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National Agency for Medicines and Medical Devices

Decisions of the NAMMD Scientific Council

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DECISIONS OF THE NAMMD SCIENTIFIC COUNCIL

DECISION
No. 1/22.02.2011

on accreditation of Good Clinical Practice training national providers

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), set up 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 22.02.2011, in accordance with Article 12(5) of the Romanian Government Decision No. 734/2010 on establishment, organisation and operation of the National Agency for Medicines and Medical Devices, as amended, and following resumed debate in the ordinary meeting of 03.05.2011, adopts the following

DECISION

Art. 1. – In view of enforcing the provisions of Art. 13 of the Order of the Minister of Public Health No. 904/2006 and of Art. 37 and 39 of Scientific Council Decision No. 39/2006, related to the qualification and training of investigators, as well as to the knowledge of and compliance with Good Clinical Practice (GCP) rules and legal provisions in this field, the investigator(s)/subinvestigator(s) should attest the graduation of the GCP course conducted by an European body in the field of the medicinal product for human use or of a course whose provider is accredited by a competent authority of an EU Member State or of another accredited European body.

Art. 2. – The national provider of the GCP training course, hereinafter referred to as *the provider*, is a public/private medical educational institution (state/private institutions of higher education in medicine and pharmacy, universities/faculties of medicine and pharmacy, respectively), a consortium or a legal entity whose scope includes medical education activities.

Art. 3. - (1) National providers are accredited by the NAMMD according to the criteria and documents mentioned in Annexes 1 and 2, which are integral part of this decision.

(2) The staff involved in the conduct of GCP training activities should include a course coordinator, in the teaching staff of a state/private higher education medical and pharmaceutical institution and a team whose members are graduates of a state/private higher education medical and pharmaceutical institution and have graduated from a GCP course.

(3) In view of accreditation, the applicants shall submit a standard application to the NAMMD, as shown in template in Annex 3, which is integral part of this decision.

(4) the "Certificate of accreditation as Good Clinical Practice training national providers" as shown in Annex 4 shall represent the proof for accreditation.

Art. 4. – (1) The proof of GCP training graduation is provided by a "Certificate of Good Clinical Practice training graduation", issued by a training provider as included on the "List of NAMMD accredited GCP training providers".

(2) The mandatory template for the accreditation certificate is shown in Annex 5, which is integral part of this decision.

(3) The graduation certificate is granted following graduation from the final assessment of the gathered knowledge referring to Good Clinical Practice rules and to legal regulations in the field, qualifying either as "well" or "very well", or with a minimum of 8.

(4) The required final assessment is performed by means of a questionnaire consisting of at least 20 questions.

(5) The graduation certificate is valid for no longer than 3 years.

Art. 5. – (1) The provider accreditation certificate, granted by the NAMMD, is valid for 5 years.

(2) Reaccreditation is performed in the same manner as the accreditation, based on an application submitted to the NAMMD, 6 months prior to the Accreditation Certificate expiry date.

Art. 6. – This decision applies to all applications for approval of clinical trials submitted to the NAMMD as of 1 January 2012.

Art. 7. – All certificates issued previously by GCP training national providers not accredited by the NAMMD will no longer be valid as of 1 January 2012.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Acad. Prof. Dr. Leonida Gherasim

ANNEX 1

The criteria for accreditation as GCP training national provider are as follows:

a) a presentation by higher education medical and pharmaceutical institutions, namely by state/private medical/pharmaceutical universities/faculties of the accreditation performed by the competent authority, i.e. by the Ministry of Education (ME);
b) the inclusion of medical education activities within the scope of legal entities, other than medical and pharmaceutical schools, or of the consortium;
c) the proof of qualification and professional/teaching competence of the staff assigned to perform GCP related training activities;

Documents needed in view of accreditation:

a) the articles of incorporation and the final judicial decision for legal entities, other than state/private higher education medical and pharmaceutical institutions;
b) the proof of accreditation issued by the Ministry of Education for state/private higher education medical and pharmaceutical institutions;
c) the documents attesting the qualification and professional/teaching competence of the staff assigned by the provider to perform GCP related training activities:
   - A CV containing the following attachments:
   - for the training coordinator:
     - a graduate diploma granted by a state/private higher education medical and pharmaceutical institution;
     - the certification of academic and professional-scientific degrees.
   - for team members:
     - a graduate diploma granted by a state/private higher education medical and pharmaceutical institution;
     - a graduation certificate from a GCP course.
d) The mandatory minimum training curriculum, in accordance with Annex 2;
e) The course timetable showing:
   - the minimum 6-hour training day;
   - at least 2-day training duration;
   - inclusion of all sections of the mandatory minimum curriculum.
f) The proof of the ability to ensure the space and material equipment related conditions required for in view of an efficient performance of training.

ANNEX 2

THE MANDATORY MINIMUM TRAINING CURRICULUM

1. The Romanian legislation concerning Good Clinical Practice.

- Order of the Minister of Public Health No. 903/2006 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;

- Order of the Minister of Public Health No. 904/2006 on approval of rules relating to the implementation of Good Clinical Practice in the conduct of clinical trials on medicinal products for human use;

- 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;

- Decision of the Scientific Council of the National Medicines Agency No. 39/2006 on approval of the Guideline on Good Clinical Practice (GCP Guideline);

- Decision of the Scientific Council of the National Medicines Agency No. 26/2007 on approval of Guideline on the collection, verification and presentation of adverse reaction reports arising from clinical trials on medicinal products for human use

- Decision of the Scientific Council of the National Medicines Agency No. 42/2006 on approval of Guidelines on classification of inspection findings in verification of Good Clinical Practice compliance;

- Decision of the Scientific Council of the National Medicines Agency No. 23/2010 on approval of the Guideline on Good Manufacturing Practice (GMP Guideline) for medicinal products for human use.

2. Regulatory bodies in the field of clinical trials in Romania

3. General considerations about clinical trials

4. **Ethical principles in conduct of clinical trials. The role of national and institutional Ethics Committees. The collection and recording of the informed consent of the subjects**

5. **Clinical trial team: organisation, responsibilities**

6. **Standard Operating Procedures in conduct of clinical trials at the investigation sites: design, SOP compliance, recording**

7. **Essential documents related to the clinical trial: design, archiving**

8. **Recruitment of patients, preparation of source documents, completion of case report forms**

9. **Handling of IMPs at investigation sites**
   Documentation related to IMP handling, randomisation/decoding, storage at IMP investigation sites

10. **Reporting of adverse reactions, serious adverse reactions, suspected unexpected serious adverse reactions occurring in clinical trials**

11. **GCP inspections**

ANNEX 3

APPLICATION FORM
FOR ACCREDITATION GCP TRAINING NATIONAL PROVIDERS

1. Name and contact information of the provider
Name .....
Address .....
.....
Telephone number. ..... Fax number.....

2. Training coordinator (please specify the academic and professional-scientific degree)
Surname ..... First name .....
Title .....
Address .....
.....
Telephone number ..... Fax number .....
E-mail .....

3. Contact person assigned by the provider
Surname ..... First name .....
Title .....
Address .....
.....
Telephone number ..... Fax number .....
E-mail .....

4. Experience in the organisation of GCP training (please specify GCP training sessions organised in the past three years, if any)
.....

5. Staff assigned by the provider to perform GCP training activities (please specify the professional degree)
.....

Date: Signature:

ANNEX 4

NAMMD logo

Accreditation certificate
of Good Clinical Practice training national providers

This is to certify that {name of the university/faculty of medicine or pharmacy/ legal entity/ consortium} meets the accreditation conditions as Good Clinical Practice training provider of courses in, based on the available documents.

The NAMMD shall be informed on any further change in documents submitted for accreditation.

This certificate is valid 5 years as of its date of issue.

PRESIDENT,

No. ….. of {DD/MM/YYYY}

ANNEX 5

{Header of the Provider}

Provider of GCP courses accredited by the NAMMD

GRADUATION CERTIFICATE
GOOD CLINICAL PRACTICE TRAINING

This is to certify that Mr./Mrs. {Surname and First name}

has graduated from the GCP training conducted at {site} during/on ....., grading 8/9/10/well/very in the final assessment.

Graduation certificate No. ……

Date of issue …..

Training coordinator,
{Surname, First name}

{Academic and professional-scientific degree}

DECISION

No. 4/22.02.2011

on approval of basic criteria for NAMMD inspectors' acceptance of free sample provision and approval of the annex to Scientific Council Decision No. 3/23.03.2010 on approval of Implementation rules on provision of free samples of medicinal products for human use authorised for marketing in Romania, approved through Scientific Council Decision No. 17/27.11.2009

The Scientific Council (SC) 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 22.02.2011, in accordance with Article 12(5) of Government Decision No. 734/2010 on establishment, organisation and operation of the National Agency for Medicines and Medical Devices, as amended, following another discussion held during the ordinary meeting of the Scientific Council of 3.05.2011, adopts the following

DECISION

Art. 1 – The basic criteria for NAMMD inspectors' acceptance of free sample provision of medicinal products for human use authorised for marketing in Romania are approved as provided in Annex 1, which is integral part of this decision.

Art. 2 – Amendment is approved of the Annex to Scientific Council Decision No. 3/23.03.2010 on approval of Implementation rules on provision of free samples of medicinal products for human use authorised for marketing in Romania, endorsed through Scientific Council Decision No. 17/27.11.2009 as presented in Annex 2, which is integral part of this decision.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Acad. Prof. Dr. Leonida Gherasim

ANNEX 1

Acceptance criteria for NAMMD inspectors concerning provision of free samples of medicinal products for human use

In accordance with provisions of Law No. 95/2006 on healthcare reform, as amended, NAMMD inspectors may under exceptional circumstances accept provision of free samples meant to support prescribers in becoming acquainted with a certain medicinal product, i.e. gain experience in its use and for emergency use.

The criteria according to which NAMMD inspectors accept supply of free samples of medicinal products for human use are as follows:

1. Medicinal product with a unique International Non-proprietary Name (INN) in Romania/the European Union.

2. Medicinal product having a new INN combination in Romania/the European Union.

3. Advanced therapy medicinal products, orphan medicinal products.

4. Original medicinal product authorised for marketing through national/centralised procedure, marketed in Romania for no longer than 3 years as of its inclusion in the list of subsidised/free medicinal products.

5. Generic medicinal products authorised for marketing through national/centralised/MRP/DCP procedure, marketed in Romania for longer than 1 year after inclusion in the list of subsidised/free medicinal products.

6. Medicinal products for which the NAMMD has approved a new therapeutic indication for the same INN, if justified; in this case, the provision of free samples is allowed for no longer than 3 years as of the approval of the variation to Marketing Authorisation terms.

In support of the application for approval to provide free samples, the Marketing Authorisation Holder must prove actual introduction of the authorised medicinal product on the Romanian pharmaceutical market, as well as inform the NAMMD about the date of the respective medicinal product inclusion in the list of subsidised/free medicinal products.

ANNEX 2

Supplementation to Annex to SCD No. 3/23.03.2010 on approval of Implementation rules on provision of free samples of medicinal products for human use authorised for marketing in Romania, approved through SCD No. 17/27.11.2009

The Implementation rules on provision of free samples of medicinal products for human use authorised for marketing in Romania, approved through SCD No. 17/27.11.2009, as mentioned in the Annex to SCD No. 3/23.03.2010 is supplemented with the following article:

«**Art. 10. –** In accordance with provisions of Art. 807 of Law No. 95/2006, "free samples shall be provided on an exceptional basis only to persons qualified to prescribe/distribute" medicinal products; the number of free samples provided shall be in accordance with the posology approved in the Summary of Product Characteristics, but limited to treatment of no more than 10 patients/year/physician for each medicinal product for human use.»

DECISION

No. 5/22.02.2011

on approval of mandatory monthly reporting of marketing in Romania, i.e. of medicinal product for human use sales 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 22.02.2011, in accordance with Article 12(5) of Government Decision No. 734/2010 on establishment, organisation and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following

DECISION

Art. 1. – Mandatory monthly reporting to the NAMMD by wholesale distributors of trade operations with medicinal product for human use in their own portfolio is hereby approved.

The end purpose is to ensure medicinal product traceability over the entire chain from manufacture and/or distribution to the level of community pharmacy, hospital pharmacy, drugstore, check accuracy of prescription and dispensation of on-prescription or over-the-counter medicinal products, identify counterfeit medicines and prevent their penetration of the distribution chain as well as to combat duplicate medicinal product outlets and respectively warrant prompt recall of noncompliant medicinal product batches or in circumstances of health emergency.

Art. 2. – The report will be submitted to the NAMMD – the Pharmaceutical Inspection department, and will consist of the following:

- List of medicinal products for human use entered released from the inventory of authorised importers/wholesalers according to Order of the Ministry of Health No. 312/2009 and Order of the Ministry of Public Health No. 1964/2008, respectively, on the various types of import/wholesale distribution, including the amounts, manufacturing batches, medicinal

product provider(s) and beneficiary(ies), respectively, as well as identification data of fiscal accompanying documents (number, batch, invoicing date and/or advice of delivery).

- List of medicinal products for human use released from the inventory of Romanian manufacturers authorised in line with Minister of Health Order no. 312/2009, including the amounts, manufacturing batches, medicinal product provider(s) and beneficiary(ies), respectively, as well as identification data of fiscal accompanying documents (number, batch, invoicing date and/or advice of delivery)

Art. 3. – (1) The report is performed electronically and accompanied by a sworn statement of the company legal representative conduction reporting on the accuracy of data submitted.

(2) It is mandatory that the first report contain a mention of the Romanian distributor's/importer's/manufacturer's stock on reporting.

(3) The reporting format as well as the e-mail address for submission will be posted on the NAMMD website before 01.05.2011.

Art. 4. – This decision comes into force on 01.05.2011.

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

Acad. Prof. Dr. Leonida Gherasim

DECISION

No. 8/05.04.2011

on approval of amendment of the Regulation on organisation and operation of the Scientific Council of the National Agency for Medicines and Medical Devices

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 05.04.2011, in accordance with Article 12(5) of Government Decision No. 734/2010 on establishment, organisation and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following

DECISION

Sole article - Amendment of the Regulation for the organisation and operation of the Scientific Council of the National Agency for Medicines and Medical Devices is approved as follows:

Chapter 2. – A new paragraph is added under Organisation and operation, Article 9, reading as follows:

"(3) A juridical approval is to be mentioned on all draft and final decisions of the Scientific Council".

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Acad. Prof. Dr. Leonida Gherasim

DECISION

No. 10/05.04.2011

on approval of Regulations for handling of proposed "umbrella" trade names and other trade names for medicinal products for human use, as related to food supplements and products for cosmetic use

Following resumed debate in the ordinary meeting of 03.05.2011, 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 05.04.2011, in accordance with Article 12(5) of Government Decision No. 734/2010 on establishment, organisation and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following

DECISION

Sole article. - The Regulations for handling of proposed "umbrella" trade names and other trade names for medicinal products for human use, as related to food supplements and products for cosmetic use are approved according to the annex which is integral part of this decision.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Acad. Prof. Dr. Leonida Gherasim

ANNEX

Regulations for handling of proposed "umbrella" trade names and other trade names for medicinal products for human use, as related to food supplements and products for cosmetic use

Art. 1. – Considering the new issues that have emerged on the market of medicinal products for human use, in relation to food supplements and products for cosmetic use, related to "umbrella" trade names or even to the same trade names for medicinal products for human use and for food supplements/products for cosmetic use, the National Agency for Medicines and Medical Devices hereby issues the following regulations, based on the legal provisions operating the difference between medicinal products and products of the aforementioned type:

- Law No. 95/2006, Title XVII – The medicinal product, transposing Directive 2001/83/EC as amended;
- Directive 2002/46/EC relating to food supplements;
- Directive 76/768/EEC relating to products for cosmetic use;
- Order of the Minister of Public Health No. 1453/2005 on approval of the Guidebook regarding "umbrella" trade names;
- Scientific Council Decision No. 2/2008 on approval of the Guideline on the trade name of medicinal products for human use;
- Scientific Council Decision No. 14/2010 on approval of National Medicines Agency policy concerning resolution of proposed "umbrella" trade names and other trade names.

Art. 2. – The following shall not be accepted as regards medicinal products for human use:

1) The proposal of an "umbrella" trade name, in case the respective "umbrella" segment can also be found in the trade name of a food supplement, marketed by the same legal entity.

2) Preservation of an approved "umbrella" trade name as of placement on the market by the same legal entity, of a food supplement/product for cosmetic use containing the respective "umbrella" segment in its trade name.

In this case, within 30 days as of start of the marketing of the food product/product for cosmetic use, the Marketing Authorisation Holder is required to submit an application for variation to marketing authorisation terms for the respective medicinal products, related to the change of their trade name.

Otherwise, sanctions shall be enforced as mentioned under Art. 836 (i) of Law No. 95/2006 on healthcare reform, Title XVII – The medicinal product, as amended.

3) The proposal of the same trade name as that of a food supplement/product for cosmetic use, placed on the market by the same legal entity.

4) Preservation of the same approved trade name as of placement on the market by the same legal entity, of a food supplement/product for cosmetic use with the same trade name.

In this case, within 30 days as of start of the marketing of the food product/product for cosmetic use, the Marketing Authorisation Holder is required to submit an application for variation to marketing authorisation terms for the respective medicinal products, related to the change of their trade name.

Otherwise, sanctions shall be enforced as mentioned under Art. 836 (i) of Law No. 95/2006 on healthcare reform, Title XVII – The medicinal product, as amended.

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

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 05.04.2011, in accordance with Article 12(5) of Government Decision No. 734/2010 on establishment, organisation and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following

DECISION

Sole article – Amendment of SCD No. 31/01.11.2010 is approved as follows:

Article 5 is amended and will read as follows:

"Each advertising material submitted for NAMMD assessment, following which an approval has been granted will include the following specification "approval for advertising no. …./date ….".

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Acad. Prof. Dr. Leonida Gherasim

DECISION

No. 12/05.04.2011

on approval of new Romanian Standard Terms for certain pharmaceutical forms, primary packaging, closure systems and administration devices, administration routes and methods in line with European Pharmacopoeia approved terms

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 05.04.2011, in accordance with Article 12(5) of Government Decision No. 734/2010 on establishment, organisation and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following

DECISION

Sole article – The New Romanian Standard Terms for certain pharmaceutical forms, primary packaging, closure systems and administration devices, administration routes and methods in line with European Pharmacopoeia approved terms are approved, according to the annex which is integral part of this decision.

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

Acad. Prof. Dr. Leonida Gherasim

ANNEX

New Romanian Standard Terms

Part 1: Pharmaceutical forms

Preparate bucofaringiene *Oromucosal preparations*			
Normal terms		No.[1] Ph. Eur. monograph	**Notes**
Romanian	**English**		
Spray bucofaringian, soluţie	*Oromucosal spray, solution*	No. 1807	Multidose liquid preparation, solution, for oromucosal use. To be administered by spraying into the oral cavity or on a certain side of the oral cavity/throat. Included in a spraying pump container or pressurised vial, with or without a dosing valve. Sublingual sprays are excluded.
Spray bucofaringian, suspensie	*Oromucosal spray, suspension*	No. 1807	Multidose liquid preparation, suspension, for oromucosal use. To be administered by spraying into the oral cavity or on a certain side of the oral cavity/throat. Included in a spraying pump container or pressurised vial, with or without a dosing valve. Sublingual sprays are excluded.
Spray bucofaringian, emulsie	*Oromucosal spray, emulsion*	No. 1807	Multidose liquid preparation, emulsion, for oromucosal use. To be administered by spraying into the oral cavity or on a certain side of the oral cavity/throat. Included in a spraying pump container or pressurised vial, with or without a dosing valve. Sublingual sprays are excluded.
Unguent bucofaringian	*Oromucosal ointment*	No. 1807	Semisolid preparation, ointment, for oromucosal use. To be applied inside the oral cavity or on a certain side of the throat for systemic effect.
Spray transdermic, soluţie	*Transdermal spray, solution*	No. 927 523	Multidose preparation, solution, included in a pressurised vial containing a spraying valve or a spraying pump container. This solution is for transdermal use.
Gel transdermic	*Transdermal gel*	No. 132	Single-dose or multidose semi-solid preparation for transdermal use. The active substance(s) is/are dissolved/ dispersed into a hydrophilic/hydrophobic base.

Part 2: Routes of administration

Căi şi moduri de administrare *Routes and method of administration*		
Romanian	**English**	**Notes**
Infiltrare	*Infiltration*	Method of administration, usually via injection.
Implantare	*Implantation*	Administration of an implant into a live tissue.
Bucală	*Buccal use*	Administration of a medicinal product in the oral cavity (between the cheek and the gum), for systemic effect.
Intra-cartilaginoasă	*Intra-cartilaginous use*	Administration of a medicinal product in a cartilage.
Intracisternală	*Intracisternal use*	Administration of a medicinal product into the cerebellomedullary cistern (Cisterna Magna).
Periosoasă	*Periosseous use*	Administration of a medicinal product on/around a bone.

Part 3: Containers

Ambalaje primare, sisteme de închidere şi dispozitive de administrare *Containers, closures and administration devices*		
Romanian	**English**	**Notes**
Recipient multidoză cu pompă	*Multidose container with pump*	Multidose container with pump. The following are excluded: metering pump, spray pump and multidose container with pump to prevent air penetration.
Injector fără ac	*Needle-free injector*	Device for injection of a medicinal product, usually a liquid one, needle-free, through the skin barrier, by exertion of high pressure.
Recipient cu bilă (roll-on)	*Roll-on container*	A container, usually a vial, with a roll-on device (roll-on).

DECISION

No. 13/05.04.2011

on approval of Guidelines on consultations with target patient groups for the package leaflet and documentation on criteria for certification and inspection by the National Agency for Medicines and Medical Devices of operators performing consultations with target patient groups

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 05.04.2011, in accordance with Article 12(5) of Government Decision No. 734/2010 on establishment, organisation and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following

DECISION

Art. 1. –The Guidelines on consultations with target patient groups for the package leaflet, according to Annex No. 1 are approved as well as the Checklist and recommendations on assessment of consultations with target patient groups, according to AnnexNo.2 which is integral part of this decision.

Art. 2. –The criteria for certification of operators performing consultations with target patient groups according to Annex No. 3 are approved as well as the Form for request of an Accreditation Certificate according to Annex No. 4, which is integral part of this decision.

Art. 3. – On this decision coming into force, SCD No.6/23.03.2010, as amended, shall be repealed.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Acad. Prof. Dr. Leonida Gherasim

ANNEX 1

Guideline
on the consultations with target patient groups for the package leaflet

Chapter I
Introduction and legal basis

Art. 1. – (1) The European legislation which lies at the core of consultations performed with target patient groups for the package leaflet is regulated through Guideline EC/2009 on the consultations with target patient groups for the package leaflet in accordance with Art. 59(3) and 61(1) of Directive 2001/83/EC, amended through Directive 2004/27/EC.

(2) The national legislation in this field consists of Law No. 95/2006 on healthcare reform, Title XVII – The medicinal product, as amended, as well as by Scientific Council Decisions (SCDs) of the National Agency for Medicines and Medical Devices (NAMMD) No. 12/2007, 21/2008 and 8/2009 – translations and adaptations of the European Guideline on the readability of the labelling and package leaflet of medicinal products for human use and by SCD No. 22/2008 – translation and adaptation of the CMDh Guideline on consultation with target patient groups without the need for a full test - recommendations for bridging.

Art. 2. – (1) This Guideline is not legally binding.

(2) Other approaches are acceptable provided they have a sufficiently solid foundation.

(3) In case different approaches are preferred concerning the methods of consultation with target patient groups, prior consultation with the NAMMD is suggested.

Chapter II
Purpose for consultations with target patient groups

Art. 3. – (1) The purpose of such consultations with target patient groups is to ensure and demonstrate the legibility, clarity and usability of the leaflet.

(2) The information provided should be accessible and intelligible for users, so that they may use the respective medicinal product in accordance with adequate and safety conditions.

(3) This Guideline provides information concerning the performance of consultations with target patient groups by compiling and presenting the chapters to be included in the study report.

Chapter III
Implementation and procedure

Art. 4. – (1) These recommendations are applicable to applications for marketing authorisation/marketing authorisation renewal through national procedure.

(2) Companies are encouraged to apply these recommendations as soon as possible for all medicinal products.

(3) As regards applications for marketing authorisation/marketing authorisation renewal through national procedure submitted prior to November 2008, outcomes of consultations with patient target groups are to be submitted within 1 year as of their marketing authorisation coming into force.

(4) For applications for marketing authorisation/marketing authorisation renewal through national procedure submitted after November 2008, submission of outcomes of consultations with patient target groups are mandatory. They are submitted either at the same time with the application for marketing authorisation/marketing authorisation renewal or during the marketing authorisation/marketing authorisation renewal procedure.

(5) As regards authorised medicinal products for which applications for safety variation have been submitted, outcomes of consultations with patient target groups are to be submitted within 1 year as of their approval when an application for type II variation is to be submitted, including outcomes of consultations with patient target groups.

(6) For all other authorised medicinal products, irrespective of the time of their authorisation/renewal, an application should be submitted by 1 September 2011 for approval of a type II variation to marketing authorisation terms, including the outcomes of consultations with target patient groups.

(7) Marketing authorisation holders and companies performing consultations with patient target groups on their behalf may be certified and periodically inspected by the National Agency for Medicines and Medical Devices (NAMMD) based on documentation approved by the NAMMD President and validated by the Scientific Council.

(8) There are an unlimited number of certifications for both marketing authorisation holders and companies performing consultation with target patient groups.

(9) Tests concerning consultation with target patient groups can be performed by any internal or external operator complying with rules and requirements of national legislation governing this area.

(10) If the report on the outcomes of consultation with target groups is carried out by a certified NAMMD operator, the Agency considers that the procedures have been followed, which allows expedited assessment and

approval.

(11) For reports containing the outcomes of consultation with target groups performed by a non-NAMMD certified operator, the entire assessment procedure will also require verification by the operator meeting the criteria for technical and professional capacity as well as capacities related to assurance of the NAMMD instated quality system.

Art. 5. – Information on the consultations with target patient groups is to be included in the authorisation/marketing authorisation renewal dossier submitted to the NAMMD.

Art. 6. – (1) The report on consultations with target patient groups is to be submitted, containing a declaration of the company undertaking the test concerning compliance with Art. 59(3) and 61(1) of Directive 2001/83/EC, as amended through Directive 2004/27/EC.

(2) This declaration should be dated and signed by the person(s) undertaking the report, the quality assurance responsible person as well as by the representative of the marketing authorisation holder/sponsor.

Presentation of the medicinal product

Art. 7. – (1) Identification data related to consultation should be presented (the international non-proprietary name of the medicinal product, the marketing authorisation holder/sponsor).

(2) The Pharmacotherapeutic group and the therapeutic indications for the concerned medicinal products should be mentioned.

Chapter IV
Features of the package leaflet mock-up

Art. 8. – (1) The object of consultations with target patient groups is the final version of the package leaflet as approved of/agreed on by the NAMMD or a colour mock-up closely replicating the NAMMD approved /agreed specimen package leaflet at a 1:1 scale.

(2) Features such as font size and type of the leaflet/mock-up layout used for testing and the employed font type, paragraph lines, contrast, alignment, titles, colours, the design and layout of the information should be described.

Chapter V
Presentation of the team

Art. 9. – (1) Testing of the package leaflet may be performed by the marketing authorisation holder or by a certified company, on its behalf.

(2) In the consultation with target patient groups' dossier, this company should submit documents attesting the professional training and qualification of the persons who have performed this study.

Art. 10. – (1) The report on the consultation with target patient groups should mention the name of the company who has undertaken the testing, the names and qualifications of the persons who have undertaken the testing throughout each of its phases: design, testing proper, verification, coordination.

(2) The testing should be undertaken by an experienced interviewer with good listening, observational and interviewing skills.

(3) Ideally, to enable direct transfer of learning, the person writing the package leaflet should occasionally accompany the interviewer during the testing process.

Chapter VI
Brief summary on the manner of testing

Art. 11. – A brief summary on the manner of testing should be presented, containing the following: the team and its experts, premises, premises and location city, testing period, brief presentation of the working methodology.

Art. 12. – The success criterion applicable to these consultations with target patient groups should be presented, as for instance: A satisfactory test outcome for the method is when the information requested within the package leaflet can be found by 90% of test participants, of whom 90% can show that they understand it.

Chapter VII
Identification of the aspects characterising the medicinal product

Art. 13. – (1) Definition and identification of the general and specific issues characterising the medicinal product information are required.

(2) This stage is mandatory in the questionnaire drawing up process.

(3) See below an example of a table aiming at identification and presentation of issues characteristic of the product information, as well as the mandatory and optional number of questions.

		Route of administration			
		Oral/Parenteral		Topical use	
Field	Section of the leaflet	Number of questions		Number of questions	
		mandatory	optional	mandatory	optional
Area of use	Indications	1		1	
	Contraindications	1	+1	1	+1
	Warnings	1	+1	1	+1
	Special groups	1	+1	1	+1
Adverse events	Adverse reactions	2	+1	1	+1
	Interactions	1	+1	1	+1
Dosage	Doses	1	+1	1	
	Application	1		2	+1
	Overdose	1	+1	1	
	Duration of use	1		1	
Handling	Shelf-life	1		1	
	Storage				

Chapter VIII
Identification of package leaflet key-messages

Art. 14. - (1) The leaflet key-messages should be identified and presented.

(2) Following the identification of the leaflet key-messages, appropriate questions should be established for each message.

Chapter IX
Drawing up the questionnaire

Art. 15. - (1) The questionnaire should contain both specific and general questions, i.e. technical questions, as well as questions concerning the positive/negative feedback provided by the subjects on the leaflet form, as well as on the design and layout of the information.

(2) This questionnaire should cover a balance of general and specific issues; e.g. a general issue may be what to do when a dose is missed, while a specific issue may relate to a side effect occurring particularly with the medicinal product concerned.

(3) Questions referring to all important and difficult issues are to be included, especially related to specific compliance and safety issues, and strict assessment criteria will be used (which are to be standardised).

(4) Questions will reflect all specific issues related to safe use and efficacy, as well as related to compliance of the tested medicinal product.

(5) Avoidance during user opinion testing of serious safety issues caused by the medicinal product results in invalidation of the testing.

Art. 16. - (1) The number of questions employed should be kept to a minimum; normally, 12 – 15 questions will suffice.

(2) If the medicinal product belongs to one of the following categories:

a) chemotherapy and antibacterial medicinal products
b) medicinal products with complex instructions for use
c) medicinal products raising concerns about safe management
d) fixed combinations, minimum 18 questions are needed to entirely cover safety and compliance issues.

Art. 17. – Each question should point to the place of the related answer in the leaflet.

Art. 18. – There should be a standard number of questions for each section of the leaflet, depending on the route of administration, complexity of information e.g. indications, contraindications, warnings, special patient groups, interactions, adverse reactions, doses, route of administration, overdose, duration of treatment, shelf life/storage conditions.

Art. 19. – (1) Questions should be formulated in terms other than those used in the leaflet, in order to avoid the "copy-paste" type of answers, solely based on the identification of word groups.

(2) Questions should appear randomly (not in the order shown in the leaflet).

Art. 20. – Questions involving self-assessment should be avoided (e.g. "According to you, is paragraph X accurate?").

Art. 21. – Questions involving a long list of answers should be avoided (e.g. "Which are the adverse reactions to this medicinal product?").

Art. 22. – There should be about 4 standardised questions related to the layout and design of the information – syntax, font types, fonts used, blanks, contrast, alignment, titles, use of colours.

Art. 23. – Questions for each key-message should be argumented.

Art. 24. – The annex should include the leaflet template throughout all its phases.

Chapter X
Method and methodology

X.1. Presentation of the method

Art. 25. - The method chosen for performing user opinion testing should be presented.

X.2. Drawing up of the research plan

Art. 26. – (1) The research plan should be established and presented: stages and number of subjects.

(2) A pilot phase should be organised including about 3 – 6 participants to check functionality of the questions in practice.

(3) At least two subsequent meetings should be organised, including minimum 10 persons each, to assess outcomes of the first meeting and

introduction into the package leaflet of necessary changes.

(4) Tests should be repeated until satisfactory data have been collected from a group of at least 10 participants.

(5) A final testing on another minimum 10 participants should be performed to assess compliance with success criteria (i.e. minimum 20 participants in all).

X.3. Selection and presentation of the testing group

Art. 27. - (1) The recruiting methodology should be thoroughly defined.

(2) The selection of the target group should be justified. The target group selected must be representative for both the population of Romania and the medicinal product whose package leaflet is to be tested.

(3) A small number of participants is sufficient, i.e. minimum 23 participants.

(4) Insurance of a variety of person typologies is required, as regards age, gender, level of education, experience in medicinal product use, present level of knowledge related to the condition, who are able to envision the need to use the medicinal product.

(5) In case the medicinal product is for a rare disease, the leaflet should be as much as possible experiencing/having experienced that condition.

Art. 28. – The fact should be taken into account that all users may benefit from the information usable by the least capable person.

Art. 29. – When selecting the group of subjects to be interviewed, emphasis should be placed upon the following inclusion criteria: low education and training level, and therefore inferior text comprehension abilities to ensure an adequately established testing group.

Art. 30. When selecting the appropriate participants, the following special target groups of persons should not be overlooked:

(a) youth and elders – especially if the medicinal product is particularly relevant for the age group they belong to;

(b) new users/persons who do not commonly use medicinal products, especially for testing the information on new medicinal products likely to be used by a wide variety of persons (e.g. analgesics or antihistaminics);

(c) caregivers may represent the adequate target group (e.g. for medicinal products for Alzheimer’s disease, antipsychotics and paediatric medicinal products);

(d) persons not involved in documentation work;

(e) persons who encounter difficulties when reading the information.

Art. 31. – Persons who have taken part in the performance of such consultations should not be recruited more frequently than once every 6

months to participate in a different testing.

Art. 32. – The presentation of the groups of subjects should be done in detail, according to demographic data (gender, age, profession, training level) with the help of charts or graphics.

X.4. Indications and recommendations for interviewers and tested subjects

Art. 33. – (1) The team undertaking the interview is recommended to perform an audio and video recording of the interview.

(2) These recordings should be kept for 3 years, should they be requested by the NAMMD to ascertain their reliability.

Art. 34. – Additional recommendations for the interviewer and the person in charge of recording the outcomes:

(a) to allow participants a 15-minute timeframe in order to read the leaflet.

(b) to use a written set of questions as reference material.

(c) to ask questions verbally.

(d) to adopt a conversational interviewing manner, allowing for many opportunities to interact with the participant.

(e) to record, assess/grade the answers to the questions and to observe each participant's individual manner of handling the leaflet and of searching the information.

(f) to take into account these notes which may turn into valuable information on improvements to be made to the structure of the package leaflet.

Art. 35. – (1) Tested subjects are required to become familiar with the leaflet information in the same way they would prior to taking the medicinal product.

(2) If the time allocated by the interviewer is not sufficient, participants should be encouraged to require longer time.

Art. 36. – (1) Test participants should be required to indicate the location in the leaflet of the information related to a certain issue.

(2) The interviewer should grade the ease of finding the information taking the following into account: the subject has immediately located the information, has referred to the leaflet, has found it necessary to turn the leaflet over, how many times the question needed repeating, the subject looked lost or became confused.

(3) Note will also be taken of interviewer's help to the participant in finding the text passages.

Art. 37. – (1) Once the information found, participants should be required not to repeat it textually, but to convey it in their own words, if needed.

(2) The test should not be directed toward the subjects' memory.

(3) The subjects interviewed should not be allowed to read from the leaflet.

(4) Only the degree of understanding of the information should be graded (e.g. 1 = no answer, 2 = wrong answer, 3 = incomplete answer, 4 = ambiguous answer, 5 = complete and correct answer).

(5) It should be clarified whether the problems encountered have to do with text comprehension or the layout of the information.

Art. 38. – As regards the design and layout of the leaflet information, a grading scale may be used (e.g. ranging from 0 to 10) or a positive/negative assessment.

X.5. Testing time

Art. 39. – (1) On test design, care should be exerted so that the test does not exceed 45 minutes, in order to avoid participants' getting tired.

(2) In the event that it is subjects who request longer time, the interviewer should grant it.

X.6. Manner of data recording

Art. 40. – (1) The manner of data recording should be accurately described.

(2) The manner of converting verbal assessments into scalar responses should be clearly specified.

(3) An Outcome Record Sheet should be provided for raw data as well as for notes, verbal comments and other types of nonverbal feedback.

X.7. Standardisation

Art. 41. – (1) Pre-established standards for interviewing contribute to attaining the adequate level of information quality.

(2) This also contributes to establishing credibility of such testing, confirming its accuracy of design, record and reporting.

(3) Setting high quality standards throughout the entire process is important.

Art. 42. – Three levels of focus will be established during the standardisation process: finding of information, understanding of information and use of information.

Art. 43. – (1) To find information, tested subjects will be required to indicate the location in the leaflet of the information related to a certain issue.

(2) The ease in finding information should be graded and recorded according to a response scale containing at least 4 response alternatives.

(3) Each of these response alternatives should be defined and presented as such.

(4) A correct and efficient record of subject responses can only be done in the context of an accurate definition and presentation.

Art. 44. – (1) To assess their level of understanding, subjects will be required to respond in their own words to questions related to certain

information included in the leaflet.

(2) Standardisation of this coordinate requires a response scale containing at least 2 response alternatives.

(3) Each of these should be defined and presented in detail.

(4) Any degree of difficulty in understanding information should be entered into the Outcome Record Sheet.

(5) Interviewer's help to the subject should also be taken into consideration.

Art. 45. – (1) Interviewed subjects will be required to imagine themselves in a particular situation to assess their capacity to use the information.

(2) Subsequently, a question should be asked concerning a piece of information in a certain leaflet section related to the respective context.

(3) Information usability can actually be translated into the subject's capacity to answer a question following a few cognitive steps based on the leaflet information.

(4) Standardisation of this coordinate require a response scale containing at least 2 response alternatives.

Art. 46. – For questions related to each tested subject's personal appreciation of the layout and design of the information – syntax, font, spaces, contrast, alignment, titles, use of colours, as well as questions related to the layout and design of the information – a grading scale should be drawn up ranging from 1 to 10 (where 1 means totally unsatisfactory and 10 means very satisfactory) or a scale of at least 6 grades recording personal responses and encoding the subjects' feedback in raw marks.

X.8. Data analysis (Statistics)

Art. 47. – (1) The chapter on descriptive statistics should present participants' individual raw scores.

(2) A graphic or tabulated presentation of the raw values obtained should be presented.

Art. 48. – (1) Outcomes should be reviewed for each round performed.

(2) Presentations may be undertaken taking into account various variables analysed: gender, age, level of education.

(3) Each subject's comments on the tested leaflet mock-up should be attached.

Art. 49. – The chapter related to quality statistics should include a description of the manner for encoding raw information, their review and their tabulated, graphic presentation.

Art. 50. – (1) A statistic analysis is required by subject, by question and by stage.

(2) Emphasis should be placed upon the subjects and questions not meeting the success criterion (90%).

Art. 51. – (1) Following the statistic analysis of questions not meeting the success criterion, corrections will be brought to the leaflet mock-up, by replacing terms, rephrasing or other methods meant to improve its degree of understanding.

(2) Subjects' suggestions or comments should also be taken into account in that case.

(3) The comments and feedback received from the subject concerned should also be presented, therefore motivating subsequent changes to the leaflet mock-up.

Art. 52. – It will be clearly specified which subject comments have been ignored, as well as the grounds for their disregard.

Art. 53. – Following the meeting of the success criterion, a comparative analysis should be undertaken between the previous stages and the most recent stage which has fulfilled the success criterion.

Chapter XI
Conclusions

Art. 54. – The conclusions should:

a) ensure the readability and clarity of the package leaflet information
a) ensure proper use of the leaflet by potential beneficiaries
b) forward the intelligibility and utility of information
c) assess the ability to understand the leaflet
d) be compliant with the statistical data recorded
e) be presented in accurate, concise, well-structured manner.

Art. 55. – (1) *ANNEX 2* "Checklist and recommendations for assessment of user consultation" is part of this Guideline and will be used as a scale for assessment of consultations with patient target groups. The points in the list are in line with chronological steps. Critical deficiencies in one of the criteria lead to discontinuation of the review for the following points.

(2) *ANNEX 2* becomes a reference document attached to the Assessment Report of medicinal products for marketing authorisation/marketing authorisation renewal.

ANNEX 2

Checklist and recommendations for assessment of user consultation

1. Information on the medicinal product

Medicinal product name:	{(Invented) Name, strength, pharmaceutical form}
Name and address of the applicant:	
Name of the company having performed user consultation:	
Name of the persons having undertaken this research, and their qualification:	
Type of application for marketing authorisation/ marketing authorisation renewal:	{Generic, well-established medical use etc.}
Active substance:	
Pharmacotherapeutic group (ATC code):	
Therapeutic indication(s):	
Orphan medicinal product designation:	☐ yes ☐ no

- Report submitted ☐ yes ☐ no

- Justification for not submitting the report for assessment:
  - ☐ extensions of the same route of administration
  - ☐ reference to already existing consultations for the same medicinal product class
  - ☐ reference to already existing consultations on the same safety issues
  - ☐ other justifications _____

- Is the justification valid concerning lack of submission of report for assessment?

Grounds *[assessor's opinion on acceptance or rejection of the justification – assessment of justification]*

_____
_

2. Characteristics of package leaflet mock-up

The features of the package leaflet mock-up are satisfactorily described.

☐ yes ☐ no

Further comments/details:

_____

Recommendations
Description and analysis of each of the following items in characterisation of the leaflet mock-up will be assessed: size and font, spaces, contrast, alignment, titles, colours used, design and layout of the information.

3. Presentation of the team

The people undertaking testing are presented and the documents attesting their training are made available.

☐ yes ☐ no

Further comments/details:

_____

4. Identification of the sections describing the medicinal product

General and specific sections describing the medicinal product are identified.

☐ yes ☐ no

Further comments/details:

_____

5. Identification of the package leaflet key-messages

Package leaflet key-messages are properly identified and described.

☐ yes ☐ no

Further comments/details:

_____

6. Drawing up of the questionnaire

6.1. The X number of questions is sufficient. ☐ yes ☐ no

6.2 Questions cover important (safety) issues as compared with the leaflet in question ☐ yes ☐ no

Further comments/details:

_____

Recommendations

The following issues should be taken into account when drawing up the questionnaire*:*

- *The applicant has identified the key-messages for safe use.*

- *Questions cover key-messages, as well as the following areas:*

  => General impressions on the leaflet;

  => The "diagnosis" section of the leaflet (in other terms, questions aiming to assess participants' ability to find information effortlessly and rapidly under each section of the leaflet, as well as their ability to understand them properly; the questionnaire should mainly focus on safe and proper use of the medicinal product and on participant's understanding ensuring safe use – approach of the essential safety messages should be ensured);

  => Aspects such as the information manner of design and layout.

- *The number of questions is sufficient? (too few or too many, e.g. 12- 15)*

- *The location in the leaflet of each answer to each question is specified.*

- *Questions refer to "phrasing issues"? Interviewees readily understand the text they are reading.*

- *Do questions allow for open answers or do they imply multiple choice answers? Interviewees should not be provided ready-made answers, therefore increasing the possibility for positive results. Questions should be open, in a random order to allow observation of how patients use the leaflet and should not suggest the answer. Questions requiring self-assessment should be avoided (e.g. According to you, is paragraph X clear?). Likewise, questions involving a long list of answers should be avoided (e.g. "Which are the adverse events to this medicinal product?").*

7. Method and methodology

7.1**.** The method and the research plan are adequately described?

☐ yes ☐ no

Further comments/details:

7.2. Number of consultation rounds, the pilot phase included ____

Further comments/details:

_____

Recommendations

When assessing the methodology, the following issues should be taken into account*:*

- *Does the test rely on various rounds? (at least 2 rounds are required, involving at least 10 participants each: Since this is an iterative process, several rounds may be required to meet the success criteria; the test may be preceded by a pilot phase (involving 3 to 6 persons) ensuring the legibility of the questionnaire and avoiding major omissions.*
  For example, a satisfactory result would be the identification in the leaflet of the information required by 90% of adults with basic education, of whom 90% are able to prove the understanding of the information, which means that at least 81% of the participants can answer correctly to each question, without any exception.

- *There have been modification stages between the consultation rounds for maximum simplification of text comprehension?*
- *Interviewers have used live scenarios or demonstrations (e.g. to increase the efficiency of the text, if needed).*

7.3. The population interviewed is acceptable. ☐ yes ☐ no

Further comments/details:

_____

Recommendations

The following issues should be taken into consideration when assessing the recruitment methods:

- *The recruitment method is thoroughly defined? Is it clear that attention has been paid to the composition of the group consulted? (e.g. as regards variables such as gender, age, education, experience in the use of the medicinal products, current level of knowledge on the condition etc.)*
- *How was the consulted group recruited? Are the recruited persons new users or patients, parents or caregivers?*
- *Is it clear how many persons have been involved in the consultation/rounds of consultation?*
- *Is the respective number of persons sufficient? (The leaflet should be tested in at least 2 rounds involving at least 10 participants each)*
- *Is the group of subjects presented taking demographic data into account?*

7.4. The interview has been taken in a well organised/structured manner?

☐ yes ☐ no

Further comments/details:

Recommendations

While assessing interview aspects, the following issues should be taken into account:

- *Are there precise instructions for the instructor(s)? (e.g. instructions on the manner to obtain more information from user consultation, whether help should be provided or not etc.)*
- *Interviewers allow the interviewed to specify the location of the information in the leaflet.*
- *The interviewed are required to answer in their own words, not to rely on their memory?*

7.5. The time allocated for answering is acceptable. ☐ yes ☐ no

7.6. The duration of the interview is acceptable. ☐ yes ☐ no

Further comments/details:

_____

Recommendations

The following should be considered when assessing time-related issues*:*
- Is it clear how long the consultation has lasted?
- The time allocated to interviewees for reading the questions and answering has been adequate. How long has the interview lasted? [The test should be designed in such a way as not to take longer than 45 minutes, in order to avoid participants getting tired]

7.7. The information is well recorded and documented? ☐ yes ☐ no

Further comments/details:

_____

Recommendations

When assessing data processing, the following issues should be considered:
- Is it clear how the information is recorded?
- Is the information satisfactorily recorded?
- Was the information satisfactorily processed? (e.g. is it clear the manner in which the verbal assessments have been transformed into scalar responses?)
- Was the assessor given the leaflets used during the (various rounds of the) consultation?
- Are the reviews of the leaflet explained/justified? Moreover, is it clear which comments of the participants have been ignored and why?

7.8. Quantitative assessment of the answers is acceptable. ☐ yes ☐ no

Further comments/details:

_____

Recommendations

When assessing the response scoring system, the following issues should be considered:
- How are the responses coded? (e.g. 1= no answer, 2=wrong answer, 3=incomplete answer, 4=ambiguous answer, 5=complete and correct answer)

7.9. Qualitative assessment of the answers is acceptable. ☐ yes ☐ no

_____

7.10. The assessment methodology meets a minimum of essential conditions. ☐ yes ☐ no

Further comments/details:

_____

Recommendations

When evaluating the assessment system, the following issues should be considered:
- *Assessment is based on a checklist covering the following three main issues:*
The interviewee has been able:
⇒ ***to find*** *the information (e.g. the interviewee can readily find dosage related information)*
⇒ ***to understand*** *the information (e.g. the interviewee can express in his/her own words what the correct dosage and instructions for use are.)*
⇒ ***to use*** *the information (e.g. "imagine yourself in situation X and Y occurs, what are you supposed to do?")*

7.11. The general principles in the Guideline for leaflet readability are followed regarding the design of information ☐ yes ☐ no

7.12. The language includes descriptions accessible to the patient ☐ yes ☐ no

7.13. Easy text orientation. ☐ yes ☐ no

7.14. The use of diagrams is acceptable. ☐ yes ☐ no

Further comments/details:
_____

Recommendations

The following issues should be considered:
- *Does the report make a clear distinction between quantity and quality outcomes?*
- *Do the interviewees consider that the design and layout of the leaflet information are satisfactory?*

Special attention should be given to the following issues:

- *Syntax (simple language, short sentences, use of markers)*
- *Font characteristics (font size, italic/underlined characters, lower-cases/capitals)*
- *Layout of the information (spaces, blank spaces, contrast, left alignment, text presentation in columns)*
- *Titles (consistency in location, highlight)*
- *Use of colours (adequate, obvious contrast)*

- *Pictograms should be included in consultations, as it is well known that patients may find them confusing.*
- *Interviewees have difficulty in properly locating and using (if needed) information in the leaflet.*

8. Data analysis

8.1. The methodology is compliant with the recommendations in the Guideline on data analysis and interpretation. ☐ yes ☐ no

8.2. Every question, without exception, meets the 90% correct answers criterion for finding the information. ☐ yes ☐ no

8.3. Every question, without exception, meets the 81% correct answers criterion for understanding the information. ☐ yes ☐ no

8.4. Has there been any weak point identified in the leaflet? ☐ yes ☐ no

8.5. Such weak points have been adequately addressed. ☐ yes ☐ no

Further comments/details:

_____

Recommendations

When assessing diagnosis quality/assessment, the following issues should be taken into account:

- *Outcomes are as much as possible connected to actual text passages.*
- *Is there any attempt to explain the fact that readers' difficulties have arisen from certain characteristics of these passages (e.g. something was hard to find because of an ill chosen title, or a paragraph could not be clearly understood because of a poorly phrased negation, or the specific information could not be correctly applied because of certain unclear terms)?*
- *Has a second revision of the text been performed?*
- *Have the weak points of the first round been clearly identified and properly addressed? (e.g. questions with a lower score have resulted in changes to the leaflet => introduction of stylistic modifications to facilitate the leaflet understanding process or elimination of redundant/confusing information)*
- *Is it clear which paragraphs have been revised, in which manner and following which notes from the first round?*
- *Similarly, is it clear what information has been ignored when performing the revision and why?*
- *Have the changes been tested and proven to facilitate understanding?*

9. CONCLUSIONS

9.1. The main objectives of user consultation have been reached? ☐ yes ☐ no
9.2. The applicant's conclusion is correct. ☐ yes ☐ no
9.3. Overall impression on methodology ☐ positive ☐ negative
9.4. Overall impression on the leaflet ☐ positive ☐ negative

CONCLUSIONS _____

Recommendations

Under this section, an overall opinion concerning the user consultation performed should be provided, related to users' opinion and the easiness of understanding, as well as to the leaflet general quality.

The following issues should be taken into account when drawing the conclusions:

1. Reflection of the outcomes of user consultation to make sure that the leaflet meets patients' demands and allows them to use the medicinal product under efficacy and safety condition.

2. Assessment of the degree of understanding the leaflet

3. Identification of issues concerning the readability and utility of the information

4. Provision of potential changes to the leaflet for its better understanding.

- Does the report clearly emphasize the foundations of the specific conclusions on consultation outcomes?

- Is there a match between conclusions and outcomes, considering actual outcomes, are conclusions too favourable, "too good to be true"?

- The conclusions are clear, concise and well organised?

- Moreover, have all revisions of the text incorporated the recommendations and conclusions?

ANNEX 3

DOCUMENTATION
on criteria for accreditation and inspection by operators of the National Agency for Medicines and Medical Devices carrying out consultation with patient target groups for the package leaflet

1. Purpose

This documentation establishes the general criteria to be met by operators undertaking mandatory patient target groups consultation for development of the package leaflet.

The National Agency for Medicines and Medical Devices grants, renews or withdraws accreditation granted to operators by applying the rules and criteria laid down in this documentation.

2. Applicability

The criteria in this documentation apply to applicants seeking accreditation to conduct target group consultation activities necessary to develop the package leaflet and approval by the National Agency for Medicines and Medical Devices.
In order to comply with quality standards for consultation activities, accreditation of operators by the National Agency for Medicines and Medical Devices is optional and the number of operators who may request and obtain accreditation is unlimited.

Grant of accreditation by the National Agency for Medicines and Medical Devices provides accredited operators no warranted contract by beneficiaries of consultation services for which accreditation has been granted.

Contracting and conduct of consulting activities are the sole responsibility of accredited operators and beneficiaries.

Consultation activities are carried out by accredited operators upon request and at the expense of beneficiaries (the Marketing Authorisation Holders).

3. Relevant legislation and regulations

• Government Ordinance No. 72/30.06.2010 published in the Official Gazette of Romania, Part I, No. 452/02.07.2010 on set up of the National Agency for Medicines and Medical Devices by merger with the amalgamation and merger of the National Agency Medicines with the Technical Office for Medical Devices.
• Government Decision No. 734/21.07.2010 published in the Official Gazette of Romania, Part I, No. 531/29.07.2010 on NAMMD organisation and operation.
• Law No. 95/14.04.2006 on healthcare reform, Title XVII – The medicinal product, published in the Official Gazette of Romania, Part I, No. 372/28.04.2006, as amended.
• Scientific Council Decision No. 21/07.11.2008 on approval of the Guideline on consultations with target patient groups for the package leaflet.
• Scientific Council Decision No. 22/07.11.2008 on approval of the Guideline on consultations with target patient groups - meeting the requirements of Article 59(3) of Directive 2001/83/EC without the need for a full test - recommendations for bridging.
• Scientific Council Decision No. 8/26.06.2009 on approval of the Guidelines on the readability of the labelling and package leaflet of medicinal products for human use.
• Scientific Council Decision No. 6/23.03.2010 on approval of Guidelines on consultations with target patient groups for the package leaflet.
• Scientific Council Decision No. 16/07.06.2010 on changing the deadline for implementing the Guidelines on consultations with target patient groups for the package leaflet, approved by SCD No. 6/23.03.2010.
• Decision No. 161/23.03.2010 on the progress of activities in the Authorisation Department – The National Procedure Evaluation Service as of March 2010.

4. Definitions and abbreviations

Accreditation - Procedure by means of which an institution of a particular authority officially acknowledges that a body or person is competent to perform specific tasks.
Operator – active legal entity whose scope of work includes conduct of activities such as those for which accreditation is sought; the term operator is understood in a broad sense, referring to corporate or non-profit entities, unincorporated partnerships included.
MA – Marketing Authorisation
NAMMD – the National Agency for Medicines and Medical Devices

5. Responsibility and authority

Accreditation criteria are devised by the National Procedure Department – the National Procedure Evaluation Service and the Pharmaceutical Inspection Department and approved by the President of the National Agency of Medicines and Medical Devices.

6. Criteria for accreditation

6.1. Criteria for legal capacity

The operator seeking accreditation must be a legal, identifiable, entity, established in accordance with the laws in force in Romania or any other EU member state, with or without profit-making activities, whose scope of work includes conduct of activities such as those for which accreditation is sought. At the same time, accreditation may also be required by unincorporated partnerships cumulatively meeting all criteria for accreditation.

To prove fulfilment of this criterion, operators will provide the National Agency for Medicines and Medical Devices supporting documents showing:
• Identification Date: name, acronym, as appropriate, legal status, unique registration code, tax code, year of establishment;

• Contact Date: office address, addresses of work points, phone, fax, e-mail, web page etc.
• Data on ownership structure, membership, affiliation or other links with other bodies, professional associations, etc.

Operators seeking accreditation will need to prove they are not subject to liquidation or bankruptcy procedures by submission of the ascertaining certificate.

6.2. Criteria for economic and financial capability

Operators seeking accreditation will need to demonstrate their stable economic and financial situation (balance sheet submission). Assessment of this norm will take into account contracts executed and completed in the same type of contract, i.e. services of social and marketing research.

6.3. Criteria for technical and professional capacity

Operators applying for accreditation will prove their technical and professional capacity (facilities) by providing evidence on their technical equipment and specialised personnel as well as by submitting the technical offers they intend to submit to beneficiaries.

6.3.1. Technical equipment (Facilities)

Operators must bring evidence of their electronic storage capacity and specialised software, audio/video recording means as well as adequate room for conduct of the specific research activities. At the same time, they must also prove their ability to archive documents electronically and on paper.
The operator must be provided with a database of subjects under the conditions laid down in SCD No. 6/23.03.2010. Verification of respective conditions will be done by inspection by NAMMD inspectors.

6.3.2. Specialised staff

The economic operator must demonstrate their technical and professional capacity by submitting a sworn statement on use of their own network of operators specialising in social research/marketing. The statement will include a summary table of its own staff, in the following form:

Project title and research objective
Period

Sample size
Reference population
Type of research (quantitative/qualitative)

Number of specialised interviewers (1)
Number county/regional coordinators (2)
Number of national coordinators (3)
Number of research assistants (4)

TOTAL own staff involved in the project (sum of lines 1, 2, 3 and 4)

The above statement needs be accompanied by:

• CVs of staff responsible for carrying out activities for which accreditation is sought. Their CV must be accompanied by copies of documents confirming the indicated professional capacity and/or experience.

Project coordinator
- University degree in sociology / psychology / economics / statistics / marketing (graduate or licence diploma), as appropriate
- Master degree in sociology / psychology / economics / statistics / marketing (graduate or licence diploma)
- Minimum 5 years experience in sociological research projects
- Coordination of at least 10 social / marketing research projects in the past 5 years
- Experience in: development of methodologies, analyses and set up of qualitative research reports within at least three research projects
- The expert's CV is to be accompanied by certificates/documents (letters of recommendation, copies of contracts, delivery-reception documents etc.), issued or countersigned by the contracting authority or by private client for at least three qualitative research projects and 2 quantitative research projects.

Medical expert
The person responsible for identifying key messages in the package leaflet:
- Medical or pharmacy higher education
- Specialisation
- Experience as physician/pharmacist
- Any different experience to prove both constant interaction with patients and frequent use of package leaflets.

Analyst expert
- University degree in sociology / psychology / economics / statistics/marketing (graduate or licence diploma)
- University of Masters graduated in sociology/psychology/economics/statistics/ marketing (graduate or licence diploma)
- Minimum 3 years' experience in research projects
- Coordination of at least 5 social / marketing research projects in the past 5 years

- Experience in development of methodologies, analyses and set up of qualitative research reports in at least 2 research projects
- Experience in coordination of at least one national research
- The expert's CV is to be accompanied by certificates/documents (letters of recommendation, copies of contracts, delivery-reception documents etc.), issued or countersigned by the contracting authority or by private client for at least 2 qualitative research projects and 1 quantitative research projects.

To demonstrate similar experience, copies will be attached of certificates or reference letters by employers or beneficiaries, accompanied by copies of education diplomas/certificates mentioned and of documents confirming the indicated work experience.

6.4. Conducting consultations with target groups for 2 products for demonstration purposes

Following review and approval of accreditation criteria, but prior to grant of the final accreditation, the NAMMD will indicate two medicinal products to the accreditation applicant operator, which are for marketing in Romania and for which the operator must conduct readability studies. This study is to be conducted on Romanian patients in line with criteria in the Guidelines on consultations with target patient groups for the package leaflet, approved by Scientific Council Decision No. 6/23.03.2010. For each of the two products, a technical proposal will be prepared containing the technical chapters listed below: Technical proposal, Research design and sampling, Relevance of the proposed questionnaire, Methodology for data verification, Data quality guarantees; Format/Content of data analysis reports, Chart of estimated performance.

6.5. Criteria for quality system assurance

To demonstrate the quality assurance system, the operator seeking accreditation must submit Standard Operating Procedures for the following activities:

6.5.1. Extracting key messages and assignment of due importance
6.5.2. Draw-up of questionnaire
6.5.3. Interviewing subjects selected
6.5.4. Interpretation of data
6.5.5. Draw-up of the final report
6.5.6. Documents archiving in electronic format and on paper.

ANNEX 4

REQUEST FORM
Accreditation Certificate for conduct of consultations with patient target groups on the package leaflet of medicinal products for human use

(please fill in all relevant sections in block letters, in black ink)

Section 1. Request form: Administrative data

1.1. Details of the applicant company:

Authorisation number (if previously authorised):	
Name of applicant company:	
Name of the representative*):	
Address:	
Postal code:	Telephone no.:
Mobile no.:	Fax no.:
E-mail	

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*) The original document is attached proving the representative status.

Copies are attached of documents demonstrating eligibility:
- company set up documents (company statutes and contract);
- irrevocable definitive decision of the delegate judge for authorisation and registration of the company or, as applicable, definitive court order;
- if applicable, copy of the Registration certificate with the Register of Commerce National Office, with respective annexes and, of needed, registration certificates with their respective specifications;
- if applicable, the fiscal registration code;

- title deed or lease contract of the room(s) for company offices
- IBAN account
- fiscal confirmation certificate

1.2. Information on the contact person (if different from the above)

Name of the contact:

Name of the represented company:

Address:

Postal code: Telephone no.:

Mobile no.: Fax no.:

E-mail:

1.3 Information on the invoice delivery address (if different from the Applicant's)

Name of the contact:
Company:

Address:

Postal code: Telephone no.:

Mobile no.: Fax no.:

E-mail:

Section 2. Details on the types of activities conducted and their sites

2.1. Information on the site for identification of key messages in the leaflet and assignment of due importance

Name of the site:

Address:

Postal code:

Name of the contact:

Telephone no.: Fax no.:

Mobile no.:

E-mail:

2.2**. Information on the site for pooling and processing of consultation with target patient groups data** ***(to be filled in only if different from 2.1.*****)**

Name of the site:

Address:

Postal code:

Name of the contac

Telephone no.: Fax

Mobile no.:

E-mail:

2.3. Information on the site where reports are set up (*to be filled in only if different from 2.1. or 2.2; if the sites are the same, please specify)*

Name of the site:

Address:

Postal code:

Name of the contact:

Telephone no.: Fax no.:

Mobile no.:

Are the contracts you own available for inspection/check-up? □ yes □ no
Please attach a copy on paper or in electronic format.

E-mail:

2.4. Other activities to be mentioned *(to be filled in only if different from 2.1., 2.2. or 2.3; if the sites are the same, please specify*)

Name of the site:

Address:

Postal code:

Name of the contact:

Telephone no.: Fax no.:

Mobile no.:

E-mail:

2.5. Other information

The information below is required for the inspectorate/expert but will not be included in the Accreditation Certificate.

Sites are ready for inspection □ yes □ no

It is your intention to operate based on a quality assurance system □ yes □ no

You are aware of relevant SCD provision in the field of consultations with target patient groups for the package leaflet □ yes □ no

There are Standard Operating Procedures (SOPs) available For conduct of activities for which you are seeking accreditation Please attach a copy thereof in electronic format or on paper. Your contracts are available for inspection/verification	□ yes □ no □ yes □ no

2.6. Equipment/Facilities of the consultation site

On a separate sheet, please provide a brief description (ca. 500 words) of facilities available for conduct of patient group consultations.

Section 3. Assigned staff

Please indicate below categories of staff employed at the site of activities.

Staff	Number
Study coordinator	
Physician	
Pharmacist	
Sociologist/Psychologist	
Specialist in statistics/ marketing	

For each staff category listed above, please fill in one of the following pages.

3.1. **Study coordinator**

Attachment of a relevant CV is required for the proposed study coordinator; nomination of the study coordinator is to be signed by the assignee and the Applicant.

Surname:

First name:

Office address:

Postal code: Telephone no.:

Fax no.: Mobile no.:

E-mail

Qualifications (relevant for the Accreditation Certificate):

Experience (brief overview of jobs and responsibilities relevant for the Accreditation Certificate):

Please give details on social/marketing research in which you have been involved, as required by Accreditation criteria (6.3.2.)

Membership in professional associations:

I hereby confirm that the details above are accurate and truthful to the best of my knowledge. I agree with nomination as study coordinator.

Signature (Nominee): .....
Date: .....
Name in print: .....
Signature (Applicant): .....
Date .....

3.2. **Medical expert**

Attachment of a relevant CV is required for the proposed medical/pharmacist expert; nomination of the medical/pharmacist expert is to be signed by the assignee and the Applicant.

Name:

Surname:

Office address:

Postal code:		Telephone no.:	
Fax no.:		Mobile no.:	
E-mail			

Qualifications (relevant for the Accreditation Certificate):

Please give details on social/marketing research in which you have been involved, as required by Accreditation criteria

Membership in professional associations:

I hereby confirm that the details above are accurate and truthful to the best of my knowledge. I agree with nomination as expert medic/pharmacist

Signature (Nominee): .....
Date: .....
Name in print: .....
Signature (Applicant): .....
Date .....

3.3. Expert analyst

Attachment of a relevant CV is required for the proposed statistics expert; nomination of the statistics expert is to be signed by the assignee and the Applicant.

Name:	

Surname:

Office address:

Postal code: Telephone no.:

Fax no.: Mobile no.:

E-mail

Qualifications (relevant for the Accreditation Certificate):

Experience (brief overview of jobs and responsibilities relevant for the Accreditation Certificate):

Please give details on social/marketing research in which you have been involved, as required by Accreditation criteria (6.3.2.)

Membership in professional associations:

I hereby confirm that the details above are accurate and truthful to the best of my knowledge. I agree with nomination as research expert.

Signature (Nominee): .....
Date: .....
Name in print: .....
Signature (Applicant): .....
Date: .....

Section 4. Data on company/consortium activities

Details will be provided on prior relevant contracts/studies: date of conduct, activities performed, site, number of staff involved, number of persons interviewed, contract details, outcome of the survey.

Section 5. Comments

Please provide any other information in support of your request. Details can also be provided on any change of address, nominees etc.

I hereby request grant of an Accreditation Certificate to the holder nominated in this Request Form, for activities accreditation is required.

Section 6. Statement

6.1. Activities will be in line with information provided in the Request or submitted in relation thereof.

6.2. To the best of my knowledge, details in this Request are accurate and comprehensive.

Signature (Applicant): .....
Date: .....
Name in print: .....
Please specify your status as a signatory: .....

DECISION
No. 14/12.05.2011

on approval of the Organisational Strategy of the National Agency for Medicines and Medical Devices 2011-2015

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

DECISION

Sole article – The Organisational Strategy of the National Agency for Medicines and Medical Devices 2011 - 2015 is approved, in accordance with the Annex which is integral part of this Decision.

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

Acad. Prof. Dr. Leonida Gherasim

ANNEX

ORGANISATIONAL STRATEGY OF THE NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES 2011 - 2015

The National Agency for Medicines and Medical Devices (NAMMD) is a public institution operating under the Ministry of Health, set up through Emergency Government Ordinance No. 72 of 30 June 2010 on reorganisation of certain healthcare facilities and amendment of public health legislation, as a result of the merger of the National Agency for Medicines and the Technical Office for Medical Devices. NAMMD organisation and operation have been approved by Government Decision No. 734 of 21 July 2010.

Brief history

For over 50 years, the present Agency has represented the drug regulatory authority in Romania. Known as the *Institute for Medicinal Product Control and Pharmaceutical Research* on its setup in 1956, the name of the institution was further changed in 1960 to become the *Institute for the State Control of Medicinal Products and Pharmaceutical Research* (ICSMCF). Between 1999-2010, by reorganisation of the former ICSMCF, the institution operated as the National Medicines Agency.

The activity related to medical devices was set up 50 years ago as well.

As early as 1958, the technical directorate of the Ministry of Health set up its own laboratory for technical testing of medical equipment, which became a distinct entity in 1973 within the Station for Verification and Maintenance of Medical Devices (SVMMD).

As of 1 February 2005, the SVMMD has been reorganised under the name of the Technical Office for Medical Devices (TOMD), which in its turn merged with the National Medicines Agency (NMA) in 2010.

The NAMMD is the Romanian competent authority in the field of medicinal products for human use, as regards marketing authorisation, surveillance of the safety of medicinal products in therapeutic use, authorisation of clinical trials and issuance of regulations in the medicinal product field, as approved by the Ministry of Health.

As far as medical devices are concerned, the NAMMD is in charge of control of the performance and security of medical devices in use as well as assessment of the capability of organisations providing services in this area.

This organisational strategy is issued and updated in the context of the legal framework establishing the relation between the NAMMD and the Ministry of Health, as well as between the NAMMD and its stakeholders. It covers a 5-year period 2011 - 2015 and is updated every year.

Additional information on NAMMD work may be found on its website, www.anmdm.ro.

MISSION, VISION AND STRATEGIC OBJECTIVES OF THE NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES

Mission of the NAMMD:

- **Evaluation at the highest scientific competence** of documentation for authorisation in view of marketing high quality, safe and effective medicinal products for human use;
- **Surveillance of the safety of medicinal products for human use** in therapeutic use by means of inspection and pharmacovigilance activities;
- **Maintaining of a high level of performance and safety of medical devices in use in by healthcare networks throughout the country, irrespective of ownership**;
- **Most demanding assessment of service providing medical-technical units in the area of medical devices, for optimum delivery of competent and quality prosthetic and repair – maintenance services;**
- **Ensuring access for patients and healthcare professionals** to useful and accurate information on medicinal products for human use authorised for marketing in Romania;
- **Ensuring institutional administrative effectiveness, efficiency and transparency** of practices and procedures in use.

Vision of the NAMMD:

- **Strengthening of its status as reference national authority** in the field of medicinal products for human use and control of the performance and safety of medical devices in use

- **Strengthening of its status as expert and reliable source of accurate and timely information** in the field of medicinal products for human use, provided to stakeholders.

Strategic objectives of the NAMMD are as follows:

- **Protection and promotion of public health**, by accomplishment of the NAMMD primary role, namely warranty of compliance of authorised *medicinal products* with the required standards, their efficacy and their acceptable level of safety;
- **Protection and promotion of public health**, by accomplishment of the NAMMD primary role, namely warranty of compliance of authorised *medical devices* with the required standards and intended purpose as well as of their acceptable level of safety;
- **Fulfilment of the NAMMD role of communication**, as an expert and reliable source of accurate and timely information, by providing clear and timely information to healthcare professionals, patients and the general public;
- **Contribution to the projection of the future legal frame** in the field of medicinal products for human use, through promotion of efficient NAMMD European and international relations;
- **Contribution to the shaping of secondary legislation** in the field of medicinal products for human use and medical devices;
- **Coordination of an organisation** endowed with quality and adequately qualified workforce, **able to cope with future challenges**.

Table of contents:

1. Introduction

1.1. – Medicinal products for human use

As of its set up in 1999, in its various stages of development, the Agency has witnessed significant developments in the legal field, both nationally (by harmonisation of national and European legislation), and on a European level (European legislation which the Agency was aiming to align with was itself undergoing major changes):

• Gradual replacement of previous national legislation with harmonised European legislation;

• Major review of the EU body of medicinal product legislation (revision of Directive 2001/83/EC);

• Introduction of certain regulatory provisions envisaging harmonisation of authorisation procedures and conducting clinical trials throughout the EU (Good Clinical Practice directives);

• Introduction of regulatory provisions meant to increase the availability of authorised medicinal products, particularly for the treatment of children (Paediatric Regulation);

• Introduction of regulatory provisions in the field of traditional herbal medicinal products (by complementation of Directive 2001/83/EC);

• Introduction of a new regulation system concerning safety and quality of homeopathic medicinal products (by complementation of Directive 2001/83/EC);

• Introduction of regulatory provisions on manufacturing of tissue engineering products and their use (Regulation on Advanced Therapies);

• Introduction of the new regulatory provisions on Pharmacovigilance (Regulation and Directive for amendment of Directive 2001/83/EC).

Medical devices

As of set up in 2005, through reorganisation of the former SVMMD, the TOMD, currently part of the NAMMD, has taken active part in generation of national regulatory acts in the field of medical devices, through:

• set up and revision of the legal framework for control through regular verification of medical devices;

• set up and revision in compliance with European legislation of the legal framework for assessment of service providers in the area of medical devices;

• set up and revision of the legal framework for ascertaining and sanctioning of violations in the area of medical devices.

1.2. - The NAMMD has enforced a number of important specific initiatives meant to improve performance of its basic activities, extend its role through appropriation of new fields of activity and improved

communication with healthcare professionals and the general public, as well as the latter's improved communication with the Agency, i.e.:

• Enforcement of a major restructuring of medicinal product operational departments, which has led to a more consistent surveillance of medicinal products throughout their lifecycle;

• Major restructuring of operational departments in the area of medical devices, leading to more efficient use of staff;

• Introduction of a new and important information system in support of the decision-making process and work in agency-level electronic format;

• Appointment of the largest number of NAMMD experts possible for the committees and working groups of European medicinal product institutions, ensuring NAMMD's ability to continue its active contribution to the EU legal and decision-making process.

• Participation with NAMMD experts in ASRO committees in the area of medical devices, ensuring NAMMD capacity to further make an active contribution to the standardisation process;

• Improved flow of information to healthcare professionals;

• Improved NAMMD profile as a communicator.

1.3. - The present organisational strategy takes into account the viewpoints expressed by stakeholders and emphasis will be placed on the core and general direction of NAMMD concerns and activities in the following 5 years.

2. Protection and promotion of public health

2.1. - Protection and promotion of public health is the NAMMD general objective, as well as the core of its activity throughout the entire process related to surveillance of the development and use of medicinal products for human use and control of the use of medical devices.

The NAMMD carries out inspections of all aspects concerning medicinal product development and manufacturing process, taking measures against the companies or persons who fail to comply with their obligations.

The NAMMD authorises performance of clinical trials with medicinal products in various stages of development and is responsible for deciding whether they are granted marketing authorisations.

The NAMMD conducts assessment of all aspects related to service delivery in the area of medical devices.

The NAMMD monitors safe use of medicinal products for human use throughout their entire lifecycle, by means of an advanced adverse reaction reporting system, so as to ensure maintenance of an acceptable risk/benefit balance for the respective products, as well as careful information in that respect of relevant interested parties, patients and healthcare professionals.

The NAMMD ascertains violations of the law and takes measures against companies and persons who fail to comply with their legal obligations as per Law 176/2000 on medical devices, as amended.

2.2. - Significant improvement of the NAMMD safety monitoring systems and their legislation underlying this activity as well as increased NAMMD efforts for better patient and public understanding of the benefits and risks associated with medicinal product use which have been apparent in late years.

For the years to come, the NAMMD plans to further develop the adverse reactions/events reporting system, in order to ensure solid proof for its regulatory decisions.

The NAMMD pursues further emphasis of the value of reports received by providing quick feedback to reporters and continued development of public and patient level of understanding of decisions concerning the risk/benefit balance of medicinal products for human use available on the Romanian pharmaceutical market.

Moreover, the NAMMD pursues to carry on its efforts directed towards the education and encouragement of healthcare professionals in view of adverse reaction reporting.

Over the past few years, significant improvement has been observed of NAMMD systems for control of medical devices in use and monitoring of service providers in the area of medical devices, of legislation underlying this control activity as well as strengthened Agency efforts towards better patient and user understanding of the benefits and risks associated with use of medical devices.

For the years to come, the NAMMD aims at further development of its operation system, so as to make sure of lawful use of medical devices throughout the country as well as highest standard of any kind of prosthesis, maintenance and repair of medical devices.

It is the NAMMD intention to continue its efforts towards the training of healthcare professionals and their encouragement with regard to reporting of incidents occurring in the use of medical devices.

2.3. - At the same time, the NAMMD plans on being actively involved in expected talks concerning future development of a European community system for monitoring medicinal product safety, which, through combined information from the 27 Member States, will further reinforce the elements underlying decision-making in safety matters.

2.4. - In the context in which regulatory authorities and the public find counterfeited medicinal products an increasingly strong reason for concern, the NAMMD has initiated and furthered collaborations with national institutions involved in combating sale of counterfeit medicinal products particularly over the Internet, as well as with its counterparts in Member States or outside the EU in setting up permanent contact points meant to

limit such criminal activities.

2.5. - For the following 5 years, the NAMMD envisages the following:

• Insurance of authorised medicinal products compliance with the adequate quality, safety, efficacy standards and authorisation in the shortest time possible;

• Authorising modifications/variations to marketing authorisation of medicinal products for human use (for new strengths or pharmaceutical forms etc.) in the shortest time possible, while safeguarding public health;

• Further authorisation of those clinical trials and investigations only that give appropriate warranty to patients, in line with harmonised community regulations;

• Further development of the National Pharmacovigilance Centre operating within the NAMMD and improvement of the adverse reactions/events reporting system, so that gathering of information is allowed from the most comprehensive sources, reporting is undertaken in the simplest manner and feedback is quickly delivered to encourage participation;

• The performance of actions for ensuring firm and efficient surveillance of medicinal products for human use throughout Romania;

• Insurance of full NAMMD undertaking of its role in enforcing EU legislation on increasing the number of authorised medicinal products, particularly for the treatment of children;

• Offering support to governmental initiatives in handling of severe public health risks (e.g. pandemic flu, bioterrorism) and fulfilling the NAMMD role in ensuring availability of relevant products to cover any increased demand;

• Provision of certain adequate information/instructions to the public on the safe use of medicinal products, as well as warnings concerning their safe use, when needed, for both on-prescription and over-the-counter (OTC) medicinal products;

• Maximum use of available instruments in support and consolidation of monitoring the safety of medicinal products for human use;

• Promotion of risk-based approach in inspection activities, in line with NAMMD public health responsibilities and optimal use of resources;

• Taking measures against counterfeiting within the larger frame of NAMMD responsibilities in enforcement of the law, development of collaboration relationships with other institutions and bodies involved in this activity and raising public awareness of the risks it is exposed to because of counterfeited medicinal products.

• Resumed analysis of regulatory acts governing control of medical devices through regular verifications, so as the list of medical devices controlled and the regularity of verifications comply with the risk

degree of medical devices;

• Ongoing improvement of procedures concerning assessment and surveillance of organisations applying for the right to deliver services in the area of medical devices and imposition of European level labor conditions;

• Investigation together with competent institutions of all incidents involving medical devices, to determine their causes and reduction of their numbers as much as possible.

3. Information and communication

3.1. - Most regulatory activities result in communication of updated information on medicinal products for human use as new knowledge thereof emerges during their use. This is usually undertaken as either information of healthcare professionals or revised versions of the Patient leaflet.

The quality of the information provided by the NAMMD is thus essential in fulfilling its role in protection of public health.

The ever increasing degree of in-use knowledge of medicinal products for human use and their manner of regulation will also contribute to media and public understanding of the safety issues and the exceptional circumstances requiring product recall from the market.

3.2. - Healthcare professionals as well need clear information and recommendations to rely on when discussing options of treatment with their patients, whereas patients and the public look for access to information on medicinal products they use in their own care, related to their mode of action, the benefits which may be expected, the risks associated with their use, as well as better understanding of the manner in which the benefit/risk balance is established.

3.3. - The NAMMD has elaborated a 5-year Communication Strategy, describing the frame for internal and external communication in this period, establishing key actions for developed communication. The Communication Strategy is renewed on a yearly basis.

The main objective of the Communication Strategy is attainment of a higher degree of understanding of the risk/benefit balance assessment and of the manner of NAMMD decision making in performance of its assignments, as well as encouragement of adverse reactions/events reporting.

In order to be able to reach the highest strategic objective, i.e. promotion and protection of public health, the Agency must be able to constantly describe the implications of its activity in that respect. The NAMMD Communication strategy has established the key messages defining the activity of the Agency, at the same time the key messages on the highest level that the NAMMD desires to and will further convey to attain the objectives provided in this strategy.

3.4. - It is the NAMMD wish that the public fully rely on the medicinal product regulatory system, acting towards its best interest, by enforcing an approach best described by openness and transparency.

Much has been accomplished to this end over the past years and the NAMMD will further improve the transparency of its own activities and its accessibility to the public. The NAMMD will also promote transparency in the activity of the industry under its regulatory scope.

3.5. - Among the NAMMD strategic priorities, closer and more effective engagement will be necessary with patients and general public associations, as with identification of general ways of bringing patient perspective in its work. This activity will be elaborated and enforced during the period covered by this strategy.

The NAMMD will continue to:

Take action in view of strengthening its status as an expert and reliable source for the latest information concerning medicinal products for human use on the market, by enforcing the NAMMD Communication strategy;

• Make sure that the information accompanying medicinal products are easy to use, through full compliance with requirements established for user testing of the leaflets;

• Establish ways to enhance transparency throughout the decision making process, on both NAMMD and industrial level under its regulatory scope;

• Address healthcare professionals with targeted information, for improved adverse reactions/events reporting and promotion of safe use of human medicinal products (e.g. by adequate description, search and request of adequate information from the NAMMD);

• Make targeted information available to the public, in view of better adverse reaction reporting by the patient, promotion of better informed patient decision concerning the use of medicinal products for human use;

• Further develop its own website so as to be acknowledged as an expert and reliable source of the latest information on medicinal products for human use;

• Contribute to better understanding by the public and/or healthcare professionals of the benefit/risk balance of medicinal products for human use;

• Cooperate with professional bodies, academic staff and others, in order to ensure an adequate content of training programmes for healthcare professionals, in such issues as safety and risk in prescription and use of medicinal products for human use;

• Devise and implement new ways of increasing patient and public involvement in NAMMD activity and optimal utilisation of their

contribution to the decision making process.

4. Shaping of a balanced legal framework

On European level

4.1. - The NAMMD will continue to assume its role as the Romanian and EU competent authority in the medicinal product field, fully integrated in the operations of EU competent authorities as well as in the work of medicinal product committees and working groups of European bodies.

As of 2008, the NAMMD also acts as Reference Member State in the coordination of assessments of marketing authorisation applications submitted in view of authorisation through the mutual recognition/decentralised procedure.

The Agency aims at maintaining its very important contribution to the activity of the European network to ensure effective and efficient functioning of these procedures.

4.2. – The NAMMD will continue to:

• Ensure active participation in technical and scientific debates regarding the set up of new legal provisions in the field of medicinal products for human use, support of an efficient activity of the European medicines agencies network;

• Ensure an as efficient as possible operation of the present regulatory system in the field of medicinal products for human use and the promptest possible implementation of future changes brought to the European regulatory framework in this field;

• Strengthen surveillance of the Romanian/European market through closer cooperation and collaboration with the other European medicines agencies;

• Provision of knowledge and expertise to other states, signatories of the *Collaboration Agreement of Drug Regulatory Authorities in European Union Associated Countries (CADREAC)/New Collaboration Agreement between Drug Regulatory Authorities in Central and Eastern European Countries (nCADREAC).*

On an International level

4.3. – Particularly following Accession, within the European pharmaceutical regulatory system, the NAMMD cooperates with all national competent authorities in the European Union (EU) and in the European Economic Area (EEA), as well as with the European Medicines Agency (EMA).

Via the EMA, the NAMMD hopes to be able to also further develop international connections with the United States Food and Drug Administration (FDA), within the cooperation framework established between the EMA/EU and the FDA/USA.

It is the NAMMD belief that, for efficient performance of its regulatory attributions in the field of medicinal products for human use, for public health benefit, it also needs good working relationships with non-EU countries, particularly with those provided with medicine development abilities, which increasingly represent a significant source of supply for the EU market.

The NAMMD will continue to improve its information and knowledge exchange with other major regulatory institutions, whose development is anticipated in the next few years.

4.4. - The NAMMD considers it advisable that regulatory authorities worldwide find a way to cooperate in set up of harmonised standards, applicable to global relations with the pharmaceutical industry.

4.5. – The Agency will further:

• Develop its international and cooperative relations;

• Aware of the global market for medicinal products, it is the NAMMD intention to become as much as possible involved in international cooperation in the field;

• Support proceedings concerning harmonisation of regulations of the International Conference on Harmonisation (ICH) in the medicinal product field;

• Develop cooperation established with NAMMD counterparts in strategically important countries, such as China and India, which will become an increasingly important source for manufacturing and development of medicinal products for human use, subject to NAMMD authorisation and surveillance.

Implications of research and innovation progress

4.6. - The NAMMD foresees significant scientific and technological progress with potential impact on the regulatory manner medicinal products for human use, in the following fields:

• Biotechnology products

• Progress in the fields of molecular biology, genomics, gene and cell therapy;

• Progress in the fields of molecular biology, genomics, gene and cell therapy;

• Use of new screening technologies and mechanisms, better adapting medicinal products to patients, development of "personalised" and "niche" medicinal products and diagnostic tests, for identification of suitable patients;

• Development of products combining a medicinal product with its own release system, in a medicinal product/medical device association;

• Use of nanotechnology, biomedical science, microelectronics and computer technology;

• Tissue engineering.

4.7. - The NAMMD may contribute to the development of efficient treatments to benefit health through promotion of a supportive context for conduct of clinical trials in Romania, according to European legislation in force.

The Agency will continue its collaboration with partner organisations and support European efforts for harmonised approach of the requirements for clinical trial authorisations, by diminishing inconsistencies and bureaucracy while maintaining safety measures regarding trial participants.

4.8. – The NAMMD will further:

• Ensure preservation, through contribution with adequate expertise in debates of scientific committees organised by European bodies, of the legislative ability to establish a proper balance between cautious approach of the safety issue and the freedom of innovation;

• Establish contacts with academic and professional centres of renown in the field of medical, pharmaceutical and legislative sciences, for ensured NAMMD capacity to rely on optimal abilities and knowledge in preservation of its own expertise;

• Promote an optimal internal context for clinical research and cooperation with EU partners for more consistent enforcement of the clinical trials directive.

Towards better regulation

4.9. - It is the NAMMD duty to ensure that medicinal product regulatory activity is proportional, adequately reflects the current level of knowledge in benefits and risks.

This amounts to NAMMD ongoing assessment of its own activity and insurance that it adequately reflects the needs of a broad range of stakeholders, provision of an effective regulatory service and orientation of activities towards compliance with the Agency's main objective of protecting public health.

Taking into account the specialised personnel shortage, the NAMMD is not able to engage in scientific advisory activities but instead it very frequently engages in regulatory counselling.

4.10. - The European Commission has launched the *Better Regulation* initiative, by developing a package aimed at simplification of the handling of variations/changes to the terms of the marketing authorisation of medicinal products for human use, which the NAMMD has started to implement and enforce.

4.11. - The NAMMD intends to carry on its risk-based approach in inspection, allowing it to focus on issues of potential concern, to fully capitalize on its inspection resources.

The Agency undertakes to further explore the scope of a risk-based approach of the NAMMD regulatory functions and search for fields with room for regulatory practice improvement, compliant with both the law and the NAMMD role in protecting public health.

4.12. - The NAMMD is also aware of the need to ensure clear and unambiguous legal provisions underlying any of its regulatory activities.

National legislation in the field of medicinal products for human use has undergone significant changes over the years, but as of entry into force of Law 95/2006, Title XVII – The medicinal product, it has been fully harmonised with European legislation, being amended in accordance with new European regulations.

4.13. – The NAMMD will continue to:

• Develop NAMMD risk-based inspection and search for other opportunities for reducing unnecessary legal obligations, as well as find areas allowing for attainment of the Agency's objective concerning substantiation of regulations on risk and proportionality;

• Support the European Commission's initiative for Better Regulation and continued contribution to this issue on national and European level;

• Strengthen and rationalize the law in the field of medicinal products for human use.

5. Running of a successful organisation

5.1. - Given the dynamic context for its operation, the NAMMD needs to preserve its influence in its own field, as well as its flexibility and ability to respond to change.

In recent years, the coming into force of the new European legislation has generated significant changes in workload, therefore enabling the agency to anticipate the further development of certain specific activities, whereas other activities/domains may remain constant or even diminish.

The NAMMD will take the necessary measures to maintain its flexibility and capacity to adapt to a fluctuating workload, namely to

increased/decreased demand, which would be an advantage for both the agency and stakeholders.

5.2. - The NAMMD needs good working relationships with the industry under its regulatory scope, created through efficient dialogue with the leading manufacturers' associations and marketing associations in the field of the medicinal product for human use, as well as with healthcare professionals and patients using these medicinal products.

Good co-operative relations need to be preserved with other governmental bodies, whose activity is closely related to the NAMMD work.

5.3. – The Agency will further:

• Make investments and develop efficient information management systems in support of its own activity and assume an active role in the context of the EU debate on elaboration and enforcement of adequate and consistent systems;

• Ensure that its own work reflects the needs of interested parties and thus meets its main objective of protecting public health;

• Maintain efficient relations with other governmental bodies;

• Maintain and improve collaboration and cooperation with the pharmaceutical industry and to continue adequate contacts with leading manufacturers' associations and marketing associations in the field of the medicinal product for human use.

• Maintain and improve collaboration and cooperation with the medical devices industry and preserve appropriate contact with the ASRO, RENAR and the Health insurance houses.

Agency staff

5.4. - Staff represents the NAMMD most important resource. Enforcement of efficient regulation for protection of public health requires **preservation of highly qualified and motivated workforce**.

This goal is particularly difficult under the present circumstances when current public system possibilities to reward its employees can hardly compete with opportunities on the private market, that have attracted specialists whose expertise is due to their work in the Agency.

The NAMMD will have to further its efforts to preserve its currently available staff with regulatory and scientific expertise, providing at least motivation through adequate assessment of performance and acknowledgment of professional competence, respectively, until creation of a favourable legislative context allowing for appropriate financial motivation for reward of special professional merits.

5.5. - Depending on the development of the current economic crisis, the NAMMD seeks to:

• Perform efficient recruitment and selection of new staff, particularly from among new graduates of medical-pharmaceutical higher education.

• Implement promotion policies to ensure the human resources in the NAMMD, mainly in areas where analysis reveals deficits of personnel of higher education;

• Provide staff with a wide range of professional training and opportunities for improvement, for developed human resources.

Financing of Agency operations

5.6. - At the end of 2009, the **Agency has been reorganised as a public institution fully funded from the state budget**, in accordance with Law No. 329/2009 on the reorganisation of certain authorities and public institutions, the rationalisation of public expenditure, support to business and compliance with the framework agreements with the European Commission and the International Monetary Fund.

On legislative level, in 2009-2010, regulation has continued of certain financial-fiscal measures with significant negative impact on the management of human resources and implicitly on the funding of the entire operation of the Agency.

Set up in July 2010 through NMA merger with the of the TOMD, the NAMMD aims at least maintaining its financial stability by means of a balance budget exercise within the limits of the allocated budget in compliance with legislation in force.

5.7. - The NAMMD periodically updates its tariffs depending on changes in its activities.

The NAMMD aims at further finding activities able to enhance its income, such as organising conferences, training sessions etc.

Conclusions

The NAMMD is a mature institution, fully able to manage the activities arising from its status as an EU competent authority.

This is also the case in the European area, where the NAMMD is met with recognition and appreciation as Romania’s competent authority in the field of medicinal products for human use.

The context for NAMMD operation has been subject to numerous changes, which it has strived to understand and adapt to requirements of the

process related to the shaping of developments and the enforcement of new policies.

Focusing on its achievements while learning from all its past undertakings, the NAMMD will have to be prepared to cope with any possible challenges in the future.

DECISION

No. 15/12.05.2011

on approval of the Communication Strategy of the National Agency for Medicines and Medical Devices 2011-2015

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

DECISION

Sole article - The Communication Strategy of the National Agency for Medicines and Medical Devices 2011-2015 is approved, in accordance with the Annex which is integral part of this Decision.

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

Acad. Prof. Dr. Leonida Gherasim

ANNEX

COMMUNICATION STRATEGY OF THE NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES (2011-2015)

Introduction

The most important strategic objective of the NAMMD is promotion and protection of public health, by accomplishment of the NAMMD primary role, namely warranty of compliance of authorised medicinal products with the required standards as well as of their efficacy and acceptable level of safety. For successful attainment of this goal, the NAMMD will further strengthen its status as expert and reliable source of accurate and timely information in the field of medicinal products for human use, provided to its most important stakeholders, namely healthcare professionals, patients and the general public.

Scope and purpose

This document outlines the frame for internal and external activities for 2011-2015, is updated annually and establishes key actions necessary for developing communication during this time.

The Communication strategy is devised by the Communication, institutional relations and pharmacopoeia service within the Department for policies and strategies but implementation of its objectives cannot be performed without support and cooperation of the entire Agency personnel. Therefore, enforcement of the communication strategy requires actual involvement of the entire NAMMD staff in issues related to relationships with the mass-media, development of the NAMMD website, finding stakeholders' needs and organisations of meetings with them.

The general objective of the Communication strategy is achievement of a higher level of understanding of risk/benefit assessment and NAMMD decision – making for performance of its duties as well as stimulation of adverse reactions/events reporting.

The purpose of the NAMMD communication strategy envisages:

- Development of communication through improvement and development of its infrastructure;
- coming into prominence in relation to other bodies, i.e. acknowledgment of NAMMD status as expert and reliable source of accurate information in the field of medicinal products for human use;

- insuring wide availability of information and their immediate accessibility;

- insuring bilateral quality communication with the various stakeholders (by means of message exchanges and response to questions);

- maintaining NAMMD reliance through continued and constant attainment of all objectives established, irrespective of difficulties encountered in resolution of emerging problems;

As a live document, endowed with sufficiently flexible objectives to respond to a changing external context, this will remain under permanent NAMMD leadership assessment, to insure its adaptation to emerging changes.

Key messages

In order to attain its most important strategic objective related to promotion and protection of public health, the Agency must be able to constantly outline the content of activities it performs in that respect. The following key messages outline the activity of the Agency and represent key messages at the highest level, which the NAMMD will further convey through implementation of this communication strategy:

- **The NAMMD is responsible for insurance of authorised medicinal products compliance with required standards as well as efficacy of medicinal products for human use and their acceptable safety.**
- **There is no adverse reaction-free medicinal product, the essential fact being a positive risk-benefit balance.**
- **The NAMMD performs surveillance of in-use medicinal products for human use through inspection and pharmacovigilance activities by prompt adoption of appropriate decisions for public health protection whenever needed.**
- **The NAMMD pursues provision of access to information to the greatest degree possible.**
- **The NAMMD pursues insurance of transparency of institutional practices and procedures.**

The above key messages in fact correspond to elements of the NAMMD mission, expressing objectives pursued by the Agency in clear and accessible terms. Implementation of this strategy will mean NAMMD

continued communication and support of key messages, whenever necessary, while at the same time ensuring through self-assessment their uninterrupted impact on the target audience of the institution.

Objectives

- Continued support of the NAMMD mission of promoting and protecting public health through timely provision of the latest and most accurate information on medicinal products for human use;
- Insuring a high level of accessibility to information;
- Finding ways to insure the highest degree possible in decision-making on the level of both the NAMMD and the industry under its regulatory scope;
- Finding appropriate methods to appeal to healthcare professionals for improved reporting of adverse reactions and events;
- Adequate information of healthcare professionals to promote safe use of medicinal products for human use (for instance, by means of suitable prescription, search and request for adequate information from the NAMMD).
- Pursuance of thorough observance of requirements established for improved readability and understanding of patient leaflet information and labelling and user testing;
- Making information available to the general public to be able to first initiate and then develop the process of adverse reaction reporting by the patient and promotion, respectively, of patient's better informed decision on use of medicinal products for human use;
- Development and permanent update of the NAMMD website for strengthened status as reliable source of the latest information on medicinal products for human use;
- Promotion of risk understanding and directing public attention towards the danger of purchase of medicinal products over the internet;
- Promotion of risk understanding and directing public attention towards the danger of encouraging self-medication through inappropriate advertisement of medicinal products for human use;
- Contribution to better understanding by healthcare professionals and the general public of the fact that, although there are no risk-free medicinal products, their benefits for the patient and the public fully justify the risks as long as the risk/benefit ratio remains positive;
- NAMMD collaboration with professional bodies and academic staff etc. in the field, so as to insure appropriate content for

healthcare professionals' training and education in matters of risk and safety in prescribing and use of medicinal products for human use;
- Insuring recognition of NAMMD status as a competent authority through understanding the manner for NAMMD actual regulation of the medicinal product field;
- Design and implementation of new ways to improve patient and general public involvement in NAMMD work and maximum valorisation of their contribution to the decision-making process.

Strategic priorities

For attainment of its mission, the NAMMD aims at continued approach of those strategic priorities related to development of communication activities, as for example:

1. *Improved flow of information to healthcare professionals*

The NAMMD is aware that the first contact of most patients and the general public is public healthcare services and treating healthcare professionals, respectively. Therefore, healthcare professionals should be timely provided accurate high quality information able to aid them in advising their patients on use of medicinal products for human use.

That is why the Agency has focussed its entire attention on continued efficient provision of key information for healthcare professionals in that respect, in order to adequately support their or other people's patient care activity.

In this respect, the NAMMD will pursue:
- Review and update of its website for better accessibility of information for all stakeholders, healthcare professionals included;
- Assessment of communication channels currently used in relation to healthcare professionals: rapid alerts, current pharmacovigilance issues (information letters for physicians/direct communications to healthcare professionals, notifications to medical practitioners ads, pharmacovigilance regulations, submission of Summaries of Product Characteristics, patients leaflets etc.)

2. *Improved NAMMD profile as a communicator*

The NAMMD fully assumes responsibility for the communicating with the media relationship, in a context of increased demand for printed press and television interviews, the NAMMD will continue to promote a fair and efficient relationship with the press, given the increasing societal role of the media in recent years. Accurate, rapid and impactful information

conveyed in appropriate terms in the field of medicinal products for human use as well is a vital source for any type of decision, and the media is their main means of dissemination to the general public.

Considering that, in addition to its informative role, the mass media can also be used to shape opinion and ideas and develop attitudes, the NAMMD relationship with the press must be built in such a way as to insure accurate, clear and appropriately expressed medicines-related body of information, particularly related to safe use, in order to achieve a maximum degree of understanding by the general public. To a lesser or greater extent, this relates to the Agency's control over information on medicinal products for human use, and a good relationship with the press is mandatory to achieve this goal.

In exercise of its duty as a proactive and reactive communicator, the Agency aims at insuring a balance between its work and the issues it faces.

3. *Improved internal communication*

Internal communication takes place on several levels, contributing to the fulfilment of Agency objectives. Like many other organisations, the NAMMD uses the intranet and the electronic mail, because its speed and ease of use. Other internal communication alternatives are: operative meetings of the NAMMD management with the heads of the various internal structures and Agency committees, meetings on department/service/bureau level, inter-departmental meetings, internal publications on the intranet etc.

The Agency aims at:

- continuous monitoring of the development of more effective communication skills of its employees in respect of interpersonal or face-to-face communication;
- improved vertical communication mechanism ("top-down" – in line with the hierarchical organisation, and "bottom up" – from the lower to the upper hierarchical levels), in particular as regards:

- ensured possibility for "feedback" receipt;- increased speed of "feedback" receipt;

- improved communication mechanism on group level, manifested in departments, services, laboratories, offices. This level focuses on sharing of information, discussion of issues, coordination of tasks, resolution of problems and reaching consensus.

- scheduled meetings within the Agency to monitor employee awareness about the role of the communication function, the importance of ensuring good internal communication envisaging attainment of the NAMMD mission;

- collaboration with the Department for Human Resources, Payroll to develop a training program concerning better NAMMD employee communication skills;
- revaluation of existing channels of internal communication and focusing efforts towards developing of bilateral written and verbal communication.

4. *Improved involvement in Agency work of patients and the general public*

Priority will be given by the NAMMD to continued direct communication with patients' and general public associations allowing identification of more opportunities for their involvement in agency work, such as:

- planning meetings with patient/public groups of interests for proposal of specialists to participate in their meetings;
- creating a patient/public "reference group" able to, in the context of its collaboration with the NAMMD, contribute to improved decision making and level of understanding of safety issues and risk in prescription and use of medicinal products for human use.

5. *Promotion of informed debates on the various aspects involved in medicinal products for human use: the benefit/risk balance, generic versus innovator medicinal products, patient role in development of readable leaflets able to assure a high level of understanding, reporting adverse reactions, etc*.

- Debates on the issue of non-existence of risk-free medicinal products, the essential point being a positive benefit/risk ratio will provide better understanding of Agency work and set an example for transparency promotion in NAMMD policy and strategy, as the national regulatory authority in the field of medicinal products for human use.
- Continued debate on generic versus innovator medicinal product and initiation of debates on the involvement of professionals and patients in implementation of the new European Directive 2010/84/EU for amendment of Directive 2001/83/EC establishing a Community code on medicinal products for human use in terms of pharmacovigilance.

Funding in view of reaching the proposed strategic objectives

1. *Funding of the communication activity*

Despite the obstacles created in 2009-2010, of the unfavourable economic and legislative context, the NAMMD the agency is at least aiming

at further maintaining its financial stability through a balanced budget year, in accordance with the laws in force.

It is worth mentioning that, for economic reasons, print publication of both the Agency's quarterly newsletter and the NMA/NAMMD Annual Report brochure have been further cancelled, these being only posted on the Agency website. Distribution of such specific illustrative work on paper to certain interested state institutions, faculties of pharmacy and medicine abroad and at home, to certain medical and pharmaceutical personalities as well as to other national medicinal product regulatory authorities would more *widely* insure a successful agency communication strategy. Therefore, the NAMMD pursues to resume printing/distribution of such publications as soon as feasible from a financial standpoint; this will ensure an opportunity for more accurate estimate by healthcare professionals, internal and external partners of constant Agency efforts towards recognition of its reinforced status as European competent authority in medicinal products for human use.

Depending on financial, material and human resources, the Agency aims at development and diversification of communication instruments of, considering that effective communication strategy combines some or all of the following tools: Internet, print publications and other printed materials, press releases, interviews, important notifications, conferences etc. The tools used depend on the strategic objectives, the profile of the target audience (healthcare professionals, research and industry, patients and the general public), the various advantages and disadvantages of each instrument and, last but not least, the communication budget.

2. *NAMMD funding through communication activities*

The Agency aims continued identification, organisation and promotion of fundraising activities based on communication, such as conferences, training sessions etc.

Staff involved in implementation of objectives of the NAMMD communication strategy

Depending on the evolution of the economic crisis and the legislative framework, the NAMMD aims at performance of efficient action towards maintenance and recruiting of highly qualified and better motivated personnel, endowed with the communication skills necessary to meet the objectives and priorities of the Agency's communication strategy.

CONCLUSIONS

The National Agency for Medicines and Medical Devices, whose foundations were laid in 1999, is currently recognised on European and international level as an institution fully able to meet requirements imposed by consolidation of its status as regulatory authority in medicinal products for human use of a EU member states.

The most important NAMMD strategic objective is promotion and protection of public health, by accomplishment of the NAMMD primary role, namely warranty of compliance of authorised medical devices with the required standards and intended purpose as well as of their acceptable level of safety. To successfully meet this goal, the NAMMD must continue as an expert and reliable source of accurate and timely information in the field of medicinal products for human use for the most important stakeholders, including healthcare professionals, research and industry, patients and the general public.

DECISION

No. 16/01.06.2011

on approval of amendment of NAMMD Scientific Council Decision No. 13/05.04.2011 on approval of guidelines on consultations with target patient groups for the package leaflet and documentation on criteria for certification and inspection by the National Agency for Medicines and Medical Devices of operators performing consultations with target patient groups

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 line with Article 8(1) of the Regulation on organisation and operation of the NAMMD Scientific Council, hereby adopts through written procedure the following

DECISION

Art. 1. – Amendment of par. 6 of Article 4 of Annex No. 1 to NAMMD Scientific Council Decision No. 13/05.04.2011 on approval of guidelines on consultations with target patient groups for the package leaflet and documentation on criteria for certification and inspection by the National Agency for Medicines and Medical Devices of operators performing consultations with target patient groups is approved as follows:

"6) For all other authorised medicinal products, irrespective of the time of their authorisation/renewal, an application shall be submitted by 1 September 2011 for approval of a type II variation to marketing authorisation terms, including the outcomes of consultations with target patient groups; noncompliance with provisions in this paragraph shall result in application of provisions in Article 836 (1) i) in Law No. 95/2006 on healthcare reform, as amended."

Art. 2. - On this decision coming into force, NAMMD Scientific Council Decision No. 13/05.04.2011 shall be duly amended.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Acad. Prof. Dr. Leonida Gherasim

Medicinal product batches recalled during the 2nd quarter of 2011

No. crt.	Product recalled	Pharm. form	Strength	INN	Manufacturer/ MAH	Batch	Grounds for recall	Action proposed	Recall date
1	REGENON RETARD	Prolonged-release capsules	60 mg	amfepramonum	Temmler Pharma &Co KG, Germany/ Temmler Pharma &Co KG, Germany	08010, 08010A, 08011, 09012, 09012A, 09012B, 10014, 10015	Voluntary withdrawal from the market following a rapid alert issued by the German competent authority; noncompliant parameter "waste products"	Destruction	23.02.2011
2	CETEBE 500 mg	Prolonged-release capsules	500 mg	acidum ascorbicum	GlaxoSmithKline Consumer Healthcare – Great Britain	All batches	Voluntary withdrawal by the MAH in accordance with Order of the Minister of Health No. 279/30.03.2005	Destruction	22.03.2011
3	ULTRAPROCT SUPOZITOARE	Suppositories	-	combinations	Intendis Manufacturing S.P.A. – Italy/ Intendis GmbH - Germany	02731A, 02732A, 03756A, 03757A, 93579A	Voluntary withdrawal initiated by the manufacturer following the identification of a noncompliance concerning the imprint of the secondary package	Destruction	06.04.2011
4	ULTRALAN® CREMĂ	Cream	0.25%	fluocortolonum	Intendis Manufacturing S.P.A. – Italy/ Intendis GmbH - Germany	91023B, 93027B	Voluntary withdrawal initiated by the manufacturer to perform the update of leaflet information	Destruction	06.04.2011
5	ULTRALAN® UNGUENT	Ointment	0.25%	fluocortolonum	Schering AG – Germany/ Schering AG- Germany	01037B, 91031C	Voluntary withdrawal initiated by the manufacturer to perform the update of leaflet information	Destruction	06.04.2011
6	CONTROLOC 20 mg	Gastro-resistant film-coated tablets	20mg	pantoprazolum	Nycomed GMBH – Germany/ Nycomed GMBH – Germany	124723 (exp. 07.2012)	Withdrawal following the identification of a quality noncompliance related to the imprint of the primary packaging	Destruction	07.04.2011
7	DOCETAXEL TEVA 20 mg	Concentrate and solvent for solution for infusion	20mg	docetaxelum	Pharmachemie B.V. – Holland/ Teva Pharma B.V. - Holland	5480910 (exp.03.2012)	Voluntary withdrawal initiated by the MAH as a precautionary measure, following the identification of an outcome outside the approved specification limits of the finished	Destruction	18.04.2011

No. crt.	Product recalled	Pharm. form	Strength	INN	Manufacturer/ MAH	Batch	Grounds for recall	Action proposed	Recall date
							product, implying no doubt over patient safety		
8	SAB SIMPLEX	Oral suspension	-	simethiconum	Pharmachemie B.V. – Holland/ Teva Pharma B.V. - Holland	0801905B, 0803846B, 0808708B, 0901826E, 0905811A, 0A02178B, 0A02884B, 0A04880D	Voluntary withdrawal initiated by the MAH for not ranging between the limits of the specification approved for the parameter "Dose and dose uniformity"	Destruction	19.04.2011
9	NOVYNETTE	Film-coated tablets	-	combinations	Gedeon Richter PLC, Hungary/ Gedeon Richter PLC, Hungary	T11345A	Voluntary withdrawal initiated by the MAH due to a noncompliance in the design process of the package leaflet	Withdrawal of noncompliant batches	19.04.2011
10	RISPEN 1	Film-coated tablets	1 mg	risperidonum	Zentiva AS, Czech Republic/ Zentiva AS, Czech Republic	2111010 (exp. 09.2012)	Voluntary withdrawal following a Rapid Alert received from the Czech competent authority due to the lack of the median line of certain tablets	Destruction	18.05.2011
11	KETOTIFEN LPH® 1 mg	Tablets	1 mg	ketotifenum	Labormed Pharma S.A., Romania/ Labormed Pharma S.A., Romania	1010010146 (exp. 01.2014), 1020020251 (exp. 02.2014)	Voluntary withdrawal initiated by the manufacturer following the identification of a non-compliance concerning the imprint of the blister	Destruction	24.05.2011
12	PROSPAN PICĂTURI ORALE, SOLUȚIE	Eye drops, solution	20 mg/ml	herbs	Engelhard Arzneimittel GMBH & CO. KG. – Germany/ Engelhard Arzneimittel GMBH & CO. KG. – Germany	09F074D (exp. 05.2013)	Withdrawal from the market following the identification of a quality noncompliance (particles in suspension within the solution)	Destruction	24.05.2011
13	PRAZOLEX 1mg, PRAZOLEX 0.25mg	Tablets	1 mg, 0.25 mg	alprazolam	Gedeon Richter SA, ROMANIA/ Gedeon Richter SA, Romania	Prazolex 1 mg: 02100166, 02110132 Prazolex 0.25mg: 06100581, 11101009,	Voluntary withdrawal initiated by the manufacturer following the identification of a noncompliance concerning the imprint of the primary	Destruction	23.06.2011

No. crt.	Product recalled	Pharm. form	Strength	INN	Manufacturer/ MAH	Batch	Grounds for recall	Action proposed	Recall date
						11101008, 01110076, 04110365	package (does not contain the name of the active substance)		
14	LINCODAR	Capsules	500 mg	lincomycinum	Dar Al Dawa Pharma SRL, Romania/ Dar Al Dawa Pharma SRL, Romania	544DMFG (exp. 03.2014), 1310MFG (exp. 10.2012)	Withdrawal due to the identification of a noncompliance concerning the imprint of the secondary packaging	Destruction	23.06.2011

Applications for marketing authorisation/marketing authorisation renewal submitted to the NAMMD during the 1st quarter of 2011

During the 1st quarter of 2011, 526 marketing authorisation/renewal applications for medicinal products corresponding to the following therapeutic groups have been received:

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
A08 – Antiobesity preparations (excluding diet products)
A09 - Digestives, including enzymes
A10 - Drugs used in diabetes
A11 - Vitamins
A12 - Mineral supplements
A14 – Anabolic agents for systemic use
B01 - Antithrombotic Agents
B02 - Antihemorrhagics
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
D07 – Corticosteroids for dermatological use
G03 - Sex hormones and modulators of the genital system
G04 - Urologicals
H01 - Pituitary and hypothalamic hormones
H02 – Corticosteroids for systemic use
H05 – Calcium homeostasis
J01 - Antibacterials for systemic use
J05 – Antivirals for systemic use
J06 – Immune sera and immunoglobulins

L01 – Antineoplastic agents
L02 – Endocrine therapy
L03 - Immunostimulants
M01 - Anti–inflammatory and anti–rheumatic medicinal products
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
P02 - Anthelmintics
R01 – Nasal preparations
R02 - Throat preparations
R03 - Drugs for obstructive airway diseases
R05 - Cough and cold preparations
R06 - Antihistamines for systemic use
R07 – Other respiratory system products
S01 - Ophthalmologicals
V03 – All other therapeutic products
V06 – General nutrients
V08 – Contrast media
V09 – Diagnostic radiopharmaceuticals
XR – Homeopathic products

Medicinal products authorised for marketing by the NAMMD during the 1st quarter of 2011

INN	Invented name	Pharmaceutical form	Strength	Manufacturer	Country	MA Number		
ACIDUM ACETYLSALICYLICUM	PROTECARDIN 75mg	gastroresistant tablets	75mg	BIOFARM S.A.	ROMANIA	3159	2011	02
ACIDUM ACETYLSALICYLICUM	ACID ACETILSALICILIC ZENTIVA 500 mg	tablets	500mg	ZENTIVA S.A.	ROMANIA	3338	2011	02
ACIDUM ALENDRONICUM	ACID ALENDRONIC PFIZER 70 mg	tablets	70mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	3241	2011	09
ACIDUM IBANDRONICUM	QUODIXOR 150 mg	film-coated tablets	150mg	PHARMATHEN S.A.	GREECE	3157	2011	02
ACIDUM IBANDRONICUM	MIRDEZEL 150 mg	film-coated tablets	150mg	PHARMATHEN S.A.	GREECE	3278	2011	02
ACIDUM RISEDRONICUM	RISEDRONAT SODIC SANDOZ 35mg	film-coated tablets	35mg	SANDOZ S.R.L.	ROMANIA	3154	2011	16
ACIDUM RISEDRONICUM	RISEDRONAT IVOWEN 35mg	film-coated tablets	35mg	IVOWEN LIMITED	IRELAND	3299	2011	02
ACIDUM RISEDRONICUM	RIDROSEN 35 mg	film-coated tablets	35mg	IVOWEN LIMITED	IRELAND	3298	2011	02
AMIFOSTINUM	ETHYOL 500 mg	powder for solution for infusion	500 mg	SCHERING-PLOUGH EUROPE	BELGIUM	3343	2011	01
ANASTROZOLUM	ANASTROZOL BLUEFISH 1mg	film-coated tablets	1mg	BLUEFISH PHARMACEUTICALS AB	SWEDEN	3150	2011	04
AZATHIOPRINUM	IMMUNOPRIN 75 mg	film-coated tablets	75mg	EBEWE PHARMA GES.M.B.H. NFG. KG	AUSTRIA	3242	2011	02
AZATHIOPRINUM	IMMUNOPRIN 100 mg	film-coated tablets	100mg	EBEWE PHARMA GES.M.B.H. NFG. KG	AUSTRIA	3243	2011	02
BICALUTAMIDUM	BICALUTAMIDA ATB 50mg	film-coated tablets	50mg	ANTIBIOTICE S.A.	ROMANIA	3256	2011	01
BUDESONIDUM	BUDESONIDE WYVERN 0.5mg/2 ml	nebuliser solution for inhalation	0.5 mg/2 ml	WYVERN MEDICAL LIMITED	GREAT BRITAIN	3359	2011	09
CANDESARTANUM CILEXETIL	HIPOSTYN 4 mg	tablets	4mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	3146	2011	15
CANDESARTANUM CILEXETIL	HIPOSTYN 8 mg	tablets	8mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	3147	2011	15
CANDESARTANUM CILEXETIL	HIPOSTYN 16 mg	tablets	16mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	3148	2011	15
CANDESARTANUM CILEXETIL	HIPOSTYN 32 mg	tablets	32mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	3149	2011	15
CARVEDILOLUM	CARVEDILOL AUROBINDO 6.25 mg	film-coated tablets	6.25mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	3180	2011	10

CARVEDILOLUM	CARVEDILOL AUROBINDO 12.5 mg	film-coated tablets	12.5mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	3181	2011	10
CARVEDILOLUM	CARVEDILOL AUROBINDO 25 mg	film-coated tablets	25mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	3182	2011	10
CEFEPIMUM	CEFEPIME KABI 1 g	powder for solution for injection/infusion	1g	FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	3197	2011	03
CEFEPIMUM	CEFEPIME KABI 2 g	powder for solution for injection/infusion	2g	FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	3198	2011	03
CEFTRIAXONUM	CEFTRIAXONA ACTAVIS 1g	powder for solution for injection	1 g	ACTAVIS GROUP PTC EHF	ICELAND	3313	2011	04
CEFTRIAXONUM	CEFTRIAXONA ACTAVIS 2g	powder for solution for injection/infusion	2 g	ACTAVIS GROUP PTC EHF	ICELAND	3314	2011	08
CLINDAMYCINUM	CLINDAMYCIN - MIP 150mg/ml	solution for injection/infusion	150 mg/ml	MIP PHARMA GMBH	GERMANY	3331	2011	04
CLOPIDOGRELUM	XOVAL 75 mg	film-coated tablets	75 mg	DR. REDDY'S LABORATORIES (UK) LTD.	GREAT BRITAIN	3293	2011	12
COMBINATIONS	CLO-EKARZIN 0.50 mg/10 mg	cream	0.50mg/10mg	ANTIBIOTICE S.A.	ROMANIA	3332	2011	01
COMBINATIONS (AMINOACIZI)	GAVISCON MENTOL	oral suspension		RECKITT BENCKISER HEALTHCARE LTD.	GREAT BRITAIN	3227	2011	12
COMBINATIONS (AMINOACIZI)	GAVISCON MENTOL	oral suspension/ envelope		RECKITT BENCKISER HEALTHCARE LTD.	GREAT BRITAIN	3228	2011	17
COMBINATIONS (AMINOACIZI)	GAVISCON MENTOL	chewable tablets		RECKITT BENCKISER HEALTHCARE LTD.	GREAT BRITAIN	3229	2011	22
COMBINATIONS (BUDESONIDUM + FORMOTEROLUM)	BUDFOR 80 micrograms/ 4.5 micrograms/inhalation	inhalation powder	80 micrograms/ 4.5 micrograms/ inhalation	ASTRAZENECA AB	SWEDEN	3164	2011	10
COMBINATIONS (BUDESONIDUM + FORMOTEROLUM)	BUDFOR 160 micrograms/ 4.5 micrograms/inhalation	inhalation powder	160 micrograms/ 4.5 micrograms/ inhalation	ASTRAZENECA AB	SWEDEN	3165	2011	10
COMBINATIONS (BUDESONIDUM + FORMOTEROLUM)	BUDFOR 320 micrograms/ 9 micrograms/inhalation	inhalation powder	320 micrograms/ 9 micrograms/ inhalation	ASTRAZENECA AB	SWEDEN	3166	2011	05
COMBINATIONS (BUDESONIDUM + FORMOTEROLUM)	EDOFLO 320 micrograms/ 9 micrograms/inhalation	inhalation powder	320 micrograms/ 9 micrograms/ inhalation	ASTRAZENECA AB	SWEDEN	3163	2011	05
COMBINATIONS (BUDESONIDUM + FORMOTEROLUM)	EDOFLO 160 micrograms/ 4.5 micrograms/ inhalation	inhalation powder	160 micrograms/ 4.5 micrograms/ inhalation	ASTRAZENECA AB	SWEDEN	3162	2011	10

COMBINATIONS (BUDESONIDUM + FORMOTEROLUM)	EDOFLO 80 micrograms/ 4.5 micrograms/inhalation	inhalation powder	80 micrograms/ 4.5 micrograms/ inhalation	ASTRAZENECA AB	SWEDEN	3161	2011	10
COMBINATIONS (BUDESONIDUM + FORMOTEROLUM)	SYMBICORT TURBUHALER 80 micrograms/ 4.5 micrograms/inhalation	inhalation powder	80 micrograms/ 4.5 micrograms/ inhalation	ASTRAZENECA AB	SWEDEN	3167	2011	10
COMBINATIONS (BUDESONIDUM + FORMOTEROLUM)	SYMBICORT TURBUHALER 160 micrograms/ 4.5 micrograms/inhalation	inhalation powder	160 micrograms/ 4.5 micrograms/ inhalation	ASTRAZENECA AB	SWEDEN	3168	2011	10
COMBINATIONS (BUDESONIDUM + FORMOTEROLUM)	SYMBICORT TURBUHALER 320 micrograms/ 9 micrograms/inhalation	inhalation powder	320 micrograms/ 9 micrograms/ inhalation	ASTRAZENECA AB	SWEDEN	3169	2011	05
COMBINATIONS (CANDESARTANUM CILEXETIL+ HYDROCHLOROTHIAZIDUM)	HIPOSTYN 8 mg/12.5 mg	tablets	8mg/ 12.5mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	3206	2011	15
COMBINATIONS (CANDESARTANUM CILEXETIL+ HYDROCHLOROTHIAZIDUM)	HIPOSTYN 16 mg/12.5 mg	tablets	16mg/ 12.5mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	3207	2011	15
COMBINATIONS (DORZOLAMIDUM+ TIMOLOLUM)	OPTIKUM 20 mg/ml + 5 mg/ml	eye drops, solution	20mg/ml+ 5mg/ml	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	3140	2011	05
COMBINATIONS (ESTRADIOLUM+ DIDROGESTERONUM)	FEMOSTON MINI 0.5mg/2.5mg	film-coated tablets	0.5mg/ 2.5mg	SOLVAY PHARMACEUTICALS GMBH	GERMANY	3145	2011	04
COMBINATIONS (ETONOGESTRELUM+ ETINILESTRADIOLUM)	CIRCLET 0.120 mg/0.015 mg per 24 h	vaginal release system	0.120mg/ 0.015mg	N.V. ORGANON	HOLLAND	3144	2011	02
COMBINATIONS (IPRATROPII BROMIDUM+ SALBUTAMOLUM)	IPRATROPIU/ SALBUTAMOL TEVA 0.5mg/2.5 mg per 2.5 ml	nebuliser solution for inhalation	0.5mg/2.5mg per 2.5ml	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	3205	2011	09
COMBINATIONS (PERINDOPRILUM+ INDAPAMIDUM)	CO - CONDERAN 4 mg/1.25 mg	tablets	4 mg/ 1.25 mg	MEDICO UNO PHARMA KFT.	HUNGARY	3309	2011	04
COMBINATIONS (PERINDOPRILUM+ INDAPAMIDUM)	CO - CONDERAN 2 mg/0.625 mg	tablets	2 mg/ 0,625 mg	MEDICO UNO PHARMA KFT.	HUNGARY	3308	2011	04
COMBINATIONS (VALSARTANUM+ HYDROCHLOROTHIAZIDUM)	CO - VALSACOR 80mg/12.5mg	film-coated tablets	80 mg/ 12.5 mg	KRKA ,D.D., NOVO MESTO	SLOVENIA	3321	2011	12
COMBINATIONS (VALSARTANUM+ HYDROCHLOROTHIAZIDUM)	CO - VALSACOR 160mg/12.5 mg	film-coated tablets	160 mg/ 12.5 mg	KRKA ,D.D., NOVO MESTO	SLOVENIA	3322	2011	12
COMBINATIONS (VALSARTANUM+ HYDROCHLOROTHIAZIDUM)	CO - VALSACOR 160mg/25 mg	film-coated tablets	160 mg/ 25 mg	KRKA ,D.D., NOVO MESTO	SLOVENIA	3323	2011	12

COMBINATIONS (VALSARTANUM+ HYDROCHLOROTHIAZIDUM)	CO - VALSACOR 320mg/12.5 mg	film-coated tablets	320mg/ 12.5mg	KRKA ,D.D., NOVO MESTO	SLOVENIA	3324	2011	14
COMBINATIONS (VALSARTANUM+ HYDROCHLOROTHIAZIDUM)	CO - VALSACOR 320mg/25 mg	film-coated tablets	320mg/ 25mg	KRKA ,D.D., NOVO MESTO	SLOVENIA	3325	2011	14
DESOGESTRELUM	AZALIA 75 micrograms	film-coated tablets	75 micrograms	GEDEON RICHTER ROMANIA S.A.	ROMANIA	3203	2011	02
DONEPEZILUM	YASNAL 5 mg	orodispersible tablets	5 mg	KRKA D.D.	SLOVENIA	3310	2011	10
DONEPEZILUM	YASNAL 10 mg	orodispersible tablets	10 mg	KRKA D.D.	SLOVENIA	3311	2011	10
DOXORUBICINUM	DOXORUBICINA ACCORD 2 mg/ml	concentrate for solution for infusion	2mg/ml	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	3139	2011	03
DOXORUBICINUM	DHARUXO 2 mg/ml	concentrate for solution for infusion	2mg/ml	ROMASTRU TRADING S.R.L.	ROMANIA	3222	2011	05
DOXYCYCLINUM	DOXICICLINA ATB 100mg	capsules	100 mg	ANTIBIOTICE S.A.	ROMANIA	3356	2011	02
DROTAVERINUM	SPAVERIN 40 mg	capsules	40 mg	ANTIBIOTICE S.A.	ROMANIA	3363	2011	02
DROTAVERINUM	SPAVERIN 80 mg	capsules	80 mg	ANTIBIOTICE S.A.	ROMANIA	3364	2011	02
ESCITALOPRAMUM	ESCITOTAB 10 mg	film-coated tablets	10mg	GENTHON BV	HOLAND	3287	2011	24
ESCITALOPRAMUM	ESCITOTAB 15 mg	film-coated tablets	15mg	GENTHON BV	HOLAND	3288	2011	24
ESCITALOPRAMUM	ESCITOTAB 20 mg	film-coated tablets	20mg	GENTHON BV	HOLAND	3289	2011	28
ESOMEPRAZOLUM	NEXIUM 10 mg	gastroresistant granules for oral suspension	10mg	ASTRAZENECA AB	SWEDEN	3268	2011	01
ESOMEPRAZOLUM	MEPRENE 20 mg	gastroresistant capsules	20mg	ETHYPHARM	FRANCE	3273	2011	18
ESOMEPRAZOLUM	MEPRENE 40 mg	gastroresistant capsules	40mg	ETHYPHARM	FRANCE	3274	2011	18
EXEMESTANUM	EXEMESTAN ACTAVIS 25mg	film-coated tablets	25mg	ACTAVIS GROUP PTC EHF.	ICELAND	3244	2011	06
EXEMESTANUM	EXEMESTAN CHANELLE MEDICAL 25 mg	film-coated tablets	25mg	CHANELLE MEDICAL	IRELAND	3276	2011	08
FINASTERIDUM	FINASTERIDA ACCORD 1mg	film-coated tablets	1mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	3137	2011	02
FINASTERIDUM	FINASTERIDA ACCORD 5mg	film-coated tablets	5mg	ACCORD HEALTHCARE LIMITED	GREAT BRITAIN	3138	2011	15
FLUCONAZOLUM	FLUCONAZOL ACTAVIS 50mg	capsules	50mg	ACTAVIS GROUP PTC EHF.	ICELAND	3190	2011	16
FLUCONAZOLUM	FLUCONAZOL ACTAVIS 100 mg	capsules	100mg	ACTAVIS GROUP PTC EHF.	ICELAND	3191	2011	16
FLUCONAZOLUM	FLUCONAZOL ACTAVIS 150 mg	capsules	150mg	ACTAVIS GROUP PTC EHF.	ICELAND	3192	2011	16
FLUCONAZOLUM	FLUCONAZOL ACTAVIS 200 mg	capsules	200mg	ACTAVIS GROUP PTC EHF.	ICELAND	3193	2011	16

FLUPIRTINUM	FLUPIZEN 100 mg	capsules	100 mg	ZENTIVA K.S.	CZECH REPUBLIC	3354	2011	05
GEMCITABINUM	GITRABIN 40 mg/ml	powder for solution for infusion	40mg/ml	ACTAVIS GROUP PTC EHF.	ICELAND	3170	2011	03
GEMCITABINUM	GETMISI 40 mg/ml	powder for solution for infusion	40mg/ml	SIGILLATA LTD.	GREAT BRITAIN	3186	2011	03
GEMCITABINUM	GEMSOL 40 mg/ml	powder for solution for infusion	40 mg/ml	EBEWE PHARMA GES.M.B.H. NFG. KG	AUSTRIA	3294	2011	10
GLICLAZIDUM	GLICLAZIDA GAMMA 30mg	modified-release tablets	30mg	WORWAG PHARMA GMBH & CO.KG	GERMANY	3248	2011	15
HALOPERIDOLUM	HALOPERIDOL ROMPHARM 2 mg/ml	eye drops, solution	2 mg/ml	ROMPHARM COMPANY S.R.L.	ROMANIA	3330	2011	01
IBUPROFENUM	NUROFEN PENTRU COPII, CU AROMĂ DE CAPŞUNI	oral suspension	200mg/5ml	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED	GREAT BRITAIN	3272	2011	04
IBUPROFENUM	NUROFEN PENTRU COPII, CU AROMĂ DE PORTOCALE	oral suspension	200mg/5ml	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED	GREAT BRITAIN	3271	2011	04
IMIPENEMUM + CILASTATINUM	IMECITIN 250 mg/250 mg	powder for solution for infusion	250mg/ 250mg	ACTAVIS GROUP PTC EHF	ICELAND	3141	2011	02
IMIPENEMUM + CILASTATINUM	IMECITIN 500 mg/500 mg	powder for solution for infusion	500mg/ 500mg	ACTAVIS GROUP PTC EHF	ICELAND	3142	2011	02
IMIPENEMUM + CILASTATINUM	IMIPENEM/ CILASTATIN HOSPIRA 500 mg/500 mg	powder for solution for infusion	500mg/ 500mg	HOSPIRA UK LIMITED	MAREA BRITANIE	3261	2011	02
IRBESARTANUM	IRBESARTAN RICHTER 75mg	film-coated tablets	75 mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	3300	2011	07
IRBESARTANUM	IRBESARTAN RICHTER 150mg	film-coated tablets	150 mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	3301	2011	07
IRBESARTANUM	IRBESARTAN RICHTER 300mg	film-coated tablets	300 mg	GEDEON RICHTER ROMANIA S.A.	ROMANIA	3302	2011	07
IRINOTECANUM	IRINOTECAN KABI 20mg/ml	concentrate for solution for infusion	20 mg/ml	FRESENIUS KABI ONCOLOGY PLC	GREAT BRITAIN	3312	2011	04
ITRACONAZOLUM	ITRACONAZOL UNIVERSAL FARMA 100mg	capsules	100 mg	UNIVERSAL FARMA, S.L.	SPAIN	3153	2011	11
LATANOPROSTUM	LATALUX 50 micrograms/ml	eye drops, solution	50 micrograms/ml	JELFA S.A.	POLAND	3275	2011	03
LEFLUNOMIDUM	LEFLUNOMIDA SANDOZ 10 mg	film-coated tablets	10 mg	SANDOZ S.R.L.	ROMANIA	3306	2011	12
LEFLUNOMIDUM	LEFLUNOMIDA SANDOZ 20mg	film-coated tablets	20 mg	SANDOZ S.R.L.	ROMANIA	3307	2011	12
LETROZOLUM	LETROZOL STADA 2.5mg	film-coated tablets	2.5mg	STADA ARZNEIMITTEL AG	GERMANY	3240	2011	03
LETROZOLUM	LETROZOL TERAPIA 2.5mg	film-coated tablets	2.5 mg	TERAPIA S.A.	ROMANIA	3342	2011	06

LEVOFLOXACINUM	CENOMAR 5 mg/ml	solution for infusion	5mg/ml	STADA ARZNEIMITTEL AG	GERMANY	3202	2011	06
MESALAZINUM	SALOFALK 1 g	suppositories	1g	DR. FALK PHARMA GMBH	GERMANY	3213	2011	07
METHYLFENIDATUM	MEDIKINET 10mg	tablets	10mg	MEDICE ARZNEIMITTEL PUTTER GMBH & CO KG	GERMANY	3220	2011	02
METHYLFENIDATUM	MEDIKINET EM 5mg	modified-release capsules	5mg	MEDICE ARZNEIMITTEL PUTTER GMBH & CO.KG	GERMANY	3214	2011	02
METHYLFENIDATUM	MEDIKINET EM 10 mg	modified-release capsules	10mg	MEDICE ARZNEIMITTEL PUTTER GMBH & CO.KG	GERMANY	3215	2011	02
METHYLFENIDATUM	MEDIKINET EM 20 mg	modified-release capsules	20mg	MEDICE ARZNEIMITTEL PUTTER GMBH & CO.KG	GERMANY	3216	2011	02
METHYLFENIDATUM	MEDIKINET EM 30 mg	modified-release capsules	30mg	MEDICE ARZNEIMITTEL PUTTER GMBH & CO.KG	GERMANY	3217	2011	02
METHYLFENIDATUM	MEDIKINET EM 40 mg	modified-release capsules	40mg	MEDICE ARZNEIMITTEL PUTTER GMBH & CO.KG	GERMANY	3218	2011	02
METHYLFENIDATUM	MEDIKINET 5 mg	tablets	5mg	MEDICE ARZNEIMITTEL PUTTER GMBH & CO KG	GERMANY	3219	2011	02
METHYLFENIDATUM	MEDIKINET 20 mg	tablets	20mg	MEDICE ARZNEIMITTEL PUTTER GMBH & CO KG	GERMANY	3221	2011	02
MIRTAZAPINUM	MIRTAZAPINA PFIZER 15mg	orodispersible tablets	15mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	3183	2011	06
MIRTAZAPINUM	MIRTAZAPINA PFIZER 30mg	orodispersible tablets	30mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	3184	2011	06
MIRTAZAPINUM	MIRTAZAPINA PFIZER 45mg	orodispersible tablets	45mg	PFIZER EUROPE MA EEIG	GREAT BRITAIN	3185	2011	06
MIRTAZAPINUM	MIRTAZAPINA ESP PHARMA 15 mg	orodispersible tablets	15mg	ESP PHARMA LTD.	GREAT BRITAIN	3199	2011	16
MIRTAZAPINUM	MIRTAZAPINA ESP PHARMA 30 mg	orodispersible tablets	30mg	ESP PHARMA LTD.	GREAT BRITAIN	3200	2011	16
MIRTAZAPINUM	MIRTAZAPINA ESP PHARMA 45 mg	orodispersible tablets	45mg	ESP PHARMA LTD.	GREAT BRITAIN	3201	2011	16
MODAFINILUM	ASPENDOS 100 mg	tablets	100mg	MEDOCHEMIE LTD	CIPRU	3260	2011	04
MONTELUKASTUM	MONTELUKAST PHARMATHEN5 mg	chewable tablets	5mg	PHARMATHEN S.A.	GREECE	3156	2011	01
MONTELUKASTUM	MONTELUKAST PHARMATHEN 4 mg	chewable tablets	4mg	PHARMATHEN S.A.	GREECE	3155	2011	01
MONTELUKASTUM	MONTELUKAST INVENT FARMA 4 mg	chewable tablets	4mg	INVENT FARMA, S.L.	SPAIN	3230	2011	16
MONTELUKASTUM	MONTELUKAST INVENT FARMA 5 mg	chewable tablets	5mg	INVENT FARMA, S.L.	SPAIN	3231	2011	18
MONTELUKASTUM	MONTELUKAST INVENT FARMA 10mg	chewable tablets	10mg	INVENT FARMA, S.L.	SPAIN	3232	2011	18

MONTELUKASTUM	MONTELUKAST ACTAVIS 10 mg	chewable tablets	10mg	ACTAVIS GROUP PTC EHF	ICELAND	3226	2011	07
MONTELUKASTUM	MONTELUKAST LANNACHER 4 mg	chewable tablets	4mg	LANNACHER HEILMITTEL GES.M.B.H.	AUSTRIA	3250	2011	08
MONTELUKASTUM	MONTELUKAST LANNACHER 5 mg	chewable tablets	5mg	LANNACHER HEILMITTEL GES.M.B.H.	AUSTRIA	3251	2011	08
MONTELUKASTUM	MONTELUKAST LANNACHER 10 mg	chewable tablets	10mg	LANNACHER HEILMITTEL GES.M.B.H.	AUSTRIA	3252	2011	08
MONTELUKASTUM	MONTEXAL 4 mg	chewable tablets	4mg	ICN POLFA RZESZOW S.A.	POLAND	3253	2011	07
MONTELUKASTUM	MONTEXAL 5 mg	chewable tablets	5mg	ICN POLFA RZESZOW S.A.	POLAND	3254	2011	07
MONTELUKASTUM	MONTEXAL 10 mg	chewable tablets	10mg	ICN POLFA RZESZOW S.A.	POLAND	3255	2011	07
MONTELUKASTUM	STANGEN 4 mg	chewable tablets	4mg	DR. REDDY'S LABORATORIES	ROMANIA	3262	2011	05
MONTELUKASTUM	STANGEN 5 mg	chewable tablets	5mg	DR. REDDY'S LABORATORIES	ROMANIA	3263	2011	08
MONTELUKASTUM	STANGEN 10 mg	chewable tablets	10mg	DR. REDDY'S LABORATORIES LTD.	ROMANIA	3264	2011	06
MONTELUKASTUM	MONTELUKAST VIKETO 4mg	chewable tablets	4mg	INVENT FARMA, S.L.	SPAIN	3257	2011	16
MONTELUKASTUM	MONTELUKAST VIKETO 5mg	chewable tablets	5mg	INVENT FARMA, S.L.	SPAIN	3258	2011	18
MONTELUKASTUM	MONTELUKAST VIKETO 10 mg	film-coated tablets	10mg	INVENT FARMA, S.L.	SPAIN	3259	2011	18
MONTELUKASTUM	MONTELUKAST ACTAVIS 4 mg	chewable tablets	4mg	ACTAVIS GROUP PTC EHF	ICELAND	3269	2011	09
MONTELUKASTUM	MONTELUKAST ACTAVIS 5 mg	chewable tablets	5mg	ACTAVIS GROUP PTC EHF	ICELAND	3270	2011	09
MONTELUKASTUM	ASTHATOR 5 mg	chewable tablets	5 mg	TORRENT PHARMA GMBH	GERMANY	3304	2011	08
MONTELUKASTUM	ASTHATOR 4 mg	chewable tablets	4 mg	TORRENT PHARMA GMBH	GERMANY	3303	2011	08
MONTELUKASTUM	ASTHATOR 10 mg	tablets	10 mg	TORRENT PHARMA GMBH	GERMANY	3305	2011	08
MONTELUKASTUM	MONTULIND 10 mg	film-coated tablets	10 mg	SIGILLATA LIMITED	GREAT BRITAIN	3361	2011	09
MONTELUKASTUM	MONLUCARE 5 mg	chewable tablets	5 mg	M.R. PHARMA GMBH	GERMANY	3375	2011	22
MYCOPHENOLATUM MOFETILUM	MICOFENOLAT MOFETIL STADA 250mg	capsules	250 mg	STADA HEMOFARM S.R.L.	ROMANIA	3357	2011	03
MYCOPHENOLATUM MOFETILUM	MICOFENOLAT MOFETIL STADA 500mg	chewable tablets	500 mg	STADA HEMOFARM S.R.L.	ROMANIA	3358	2011	04
NARATRIPTANUM	NACRALID 2.5 mg	film-coated tablets	2.5mg	STADA HEMOFARM S.R.L.	ROMANIA	3277	2011	07

NARATRIPTANUM	NARATRIPTAN STADA HEMOFARM 2.5 mg	film-coated tablets	2.5 mg	STADA HEMOFARM S.R.L.	ROMANIA	3360	2011	07
PANTOPRAZOLUM	PANTOPRAZOL TEVA 40mg	powder for solution for injection/infusion	40 mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	3204	2011	03
PANTOPRAZOLUM	GESOFLUX 40 mg	gastroresistant tablets	40mg	G.L. PHARMA GMBH	AUSTRIA	3210	2011	24
PANTOPRAZOLUM	GESOFLUX 20 mg	gastroresistant tablets	20mg	G.L. PHARMA GMBH	AUSTRIA	3209	2011	24
PANTOPRAZOLUM	REDACIB 20 mg	gastroresistant tablets	20mg	SANDOZ S.R.L.	ROMANIA	3223	2011	04
PANTOPRAZOLUM	PREVIFECT 20 mg	gastroresistant tablets	20mg	SANDOZ S.R.L.	ROMANIA	3224	2011	04
PANTOPRAZOLUM	EMERPAN 20 mg	gastroresistant tablets	20 mg	M.R. PHARMA GMBH	GERMANY	3295	2011	04
PANTOPRAZOLUM	PANTOPRAZOL VALE 40mg	film-coated tablets	40 mg	VALE PHARMACEU-TICALS LIMITED	IRELAND	3297	2011	04
PANTOPRAZOLUM	PANTOPRAZOL VALE 20mg	gastroresistant tablets	20 mg	VALE PHARMACEUTICALS LIMITED	IRELAND	3296	2011	04
PANTOPRAZOLUM	NOACID 20 mg	gastroresistant tablets	20 mg	EGIS PHARMACEUTICALS PLC	HUNGARY	3333	2011	06
PANTOPRAZOLUM	NOACID 40 mg	gastroresistant tablets	40 mg	EGIS PHARMACEUTICALS PLC	HUNGARY	3334	2011	06
PARACETAMOLUM	PARACETAMOL KABI 10mg/ml	solution for infusion	10mg/ml	FRESENIUS KABI ROMANIA S.R.L.	ROMANIA	3225	2011	08
PARACETAMOLUM	PARACETAMOL PANPHARMA 10mg/ml	solution for infusion	10 mg/ml	PANMEDICA	FRANCE	3337	2011	06
PERINDOPRILUM	PERYL 2 mg	tablets	2mg	ICN POLFA RZESZOW S.A.	POLAND	3175	2011	03
PERINDOPRILUM	PERYL 4 mg	tablets	4mg	ICN POLFA RZESZOW S.A.	POLAND	3176	2011	03
PERINDOPRILUM	PERYL 8 mg	tablets	8mg	ICN POLFA RZESZOW S.A.	POLAND	3177	2011	03
PERINDOPRILUM	PRICORON 2 mg	tablets	2 mg	ZENTIVA K.S.	CZECH REPUBLIC	3339	2011	02
PERINDOPRILUM	PRICORON 4 mg	tablets	4 mg	ZENTIVA K.S.	CZECH REPUBLIC	3340	2011	02
PERINDOPRILUM	PRICORON 8 mg	tablets	8 mg	ZENTIVA K.S.	CZECH REPUBLIC	3341	2011	02
PILOCARPINUM	PILOCARPINA ROMPHARM 10 mg/ml	eye drops, solution	10 mg/ml	ROMPHARM COMPANY S.R.L.	ROMANIA	3328	2011	01
PILOCARPINUM	PILOCARPINA ROMPHARM 20 mg/ml	eye drops, solution	20 mg/ml	ROMPHARM COMPANY S.R.L.	ROMANIA	3329	2011	01

PIPERACILLINUM + TAZOBACTAMUM	PIPERACILINA/ TAZOBACTAM PHARMASWISS 4g/0.5g	powder for solution for injection/infusion	4g/0.5g	PHARMASWISS CESKA REPUBLIKA S.R.O.	CZECH REPUBLIC	3187	2011	01
PIROXICAMUM	PIROXICAM ATB 20 mg	suppositories	20 mg	ANTIBIOTICE S.A.	ROMANIA	3355	2011	03
PLANTE	BRONCHIPRET TP	film-coated tablets		BIONORICA SE	GERMANY	3362	2011	03
PRAMIPEXOLUM	PRAMIPEXOL BLUEFISH 0.7 mg	tablets	0.7mg	BLUEFISH PHARMACEUTICALS AB	SWEDEN	3151	2011	02
PRAMIPEXOLUM	PRAMIPEXOL BLUEFISH 0.18 mg	tablets	0.18mg	BLUEFISH PHARMACEUTICALS AB	SWEDEN	3152	2011	02
PROTOXID DE AZOT + OXIGEN	ENTONOX 50%/50%	Medicinal gas, compressed	50%/ 50%	AGA AB	SWEDEN	3143	2011	08
RABEPRAZOLUM	ZULBEX 10 mg	gastroresistant tablets	10mg	KRKA, D.D., NOVO MESTO	SLOVENIA	3178	2011	11
RABEPRAZOLUM	ZULBEX 20 mg	gastroresistant tablets	20mg	KRKA, D.D., NOVO MESTO	SLOVENIA	3179	2011	11
RABEPRAZOLUM	RABELINZ 10 mg	gastroresistant tablets	10 mg	ALCHEMIA LIMITED	GREAT BRITAIN	3352	2011	12
RABEPRAZOLUM	RABELINZ 20 mg	gastroresistant tablets	20 mg	ALCHEMIA LIMITED	GREAT BRITAIN	3353	2011	12
REMIFENTANILUM	REMIFENTANIL TEVA 1 mg	powder for solution for injection/infusion	1 mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	3315	2011	02
REMIFENTANILUM	REMIFENTANIL TEVA 2 mg	powder for solution for injection/infusion	2 mg	TEVA PHARMACEUTICALS S.R.L	ROMANIA	3316	2011	02
REMIFENTANILUM	REMIFENTANIL TEVA 5 mg	powder for solution for injection/infusion	5 mg	TEVA PHARMACEUTICALS S.R.L	ROMANIA	3317	2011	02
REPAGLINIDUM	REPAGLINIDA DR. REDDY'S0.5 mg	tablets	0.5mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	3245	2011	06
REPAGLINIDUM	REPAGLINIDA DR. REDDY'S 1 mg	tablets	1mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	3246	2011	06
REPAGLINIDUM	REPAGLINIDA DR. REDDY'S 2 mg	tablets	2mg	DR. REDDY'S LABORATORIES ROMANIA S.R.L.	ROMANIA	3247	2011	06
RILMENIDINUM	RILMENIDINA TEVA 1 mg	tablets	1mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	3158	2011	05
RIVASTIGMINUM	LORISTIVEN 1.5 mg	capsules	1.5mg	PHARMATHEN S.A.	GREECE	3211	2011	02
RIVASTIGMINUM	LORISTIVEN 3.0 mg	capsules	3,0mg	PHARMATHEN S.A.	GREECE	3212	2011	02
ROPINIROLUM	ROLPRYNA EP 2 mg	prolonged-release tablets	2 mg	KRKA ,D.D., NOVO MESTO	SLOVENIA	3318	2011	04

ROPINIROLUM	ROLPRYNA EP 4 mg	prolonged-release tablets	4 mg	KRKA ,D.D., NOVO MESTO	SLOVENIA	3319	2011	04
ROPINIROLUM	ROLPRYNA EP 8 mg	prolonged-release tablets	8 mg	KRKA ,D.D., NOVO MESTO	SLOVENIA	3320	2011	04
SILDENAFILUM	SILDENAFIL MYLAN 25mg	film-coated tablets	25mg	MYLAN S.A.S.	FRANCE	3265	2011	05
SILDENAFILUM	SILDENAFIL MYLAN 50mg	film-coated tablets	50mg	MYLAN S.A.S.	FRANCE	3267	2011	05
SILDENAFILUM	SILDENAFIL MYLAN 100mg	film-coated tablets	100mg	MYLAN S.A.S.	FRANCE	3265	2011	05
SILIBINUM	SILIMARINA BIOFARM 150mg	tablets	150mg	BIOFARM S.A.	ROMANIA	3160	2011	01
TACROLIMUSUM	TALIXIMUN 0.5 mg	capsules	0.5mg	ICN POLFA RZESZOW S.A.	POLAND	3134	2011	04
TACROLIMUSUM	TALIXIMUN 1 mg	capsules	1mg	ICN POLFA RZESZOW S.A.	POLAND	3135	2011	04
TACROLIMUSUM	TALIXIMUN 5 mg	capsules	5mg	ICN POLFA RZESZOW S.A.	POLAND	3136	2011	04
TACROLIMUSUM	TACNI 0.5 mg	capsules	0.5 mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	3290	2011	07
TACROLIMUSUM	TACNI 1 mg	capsules	1 mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	3291	2011	07
TACROLIMUSUM	TACNI 5 mg	capsules	5 mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	3292	2011	07
TACROLIMUSUM	TACROLIMUS ASTRON 0.5mg	capsules	0.5 mg	ASTRON RESEARCH LIMITED	GREAT BRITAIN	3335	2011	05
TACROLIMUSUM	TACROLIMUS ASTRON 1mg	capsules	1 mg	ASTRON RESEARCH LIMITED	GREAT BRITAIN	3336	2011	06
TAPENTADOLUM	PALEXIA 50 mg	film-coated tablets	50mg	GRUNENTHAL GMBH	GERMANY	3279	2011	22
TAPENTADOLUM	PALEXIA 75 mg	film-coated tablets	75mg	GRUNENTHAL GMBH	GERMANY	3280	2011	22
TAPENTADOLUM	PALEXIA 100 mg	film-coated tablets	100mg	GRUNENTHAL GMBH	GERMANY	3281	2011	22
TAPENTADOLUM	PALEXIA RETARD 50mg	prolonged-release tablets	50mg	GRUNENTHAL GMBH	GERMANY	3282	2011	22
TAPENTADOLUM	PALEXIA RETARD 100mg	prolonged-release tablets	100mg	GRUNENTHAL GMBH	GERMANY	3283	2011	22
TAPENTADOLUM	PALEXIA RETARD 150mg	prolonged-release tablets	150mg	GRUNENTHAL GMBH	GERMANY	3284	2011	22
TAPENTADOLUM	PALEXIA RETARD 200mg	prolonged-release tablets	200mg	GRUNENTHAL GMBH	GERMANY	3285	2011	22
TAPENTADOLUM	PALEXIA RETARD 250mg	prolonged-release tablets	250mg	GRUNENTHAL GMBH	GERMANY	3286	2011	22

TAPENTADOLUM	YANTIL 50 mg	film-coated tablets	50 mg	GRUNENTHAL GMBH	GERMANY	3344	2011	22
TAPENTADOLUM	YANTIL 75 mg	film-coated tablets	75 mg	GRUNENTHAL GMBH	GERMANY	3345	2011	22
TAPENTADOLUM	YANTIL 100 mg	film-coated tablets	100 mg	GRUNENTHAL GMBH	GERMANY	3346	2011	22
TAPENTADOLUM	YANTIL retard 50 mg	prolonged-release tablets	50 mg	GRUNENTHAL GMBH	GERMANY	3347	2011	22
TAPENTADOLUM	YANTIL retard 100 mg	prolonged-release capsules	100 mg	GRUNENTHAL GMBH	GERMANY	3348	2011	22
TAPENTADOLUM	YANTIL retard 150 mg	prolonged-release tablets	150 mg	GRUNENTHAL GMBH	GERMANY	3349	2011	22
TAPENTADOLUM	YANTIL retard 200 mg	prolonged-release tablets	200 mg	GRUNENTHAL GMBH	GERMANY	3350	2011	22
TAPENTADOLUM	YANTIL 250 mg	prolonged-release tablets	250 mg	GRUNENTHAL GMBH	GERMANY	3351	2011	22
TERBINAFINUM	TERBISIL10 mg/g	cream	10mg/g	GEDEON RICHTER PLC.	HUNGARY	3208	2011	01
TETRABENAZINUM	TETMODIS 25 mg	tablets	25mg	ORPHA-DEVEL HANDELS UND VERTRIEBS GMBH	AUSTRIA	3249	2011	01
VALSARTANUM	GERVATON 40 mg	film-coated tablets	40mg	SYNTHON BV	HOLAND	3171	2011	11
VALSARTANUM	GERVATON 80 mg	film-coated tablets	80mg	SYNTHON BV	HOLAND	3172	2011	11
VALSARTANUM	GERVATON 160 mg	film-coated tablets	160mg	SYNTHON BV	HOLAND	3173	2011	11
VALSARTANUM	GERVATON 320 mg	film-coated tablets	320mg	SYNTHON BV	HOLAND	3174	2011	11
VALSARTANUM	VASOPENTOL 40 mg	film-coated tablets	40mg	EGIS PHARMA-CEUTICALS PLC	HUNGARY	3233	2011	14
VALSARTANUM	VASOPENTOL 80 mg	film-coated tablets	80mg	EGIS PHARMA-CEUTICALS PLC	HUNGARY	3234	2011	14
VALSARTANUM	VASOPENTOL 160 mg	film-coated tablets	160mg	EGIS PHARMA-CEUTICALS PLC	HUNGARY	3235	2011	14
VANCOMYCINUM	VANCOMICINA PHARMASWISS 500 mg	powder for solution for infusion	500mg	PHARMASWISS CESKA REPUBLIKA S.R.O.	CZECH REPUBLIC	3188	2011	02
VANCOMYCINUM	VANCOMICINA PHARMASWISS 1000 mg	powder for solution for infusion	1000mg	PHARMASWISS CESKA REPUBLIKA S.R.O.	CZECH REPUBLIC	3189	2011	02
ZIPRASIDONUM	ZIPRASIDONA TEVA 20mg	capsules	20mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	3236	2011	05
ZIPRASIDONUM	ZIPRASIDONA TEVA 40mg	capsules	40mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	3237	2011	05
ZIPRASIDONUM	ZIPRASIDONA TEVA 60mg	capsules	60mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	3238	2011	04

ZIPRASIDONUM	ZIPRASIDONA TEVA 80mg	capsules	80mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	3239	2011	04

EMA newly centrally authorised medicinal products for which the European Commission issued a decision during the 1st quarter of 2011

INN	Invented name	Pharmaceutical form	Strength	MA Holding Company	Country	MA number		
COMBINATIONS (LAMIVUDINUM+ ZIDOVUDINUM)	LAMIVUDINA/ ZIDOVUDINA TEVA	film-coated tablets	150 mg/ 300mg	TEVA PHARMA B.V.	HOLAND	663	2011	02
TOPOTECAMUM	POTACTASOL 1mg	powder for concentrate for solution for infusion	1mg/ml	ACTAVIS GROUP PTC EHF	ROMANIA	660	2011	01
TOPOTECAMUM	POTACTASOL 4mg	powder for concentrate for solution for infusion	1mg/ml	ACTAVIS GROUP PTC EHF	ICELAND	660	2011	01