiopharmaceuticals are administered to a clinical trial population to measure the function of a certain organ before and after the subject has been given an IMP whose effects in this organ are the primary end-point of the clinical trial.

Arterial wall function

Acetylcholine is administered directly in coronary arteries to evaluate coronary endothelium dysfunction. The test is performed at baseline – before the first administration of an IMP, and at the end of the study, after the treatment period.

4. Concomitant medicinal products systematically prescribed to the study patients

Description:

This type of NIMP is given to clinical trial participants as required in the protocol as part of their standard care for a condition which is not the indication for

which the IMP is being tested, and is therefore not the object of the study.

Example:

Symptom relief

Testing a non-oncologic medication in a cancer patient, where the objective of the clinical trial is to assess the analgesic effect of a new opiate product. The study design would test the opiate versus active comparator for pain control, in patients treated for cancer with the same anticancer treatment in the two groups, regardless of the trial.

5. Background treatment

Description:

This type of medicinal product is administered to each of the clinical trial subjects, regardless of randomisation group, to treat the indication which is the object of the study. Background treatment is generally considered to be the current standard care for the particular indication. In these trials, the IMP is given in addition to the background treatment and safety efficacy are assessed. The protocol may require that the IMP plus the background treatment is compared to an active comparator or to placebo plus background treatment.

The timing of the start of standard care as a background treatment may be different.

For instance:

• Subjects may already be taking the standard care medicine(s) when entered into the study, and this treatment would be one of the inclusion criteria; or

• Newly diagnosed subjects may be assigned to the standard care medicines at the same time as they are assigned to the IMP.

The nature of the background medicine(s) will be specified in the protocol e.g. as the standard treatment given according to local clinical practice, by the name of active substances or medicinal products prescribed depending on patient needs and according to the doctor's judgement.

The standard care medicine(s) for a specific indication (recognised standard of care), or a component of the standard care for a particular medical indication, is based on national and international consensus.

Examples:

Development of a new medicinal product for HIV patients who need prophylaxis against cytomegalovirus (CMV) is likely to include patients on standard of care medicine(s) for their primary disease (e.g. antiretroviral medicinal products).

In oncology, patients often receive combination treatments. These may all be approved for the treatment of the disease to be investigated but may not be completely defined in the protocol. For example, the development of a new indication for a medicine used in women with breast cancer recently compared that medicine versus observation in patients who had received, regardless of trial, at

least four cycles of neoadjuvant or adjuvant chemotherapy and were allowed concurrent hormonal adjuvant therapy. In this case, that medicine would be considered an IMP and the neoadjuvant or adjuvant chemotherapy and hormonal therapy products would be NIMPs.

ANNEX 2

SIMPLIFIED DOCUMENTATION REQUIREMENTS FOR NIMPS IN THE APPLICATION DOSSIER ('SIMPLIFIED DOSSIER')

1) Simplified dossier in view of marketing authorisation (MA) status:

		NIMP is an authorised medicinal product in a EU Member State	**NIMP is an approved medicinal product in an ICH country or a country which has a Mutual Recognition Agreement with the EU ('MRA country')**	**NIMP is an approved medicinal product in a third country not being an ICH or MRA country**	**NIMP has no marketing authorisation but the drug substance is contained in a medicinal product authorised in an EU Member State**	**NIMP is an unauthorised product where the active substance has been previously administered to humans**
The justification of IMP selection according to the „waterfall" specified under Art. 93 of the Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial in Romania, approved through Scientific Council Decision (SCD) No. 22/2010		**X**, if MA in another Member State	**X**	**X**	**X**	**X**
Copy of the SmPC[i, ii]		**X**	**X**			
Evidence of regulatory status in the country where the product is approved		X, if MA in another Member State[iii]	**X**	**X**		
Justification for safe and effective use[iv]		X, if used outside the MA	X, if used outside the MA	**X**	**X**	**X**[v]
Quality data						
Documents on quality and manufacturing as per EU Guideline[vi]				**X**	**X**	**X**[vii]
GMP compliance						
NIMP is manufactured in the EU as medicinal product or IMP approved in Romania	Manufacturers authorisation		**X**	**X**	**X**	**X**
NIMP is imported	Importers authorisation		**X**	**X**	**X**	**X**
	Certification of GMP compliance of manufacturing site by QP[viii]		**X**	**X**	**X**	**X**
	Results of reduced testing (e.g. identity) by analytical testing or an appropriate method by QP or appropriately experienced individual			**X**	**X**	**X**
In case of repackaging or relabelling	Information of repackaging or relabelling, and list of sites involved	**X**	**X**	**X**		
	Acceptable evidence of GMP compliance[ix] for the repackaging or relabelling or a justification for its absence	**X**	**X**	**X**		

2) Other possibilities for simplified dossier requirements:

a) NIMP is defined in the protocol but is not fixed to a particular product (any NIMP used is authorised in Romania)

In this situation, the product to be used is authorised in Romania, but a particular brand is not specified in the protocol.

This information should be included in the covering letter. The medicinal product used should be identified by general means, such as INN. No additional information is required.

b) NIMP is an unauthorised product which has been used as an IMP or NIMP in a previous trial conducted in the concerned Member State by the same sponsor or another sponsor where a letter of access to the data from that sponsor is available

Simplified dossier is required containing:

- EudraCT number of previous trial;
- Confirmation that the trial population is in line with that of the previously approved trial or justification of any differences;
- Confirmation that the dose/duration of dosing does not exceed that of the previously approved trial or justification of any differences;
- Justification for the safe use of the product in the trial including any potential for interactions between the NIMP and the IMPs to be used in the trial;
- Confirmation that there were no safety or quality issues arising from the previous trial;
- Confirmation that the NIMP is manufactured and controlled (including formulation, site of manufacture, quality control and specifications) in line with the conditions of the previously approved trial taking account of both the initial dossier and any subsequent amendments.

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[i] If, in multinational trials, the SmPC varies between the Member States, the SmPC which is best suited to ensure patient safety should be chosen.

[ii] Or local equivalent (in other regions than EU).

[iii] Not required if NIMP is used as challenge agent or agent to assess endpoints.

[iv] Including considerations of any potential for interactions between the NIMP and the IMPs used in the trial.

v Including:

- Rationale for efficacy and safe use in the trial including information on the extent of previous human exposure, including any potential for interactions between the NIMP and the IMPs to be used in the trial;
- Where there is insufficient clinical data to demonstrate safety, evidence that existing nonclinical safety data support the use in the proposed trial;
- Explanation about the previous administration of the active substance to humans.

[vi] Guideline on the Requirements to the Chemical and Pharmaceutical Quality Documentation concerning Investigational Medicinal Products in Clinical Trials - CHMP/QWP/185401/2004; For biologicals: Guideline on the Requirements for Quality Documentation Concerning Biological Investigational Medicinal Products in Clinical Trials - EMA/CHMP/BWP/534898/2008.

[vii] Where comprehensive data on manufacturing can not be provided, applicants should show that the NIMP is appropriate for the use by providing information regarding the source of the NIMP and a justification that this source ensures the quality of the NIMP and is appropriate for the intended use.

[viii] Account should be taken of specific qualifications for certain types of medicinal products, such as radiopharmaceuticals.

[ix] For EU-sites: manufacturers authorisation; for non-EU sites: certification of GMP compliance by QP.

DECISION

No. 21/31.08.2011

on approval of the Guideline on evaluation of advertising in medicinal products for human use

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 1123/18.08.2010, in accordance with the Regulation on the organisation and operation of the NAMMD Scientific Council, Art. 8 (1), adopts through written procedure the following:

DECISION

Art. 1. – The Guideline on the evaluation of advertising in medicinal products for human use is approved, in accordance with the Annexes which are integral parts of this Decision.

Art. 2. – On this Decision coming into force, the following Decisions shall be repealed:

- NAMMD Scientific Council Decision No. 20/03.09.2010 on approval of the Guideline on evaluation on advertising in medicinal products for human use;
- NAMMD Scientific Council Decision No. 31/01.11.2010 on approval of Regulations for advertising of medicinal products for human use;
- NAMMD Scientific Council Decision No. 11/05.04.2011 on approval of amendment to SCD No. 31/01.11.2010 on approval of Regulations for advertising of medicinal products for human use.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,

Acad. Prof. Dr. Leonida Gherasim

ANNEX
(SCD No. 21/08.09.2011)

GUIDELINE
ON EVALUATION OF ADVERTISING IN MEDICINAL PRODUCTS FOR HUMAN USE

CHAPTER I
Introduction, definitions, scope, provisions

SECTION 1
Introduction

Art. 1. - The mission of the National Agency for Medicines and Medical Devices (hereinafter, NAMMD) is to contribute to the protection and promotion of public health. The NAMMD is the competent authority in respect of approval of advertising materials and any other forms of publicity related to medicinal products for human use, according to provisions of Law no. 95/2006 on healthcare reform, Title XVII – The Medicinal Product.

Art. 2. – (1) In all activities regarding medicinal product advertising, standards and regulations must be defined and observed which would organise and regulate this activity.

(2) The entire activity concerning advertising and promotion of medicinal products must be carried out responsibly, ethically and at the highest standards in order to ensure safe use of medicines, both in self-medication and in case of medicines administered under medical guidance and supervision.

Art. 3. – (1) Advertising, that for medicines included, is only accepted provided compliance with legislation in force.

(2) This guideline aims at facilitating application of regulations in force by clarifying certain detail aspects, so that advertising for any medicine, irrespective of its form (in order to provide interest for the consumers) should be at a high standard and observe legal provisions.

(3) Medicinal product advertising should not include anything offensive or misleading for the consumer.

SECTION 2
Definitions

Art. 4. – In line with this Guideline, the used terms and notions have the following meanings:

1. ***Competent authority*** – The National Agency for Medicines and Medical Devices (NAMMD, set up through Emergency Government Ordinance No. 72 of 30 June 2010 on reorganisation of healthcare facilities and amendment of public health legislation, following the fusion of the National Medicines Agency and the Medical Devices; the organisation and functioning of the NAMMD have been approved through Government Decision No. 734 of 21 July 2010);

2. ***Advertising agent/agency*** – any person (physical or legal) appointed by a pharmaceutical company to provide advertising services of any kind to its benefit, on the grounds of an agreement;

3. ***Pharmaceutical company*** – any legal person undertaking and carrying out any sort of activities in the pharmaceutical industry, whether or not a parent-company (for instance main office, control or company office), company subsidiary, branch or any other form of enterprise or organisation;

4. ***Strength of the medicinal product*** - the content of the active substances expressed quantitatively per dosage unit, per unit of volume or weight according to the pharmaceutical form;

5. ***Common Name*** – the international non-proprietary name recommended by the World Health Organisation (WHO) or, if one does not exist, the usual common name;

6. ***Name of the medicinal product*** – the name assigned to a medicinal product, which can be an invented name not leading to confusions with the common name or a common or scientific name, accompanied by the trademark of the marketing authorisation holder;

7. ***Medical manifestations –*** planned scientific manifestations (events), addressing healthcare professionals, initiated and organised locally, regionally, nationally or internationally, such as: congresses, symposia, round tables, workshops, classes, Advisory Boards (expert meet-ups);

8. ***Advertising (promotional) material*** – any means used for advertising (promotional) purposes as defined by the concept of "promotion";

9. ***Educational materials***

a) ***Educational material*** – material addressed to the public and/or specialists in the healthcare field, which aims at informing the target public on a certain pathology or medicine, used for scientific/educational purposes and which does not encourage the prescription, delivery, sale, administration, recommendation or consumption of the respective medicine;

b) The materials which are part of consolidated risk management actions and are not subject to this Guideline (except for the manner of submission of the application and tax) are not considered educational materials.

10. Medicinal product/Medicine

a) any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or

b) any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

11. ***On prescription medicinal product*** – any medicine for which the consumer must present a medical prescription in order to have it released;

12. ***Generic medicinal product*** – medicinal product with the same qualitative and quantitative composition as regards the active substances and the same pharmaceutical form as the reference medicinal product and whose bioequivalence with the reference medicine has been proved by proper bioavailability studies. Various salts, esters, ethers, isomers, mixtures of isomers, compounds or derivates of an active substance are considered as the same active substance, if they do not present significantly different properties with respect to safety and/or efficacy. The applicant does not have to provide bioavailability studies, if he/she can prove that the generic medicinal product meets the relevant criteria as defined in the proper detailed guidelines;

13. ***Homeopathic medicinal product*** - any medicinal product prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia; a homeopathic medicine can contain number of active principles;

14. ***Reference medicinal product*** - a medicine authorised according to art. 700 and 702 of Law no. 95/2006 or a medicine authorised in one of the Member States of the European Union or by centralised procedure;

15. ***OTC (over-the-counter) medicinal product*** – any medicine that is available without a medical prescription;

16. ***Sample*** – medicine supplied on a free basis to healthcare professionals so that they can become accustomed to the product and acquire experience with it;

17. ***Administrative staff*** – the decision-making staff from public and private healthcare institution and the members or presidents of medicine therapeutic commissions;

18. ***Medical prescription*** – any medicine prescription issued by a person qualified to this end;

19. ***Healthcare professionals*** - physicians, dentists, pharmacists and nurses;

20. ***Promotion*** – it relates to any organised activity encouraging the prescription, delivery, sale, administration, recommendation or use of medicines;

21. ***Medicinal product advertising (commercial)*** – any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products; it shall include in particular:

a) advertising of medicinal products to the general public;

b) advertising of medicinal products to persons qualified to prescribe or supply them;

c) visits by medical sales representatives to persons qualified to prescribe medicinal products;

d) supply of samples;

e) sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products;

f) sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products and in particular payment of their travelling and accommodation expenses in connection therewith;

22. ***Reminder*** – a short advert addressed to the target public, which by exception from the common law in the field, may include only the name of the medicine or the international non-proprietary name, if there is one, or the make of the medicine. The reminder may be used only within a campaign where the full advertising material is presented according to legislation in force;

23. ***Essential information in the SmPC***: minimum information in the summary of product characteristics necessary for a correct use of the medicine. This will generally include information in sections 1-4 and 6-7 of the summary of product characteristics. Abbreviation or removal of information deemed unessential of these sections may be acceptable;

24. ***Comparative advertising*** – any form of advertising explicitly or implicitly identifying the competition and/or comparative description;

25. ***Misleading advertising*** – any form of advertising which, under any form, presentation included misleads or is liable to mislead any person;

26. ***Subliminal advertising*** – advertising using adverts whose beneficiary is not aware thereof, for instance expressed with a low acoustic intensity or displayed on a screen for a short period of time, not longer than a second;

27. ***Adverse reaction*** – a harmful and unwanted response to a medicinal product, and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function;

28. ***Serious adverse reaction*** - an adverse reaction which results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly/birth defect;

29. ***Unexpected adverse reaction*** - an adverse reaction, the nature, severity or outcome of which is not consistent with the summary of product characteristics;

30. ***Representative of the marketing authorisation holder*** – person, usually known as the “local representative”, appointed by the marketing authorisation holder (MAH) to represent it in Romania;

31. ***Medical representative*** – a person paying visits to healthcare professionals and appropriate administrative staff regarding promotion of medicines, such as but not limited to assigned sale managers, product managers, marketing managers etc.;

32. ***Risks related to use of the medicinal product***:

a) any risk for the patient's or public health, regarding the quality, safety or efficacy of the medicinal product;

b) any risk of unwanted effects on the environment;

33. ***Healthcare services*** – the totality of medical or pharmaceutical services accomplished by healthcare professionals in order to treat or prevent disease in humans.

SECTION 3
Scope

Art. 5. – (1) This Guideline regulates the advertising activity for medicinal products for human use (whether original or generic medicines, on prescription medicinal products to healthcare professionals or OTC medicines).

(2) By "advertising activity" or "promotion", one understands any activity carried out, organised or sponsored by a pharmaceutical company (or with its authorisation by an advertising agency) resulting in encouragement of prescription, issue, sale, administration or use of a medicine.

(3) This Guideline relates to the activity of promotion and advertising aimed not only at physicians, but also to all other healthcare professionals who, within the professional activities they carry out, can prescribe, supply, administer a medicine or encourage its sale, distribution or use.

Art. 6. - This Guideline relates to all promotion methods, namely to those mentioned under Art. 4 (21), as well as the visits from medical representatives accompanied by delivery of promotional materials, advertising in newspapers or magazines, scientific publications, direct e-mail advertising, and other means of electronic communication (sites, webpages, blogs, forums), use of audiovisual systems (such as movies, video recordings, data storage services).

Art. 7. - The guideline is not meant to limit or restrict the supply of medical or scientific information to healthcare professionals or the public.

Art. 8. - This guideline does not cover the following fields:

a) summaries of product characteristics, as provided by relevant legislation, labelling and patient leaflets of medicines, if they are not promotional;

b) correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product but only if exclusively related to the letter subject or the question subject and if not promotional;

c) general, non-promotional information about companies (such as information addressed to investors or current/prospective employees), including financial data, descriptions of research and development programs and discussions on regulation affecting the company and its products.

Art. 9. - This Guideline is issued according to provisions of the following documents:

(1) Law no. 95/2006 on healthcare reform, Title XVII – The medicinal product, published in the Official Gazette of Romania, Part I, no. 372 of 28/04/2006, as amended, transposing Directive 2001/83/EC on the Community code relating to medicinal products for human use, published in the Official Journal (OJ) of the European Union No. L 311 of 28 November 2001, as amended;

(2) Law no. 148/2000 regarding advertising, published in the Official Gazette of Romania, Part I, No. 359/2000, as amended;

(3) Law no. 158/2008 regarding misleading advertising and comparative advertising, published in the Official Gazette of Romania, Part I, No. 559/2008;

(4) The Law of audiovisual No. 504/2002, published in the Official Gazette of Romania, Part I, No. 534/2002, as amended;

(5) The Audiovisual Code – Decision No. 220/2011 concerning the regulation of audiovisual content, published in the Official Gazette of Romania, Part I, No. 174/2011, supplemented through National Audiovisual Council No. 459/2011, published in the Official Gazette of Romania, Part I, No. 534/2011;

(6) The European Federation of Pharmaceutical Industries and Associations (EFPIA) Code of Practice on promotion of prescription-only medicines to, and interactions with healthcare professionals, adopted in July 2007 and updated in June 2011.

Art. 10. – This Guideline applies not only to pharmaceutical companies *per se*, not only to their affiliated companies or representatives, but to other partners as well (agents, agencies, MAH representatives) with whom the pharmaceutical companies have established a contractual relationship in view of conducting any type of medicinal product advertising.

Art. 11. – (1) Pharmaceutical companies and their representatives are responsible for ensuring compliance with the regulatory regulations in this Guideline, even in case of granting to third parties (e.g. marketing contractors, consultants, market research companies, advertising agencies) of promotional activities, advertising activities or enforcement activities or activities related to hiring, on their account, through the advertising actions regulated by this Guideline.

(2) Pharmaceutical companies should ensure that any of the third parties who have granted the advertising materials for medicinal products are compliant with the provisions of this Guideline.

(3) The pharmaceutical companies and their representatives are not considered responsible for promotional activities initiated by third parties without having a contract with the MAH/his/her representative, whose scope is clearly specified as a promotional activity.

SECTION 4
Provisions

Art. 12. – Medicinal product advertising (commercial) refers to any type of organised activity aiming to provide information via direct/indirect means, as well as to any type of promotion form meant to encourage the prescription, distribution, sale, administration, recommendation or use of one or several medicinal products for human use. Medicinal product advertising may address healthcare professionals or the public.

Art. 13. – (1) Advertising for a medicinal product:

a) should be precise, balanced, equitable, objective and containing enough information in order to allow the addressee to form their own opinion concerning the therapeutic value of the given medicinal product;

b) should be based on the updated evaluation of all relevant proofs and clearly reflect these proofs;

c) should encourage the rational use of the medicinal product, by its objective presentation, without boasting its properties and therapeutic qualities;

d) should not encourage self-medication or the irrational use of the medicinal product;

e) should not be deceptive, subliminal or misleading by distortion, overstatement, unjustified emphasis, deficiency etc.;

f) should not suggest that a medicinal product/active ingredient has any particular merit, quality or property, unless supported by scientific data;

g) should not be detrimental to the respect for human dignity and public moral;

h) should not include discrimination based on race, gender, language, origin, social background, ethnic identity or nationality;

i) should not be detrimental to the image, honour, dignity and private life of person.

(2) All information included in this advertising material to a medicinal product should be compliant with the information stipulated in the SPC.

Art. 14. – (1) As a general rule, advertising addressing the public is prohibited for the following categories of medicinal products:

a) medicinal products which do not own a marketing authorisation available in Romania;

b) medicinal products released only by medical prescription.

(2) a) Exceptionally, manufacturing companies or their representatives in Romania may spread clearly stated information to medical assistance authorities or to authorities from the Administration Council of the Medical Assistance Institutions, e.g. persons in charge of the establishment of institutional budgets, such as those referring to new medicinal products or new methods of administration of already authorised medicinal products in view of marketing, whose use may have a

substantial impact on associated costs, in view of long-term planning for the estimated fees for medical assistance.

The distribution of these materials should be specifically directed to the budget decision-making staff.

b) Likewise, manufacturing companies and their representatives in Romania may distribute relevant information in case they receive specific requests from medical assistance authorities.

Art. 15. – Responsible parties:

(1) The MAH or his/her representative is responsible for the content of advertising/promotional materials issued by the former for a given medicinal product.

(2) The MAH is also responsible for the training and conduct of medical representatives towards the use and distribution of advertising/promotional materials.

(3) Apart from an existing contract with a third party, the MAH does not undertake the responsibility for the manner of distribution and use of promotional materials.

(4) Pharmaceutical companies set up, internally, training systems related to the manner in which promotional materials are used by their representatives in promotional campaigns.

(5) Within a company, the final approval of all advertising/promotional materials is appointed to a responsible person. Moreover, the NAMMD may request the MAHs or their representatives to communicate the names of the appointed persons in view of the final approval of advertising/promotional materials, as well as the names of their alternates.

(6) Although the main responsibility for ensuring compliance with the regulations in force of all advertising materials referring to a medicinal product goes to the MAH, some third parties involved in the manufacturing and distribution stages for incriminating promotional materials may be responsible as well. This provision also enables the enforcement of sanctioning measures for the third parties involved in the manufacturing and distribution process of incriminated advertising materials.

Art. 16. The notification, submission in view of approval, evaluation and storage of materials:

(1) The MAH is requested to submit to the NAMMD in view of approval all advertising materials meant for the public/patients and to market them only after receiving advertising approval.

(2) Advertising materials for OTC medicinal products, as well as educational materials addressing the public/patients are subject to Art. 16 (1).

(3) Advertising materials are submitted together with the application form for the evaluation of the material and the payment form.

(4) The taxation of the evaluation is carried out for each product appearing in the advertising material and for each communication channel of the respective advertising.

(5) The evaluation of advertising materials at the NAMMD is performed only after confirming the encashment of the respective fee; the evaluation may result either in the approval of the submitted advertising materials or in the wording of applications for their modification.

(6) The application for change or potential non-compliance are forwarded to the MAH, namely to the representatives appointed by the MAH, via e-mail.

(7) In case NAMMD approval is obtained for a modified approval (as compared to the initially submitted approval), the MAH is required to submit a printed copy of the material in the final approved form, (the variant effectively marketed) and another in unprintable electronic form in view of assessing compliance.

(8) Advertising materials meant for healthcare professionals, for medicinal products released with or without medical prescription, are assessed by the NAMMD after dissemination via polling, or following notifications.

(9) The participation of the MAH to medical events is notified to the NAMMD prior to the event.

(10) In view of assessing compliance, NAMMD establishes a 3-year period as a minimal mandatory period for storage of advertising materials by the MAH, for both printed materials and electronically submitted ones.

(11) The period mentioned under Art. 16 (10) is measured from the moment of the first use of the advertising material.

Art. 17. – The main forms of advertising used in the pharmaceutical industry are as follows:

(1) Printed materials (prints):

These materials are defined in Annex 1 to this Guideline.

a) materials of scientific character dedicated to healthcare professionals;

b) printed advertising materials meant for the public:

c) education materials meant for patients and patient organisations/associations;

d) posters, invitations;

e) reminding materials (reminders);

(2) Audio-visual advertising (radio, television)

(3) Billboards or any other form of outdoor advertising;

(4) Internet advertising (web pages, e-mail, forums, blogs or any other form of electronic support);

(5) Sampling;

(6) Promotional objects (relevant for medical practice).

CHAPTER II
Misleading advertising and comparative advertising, encouragement of rational use, conformity with SmPC content

SECTION 1
Misleading advertising

Art. 18. - (1) Misleading advertising means any form of advertising which, in any way, including by presentation method, misleads or may mislead any person.

(2) Any form of advertising must not suggest that a medicine or an active ingredient has any merits, special quality or property, if it cannot be scientifically documented. This is a provision with a wide coverage.

(3) In order to determine the misleading character of advertising, all its characteristics will be considered and, especially, its integral parts regarding:

a) a) the characteristics of the medicine (whichever they are), the extent of their compliance with the purpose and results expected from its use;

b) the omission of essential information regarding identification and appreciation of that medicine in order to mislead people to whom it is meant.

c) accurately described information, which may be deemed misleading due to the overall impression created given by the fact that it is noncompliant with the therapeutic indications. This category can include an advertising material which provides images related to driving if the medicinal product can affect the ability to drive vehicles.

SECTION 2
Comparative advertising

Art. 19. - (1) Comparative advertising means any form of advertising explicitly or implicitly identifying a competitor by its comparative description. Any comparison between different medicinal products must be based on relevant and comparable aspects.

(2) Comparative advertising for the public is forbidden.

(3) Comparative advertising addressing healthcare professionals is forbidden if:

a) the comparison is misleading, according to the above-mentioned references;

b) the trademark of a competitor is used; only international non-proprietary names are allowed.

c) the comparison is made between/among medicines with different therapeutic indications or different pharmaceutical forms;

d) objectively, there may be no comparison between one or several essential, relevant, verifiable and representative characteristics – among which the price may also be included – of some medicines;

e) confusion is created on the market between the advertised and a competitor or between/among the various trademarks, international non-proprietary names or other distinctive marks of the advertised medicinal product and those belonging to a competitor;

f) discredit or unfair criticism of the trademark, international non-proprietary name, other distinctive marks, activities or any other characteristics of a competitor;

g) the reputation of a trademark, international non-proprietary name, distinctive marks of a competitor or any other characteristics of a competitor are incorrectly profited from, without evidence to support the allegations.

SECTION 3
Encouragement of rational use

Art. 20. - (1) Any advertising material must encourage correct and adequate use of the medicine. Therefore, it is compulsory that any advertising material should include information regarding:

a) the recommended dose/administration pattern/specific administration instructions if any;

b) the exact indications of the medicine according to the SmPC;

c) special warnings and precautions according to the SmPC;

d) contraindications according to the SmPC.

(2) Any piece of information included in an advertising material must be supported by clear scientific references, without exaggerations or extrapolations not scientifically substantiated. For instance:

a) an advertising material for a medicine alleviating symptoms of a disease may not suggest that that medicine cures the disease;

b) an advertising material in which data of clinical trials results are not accurately presented or out of context will be deemed as exaggerating the properties of that medicine.

SECTION 4
Conformity with SmPC content

Art. 21. - (1) Any advertising material must not promote use of the medicine not including the therapeutic indications listed in the SmPC approved for that medicine.

(2) Moreover, an advertising material for a medicine should not promote the use of a medicine by certain categories of patients for which there are no indications in the SmPC. For instance, the presence of an infant image in an advertising material for a medicine which is not recommended to infants represents a breach of this provision.

CHAPTER III

Advertising meant for healthcare professionals

General considerations, advertising forms

SECTION 1

General considerations

Art. 22. – (1) No medicine must be promoted before grant of the marketing authorisation allowing for its sale or distribution.

(2) Interpretation of legal provisions in force shows that off-the-label promotion of a medicinal product is also forbidden.

Art. 23. – (1) Any form of advertising must be in compliance with provisions listed in the approved SmPC and with the marketing authorisation terms as granted by the NAMMD or, as the case may be, in compliance with the European Commission Decision.

(2) It is forbidden to advertise medicines in any form not covered by the marketing authorisation.

(3) a) Information regarding some indications of a medicinal product which are not specified in the marketing authorisation (MA) ("off-label indications") and may only be supplied as response to an appropriately documented request from a healthcare professional.

b**)** It is forbidden to use such information in order to promote the medicine in unauthorised indications or promote the use of the medicine under any terms than those listed in the approved SmPC.

c**)** In this case, the MAH makes sure that the provided information is informative, non-promotional, clearly stating that the respective information is "off-label".

Art. 24. – (1) Any form of advertising for a medicine meant for persons qualified to prescribe or supply such products must include:

a) essential information compatible with the approved SmPC;

b) the classification for supply of the medicine;

c) mentions regarding the date on which the documentation used for accomplishment of the advertising material or any other form of advertising was drawn up or last revised.

(2) All the information included in the documentation mentioned in Art. 24 (1) must be exact, updated, verifiable and complete enough to allow the recipient to have his/her own opinion regarding the therapeutic quality of the medicine concerned.

(3) The quotations, tables or other illustrative materials taken from medical publications or other scientific works, in order to be used in the above-mentioned

documentation, must be faithfully reproduced and with the exact indication of the source (references).

(4) All the illustrations in the promotion materials, including graphs, images, pictures and tables, taken from published studies must meet the following conditions:

a) to show a clear source/exact sources of the pictures;

b) to be faithfully rendered, except for the case where they must be adapted or changed for compliance with any applicable code/codes, in which case it must be clearly mentioned that the pictures have been adapted and/or changed.

c) Special attention must be paid that the pictures included in any form of advertising should not be misleading regarding the nature of the medicine (for instance, if it is adequate for child use or not) or regarding a statement or a comparison (for example, using incomplete information, statistically irrelevant or inappropriate comparisons).

Art. 25. - The words "safe" or "risk-free" must never be used to describe a medicinal product without the appropriate scientific arguments.

Art. 26. - The word "new" should never be used to describe a product or a form of presentation which was generally available or a therapeutic indication generally promoted for more than a year (in Romania).

Art. 27. - A product may not be presented as having no adverse reactions, risks of toxicity or risks of addiction, except in those cases mentioned in the SPC.

Art. 28. - The design and presentation of advertising must allow a clear and easy understanding. When footnotes are used, these must be obvious, have a proper size, be easily legible and have a duration which allows reading.

Art. 29. - The advertising addressed to persons qualified for medicinal product prescription or supply should not promise gifts, advantages in cash or in kind.

SECTION 2
Advertising forms

Art. 30. - Printed advertising materials meant for healthcare professionals

(1) Advertising (promotional) material for on prescription medicinal products must be sent or distributed only to healthcare professionals.

a) It is forbidden that such promotional materials be left in places accessible to the public such as, but not limited to, pharmacies, waiting rooms of medical practices, hospital and clinic halls etc.

b) Should the advertising materials be exhibited in this way to the public, the liability is presumed to lie with the pharmaceutical company, which may prove the contrary with documents.

(2) Any printed advertising material meant for healthcare professionals must include at least the following information:

a) the name of the medicine and the active substance (INN = international non-proprietary name);

b) the pharmaceutical form and strength;

c) the dosage for each administration route and each therapeutic indication, as the case may be;

d) the date of the first authorisation or the authorisation renewal;

e) essential information in the SmPC;

f) the date of the text revision (for the SmPC);

g) the mention: "This promotional material is meant for healthcare professionals."

h) the way the medicine is dispensed and the type of prescription based on which it is dispensed;

i) The information in the SmPC are printed using font *10*, irrespective of the font type.

(3) Messages asserting or suggesting medicine safety in use are forbidden within printed advertising materials, except for the cases mentioned in the SmPC.

(4) All steps must be taken for healthcare professionals not to be misled by allegations that a product is better or safer than another unless the allegation is scientifically supported.

Art. 31. – Posters, invitations:

(1) If not related to the therapeutic effects of a medicinal product, invitations to medical events addressing healthcare professionals can only include the name of the product or its international non-proprietary name, if any, or its trademark and, if necessary, a mere statement of the indications meant to designate the therapeutic category of the product or its means of administration. Otherwise, these will be subject to regulations provided in Art. 30, **"**Printed advertising material meant for healthcare professionals**".**

(2) Posters as well as the invitations aimed at promoting certain actions, activities, scientific medical events, educational programs, or leading to the increase of notoriety of a certain pathology and exhibited in public places will comply with regulations provided in Art. 51 "Printed advertising materials meant for the public".

Art. 32. – Short commercials (reminders):

By way of exemption from provisions of Art. 30, "Printed advertising materials meant for healthcare professionals", in the case of short commercials meant as reminders, the advertising for a medicinal product addressing healthcare professionals should only include the name of the medicinal product or its International Non-proprietary Name, if any, or its trademark.

Art. 33. - International publications for healthcare professionals

Promotional materials included in international publications to be distributed by the MAH or their representatives in Romania must be in compliance with regulations in force.

Art. 34. – Advertising over the Internet

(1) Since advertising via the internet is usually accessible to the public, Internet advertising of medicines dispensed on medical prescription is only allowed if compliant with regulations in force.

a) In such cases, the MAH must prove restriction of access to this information only for healthcare professionals, by a valid and verifiable system of password protection. A complete SmPC is mandatory for the information included.

b) Likewise, website providers should make sure that the materials published on the site do not contain information non-compliant with national and international legal regulations in force. As for other advertising forms, this type of promotion for medicinal products released by medical prescription addressing the public is prohibited.

(2) As in the case of the other advertising materials, the medical information must be supported by scientific references compatible with the approved SmPC.

(3) Romanian users should be specifically informed whether some websites provide links addressing foreign users.

(4) The following aspects represent good practice rules for the advertising of medicinal products for human use:

a) Romanian users should have direct access to any website containing information related to the medicinal product (SmPC – for websites addressing healthcare professionals, leaflet – for websites addressing the public);

b) the website should mention the category of users it addresses;

c) any information about websites addressing healthcare professionals representing an advertising form should be compliant with the legal provisions regulating the content and format of the commercials, as well as the manner of advertising of medicinal products.

Art. 35. – **Hospitality**

Hospitality to healthcare professionals is allowed at scientific/professional events only under the terms provided by legislative regulations in force. This means that it should be limited to the main objective of the meeting and cannot be extended to other people outside the healthcare professionals' category or for which the scientific field providing the theme of the hospitality has no professional relevance.

Art. 36. - Sponsorship

(1) Any type of sponsorship of healthcare professionals should not be correlated to the name of a medicinal product, regardless of its status when being released with or without medical prescription.

(2) Sponsorship activities should not imply the use of direct/indirect promotional messages for medicinal products, regardless of their release status – with or without medical prescription.

Art. 37. - Facilitation of access to educational programs, scientific materials, medical goods or services

(1) The programs initiated by the MAH or their legal representatives aimed at

providing sponsorship for scientific research activities, study visits etc. are allowed provided that:

a) they should not include promotional elements regarding a medicine;

b) they should not be conditioned by the prescription of a medicine or the stimulation of a prescription.

(2) The supply of goods and services to hospitals or other healthcare institutions:

a) must aim at patients' benefit;

b) should not be conditioned by the prescription, distribution or stimulation of the prescription of a medicinal product;

c) should not generally relate to a medicinal product.

Art. 38. – Advertising on medicinal events

(1) Local, regional, national or international medical events are subject to this provision. These are forms of advertising addressed only to healthcare professionals and therefore the MAH or their representatives must notify the NAMMD with respect to the following aspects:

a) the type of event to which the MAH participates;

b) The materials to be distributed within or after the event (shall be listed, not presented as such);

c) The medical information supplied within these events – the set of slides making reference to product characteristics and not the entire presentation;

d) Romanian specialists participating to international events who provide medical information referring to the characteristics of a product should notify the set of slides referring to the characteristics of the product, not to the entire presentation;

e) the promotional objects distributed (please specify);

f) The target physicians the information addresses.

(2) Irrespective of the information support, none of the advertising materials used in this context must go against regulations in force. The MAH or their representatives will introduce all the recommended information in these materials.

(3) A single notification suffices during the advertising campaign of a medicinal product if, at the beginning of the campaign, a set of studies is used, accompanied by a plan containing all manifestations in the company.

(4) If prizes are offered within such events, they should not be of value and they should not be conditioned by the prescription of a medicinal product. Notification is to be made prior to the event.

Art. 39. – Sample granting

Exceptionally, free samples are only offered to persons qualified for prescription of such products and under the terms imposed by the legislation and regulations in force.

Art. 40. – Promotional objects

(1) Healthcare professionals may not be supplied with, offered or promised any gifts, financial advantages or in kind benefits as stimulant for the prescription, purchase, supply, sale or administration of a medicinal product.

(2) a) When medicines are promoted to healthcare professionals, promotional objects may only be supplied or offered to such people if not costly (not exceeding RON 150, VAT included, before personalisation) and relevant for the practice of medicine and pharmacy.

b) Objects of general use, used as promotional objects, may include pens, notebooks, calendars, watches or other similar stationary items (parasols, bath towels etc. are excluded).

(3) Promotional objects may only bear:

a) the name and logo of the pharmaceutical company;

b) the name of the medicine, or its international non-proprietary name, if any, or the trademark;

c) The strength, pharmaceutical form and a mere statement of the indications meant to designate the therapeutic category of the product;

(4) The imprinting of the commercial name of promoted medicinal products on the gowns offered to healthcare professionals as promotional objects is prohibited.

CHAPTER IV

Advertising addressing the general public

General considerations, recommendations related to the statements contained in the advertising materials addressing the public, advertising forms

SECTION 1
General considerations

Art. 41. - Advertisement to the general public is only allowed for those medicinal products, which, by their composition and purpose, are meant for use without a physician’s intervention in diagnosis, prescription or treatment monitoring, a pharmacist's advice being sufficient in case of need.

Art. 42. – (1) Advertisement to the general public is prohibited for medicinal products which:

a) are only dispensed based on a medical prescription;

b) contain substances defined as narcotic or psychotropic within the meaning established by the United Nations Organisation conventions of 1961 and 1971, and the national legislation.

(2) Advertisement to the general public is prohibited in Romania for medicinal products prescribed and dispensed within the health insurance system.

The interdiction does not apply to vaccination campaigns carried out by the pharmaceutical industry and approved by the Ministry of Health.

(3) Manufacturers are not allowed to directly distribute medicinal products to the population for promotional purposes.

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(3) Manufacturers are not allowed to directly distribute medicinal products to the population for promotional purposes.

Art. 43. – Advertisement performed by the MAHs and third parties is prohibited for medicinal products containing promotional offers addressing the public (for instance: "for one box bought, you get .....", or "X + Y" and you may receive a gift, discount etc.) or references to price, discounts, price reductions.

Commercial societies (authorised pharmacies or third parties) are also forbidden to make such advertising addressing the public.

Art. 44. – Any form of public advertising for a medicinal product must:

(1) be designed in such a way that the advertising character of the message should result clearly and the product should be clearly identified as a medicinal product;

(2) include at least the following information:

a) the name of the medicinal product, and the non-proprietary name if the medicine contains a single active substance;

b) the necessary information for the correct use of the medicinal product (therapeutic indication(s), the recommended dose according to therapeutic indication(s) it refers to;

c) an express and legible invitation to careful reading of the instructions in the patient leaflet or on the outer packaging, worded as follows: *"This medicinal product is available without medical prescription. You are recommended to carefully read the patient leaflet or the information on the package. In case of any unpleasant manifestations, please address your physician or pharmacist."*

d) the 'reminder' materials must include the name of the medicinal product and the invitation to read the instructions in the patient leaflet or on the outer package, as the case may be.

3) the number of the approval and the date when it has been granted should be imprinted and presented. The modification of the imprinting of the approval number after having been granted the approval for its prolongement is not required.

Small advertising materials i.e. rest, wobbler etc. (these materials are detailed in Annex 1 to this Guideline) are exempted from the requirement to have the approval number imprinted.

4) should not contain any element, material, date or information which:

a) gives the impression that a check-up, medical intervention or surgical procedure is not necessary, especially by offering diagnosis suggestions or distance treatment;

b) suggests that the effect of the treatment with that medicine is guaranteed or that it does not have adverse reactions (for instance: *"it gets you off……"*);

c) suggests that the subject's health condition can only be improved by use of that medicinal product, in case there is no scientific backup for this statement;

d) suggests that the subject's health condition can be affected if the medicinal product is not used;

e) suggests that the subject's health condition can be affected if the medicinal product is not used; this interdiction does not apply to vaccination campaigns;

f) addresses children exclusively or especially;

g) relates to a recommendation of scientists, healthcare professionals or persons not part of these categories, but whose celebrity can encourage the use of medicinal products;

h) suggests that the medicinal product is a food, cosmetic or other consumption product;

i) suggests that the safety or efficacy of the medicinal product is owed to the fact that it is natural;

j) can, by a detailed description or representation of a case, lead to incorrect self-diagnosis;

k) offers, in inadequate or misleading terms, insurance regarding healing;

l) uses, in inadequate, alarming or misleading terms, visual representations of the changes in the human organism caused by diseases or lesions or actions of the medicinal product on the human body or a part of it;

m) mentions, falsely, that a marketing authorisation has been issued for that medicinal product;

n) expresses violence (even not literally).

o) uses diminutives or other words (expressions) meant to trigger an emotional response on behalf of the users;

p) can present messages, images from campaigns to other types of products (cosmetics, food supplements, medical devices etc.).

SECTION 2
Recommendations regarding statements in advertising materials meant for the general public

Art. 45. - Statements suggesting the product is the same or the most efficient, such as *"No other medicine acts as fast as ……"* are forbidden because they can mislead consumers with respect to the therapeutic benefits of the medicinal product as compared to those associated to other medicines in the same category.

Art. 46. – (1) The words "safe" or "lacking risks" must never be used to describe a medicinal product without appropriate scientific argumentation.

(2) The word "new" should never be used to describe a product or a form of presentation which has generally been available or a therapeutic indication generally promoted for longer than one year on the Romanian market.

Art. 47. – (1) The advertising materials should not suggest that the medicinal product has no adverse reactions.

(2) Moreover, allegations on medicinal product manufacturing in such a way that it has lower contents of residua or is of higher quality than a similar product should not be misleading as regards its therapeutic benefits.

Art. 48. - The medicinal product's speed of action, the speed of absorption are characteristics resulting from the product's SmPC (e.g. performance of the action in less than 30 minutes).

Art. 49. - The NAMMD does not encourage advertising materials promoting use of medicinal products alongside with others with similar trade names, marketed by the same company. Such references to other products in the advertising materials can be misleading.

Art. 50. - Manufacturing companies or their representatives in Romania must not directly or indirectly communicate the idea that their product is better than others for having been granted a marketing authorisation.

SECTION 3

Advertising forms

Art. 51. – Printed advertising materials addressing the general public.

Printing advertising materials addressing the general public:

(1) may mention the name of the pharmaceutical company supporting accomplishment of the material without other references but its identification data;

(2) may contain non-promotional information regarding human health or diseases, provided there are no direct or indirect references to specific medicinal products (educational materials);

(3) may contain advice (recommendations) for a better life quality of patients, however without referring to any medicinal product (educational materials);

(4) should not encourage self-medication or irrational use of medicinal products;

(5) the presentation of the medicinal product must be objective, realistic, easy to support by arguments and without exaggerating its properties and curative effects;

(6) The design and presentation of advertising must allow for clear and straightforward understanding; when footnotes are used, these must be obvious, of sufficient size, in order to be easily legible;

(7) should contain the approval number and date of its release, in the following form: *„advertising approval No. /date….*".

Art. 52. - Posters, invitations

(1) Posters and invitations are compliant with the recommendations concerning advertising materials addressing the general public, including the recommendation to imprint the approval number and date of release, in the following form: *„advertising approval No. /date….*".

(2) Promotional brochures in pharmacies:

a) may only mention medicinal products which can be released without medical prescription;

b) may include the products' shelf price without mentioning promotional offers (e.g. „for one box bought, you get .....", or „X + Y and you may receive a gift, discount" etc.), or references to price, discounts, price reductions.

c) are submitted in view of NAMMD approval; the approval is available for 6 months;

d) should contain the approval number and the date of its release, in the following form: *„advertising approval No. /date*….".

Art. 53. Advertising broadcast on radio and television programmes, by radio-electric means, cable or any other assimilated technical system is subject to the legal provisions regarding audiovisual advertising.

(2) Audiovisual advertising of medicinal products and medical treatments refers to any form of promotion, carried out within program services, meant to stimulate distribution, consumption or sale thereof.

(3) Advertising is only allowed for medicinal products not requiring medical prescription.

(4) Medicinal product advertising must encourage their rational use, present them objectively, without exaggerating their therapeutic qualities.

(5) Promotion of medicinal products in audiovisual programs will necessarily include the following:

a) the name of the medicinal product;

b) the non-proprietary name if the medicinal product contains a single active ingredient;

c) the therapeutic indication (for what conditions the medicinal product is used);

d) an express, legible invitation to careful reading of instructions in the patient leaflet or on the packaging;

e) auditive warning: *"This is a medicinal product. You are recommended to read the patient leaflet carefully.";*

f) approval number and date of its release, in the following form: *„advertising approval No. /date*….".

(6) By derogation from previous paragraph provisions, medicinal product advertising broadcast in a short form (reminders) will include the warning: *"You are recommended to read the patient leaflet carefully."*

(7) The warnings mentioned under paragraph (5) e) and (6) will be broadcast under the following terms:

a) where the main spot is concerned, the text will be presented at the end of the advertising spot, visually, for a time long enough to ensure clear perception;

b) in the case of reminders, the text will be presented during the broadcast of the advertising spot, in terms allowing for clear perception of the message.

(8) Broadcast of medicinal product advertising presented or recommended by public personalities, cultural, scientific, sports personalities or other people who, on

account of their fame, can encourage the use of these products or treatments is prohibited.

(9) Likewise, no broadcast of advertising and teleshopping shows is allowed exhibiting physicians, pharmacists or nurses recommending or providing medical approval for medicines.

(10) No broadcast of medicinal product advertising during children's shows or advertising breaks before or after such shows is allowed.

(11) Medicinal product manufacturers and distributors may not sponsor programs of shows addressing children.

(12) Broadcast of advertising is prohibited suggesting the necessity that any person supplement their diet with vitamins and minerals and that such supplements can improve otherwise regularly good physical or mental functions.

(13) Advertising for any kind of medicinal product or treatment for weight loss or maintenance will observe the following conditions:

a) shall not address people under 18 years of age and will warn the public on this aspect by a written and / or sound insertion;

b) may not be broadcast in children's shows or advertising breaks before or after such shows;

c) shall not be directed towards obese people, will not include examples of cases with reference to or appearance of formerly obese people before using the products or services advertised for;

d) shall not suggest or assert that being underweight is adequate or desired.

(14) The design and presentation of advertising must allow for clear and easy understanding, and include the transposition, understandable by patients/final consumers, of the indications included in the SmPC in the advertising materials (e.g. varicose syndrome, pain, swelling, sensation of weight etc, if proven that these are the symptoms of the reference action).

Art. 54. - Billboards or any other form of outdoor advertising:

(1) In case of these forms of advertising, special attention must be granted to their presentation in order to avoid misleading advertising because of various associations with other encouraging promotional elements.

(2) This type of advertising material is evaluated within the NAMMD scientific council.

(3) NAMMD policy discourages outdoor advertising.

Art. 55. – Short commercials *(reminders):*

(1) This type of material must include:

a) the name of the medicinal product;

b) an express, legible invitation to careful reading of instructions in the patient leaflet or on the packaging, worded as follows: *"You are recommended to carefully read the patient leaflet or the information on the package".*

(2) A TV reminder spot means that the advertising clip cumulatively meets the following conditions:

a) it is a part, sequel and/or completion of the same advertising campaign for a certain medicinal product, carried out within the same audiovisual media service;

b) reminds the public of elements in the message broadcast in the main spot of the advertising campaign;

c) is no more than 10 seconds in length;

d) should forward the same information and messages as the integral commercial;

e) contains the approval number and its date of release, as *„advertising approval No. /date….*".

Art. 56. – **Internet advertising**

As any other form of advertising, Internet advertising, irrespective of form, must be subject to NAMMD evaluation and approval.

(1) **Web pages:**

a) Each web page must clearly identify:

- the identity and physical and electronic address of the sponsor (sponsors) for the webpage;

- the source(s) of all information included on the webpage;

- the target audience of the webpage (for instance, healthcare professionals, patients and the general public, or a combination thereof);

- approval number and date of its release, as *„advertising approval No. /date ….*"

b) The content of the web pages:

- The information included on the webpage will be regularly updated and be subject to NAMMD approval, each time substantial MA- and/or medical practice - related changes occur in the MA; this will clearly display, for each page and/or subject, as applicable, the most recent update of that information.

- Examples of information that may be included on a single web site or on multiple sites include:

1. General information about the company:

- The web pages may contain information of interest for investors, news media and the general public, including financial data, descriptions of research and development programs, discussions of regulation developments affecting the company and its products, information for prospective employees etc.

- The contents of this information are not regulated by this guideline or legal provisions of medicines advertising law.

2. Information regarding health education

- The web pages may contain non-promotional information regarding health education, characteristics of diseases, prevention methods, screening and treatment methods and other information aimed at promoting public health. These can relate to medicinal products, provided the discussion is be balanced and exact.

- Relevant information can be offered on therapeutic alternatives, including, if necessary, surgical procedures, diet, behavioural change and other interventions not requiring the use of medicines.

- Webpages containing information on health education must always recommend visitors to ask healthcare professionals for further information.

3. Promotional information for the patients and the public

- Any information on the websites addressing the patients and the public representing a promotional form should be compliant with the provisions of this Guideline, especially those mentioned under Art. 53 – „Publicity in the field of audio-visual", with the provisions of the legislation in force and with other codes of practice of the industry regulating the content and format of commercials and the manners of promoting the medicinal products.

- Such information should be clearly labelled as advertising information addressing the public.

- These advertising information should only recommend visitors to consult a healthcare professional for further information should contain an overt, legible invitation to carefully read the instruction including in the leaflet or on the package, reading as follows: *„This medicinal product can be released without medical prescription. Please read carefully the leaflet or the information on the packaging. Should any unpleasant manifestation occur, please contact your physician or pharmacist."*

4. Non-promotional information for the patients and the public

- According to Romanian laws and regulations in force, websites may include non-promotional information for patients and the public, regarding the products in the pharmaceutical company OTC portfolio (including information on indications, adverse reactions, interactions with other medicines, correct use, clinical research reports etc.) provided that the information is balanced, exact and coordinated with the approved summary of product characteristics.

- For each product discussed, the webpage must contain complete, unchanged examples of the current summary of product characteristics and the patient leaflet. These documents must be posted in conjunction with other product information or connected to the respective discussion by a visible link recommending readers to refer to them.

- Additionally, the webpage may supply a link to a full, unchanged copy of any public evaluation report issued by the Committee for Medicinal Products of Human Use (CHMP)or a relevant competent national authority.

- Trademarks must be accompanied by non-proprietary international names.

- The webpage may include links to other web pages containing reliable information on the medicinal products, including web pages mentioned by governmental authorities, medical research entities, patient organisations etc.

- The webpage must always recommend visitors to check with healthcare professionals for further information.

(2) ***Electronic mail advertising (e–mail) or SMS:***

E-mail or mobile (SMS) advertising of medicinal products for human use is not recommended

(3) ***Links from other websites:***

- Links can be created to a web site sponsored by a pharmaceutical company from websites sponsored by other people, but pharmaceutical companies should not create links from websites meant for the general public to websites sponsored by the company and meant for healthcare professionals.

- In the same way, links may be created to separate websites, including websites sponsored by pharmaceutical companies or other people.

- Links must direct to the initial page (homepage) of the intended webpage or should be treated in such a way that the reader is aware of the identity of the webpage sponsor.

(4) **Revision of scientific information**

- Pharmaceutical companies and/or their representatives must provide revision of scientific and medical information prepared for posting on the website, compliant with this guideline provisions.

- This function can be accomplished by the scientific service responsible for the information related to medicinal products marketed by the MAH, which is set up in the company in accordance with legal provisions.

(5) **Confidentiality**

The website must be compliant with legislation and applicable codes of conduct regulating the private character, security and confidentiality of personal information.

Art. 57. – Acknowledgement and prevention campaigns for certain diseases

(1) Campaigns classified as 'medical educational' are encouraged (campaigns addressing health education for the masses, related to the acknowledgement or prevention of a disease).

(2) The MAH should make sure that the materials included in the respective advertising campaign do not contain advertising messages for a medicinal product released by medical prescription and that they do not encourage abusive or excessive use of the given medicinal products.

(3) The promotion of messages which restrain the therapeutic scale of a given disease is forbidden.

(4) The MAH should also make sure that it is obvious for patients and public that the therapeutic decision belongs to the physician.

Art. 58. - Sponsorship

(1) Sponsorship of any kind to the public may not be related to the name of any medicinal product available without a prescription.

(2) More than that, sponsorship actions must not contain direct or indirect promotional messages for the medicines available without medical prescription.

(3) Mutual aid or charity programs may not be performed in the name of a medicinal product.

Art. 59. - Sampling

(1) MAHs and persons acting on their behalf on the grounds of an agreement are forbidden to provide samples for advertising purposes to the public.

(2) Commercial societies (authorised pharmacies or third parties) are not allowed to provide samples to the public for advertising purposes.

(3) Supply of samples by means of publications sent directly or by mail, adding samples in the publication packaging, and distributing vouchers or tickets for access to free medicines or discounted medicines are prohibited.

Art. 60. – Promotional objects

(1) Promotional objects given to the public should be inexpensive and promote health and wellbeing.

(2) May only be offered in view of promoting medicinal products which can be released without medical prescription.

Art. 61. – **Promotion of medical and pharmaceutical services**

(1) Clinics, consulting rooms, pharmacies or other organisations providing healthcare services should strictly limit themselves to these and cannot include the advertising to products released by medical prescription in this activity. The appropriate therapeutic approach of an ailment is the result of physician-patient cooperation.

(2) An example illustrating Art. 61 (1) is represented by beauty salons promoting "wrinkle free treatments", non-specific, neutral indication, however should not refer to a certain product – botox or botulinum toxin.

CHAPTER V

Supervision and sanctions

General considerations, notifications and potential non-compliances with the norms on the advertisement of medicinal products

SECTION 1
General considerations

Art. 62. - The NAMMD is the entitled authority to take adequate and efficient steps for evaluation and monitoring of all forms of medicinal product advertising, as follows:

(1) a) in case of non-prescription medicinal products, advertising material meant for the general public is subject to prior NAMMD approval;

b) Educational materials addressing patients undergo NAMMD approval; an approval number shall not be released for such materials.

These materials are available for 6 months from the date of granting of NAMMD approval to use them in educational campaigns.

(2) a) Advertising materials addressing healthcare professionals, promoting both medicinal products released by/without medical prescription, are analysed by

the NAMMD prior to dissemination, via polls or following notifications.

b) Educational materials addressing healthcare professionals must receive NAMMD approval; no stamp number is released for this type of materials.

Art. 63. – (1) The check-up period for all advertising forms for products, submitted for approval to the NAMMD in accordance with Art. 62 (1) and (2) b) or requested by the NAMMD in accordance with Art. 62 (2) a) generally consists of 30 days from the confirmation of payment/submission to the NAMMD (excluding the period of time in which the MAH responds to potential applications issued by the NAMMD). The MAH is warned about the evaluation requirements.

(2) The 30-day term may be preceded or surpassed, depending on the quality and/or complexity of the advertising material initially submitted for evaluation.

The NAMMD undertakes to answer regarding approval or disapproval of the advertising material within 30 days, depending on the complexity of the form of advertising subject to evaluation.

If data submitted for evaluation of the various forms of advertising are substantial and evaluation may exceed the specified deadline, the NAMMD will provide a time estimate necessary for the evaluation to end, not exceeding 60 days.

(3) In case for advertising materials submitted for second approval, if NAMMD response/approval is not granted in 30 days, their implicit approval is assumed and they continue to be marketed.

(4) Following second approval, another printing of the already printed materials in view of including the approval number and date is not required; the assessment of the compliance is performed based on the new approval issued by the NAMMD.

Art. 64. – Apart from the advertising form submitted in view of evaluation, the MAH should indicate the target public to whom it addresses.

Art. 65. – All advertising forms should have already been submitted for evaluation to the internal scientific service responsible for the surveillance of the information concerning the medicinal products marketed by the MAH.

Art. 66. – When receiving any type of advertising materials, all units involved in the distribution of medicinal products are required to make sure that the given product owns an advertising approval granted by the NAMMD or that it had been notified at the NAMMD.

Art. 67. – NAMMD may request counselling from bodies responsible for the evaluation of various advertising forms, concerning the advertising type/form, e.g. the target public, as well as the foreseen date and duration of presentation/broadcast/transmission of each advertising form submitted for evaluation.

Art. 68. - Physical and legal persons having a legitimate interest in prohibiting any advertising form for medicinal products noncompliant with legal provisions and regulations in force may notify the NAMMD in this respect, who shall answer in 60 days.

SECTION 2

The notification and sanctioning of potential non-compliances with the norms related to the advertising of medicinal products

Art. 69. – In view of ensuring the enforcement of proper, correct, unexaggerated advertising for medicinal products for human use marketed in Romania, in accordance with the legal provisions and regulations in force, addressing the public as well as healthcare professionals, the NAMMD takes all required measures in view of being compliant with the legal framework of this activity. Therefore:

(1) via its qualified staff, the NAMMD carries out inspections in distribution units of medicinal products for human use (community pharmacies, hospital pharmacies, druggist's shops, wholesale distributors), as well as to the sites of the MAHs in view of evaluating the promotional materials they hold or provide.

(2) via its qualified staff, the NAMMD also evaluates the compliance with legal provisions concerning advertisement addressing healthcare professionals at scientific events (symposia, conference, congresses) attended by healthcare professionals.

(3) in view of non-compliance with legal provisions and regulations in force related to the advertisement of medicinal products for human use, following the appointment of the responsible parts involved, the NAMMD enforces sanctions in accordance with the provisions of Art. 836 c) of Law No. 95/2006 on healthcare reform – Title XVII – The medicinal product.

Art. 70. – (1) The NAMMD notification related to the non-compliance with the norms on the advertising of medicinal products may be issued by any physical/legal person manifesting a legitimate interest in prohibiting any advertising form non-compliant with legal dispositions.

(2) The notification is made in writing, according to the following requirements:

a) presenting the claimant's contact data (for easy identification and contact by the competent fora in order to communicate the status and results of the investigation);

b) clear and comprehensive presentation of the details regarding the type, moment and place where that form of advertising has been encountered;

c) clear and specific presentation of the proponent's underlying reasons for concern;

d) if possible, a copy of the form of advertising (commercial) making the subject of the inquiry;

e) copies of any documents proving the possible prior contact with the MAH or the advertising agent for amiable resolution of the disagreement.

Art. 71. – (1) The NAMMD pays special attention to all inquiries submitted but mostly to those regarding cases in which advertising may negatively impact public health.

(2) Alternatively, a complaint may be addressed to any other regulatory body.

Art. 72. – (1) The NAMMD will record all complaints received and notify the proponent in that respect.

(2) During the entire period of the investigation, the proponent's identity must remain unknown to the defendant (whether a pharmaceutical company or an advertising agent).

(3) The NAMMD is bound to respond to the complaint received within 60 days as of its registration.

(4) If, after evaluation, the NAMMD ascertains that the legal provisions have been breached with respect to medicinal product advertising, considering the interests of all parties involved, but particularly taking public interest into account, it can take all the necessary steps for the law to be observed, including by ruling termination of the advertising and withdrawal of the advertising material.

Art. 73. - (1) In case the misleading or illegal advertising material drawn up has not been published yet, but the publication is imminent, the NAMMD can rule that this advertising be prohibited.

(2) The measures mentioned under Art. 73 (1) can be instituted by expedited procedure as well and may be temporary or permanent when a serious violation of public health is committed.

Art. 74. - (1) When the NAMMD ascertains that a form of advertising is based on inconclusive or false evidence (clinical trials, epidemiological studies or any other scientific arguments), it shall be ruled that the broadcasting of that form of advertising and the incriminated evidence and arguments should be forbidden.

(2) Moreover, in order to remove the effects of misleading advertising whose termination has been ruled by the NAMMD, the latter may request:

a) full or partial publication of the final decision under the form considered adequate;

b) publication of a corrective statement.

CHAPTER VI
Final provisions, emergency restrictions or safety variations to MA terms

SECTION 1
Final provisions

Art. 75. – MAHs have the following attributions:

(1) making available or submitting to the NAMMD a sample of all advertising material drafted at their own initiative along with a statement showing the public it addresses, the notification method and the date of the first notification;

(2) making sure that the advertising materials drafted for medicinal products they manufacture are in compliance with the legal provisions meant for informing the public, provide information in sufficient detail, clear and legible, to allow the

reader a correct opinion as regards the efficacy, safety and manner of administration of a medicinal product;

(3) checking whether his/her legal representatives have been appropriately trained and whether they fulfil their legal requirements;

(4) providing the NAMMD with the information and assistance necessary to accomplish its responsibilities;

(5) making sure that NAMMD decisions are observed immediately and fully.

Art. 76. - The NAMMD takes adequate steps to ensure application of these legal provisions and regulations in force, related to the advertising of medicinal products for human use and, in case of breach thereof, applies the sanctions provided, in accordance with the law.

SECTION 2
Urgent restrictions or variations for safety reasons to MA terms

Art. 77. – (1) The MAH or its legal representatives have to ensure that prescribers are immediately and fully informed on any important or relevant change of available information on medicinal products used in the promotional campaigns.

(2) As a result of an urgent restriction required by changes in the safety profile or of a similar variation to MA terms, persons in charge of advertising campaigns must take all necessary steps for advertising materials subsequent to this change to reflect the new form and, where necessary, to reflect possible differences in a relevant and clear manner.

ANNEX 1
(SCD No. 21/08.09.2011)

Names/definitions to advertising materials

Advertising materials to be exposed on the shelf	Description of the material
Wobbler/Stopper/Shelf talker	- applicable at the product shelf
Wobbler	- dimension: 10-15 cm + metal/PVC handle hanging outside the shelf
Stopper	- dimension: 10-15 cm + fixing system between two shelves, placed perpendicularly on the shelf, so that it can be viewed sideways
Shelf talker	- 30 – 70 cm – to be applied on the entire length of the shelf

Counter advertising materials	Description of the material
Counter Display	– Having various visual forms; may or may not include shelves of various dimensions which are placed on the counter (there are also LAMA display or totem counters measuring about 50 cm in height)
Rest **Rest Branding**	- holder carrying the change – product poster or package (included in the rest's plastic) having the same dimension as the rest, incorporated in the rest's material (PVC)
LAMA display/Totem/Floor display	- cardboard tube printed on both sides, measuring 1.54 – 2.00 m
Floor sticker	- sticker applied on the floor, at the entrance of the pharmacy or near the counter
Advertising materials to be exposed in the window	**Description of the material**
Pharmacy poster	- It can be printed on paper/cardboard/backlit poliplan and may have various dimensions and shapes depending on the pharmacy type – surrounded by frames or bright columns
Set of window materials*: ***- Self-adhesive labels**** ***- Open/close mark or pull/push or schedule**** ***- Glass frame represented by a brand sticker****	- posters directly applied on pharmacy windows; their dimensions may vary. - Sticker applied on pharmacy doors
Other advertising materials	**Description of the material**

Security door covers	- Covers made of cardboard/fabric/PVC used for security doors
Dummy box	- a much larger layout made of cardboard/PVC, compliant with the product's artwork;
Floor display	- shelf made of cardboard/ glass/plexiglass put on the floor, regardless of the pharmacy's furniture; it may contain various information and may represent the medium for other advertising materials; (it may contain mini-dummy boxes)
Ceiling hanger	- suspendable material, visible to the consumer
Flyer	- informative material addressing the consumer, distributed in pharmacies or waiting rooms of medical cabinets, clinics or hospitals
Branding water dozer	- sticker applied on the water dozer
Press layout	- informative material found in magazines/newspapers addressing the public and/or healthcare professionals
Press release*	- informative material briefly presenting information provided by the media about a medicinal product (magazines/ newspapers/ other publications); may contain the product's image of the packaging / artwork accompanied or not by other information, addressing the public and/or healthcare professionals; may coexist or not at the same time with the initial press layout and may be established as reminders of other types of materials (e.g. spots)
The banner may be: ***- Conference/exposition banner**** ***- Out-door banner*,*** ***- Online banner **** ***- Spider type****	- advertising screen of different formats and sizes (roll-up, poster) having a smaller content of information - flexible advertising screen (usually large), seated on a metallic structure that may be folded and used at a scientific

	event
- Stand/Booth type*	- exposing ensemble containing several fixed/flexible advertising screens which may also include exposing windows, projection screens, monitors, exposing tables used at scientific events. This set of advertising materials should not contain the integral/abbreviated text of the SmPC of the product specified in the commercial.
Newsletter – informative material announcing a release (press release)**	- informative material announcing a release, a new indication, an approval/authorisation of a new product, an event
Press dossier	- set of materials used at a press conference, whose adequate content depends on the target public
Promotional flyer addressing healthcare professionals	- promotional material offered to healthcare professionals, in A4 format or smaller, containing a single sheet; it contains promotional sheets larger than reminders
Informative flyer addressing healthcare professionals	- material offered to healthcare professionals, containing scientific information or information related to changes brought to primary and/or secondary packagings of medicinal products (e.g. information concerning: logo modifications; change of the colour of primary/secondary packagings; other changes of the design; changes in the wording of a medicinal product etc.). This informative material may be considered a short version of the educational material.
Leave peace/leave behind**	- Printed promotional/educational materials, addressing healthcare professionals, having the purpose of informing the target public about a disease/product
Visual aid	- Promotional materials containing detailed information about the medicinal product addressing healthcare

Promotional presentations	professionals. Used in the promotional activity performed by medical representatives and are not provided to be kept by specialists. - Advertising materials containing detailed information about the product/disease addressing healthcare professionals. Used in the promotional activity performed by medical representatives and/or at round tables/congresses/symposia.
Other advertising materials ***	**Description of the material**
	- Shall be defined as they show up

*This type of materials is considered a reminder
**Notified material
***Yet unmarketed

Endorsements:
Reminder: *– shortened commercial addressing the target public which, by exemption from the common law in the field, may only include the product's name or International Non-proprietary Name, if any, the product's trademark, company name or image of the product. The reminder must be used in a campaign displaying the integral commercial advertising material or related materials, in accordance with the legislation in force.*

An advertising material can be considered a reminder under specific circumstances:
Ex.: The pharmacy poster may be a reminder to a TV commercial

Medicinal product batches recalled during the 3rd quarter of 2011

No. crt	Product recalled	Pharmaceutical form	Strength	INN	Manufacturer/ MAH	Batch	Grounds for recall	Action proposed	Recall date
1	RECOMBINATE 250UI, 500UI	Powder and solvent for solution for injection	250IU, 500IU	octocog alfa	BAXTER SA – BELGIA/ BAXTER AG - AUSTRIA	LE04J850AD, LE04J847AB	Recall from market due to a rapid alert received from the Finnish competent authority; a potential microbiological contamination of disinfectant swabs has been identified	Destruction	18.04.2011
2	BIOPAROX	Nasal/oromucosal spray, solution	50mg/ 10ml	fusafunginum	EGIS PHARMACEUTICALS PUBLIC LIMITED COMPANY - HUNGARY/ LES LABORATOIRES SERVIER - FRANCE	1421010, 1410910	Voluntary recall initiated by the manufacturer following the identification of a noncompliance concerning the functioning of the spraying device	Destruction	14.07.2011
3	Fastum gel 25mg/g	gel	25 mg/g	ketoprofenum	A. MENARINI MANUFACTURING LOGISTICS AND SERVICES S. – ITALY/ A. MENARINI INDUSTRIE FARMACEUTICHE RIUNITE SRL - ITALY	All batches manufactured in accordance with the former terms of the Marketing Authorisation	Recall from storage, based on a Decision of the European Commission	Relabelling on an authorised manufacturing flow	01.08.2011
4	Profenid gel 25mg/g	gel	25 mg/g	ketoprofenum	AVENTIS PHARMA LTD. – IRELAND/ LAB. AVENTIS - FRANCE	All batches were manufactured in accordance with the former terms of the Marketing Authorisation	Recall from storage, based on a Decision of the European Commission	Relabelling on an authorised manufacturing flow	01.08.2011
5	KETO Spray 100 mg/g	Cutaneous spray, solution	100 mg/g	ketoprofenum	PHARBIL WALTROP GMBH – GERMANY/ CYATHUS EXQUIRERE PHARMAFORSCHUNG S GMBH - AUSTRIA	All batches were manufactured in accordance with the former terms of the Marketing Authorisation	Recall from storage, based on a Decision of the European Commission	Relabelling on an authorised manufacturing flow	01.08.2011
6	Ketonal 25 mg/g	gel	25 mg/g	ketoprofenum	LEK PHARMACEUTICALS D.D. – SLOVENIA/ LEK PHARMACEUTICALS D.D. - SLOVENIA	All batches were manufactured in accordance with the former terms of the Marketing Authorisation	Recall from storage, based on a Decision of the European Commission	Relabelling on an authorised manufacturing flow	01.08.2011
7	Rubifen 25 mg/g	gel	25 mg/g	ketoprofenum	ANTIBIOTICE SA – ROMANIA/ ANTIBIOTICE SA - ROMANIA	All batches were manufactured in accordance with the former terms of the Marketing Authorisation	Recall from storage, based on a Decision of the European Commission	Relabelling on an authorised manufacturing flow	01.08.2011

No. crt	Product recalled	Pharmaceutical form	Strength	INN	Manufacturer/ MAH	Batch	Grounds for recall	Action proposed	Recall date
8	Ketoprofen Fiterman 25 mg/g	gel	25 mg/g	ketoprofenum	FITERMAN PHARMA S.R.L. – ROMANIA/ FITERMAN PHARMA S.R.L. - ROMANIA	All batches were manufactured in accordance with the former terms of the Marketing Authorisation	Recall from storage, based on a Decision of the European Commission	Relabelling on an authorised manufacturing flow	01.08.2011
9	Ketoprofen Slavia 25 mg/g	gel	25 mg/g	ketoprofenum	SLAVIA PHARM S.R.L. – ROMANIA/ SLAVIA PHARM S.R.L. - ROMANIA	All batches were manufactured in accordance with the former terms of the Marketing Authorisation	Recall from storage, based on a Decision of the European Commission	Relabelling on an authorised manufacturing flow	01.08.2011
10	Ketoprofen Terapia 25 mg/g	gel	25 mg/g	ketoprofenum	TERAPIA SA – ROMANIA/ TERAPIA SA - ROMANIA	All batches were manufactured in accordance with the former terms of the Marketing Authorisation	Recall from storage, based on a Decision of the European Commission	Relabelling on an authorised manufacturing flow	01.08.2011
11	Ketoprofen Hyperion 25 mg/g	gel	25 mg/g	ketoprofenum	HYPERION S.A. – ROMANIA/ HYPERION S.A. - ROMANIA	All batches were manufactured in accordance with the former terms of the Marketing Authorisation	Recall from storage, based on a Decision of the European Commission	Relabelling on an authorised manufacturing flow	01.08.2011
12	Dianeal PD4 Glucose 1.36%, Dianeal PD4 Glucose 2.27%, Dianeal PD4 Glucose 3.86%	Peritoneal dialysis, solutions	1.36%, 2.27%, 3.86%	COMBINATIONS	BAXTER HEALTH CARE SA – IRELAND/ BAXTER HEALTH CARE SA - IRELAND	W1D26T0, W1E03T0, W1E12T0, W1D06T0, W1C18T0, W1D20T0	Voluntary recall performed by the MAH	Destruction	02.09.2011

Applications for marketing authorisation/marketing authorisation renewal submitted to the NAMMD during the 2nd quarter of 2011

During the 2nd quarter of 2011, 887 marketing authorisation/renewal applications for medicinal products corresponding to the following therapeutic groups have been received:

A01 – Stomatological preparations
A02 - Drugs for Acid Related Disorders
A03 - Drugs for Functional Gastrointestinal Disorders
A04 - Antiemetics and antinauseants
A05 - Bile and liver therapy
A06 - Laxatives
A07 - Antidiarrheals, Intestinal Antiinflammatory/Antiinfective Agents
A09 - Digestives, including enzymes
A10 - Drugs Used in Diabetes
A11 - Vitamins
B01 - Antithrombotic Agents
B05 - Blood Substitutes and Perfusion Solutions
C01 - Cardiac therapy
C02 - Antihypertensives
C03 - Diuretics
C04 - Peripheral Vasodilators
C05 - Vasoprotectives
C07 - Beta blocking agents
C08 - Calcium channel blockers
C09 - Agents Acting on the Renin–Angiotensin System
C10 - Lipid Modifying Agents
D01 - Antifungals for Dermatological Use
D06 – Antibiotics and chemotherapeutics for dermatological use
D07 - Corticosteroids for dermatological use
D10 – Anti-acne preparations
D11 – Other dermatological preparations
G01 – Gynecological antiinfectives and antiseptics
G02 – Other gynecologicals
G03 - Sex Hormones and Modulators of the Genital System
G04 - Urologicals
H01 - Pituitary and hypothalamic hormones
H02 - Corticosteroids for systemic use
H03 – Thyroid therapy
H05 - Calcium homeostasis

J01 - Antibacterials for systemic use
J02 – Antimycotics for systemic use
J04 - Antimycobacterials
J05 - Antivirals for systemic use
J06 - Immune sera and immunoglobulins
J07 - Vaccines
L01 - Antineoplastic Agents
L02 - Endocrine Therapy
L04 - Immunosuppressants
M01 - Anti–Inflammatory and Anti–Rheumatic Medicinal Products
M02 – Topical products for joint and muscular pains
M03 – Muscle relaxants
M05 - Drugs for treatment of bone diseases
N01 - Anaesthetics
N02 - Analgesics
N03 - Antiepileptics
N04 - Anti–Parkinson Drugs
N05 - Psycholeptics
N06 – Psychoanaleptics
N07 - Other Nervous System Drugs
P01 - Antiprotozoals
P02 - Anthelmintics
R01 - Nasal preparations
R02 - Throat Preparations
R03 - Drugs for Obstructive Airway Diseases
R05 - Cough and Cold Preparations
R06 - Antihistamines for Systemic Use
S01 - Ophthalmologicals
S02 - Otologicals
V01 - Allergens
V03 - All other therapeutic products
V07 – All other non-therapeutic products
V08 - Contrast media
XR - Homeopathic products

Medicinal products authorised for marketing by the NAMMD during the 2nd quarter of 2011

INN	Invented name	Pharmaceutical form	Strength	Manufacturer	Country	MA Number		
ACETYLCYSTEINUM	MUCOVIM 100 mg	powder for oral solution	100 mg	VIM SPECTRUM SRL	ROMANIA	3534	2011	01
ACIDUM ACETYLSALICYLICUM	SANTEPIRIN 75 mg	gastroresistant tablets	75mg	LAROPHARM S.R.L.	ROMANIA	3421	2011	01
ACIDUM ALENDRONICUM	BONASOL 70 mg	oral solution	70 mg	XEOLAS PHARMACEUTICALS LIMITED	IRELAND	3393	2011	04
ACIDUM RISEDRONICUM	RISEDRONAT BLUEFISH 35 mg	film-coated tablets	35 mg	BLUEFISH PHARMACEUTICALS AB	SWEDEN	3528	2011	02
ATORVASTATINUM	AMICOR 10 mg	film-coated tablets	10 mg	MEDOCHEMIE LTD.	CYPRUS	3506	2011	21
ATORVASTATINUM	AMICOR 20 mg	film-coated tablets	20 mg	MEDOCHEMIE LTD.	CYPRUS	3507	2011	21
ATORVASTATINUM	AMICOR 40 mg	film-coated tablets	40 mg	MEDOCHEMIE LTD.	CYPRUS	3508	2011	21
AZITHROMYCINUM	AZYTER 15 mg/g	eye drops, solution, single-dose container	15mg/g	LABORATOIRES THEA	FRANCE	3503	2011	01
BETAHISTINUM	VERTISAN 24 mg	tablets	24 mg	HENNIG ARZNEIMITTEL GMBH & CO.KG	GERMANY	3510	2011	08
BETAHISTINUM	EMPERIN 8 mg	tablets	8 mg	EGIS PHARMACEUTICALS PLC	HUNGARY	3537	2011	04
BETAHISTINUM	EMPERIN 16 mg	tablets	16 mg	EGIS PHARMACEUTICALS PLC	HUNGARY	3538	2011	07
BETAHISTINUM	EMPERIN 24 mg	tablets	24 mg	EGIS PHARMACEUTICALS PLC	HUNGARY	3539	2011	05
BETAMETHASONUM	BETADERM 1 mg/g	cream	1mg/g	EIPICO MED SRL	ROMANIA	3424	2011	01
BETAMETHASONUM	BETADERM 1 mg/g	ointment	1mg/g	EIPICO MED SRL	ROMANIA	3425	2011	01
BICALUTAMIDUM	CASODEX 150 mg	film-coated tablets	150mg	ASTRAZENECA UK LTD.	GREAT BRITAIN	3387	2011	01
BICALUTAMIDUM	BICALUTAMIDA KABI 50mg	film-coated tablets	50 mg	FRESENIUS KABI ONCOLOGY PLC	GREAT BRITAIN	3434	2011	08
BISOPROLOLUM	BISOPROLOL FUMARAT JENSON 1.25 mg	film-coated tablets	1.25 mg	JENSON PHARMACEUTICAL SERVICES LTD	GREAT BRITAIN	3436	2011	19
BISOPROLOLUM	BISOPROLOL FUMARAT JENSON 2.5 mg	film-coated tablets	2.5 mg	JENSON PHARMACEUTICAL SERVICES LTD	GREAT BRITAIN	3437	2011	19

BISOPROLOLUM	BISOPROLOL FUMARAT JENSOZ 5 mg	film-coated tablets	5 mg	JENSON PHARMACEUTICAL SERVICES LTD	GREAT BRITAIN	3438	2011	19
BISOPROLOLUM	BISOPROLOL FUMARAT JENSON 10 mg	film-coated tablets	10 mg	JENSON PHARMACEUTICAL SERVICES LTD	GREAT BRITAIN	3439	2011	19
CISPLATINUM	PLATOSIN 0.5 mg/ml	concentrate for solution for infusion	0.5 mg/ml	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	3377	2011	03
CISPLATINUM	PLATOSIN 1 mg/ml	concentrate for solution for infusion	1 mg/ml	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	3378	2011	03
CLOPIDOGRELUM	CLOPIDOGREL PFIZER 75 mg	film-coated tablets	75 mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	3428	2011	09
CLOPIDOGRELUM	CLOPIDOGREL TERAPIA 75 mg	film-coated tablets	75mg	TERAPIA S.A.	ROMANIA	3494	2011	06
COMBINATIONS	CERVUGID	ovules		IRCON SRL	ROMANIA	3435	2011	01
COMBINATIONS	SOLPADEINE 500 mg/8 mg/30 mg	effervescent tablets	500mg/ 8mg/30mg	GLAXOSMITHKLINE CONSUMER HEALTHCARE	GREAT BRITAIN	3400	2011	05
COMBINATIONS	DICLOGENOPT 1 mg/3 mg/ml	eye drops, solution	1 mg/ 3 mg/ml	ROMPHARM COMPANY S.R.L.	ROMANIA	3373	2011	01
COMBINATIONS	MOVIPREP	powder for oral solution		NORGINE LIMITED	GREAT BRITAIN	3379	2011	07
COMBINATIONS	GRIPOSTOP	granules for oral solution		SLAVIA PHARM S.R.L.	ROMANIA	3511	2011	02
COMBINATIONS (ATORVASTATINUM+ AMLODIPINUM)	DUPLECOR 10 mg/5 mg	film-coated tablets	10mg/5mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	3402	2011	01
COMBINATIONS (ATORVASTATINUM+ AMLODIPINUM)	DUPLECOR 10 mg/10 mg	film-coated tablets	10mg/ 10mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	3403	2011	01
COMBINATIONS (ATORVASTATINUM+ AMLODIPINUM)	DUPLECOR 20 mg/5 mg	film-coated tablets	20mg/5mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	3404	2011	01
COMBINATIONS (ATORVASTATINUM+ AMLODIPINUM)	DUPLECOR 20 mg/10 mg	film-coated tablets	20mg/ 10mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	3405	2011	01
COMBINATIONS (IRBERSARTANUM+ HYDROCHLOROTHIAZIDUM)	IRPREZIDE 150 mg/12.5 mg	film-coated tablets	150mg/ 12.5 mg	ACTAVIS GROUP PTC EHF	ICELAND	3458	2011	10
COMBINATIONS (IRBERSARTANUM+ HYDROCHLOROTHIAZIDUM)	IRPREZIDE 300 mg/12.5 mg	film-coated tablets	300mg/ 12.5 mg	ACTAVIS GROUP PTC EHF.	ICELAND	3459	2011	10
COMBINATIONS (IRBERSARTANUM+ HYDROCHLOROTHIAZIDUM)	IRPREZIDE 300 mg/25 mg	film-coated tablets	300 mg/ 25 mg	ACTAVIS GROUP PTC EHF.	IRELAND	3460	2011	10

COMBINATIONS (IRBERSARTANUM+ HYDROCHLOROTHIAZIDUM)	LARTOKAZ 150 mg/12.5mg	tablets	150mg/ 12.5mg	LABORATORIOS LICONSA, S.A.	SPAIN	3520	2011	04
COMBINATIONS (IRBERSARTANUM+ HYDROCHLOROTHIAZIDUM)	LARTOKAZ 300 mg/12.5mg	tablets	300mg/ 12.5mg	LABORATORIOS LICONSA, S.A.	SPAIN	3521	2011	04
COMBINATIONS (IRBERSARTANUM+ HYDROCHLOROTHIAZIDUM)	LARTOKAZ 300 mg/25mg	tablets	300mg/ 25mg	LABORATORIOS LICONSA, S.A.	SPAIN	3522	2011	04
COMBINATIONS (NAPROXEN + ESOMEPRAZOL)	VIMOVO 500 mg/20 mg	modified-release tablets	500 mg/ 20 mg	ASTRA ZENECA AB	SWEDEN	3440	2011	24
COMBINATIONS (PERINDOPRILUM+ INDAPAMIDUM)	PRINDEX PLUS 2 mg/0.625 mg	tablets	2 mg/ 0.625mg	GLENMARK PHARMACEUTICALS S.R.O.	CZECH REPUBLIC	3488	2011	03
COMBINATIONS (PERINDOPRILUM+ INDAPAMIDUM)	PRINDEX PLUS 4 mg/1.25mg	tablets	4 mg/ 1.25mg	GLENMARK PHARMACEUTICALS S.R.O.	CZECH REPUBLIC	3489	2011	03
COMBINATIONS (VALSARTANUM+ HYDROCHLOROTHIAZIDUM)	VALSARTAN/ HIDROCLOROTIAZIDA KRKA 80mg/12.5mg	film-coated tablets	80 mg/ 12.5 mg	KRKA, D.D., NOVO MESTO	SLOVENIA	3441	2011	12
COMBINATIONS (VALSARTANUM+ HYDROCHLOROTHIAZIDUM)	VALSARTAN/ HIDROCLOROTIAZIDA KRKA 160 mg/12.5 mg	film-coated tablets	160 mg/ 12.5 mg	KRKA, D.D., NOVO MESTO	SLOVENIA	3442	2011	12
COMBINATIONS (VALSARTANUM+ HYDROCHLOROTHIAZIDUM)	VALSARTAN/ HIDROCLOROTIAZIDA KRKA 160 mg/25 mg	film-coated tablets	160 mg/ 25 mg	KRKA, D.D., NOVO MESTO	SLOVENIA	3443	2011	12
COMBINATIONS (VALSARTANUM+ HYDROCHLOROTHIAZIDUM)	VALSARTAN/ HIDROCLOROTIAZIDA KRKA 320 mg/12.5 mg	film-coated tablets	320 mg/ 12.5 mg	KRKA, D.D., NOVO MESTO	SLOVENIA	3444	2011	14
COMBINATIONS (VALSARTANUM+ HYDROCHLOROTHIAZIDUM)	VALSARTAN/ HIDROCLOROTIAZIDA KRKA 320 mg/25 mg	film-coated tablets	320 mg/ 25 mg	KRKA, D.D., NOVO MESTO	SLOVENIA	3445	2011	14
DONEPEZILUM	DARIZOL 10 mg	orodispersible tablets	10mg	ROMASTRU TRADING S.R.L.	ROMANIA	3480	2011	09
DONEPEZILUM	DARIZOL 5 mg	orodispersible tablets	5mg	ROMASTRU TRADING S.R.L.	ROMANIA	3479	2011	09
DORZOLAMIDUM	OFTIDOR 20 mg/ml	eye drops, solution	20 mg/ml	JELFA S.A.	POLAND	3474	2011	03
ENALAPRILUM	ENALAPRIL SLAVIA 5 mg	tablets	5mg	SLAVIA PHARM S.R.L.	ROMANIA	3422	2011	01
ENALAPRILUM	ENALAPRIL SLAVIA 20 mg	tablets	20mg	SLAVIA PHARM S.R.L.	ROMANIA	3423	2011	01
EPIRUBICINUM	EPIRUBICINA KABI 2 mg/ml	solution for infusion/injection	2 mg/ml	FRESENIUS KABI ONCOLOGY PLC	GREAT BRITAIN	3394	2011	02

ESCITALOPRAMUM	DESPRA 10 mg	film-coated tablets	10 mg	GLENMARK PHARMACEUTICALS S.R.O.	CZECH REPUBLIC	3368	2011	24
ESCITALOPRAMUM	DESPRA 15 mg	film-coated tablets	15 mg	GLENMARK PHARMACEUTICALS S.R.O.	CZECH REPUBLIC	3369	2011	24
ESCITALOPRAMUM	DESPRA 20 mg	film-coated tablets	20 mg	GLENMARK PHARMACEUTICALS S.R.O.	CZECH REPUBLIC	3370	2011	28
ESOMEPRAZOLUM	ESOMEPRAZOL POLPHARMA 40 mg	solution for infusion/injection	40mg	PHARMACEUTICAL WORKS POLPHARMA SA	POLAND	3478	2011	02
ESOMEPRAZOLUM	S-GASTROL 20 mg	gastroresistant tablets	20mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	3501	2011	13
ESOMEPRAZOLUM	S-GASTROL 40 mg	gastroresistant tablets	40mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	3502	2011	13
ESTRIOLUM	OVESTIN 0.5 mg	ovules	0.5 mg	N. V. ORGANON	HOLLAND	3386	2011	01
EXEMESTANUM	EXEMESTAN INTANS 25 mg	film-coated tablets	25 mg	INTAS PHARMACEUTICALS LIMITED	GREAT BRITAIN	3383	2011	08
EXEMESTANUM	EXEMESTAN TERAPIA 25 mg	film-coated tablets	25mg	TERAPIA S.A.	ROMANIA	3516	2011	06
CLOTTING FACTOR VIII	OCTANATE 50 IU/ml	powder and solvent for solution for injection	50 IU/ml	OCTAPHARMA (IP) LTD.	GREAT BRITAIN	3371	2011	02
CLOTTING FACTOR VIII	OCTANATE 100 IU/ml	powder and solvent for solution for injection	100 IU/ml	OCTAPHARMA (IP) LTD.	GREAT BRITAIN	3372	2011	01
FUROSEMIDUM	FUROSEMID 20 mg/2 ml	solution for injection	10mg/ml	ZENTIVA SA	ROMANIA	3515	2011	02
GABAPENTINUM	GABAPENTIN AUROBINDO 100 mg	capsules	100 mg	AUROBINDO PHARMA LIMITED	GREAT BRITAIN	3411	2011	11
GABAPENTINUM	GABAPENTIN AUROBINDO 300 mg	capsules	300 mg	AUROBINDO PHARMA LIMITED	GREAT BRITAIN	3412	2011	11
GABAPENTINUM	GABAPENTIN AUROBINDO 400 mg	capsules	400 mg	AUROBINDO PHARMA LIMITED	GREAT BRITAIN	3413	2011	13
INDAPAMIDUM	INDAPAMIDA SR TORRENT 1.5 mg	prolonged-release tablets	1.5mg	TORRENT PHARMA S.R.L.	ROMANIA	3481	2011	01
LACTULOSUM	LACTULOZA FRESENIUS KABI 670 mg/ml	oral solution	670mg/ml	FRESENIUS KABI AUSTRIA GMBH	AUSTRIA	3382	2011	34
LAMOTRIGINUM	ARVIND 25 mg	tablets	25 mg	BELUPO S.R.O.	SLOVACIA	3512	2011	01
LAMOTRIGINUM	ARVIND 50 mg	tablets	50 mg	BELUPO S.R.O.	SLOVENIA	3513	2011	01
LAMOTRIGINUM	ARVIND 100 mg	tablets	100 mg	BELUPO S.R.O.	SLOVENIA	3514	2011	01
LATANOPROSTUM	LATANOPROST STADA HF 50 micrograms/ml	eye drops, solution	50 micro-grams/ml	STADA HEMOFARM S.R.L.	ROMANIA	3466	2011	03

LETROZOLUM	LETROZOL ATB 2.5 mg	film-coated tablets	2.5mg	ANTIBIOTICE S.A.	ROMANIA	3495	2011	03
LETROZOLUM	LETROZOL MYLAN 2.5 mg	film-coated tablets	2.5mg	GENERICS (UK) LIMITED	GREAT BRITAIN	3505	2011	34
LEVOFLOXACINUM	FLERADAY 250 mg	film-coated tablets	250 mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	3365	2011	04
LEVOFLOXACINUM	FLERADAY 500 mg	film-coated tablets	500 mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	3366	2011	03
MELOXICAMUM	TROSICAM 15 mg	orodispersible tablets	15mg	ALPEX PHARMA (UK) LIMITED	GREAT BRITAIN	3471	2011	03
MELOXICAMUM	TROSICAM 7.5 mg	orodispersible tablets	7.5mg	ALPEX PHARMA (UK) LIMITED	GREAT BRITAIN	3470	2011	03
MEROPENEMUM	LODITER 500 mg	powder for solution for injection/infusion	500mg	TERAPIA S.A.	ROMANIA	3472	2011	02
MEROPENEMUM	LODITER 1000 mg	powder for solution for injection/infusion	1000mg	TERAPIA S.A.	ROMANIA	3473	2011	02
METFORMINUM	SERDENIS 500 mg	film-coated tablets	500mg	ROMASTRU TRADING S.R.L.	ROMANIA	3491	2011	04
METFORMINUM	SERDENIS 850 mg	film-coated tablets	850mg	ROMASTRU TRADING S.R.L.	ROMANIA	3492	2011	04
METFORMINUM	SERDENIS 1000 mg	film-coated tablets	1000mg	ROMASTRU TRADING S.R.L.	ROMANIA	3493	2011	04
MONTELUKASTUM	MONLUCARE 10 mg	film-coated tablets	10 mg	M.R. PHARMA GMBH	GERMANY	3376	2011	23
MONTELUKASTUM	MONLUCARE 4 mg	chewable tablets	4 mg	M.R. PHARMA GMBH	GERMANY	3374	2011	22
MONTELUKASTUM	MONKASTA 4 mg	chewable tablets	4mg	KRKA D.D., NOVO MESTO	SLOVENIA	3414	2011	15
MONTELUKASTUM	MONKASTA 5 mg	chewable tablets	5mg	KRKA D.D., NOVO MESTO	SLOVENIA	3415	2011	15
MONTELUKASTUM	MONKASTA 10 mg	chewable tablets	10mg	KRKA D.D., NOVO MESTO	SLOVENIA	3416	2011	15
MONTELUKASTUM	METIPREGO 5 mg	chewable tablets	5mg	SIGILLATA LIMITED	GREAT BRITAIN	3420	2011	11
MONTELUKASTUM	METIPREGO 4 mg	chewable tablets	4mg	SIGILLATA LIMITED	MAREA BRITANIE	3419	2011	11
MONTELUKASTUM	MONTELUKAST HELM 4mg	chewable tablets	4mg	HELM AG	GERMANY	3517	2011	07
MONTELUKASTUM	MONTELUKAST HELM 5mg	chewable tablets	5mg	HELM AG	GERMANY	3518	2011	07
MONTELUKASTUM	MONTELUKAST HELM 10mg	film-coated tablets	10mg	HELM AG	GERMANY	3519	2011	07
MYCOPHENOLATUM MOFETILUM	MICOFENOLAT MOFETIL DR. REDDY'S 250 mg	capsules	250 mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	3367	2011	02

NATRII FLUORIDUM (18F)	IASOFLU 2 GBq/ml	solution for injection	2 GBq/ml	IASON GMBH	AUSTRIA	3426	2011	02
NOMEGESTROLUM	LUTENYL 5 mg	tablets	5mg	LABORATOIRE THERAMEX	MONACO	3401	2011	02
OLANZAPINUM	OLANZAPINA POLPHARMA 5 mg	orodispersible tablets	5 mg	PHARMACEUTICAL WORKS POLPHARMA SA.	POLAND	3461	2011	03
OLANZAPINUM	OLANZAPINA POLPHARMA 10 mg	orodispersible tablets	10 mg	PHARMACEUTICAL WORKS POLPHARMA S.A.	POLAND	3462	2011	03
OLANZAPINUM	OLANZAPINA POLPHARMA 15 mg	orodispersible tablets	15 mg	PHARMACEUTICAL WORKS POLPHARMA S.A.	POLAND	3463	2011	03
OLANZAPINUM	OLANZAPINA POLPHARMA 20 mg	orodispersible tablets	20 mg	PHARMACEUTICAL WORKS POLPHARMA S.A.	POLAND	3464	2011	03
ONDANSETRONUM	ZOFRAN 4 mg	film-coated tablets	4mg	GLAXO WELLCOME UK LIMITED	GREAT BRITAIN	3467	2011	06
ONDANSETRONUM	ZOFRAN 8 mg	film-coated tablets	8mg	GLAXO WELLCOME UK LIMITED	GREAT BRITAIN	3468	2011	06
ONDANSETRONUM	ZOFRAN 8mg/4ml	solution for injection	8mg/4ml	GLAXO WELLCOME UK LIMITED	GREAT BRITAIN	3430	2011	01
ONDANSETRONUM	ZOFRAN 4mg/2ml	solution for injection	4mg/2ml	GLAXO WELLCOME UK LIMITED	GREAT BRITAIN	3429	2011	01
OXALIPLATINUM	OXALIPLATIN KABI 5 mg/ml	concentrate for solution for infusion	5mg/ml	FRESENIUS KABI ONCOLOGY PLC.	GREAT BRITAIN	3392	2011	04
PACLITAXELUM	EGILITAX 6 mg/ml	concentrate for solution for infusion	6mg/ml	EGIS PHARMACEUTICALS PLC.	HUNGARY	3504	2011	04
PACLITAXELUM	PACLITAXEL SCHLUTTIG 6 mg/ml	concentrate for solution for infusion	6 mg/ml	PHARMA RESOURCES DR. SCHLUTTIG GMBH	GERMANY	3509	2011	04
PANTOPRAZOLUM	PANTOPRAZOL PHARMASCOPE 20mg	tablets	20mg	PHARMASCOPE LIMITED	IRELAND	3531	2011	9
PANTOPRAZOLUM	PANTOPRAZOL PHARMASCOPE 40mg	tablets	40mg	PHARMASCOPE LIMITED	IRELAND	3532	2011	09
PARACETAMOLUM	PARACETAMOL 1000 mg	effervescent tablets	1000 mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	3465	2011	08
PARACETAMOLUM	BIOFLU PENTRU COPII 120 mg/5 ml	syrup	120mg/ 5ml	BIOFARM S.A.	ROMANIA	3469	2011	02
PAROXETINUM	PAROXETIN ATB 20 mg	film-coated tablets	20 mg	ANTIBIOTICE SA	ROMANIA	3533	2011	01
PRAMIPEXOLUM	PRAMIPEXOL DR. REDDY`S 0.18 mg	tablets	0.18 mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	3389	2011	03
PRAMIPEXOLUM	PRAMIPEXOL DR. REDDY`S 0.35 mg	tablets	0.35 mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	3390	2011	03

PRAMIPEXOLUM	PRAMIPEXOL DR. REDDY`S 0.7 mg	tablets	0.7 mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	3391	2011	03
PRAMIPEXOLUM	MEROXIMER 0.088 mg	tablets	0.088 mg	ACTAVIS GROUP PTC EHF	ICELAND	3523	2011	04
PRAMIPEXOLUM	MEROXIMER 0.18 mg	tablets	0.18 mg	ACTAVIS GROUP PTC EHF	ICELAND	3524	2011	04
PRAMIPEXOLUM	MEROXIMER 0.35 mg	tablets	0.35	ACTAVIS GROUP PTC EHF	ICELAND	3525	2011	04
PRAMIPEXOLUM	MEROXIMER 0.7 mg	tablets	0.7 mg	ACTAVIS GROUP PTC EHF	ICELAND	3526	2011	04
PRAMIPEXOLUM	MEROXIMER 1.1 mg	tablets	1.1 mg	ACTAVIS GROUP PTC EHF	ICELAND	3527	2011	04
PROPRANOLOLUM	PROPRANOLOL EEL 10 mg	tablets	10 mg	BIO EEL S.R.L.	ROMANIA	3385	2011	01
QUETIAPINUM	KINPRIDE 25 mg	film-coated tablets	25 mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	3395	2011	06
QUETIAPINUM	KINPRIDE 100 mg	film-coated tablets	100 mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	3396	2011	06
QUETIAPINUM	KINPRIDE 150 mg	film-coated tablets	150 mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	3397	2011	06
QUETIAPINUM	KINPRIDE 200 mg	film-coated tablets	200 mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	3398	2011	06
QUETIAPINUM	KINPRIDE 300 mg	film-coated tablets	300 mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	3399	2011	06
REPAGLINIDUM	RENEOS 0.5 mg	tablets	0.5 mg	ZENTIVA K.S.	CZECH REPUBLIC	3447	2011	11
REPAGLINIDUM	RENEOS 1 mg	tablets	1 mg	ZENTIVA K.S.	CZECH REPUBLIC	3448	2011	11
REPAGLINIDUM	RENEOS 2 mg	tablets	2 mg	ZENTIVA K.S.	CZECH REPUBLIC	3449	2011	11
REPAGLINIDUM	ADEREGL 0.5 mg	tablets	0.5mg	SPECIFAR S.A.	GRECIA	3475	2011	06
REPAGLINIDUM	ADEREGL 1 mg	tablets	1mg	SPECIFAR S.A.	GRECIA	3476	2011	06
REPAGLINIDUM	ADEREGL 2 mg	tablets	2mg	SPECIFAR S.A.	GRECIA	3477	2011	06
RISPERIDONUM	TORENDO Q TAB 3 mg	orodispersible tablets	3 mg	KRKA, D.D., NOVO MESTO	SLOVENIA	3535	2011	02
RISPERIDONUM	TORENDO Q TAB 4 mg	orodispersible tablets	4 mg	KRKA, D.D., NOVO MESTO	SLOVENIA	3536	2011	02
RIVASTIGMINUM	RIVASTIGMINA DR. REDDY`S 1.5 mg	capsules	1.5 mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	3450	2011	10
RIVASTIGMINUM	RIVASTIGMINA DR. REDDY`S 3 mg	capsules	3 mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	3451	2011	10
RIVASTIGMINUM	RIVASTIGMINA DR. REDDY`S 4.5 mg	capsules	4.5 mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	3452	2011	10
RIVASTIGMINUM	RIVASTIGMINA DR. REDDY`S 6 mg	capsules	6 mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	3453	2011	10
SILDENAFILUM	SILDENAFIL ACCORD 25mg	film-coated tablets	25 mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	3431	2011	04

SILDENAFILUM	SILDENAFIL ACCORD 50mg	film-coated tablets	50 mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	3432	2011	04
SILDENAFILUM	SILDENAFIL ACCORD 100mg	film-coated tablets	100 mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	3433	2011	04
SILDENAFILUM	AMFIDOR 25 mg	film-coated tablets	25mg	EGIS PHARMACEUTICALS PLC	HUNGARY	3482	2011	01
SILDENAFILUM	AMFIDOR 50 mg	film-coated tablets	50mg	EGIS PHARMACEUTICALS PLC	HUNGARY	3483	2011	03
SILDENAFILUM	AMFIDOR 100 mg	film-coated tablets	100mg	EGIS PHARMACEUTICALS PLC	HUNGARY	3484	2011	03
SILDENAFILUM	SILDENAFIL HEMOFARM 25 mg	film-coated tablets	25mg	STADA HEMOFARM S.R.L.	ROMANIA	3485	2011	06
SILDENAFILUM	SILDENAFIL HEMOFARM 50 mg	film-coated tablets	50mg	STADA HEMOFARM S.R.L.	ROMANIA	3486	2011	06
SILDENAFILUM	SILDENAFIL HEMOFARM 100 mg	film-coated tablets	100mg	STADA HEMOFARM S.R.L.	ROMANIA	3487	2011	06
SOLIFENACINUM SUCCINATE	ZEVESIN 5 mg	film-coated tablets	5 mg	ZENTIVA K.S.	CZECH REPUBLIC	3380	2011	03
SOLIFENACINUM SUCCINATE	ZEVESIN 10 mg	film-coated tablets	10 mg	ZENTIVA K.S.	CZECH REPUBLIC	3381	2011	03
TAMSULOSINUM	TANYZ 0.4 mg	prolonged-release tablets	0.4mg	KRKA D.D., NOVO MESTO	SLOVENIA	3406	2011	30
TETRACYCLINUM	TETRACICLINA ATB 250mg	capsules	250mg	ANTIBIOTICE S.A.	ROMANIA	3490	2011	02
TIANEPTINUM	LYXIT 12.5 mg	film-coated tablets	12.5 mg	LABORATORIOS LICONSA, S.A.	SPAIN	3446	2011	14
TOPIRAMATUM	TOPIRAMAT TEVA 50 mg	film-coated tablets	50mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	3408	2011	11
TOPIRAMATUM	TOPIRAMAT TEVA 25 mg	film-coated tablets	25mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	3407	2011	10
TOPIRAMATUM	TOPIRAMAT TEVA 100 mg	film-coated tablets	100mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	3409	2011	11
TOPIRAMATUM	TOPIRAMAT TEVA 200 mg	film-coated tablets	200mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	3410	2011	11
TOPOTECAMUM	TOPOTECAN KABI 4 mg	powder for concentrate for solution for infusion	4 mg	FRESENIUS KABI ONCOLOGY PLC	GREAT BRITAIN	3427	2011	04
TRAMADOLUM	NOAX 50 mg	orodispersible tablets	50mg	CSC PHARMACEUTICALS HANDELS GMBH	AUSTRIA	3500	2011	04
TRIMETAZIDINUM	APSTAR 35 mg	prolonged-release tablets	35mg	GLENMARK PHARMACEUTICALS S.R.O.	CZECH REPUBLIC	3417	2011	24
TRIMETAZIDINUM	TRIMETAZIDINA MYLAN 35 mg	prolonged-release tablets	35mg	MYLAN S.A.S.	FRANCE	3418	2011	24

VACCIN BCG	BCG - medac	powder and solvent for suspension for intravesical use		MEDAC GESELLSCAFT FUR KLINISCHE SPEZIALPRÄPARATE	GERMANY	3457	2011	08
MENINGOCOCCAL POLYSACCHARIDE VACCINE, GROUP C	NEISVAC-C 0.5 ml	solution for injection in pre-filled syringe	0.5ml	BAXTER AG	AUSTRIA	3384	2011	03
VALSARTANUM	VALSARGAMMA 40 mg	film-coated tablets	40mg	WORWAG PHARMA GMBH & CO. KG	GERMANY	3496	2011	10
VALSARTANUM	VALSARGAMMA 80 mg	film-coated tablets	80mg	WORWAG PHARMA GMBH & CO. KG	GERMANY	3497	2011	10
VALSARTANUM	VALSARGAMMA 160 mg	film-coated tablets	160mg	WORWAG PHARMA GMBH & CO. KG	GERMANY	3498	2011	10
VALSARTANUM	VALSARGAMMA 320 mg	film-coated tablets	320mg	WORWAG PHARMA GMBH & CO. KG	GERMANY	3499	2011	10
VANCOMYCINUM	VANCOMICINA KABI 500 mg	powder for concentrate for solution for infusion	500mg	FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	3529	2011	01
VANCOMYCINUM	VANCOMICINA KABI 1000 mg	powder for concentrate for solution for infusion	1000mg	FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	3530	2011	01
VENLAFAXINUM	EFECTIN EP 37.5 mg	prolonged-release capsules	37.5 mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	3454	2011	06
VENLAFAXINUM	EFECTIN EP 75 mg	prolonged-release capsules	75 mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	3455	2011	06
VENLAFAXINUM	EFECTIN EP 150 mg	prolonged-release capsules	150 mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	3456	2011	06

EMA newly centrally authorised medicinal products for which the European Commission has issued decisions during the 2nd quarter of 2011

INN	Trade name	Pharmaceutical form	Strength	Manufacturer	Country	MA Number		
EXENATIDUM	BYDUREON 2 mg	prolonged-release powder and solvent for suspension for injection	2 mg	ELI LILLY NEDERLAND BV	HOLLAND	696	2011	02