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National Agency for Medicines and Medical Devices

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ORDER No. 387 of 31 March 2015
on amendment of Order of the Minster of Health No. 861/2014 for approval of criteria and methodology for assessment of health technologies, of documentation to be submitted by applicants, methodological means used in the assessment for inclusion, extension of indications, non-inclusion into or exclusion from the List of International Non-proprietary Names of on-prescription medicinal products as provided to insurants, irrespective of personal contribution, in the frame of the health insurance system, as well as of International Non-proprietary Names of medicinal products provided in national health insurance programmes, as well as the means for appeal thereof

ISSUED: THE MINISTRY OF HEALTH
PUBLISHED IN: THE OFFICIAL GAZETTE OF ROMANIA, No. 224 of 2 April 2015

On seeing Approval Report No. N. B. 3. 177 of 31 March 2015 of the Directorate for Medicinal Product and Medical Devices Policies of the Ministry of Health and notification No. 24. 008E of 30 March 2015 of the National Agency for Medicines and Medical Devices, registered with the Ministry of Health under No. NB. 3. 126 of 30 March 2015,

Taking into account provisions of Article 232^1 of Law 95/2006 on healthcare reform, as amended,

Having regard to provisions of Article 2(3) and (5) of Government Decision No. 734/2010 on the organisation and operation of the National Agency for Medicines and Medical Devices, as amended,

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

the Minister of Health hereby issues the following Order:

Article 1

Order No. 861 of 23 July 2014 on approval of criteria and methodology for assessment of health technologies, of documentation to be submitted by applicants, methodological means used in the assessment for inclusion, extension of indications, non-inclusion into or exclusion from the List of International Non-proprietary Names of on-prescription medicinal products as provided to insurants, irrespective of personal contribution, in the frame of the health insurance system, as well as of International Non-proprietary Names of medicinal products provided in national health insurance programmes, as well as the means for appeal thereof, as published in the Official Gazette of Romania, No. 557 of 28 July 2014, as amended, is hereby amended as follows:

1. A new article is introduced after Article 5, Article 5^1, reading as follows:

"ARTICLE 5^1
The form for decision of the National Agency for Medicines and Medical Devices on medicinal product inclusion, extension of indications, non-inclusion, exclusion, addition/relocation of reimbursed INNs, (*), (**), (⁂) marking of reimbursed INNs into/from the List as provided in Annex 6. "
2. Article 11 is hereby amended and shall read as follows:
"ARTICLE 11
Annexes No. 1 - 6 are integral part of this order. "
3. In Annex 1, under Article1, letter d) is repealed.
4. In Annex 1, under Article1, letter p) is hereby amended and shall read as follows:
"p) elimination from/addition to of the (*), (**), (⁂) marking – change of conditions for prescription of therapy with medicinal products corresponding to compensated INNS included into the List;".
5. In Annex 1, under Article1, a new letter is introduced after letter p), letter p^1), reading:
"p^1) Therapy line - therapeutic regimen undertaken with a single INN or INN combination, in a varying number of cycles and of varying duration. Therapy is initiated with the first line of therapy, whereas further therapy lines (the second, third and subsequent) may be instituted each time when progress of the disease is documented;".
6. In Annex 1, Article 2 is hereby amended and shall read as follows:
"ARTICLE 2
Medicinal product inclusion, extension of indications, non-inclusion, exclusion, addition/relocation of reimbursed INNs, (*), (**), (⁂) marking of reimbursed INNs into/from the List is performed according to this Annex, by decision of the National Agency for Medicines and Medical Devices, based on the report of its specialised Health Technologies Assessment unit ;".
7. In Annex 1, following Table 2 - Criteria for Reimbursable INNs with (*), (**),(⁂) or (****) marking, points (i) - (iv) are hereby amended and shall read as follows:
"(i) Products with calculated monthly therapy > 2 x GDP*)/capita/month;
(ii) Products with calculated monthly therapy between 1 x and 2 x GDP*)/capita/month;
(iii) Products with calculated monthly therapy between 1 x GDP*)/capita/month and the minimum gross wage on issuance of the decision for inclusion into the List;
(iv) Products with calculated monthly therapy < the minimum gross wage on issuance of the decision for inclusion into the List. "
8. In Annex 1, in Table 2 - Criteria for Reimbursable INNs with (*), (**),(⁂) or (****) marking, a new marking is introduced under marling (*), marking (**), reading:

"(**) Monthly therapy costs - total INN costs calculated based on maximal retail price VAT included, as entered in the National Catalogue of Prices for Medicinal Products for Human Use on assessment, based on doses and length of administration as provided in the SmPC, for one calendar month. Monthly therapy costs are calculated for each INN strength, pharmaceutical form or administration route. Reimbursed INN marking with (*), (**),(**) or (****) is determined by the most costly pharmaceutical form for monthly therapy. "

9. In Annex 1, Table 3 – Assessment criteria for reimbursable INNs in the List is hereby amended and shall read as follows:

"Table 3. - Assessment criteria for reimbursable INNs in the List

Assessment criteria	Rating	One rating chosen only	Scores may be summated
1. HTA based on estimate of the therapeutic benefit (SMR)			
1. 1. INN assessed by the HAS with major/ important SMR rating (BT 1)	0	Not exceeding 25 points	
1. 2. INN not assessed by the HAS	10		
1. 3. INN assessed by the HAS with moderate/low SMR rating (BT 2)	15		
1. 4. INN assessed by the HAS with insufficient SMR rating (BT 3)	25		
2. HTA based on cost-efficacy - GREAT BRITAIN (NICE/SMC)			
2. 1. INN approved, without restrictions, by the Great Britain authority for assessment of health technologies	0	Not exceeding 25 points	
2. 2. INN not assessed by the Great Britain authority for assessment of health technologies (**NICE/SMC)**	10		
2. 3. INN approved upon revision, with restrictions as compared to the SmPC, by the Great Britain authority for assessment of health technologies (NICE/SMC).	15		
2. 4. INN not approved for inclusion in the reimbursement system by the Great Britain authority for assessment of health technologies (NICE/SMC)/Approval for inclusion in the system has been withdrawn/included into the negative list of the Great Britain National Health Service (NHS)/withdrawn of the List of reimbursed medicinal products of the UK Public	25		

Health Medical Service.			

10. In Annex 1, the Note under Table 4 - Assessment criteria for new INNs is hereby amended and shall read as follows:
"Note:
For fixed dose combinations whose components have already been included in the List, only the cost-minimisation analysis shall be provided, comparing costs/recommended daily dosage (annual RDDs) *) with costs/annual RDDs, separately for the components of the combination. The combination shall only be included in the List if costs/annual RDDs are lower or no higher than the summated costs/annual RDDs of the separate components.
*) Costs/recommended daily dosage (annual RDDs) – total INN costs calculated based on maximal retail price VAT included as entered in the National Catalogue of Prices for Medicinal Products for Human Use on assessment, based on doses and length of administration as provided in the SmPC, for one calendar month. Cost/recommended daily dosage (annual RDDs) calculated for the same INN strength, pharmaceutical form or administration route; when both the innovative medicinal product and the generic components of the fixed combination are available on the market, the summation of costs/annual RDDs of separate components is performed based on the least costly generics in maximal retail prices including VAT, as entered in the National Catalogue of Prices for Medicinal Products for Human Use on assessment.
The 27 Member States for which reimbursement must be demonstrated are:

1. Austria
2. Belgium
3. Bulgaria
4. Cyprus
5. Croatia
6. The Czech Republic
7. Denmark
8. Estonia
9. Finland
10. France
11. Germany
12. Greece
13. Hungary
14. Ireland
15. Italy
16. Latvia
17. Lithuania
18. Luxembourg
19. Malta
20. Great Britain

21. Holland
22. Poland
23. Portugal
24. Slovakia
25. Slovenia
26. Spain
27. Sweden. ”

11. Two new tables, Table 5 – Criteria for assessment of new orphan designated INNs as approved by the European Medicines Agency and Table 6 – Criteria for assessment of new therapeutic INNs for infectious, transmissible INNs of major public health impact are hereby added under Table 4 - Assessment criteria for new INNs.

“Table 5 – Criteria for assessment of new orphan designated INNs as approved by the European Medicines Agency

Assessment criteria	Rating	
Treatment, prevention and diagnostic of life-threatening or chronically debilitating conditions affecting not more than five in 10 thousand persons in the EU. In addition, there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question authorised in the EU, or, if such method exists, the medicinal product in question will be of significant benefit to those affected by that condition.	55	
Number of EU states (out of the 27) where the product is reimbursed	No. of states	Rating
	0-2	0
	3-7	10
	8-13	20
	14-27	25

Note:
Criteria for the decision on inclusion, extension of indications or non-inclusion of orphan designated INNs as approved by the European Medicines Agency are the same as provided in Annex 2 to this order, under I, letter B, No. 1 and 2.

Table 6 – Criteria for assessment of new therapeutic INNs for infectious, transmissible INNs of major public health impact

Assessment criteria	Rating
New therapeutic INNs for infectious, transmissible INNs of major public health impact	60

Note:
Infectious, transmissible diseases of major public health impact are established by order of the minister of health based on proposals submitted by a committee, according to provisions of Article 11(1) of Government Decision No. 144/2010 on organisation and operation of the Ministry of Health, as amended, in line with the National Public Health Strategy 2014-2020, approved by Government Decision No. 1 028/2014. "

12. In Annex 2, as per point I, letter A, current number 11 is hereby amended and shall read as follows:

"11. For substantiation of the choice of the comparator relevant for medical practice in Romania, the National Agency for Medicines and Medical Devices may require the opinion of advisory committees of the Ministry of Health, within 10 calendar days of submission of documentation by the applicant."

13. In Annex 2, as per point I, letter A, current number 22 is hereby amended and shall read as follows:

"22. Therapy costs are estimated based on the comparator relevant for medical practice in Romania. Where the comparator relevant for medical practice in Romania is not found in the submitted documentation, this shall be mentioned in the interim report drafted by the National Agency for Medicines and Medical Devices, together with the of advisory committees of the Ministry of Health provided for substantiation of choice of the relevant comparator. "

14. In Annex 2, as per point I, letter A, current number 23, after Table 1 - Data required for calculation of therapy costs, a note is introduced, reading:

"Note:
Therapy costs – total INN cost calculated based on maximal retail price VAT included, as entered in the National Catalogue of Prices for Medicinal Products for Human Use on assessment, based on doses and length of administration as provided in the SmPC, for one calendar month.
Therapy costs are calculated for the same strength, pharmaceutical form or administration route as the comparator's; when both the innovative medicinal product and the generic components of chosen comparator are available on the market, therapy costs are calculated based on the least costly generic in maximal retail prices including VAT, as entered in the National Catalogue of Prices for Medicinal Products for Human Use on assessment. ”

15. In Annex 2, as per point I, letter B, current number 5 is hereby amended and shall read as follows:

"5. Criteria for decision on maintenance in the List:
a) HTA ratings under 25 de as per this methodology result in maintenance of the same reimbursement level for any INN;
b) HTA ratings 25 - 49 as per this methodology result in relocation of the INN in the sublist with the lowest reimbursement level as decided by Government Decision. "

16. In Annex 2, as per point II, current number 4 is hereby amended and shall read as follows:
"4. The Commission for resolution of appeals is approved by order of the minister of health and shall consist of one representative of the Ministry of Health, 2 representatives of the National Agency for Medicines and Medical Devices and 2 representatives of the National Health Insurance House.
Representatives of the National Agency for Medicines and Medical Devices nominated to be part of the Commission for resolution of appeals shall be different from staff of Department for Assessment of Medical Technologies and those involved in assessment.
Decisions of the Commission for resolution of appeals are made by open vote, with simple majority.
Sessions of the Commission for resolution of appeals may be attended by representatives of the appellant Marketing Authorisation Holder, of associations of medicinal product manufacturers and patient associations, who may participate as observatories with no voting rights. "
17. A new Annex is introduced after Annex 5, Annex 6, as provided in the Annex making integral part of this order.

ARTICLE II
This order is published in the Official Gazette of Romania, Part I.

p. Minister of Health,
Alin Iulian Tucmeanu,
Secretary of State

Bucharest, 31 March 2015.
No. 387.

Annex
(Annex 6 to Order No. 861/2014)

NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES

DECISION
No. . . /. . . . .

On seeing Application No. . . . . submitted by . . . . . to the Agency for Medicines and Medical Devices concerning the medicinal product . . . . . ,

Having regard for the Assessment report drafted by the Department for Assessment of Medical Technologies of the National Agency for Medicines and Medical Devices in accordance with provisions of Order No. 861/2014 for approval of criteria and methodology for assessment of health technologies, of documentation to be submitted by applicants, methodological means used in the assessment for inclusion, extension of indications, non-inclusion into or exclusion from the List of International Non-proprietary Names of on-prescription medicinal products as provided to insurants, irrespective of personal contribution, in the frame of the health insurance system, as well as of International Non-proprietary Names of medicinal products provided in national health insurance programmes, as well as the means for appeal thereof as amended,

Based on provisions of Article 8(3) of Government Decision No. of Government Decision No. 734/2010 on the organisation and operation of the National Agency for Medicines and Medical Devices, as amended,

The President of the National Agency for Medicines and Medical Devices hereby

DECIDES on:

1.
( ) Unconditional inclusion
( ) Non-inclusion
( ) Exclusion
( ) Conditional inclusion
( ) Extension of indications
( ) Addition/Relocation of reimbursed INN
( ) Reimbursed INN marking with (*), (**), (***), (****)
for INN: . . . . . .
Pharmaceutical form . . . . . .

Strength . . . . . .
for indication:. . . . . .
into the proposed List of International Non-Proprietary Names of on-prescription medicinal products as provided to insurants, irrespective of personal contribution, in the frame of the health insurance system, as well as of International Non-proprietary Names of medicinal products provided in national health insurance programmes.

2. The Applicant and the National Health Insurance House shall be notified concerning this Decision.

President of the National Agency
for Medicines and Medical Devices
. . . . . .

ORDER No. 355 of 24 March 2015
for supplementation of Order of the Minister of Health No. 888/2014 on approval of fees payable to the National Agency for Medicines and Medical Devices for services related to medicinal products for human use

ISSUED: THE MINISTRY OF HEALTH
PUBLISHED IN: THE OFFICIAL GAZETTE OF ROMANIA, No. 212 of 30 March 2015

On seeing the Approval report No. N. B. 2. 859/2015 drafted by the Directorate for Medicinal Product and Medical Devices Policies of the Ministry of Health and the proposal of the National Agency for Medicines and Medical Devices No. 4. 580/2015,

Taking into account provisions of article 10 d) of Government Decision No. 734/2010 on the organisation and operation of the National Agency for Medicines and Medical Devices, as amended,

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

the Minister of Health hereby issues the following Order:

Article I

Order of the Minister of Health No. 888/2014 on approval of fees payable to the National Agency for Medicines and Medical Devices for services related to medicinal products for human use, published in the Official Gazette of Romania, No. 572 of 31 July 2014, is hereby supplemented as follows:

- Under point III of the Annex, "Assessment of documentation for marketing authorisation/marketing authorisation renewal for medicinal products for human use and conduct of other activities", letter B "Assessment of documentation for marketing authorisation/marketing authorisation renewal through European procedures", a new item, 26^1, shall be introduced item 26. b), reading as follows:

No.	Activity	Fee -Euro-
26^1	Marketing authorisation of traditional herbal medicinal products [art. 16(a) of Directive 2001/83/EC or art. 714 of Law No. 95/2006, as amended] authorisation by simplified	1. 925

	procedure – European procedures	

Article II

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

p. Minister of Health,
Gabriel Florin Puşcău,
Secretary General 2

Bucharest, 24 March 2015.
No. 355.

ORDER
No. 194/23. 02. 2015
on Rules for assessment and approval of advertising of medicinal products for human use

ISSUED: THE MINISTRY OF HEALTH
PUBLISHED IN: THE OFFICIAL GAZETTE OF ROMANIA, No. 168 of 11 March 2015

On seeing Approval Report No. N. B. 1. 633/2015 of the Directorate for Medicinal Product and Medical Devices Policies of the Ministry of Health and notification No. N. B. 5. 787/2014 of the National Agency for Medicines and Medical Devices,

Taking into account provisions of Articles 797 – 811 of Law 95/2006 on healthcare reform, as amended, as well as Law No. 148/2000 on advertising, as amended, as well as of Law No. 158/2008 on misleading advertising and comparative advertising, republished, and the Audio-Visual Law No. 504/2002, as amended,

Having regard to Decision of the National Audi-Visual Board No. 220/2011 on Code of Rule of audio-visual content, as amended,

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

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

the Minister of Health hereby issues the following Order:

Article 1. – The Rules for assessment and approval of advertising of medicinal products for human use are hereby approved, as provided in the Annex which is integral part of this Order.

Article 2. – This Order shall be published in the Official Gazette of Romania, Part I.

p. **the Minister of Health**,
Francisk Iulian Chiriac,
Secretary of State

Bucharest 23 February 2015.
Nr. 194.

Annex 1 to
Order of the Minister of Health No. 194/2015

RULES
FOR ASSESSMENT OF ADVERTISING AND APPROVAL OF MEDICINAL PRODUCTS FOR HUMAN USE

CHAPTER I
Introduction, definitions, scope, provisions

SECTION 1
Introduction

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

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

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

Article 3. – (1) Medicinal product advertising for human use is only accepted provided compliance with legislation in force.

(2) These rules aim at facilitating application of regulations in force by clarifying certain detail aspects, so that advertising for any medicinal product, irrespective of its form (in order to arouse consumers' interest) be at a high standard and observe legal provisions.

(3) Medicinal product advertising must not be consumer offensive or misleading in either form or content.

SECTION 2

Definitions

Article 4. – For the purposes of these Rules, the following terms and concepts shall have the following meaning:

1. *Competent authority* – the National Agency for Medicines and Medical Devices;

2. *Advertising agent/agency* – any person (natural or legal) appointed by a pharmaceutical company to provide any contract advertising services to its benefit;

3. *Pharmaceutical company* – any legal person undertaking and carrying out any activities in the pharmaceutical industry;

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

5. *Common Name* – the International Non–Proprietary Name recommended by the World Health Organisation (WHO) or, if not available, the common name;

6. *International Non–proprietary Name* – name assigned to a medicinal product on recommendation of the World Health Organisation or, if not available, the common name;

7. *Medical events* – planned scientific events, addressing healthcare professionals, initiated and organised locally, regionally, nationally or internationally, such as: congresses, symposia, round tables, workshops, classes, advisory boards (expert meetings);

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

9. *Educational material:*

a) material targeting the general public and/or healthcare specialists, for of the target audience, in addition to the Patient Leaflet, on a certain pathology or medicinal product, used for scientific/educational purposes, as material in awareness raising campaigns, not encouraging prescription, distribution, sale, administration, recommendation or use of the respective medicinal product; programmes for increased adherence to treatment are considered educational material;

b) For the purposes of this order, material drafted as part of consolidated risk management actions, not subject to these Rules (except for the manner of application submission and fee) shall not be considered educational material.

10. *Medicinal product/Medicine:*

a) any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
b) any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.
11. *On–prescription medicinal product* – any medicinal product requiring a medical prescription for dispensing;
12. *Generic medicinal product* – a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines;
13. *Homeopathic medicinal product* – any medicinal product prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia; a homeopathic medicinal product may contain number of active principles;
14. *Reference medicinal product* – a medicinal product authorised according to Article 700 and 702 of Law No. 95/2006, Title XVII – The Medicinal product, as amended, or a medicinal product authorised in one of the Member States of the European Union or in the European Union by centralised procedure;
15. *OTC (over–the–counter) medicinal product* – any medicinal product that is available without a medical prescription;
16. *Sample* – medicinal product supplied free of charge to healthcare professionals for them to become accustomed with the product and acquire experience with its use;
17. *Healthcare organisation* – legal or natural person, profit or non–profit, carrying aut activities related to human health, medical or pharmaceutical care;
18. *Administrative staff* – decision–making staff in public and private healthcare institutions and members or chairpersons of medicinal product therapeutic commissions;

19. *Medical prescription* – any medicinal product prescription generated by a person qualified to this purpose*;*
20. *Healthcare professionals* – physicians, dentists, pharmacists and nurses;
21. *Promotion* – any activity organised, conducted or sponsored/ authorised by a pharmaceutical company, that encourages prescription, dispensing, sale, administration, recommendation or use of medicinal products;
22. *Medicinal product advertising* – any door–to–door information, or any promotion meant to stimulate the prescription, distribution, sale or use of medicinal products; it shall include in particular:
a) medicinal product advertising to the general public;
b) medicinal product advertising to persons qualified for their prescription or distribution;
c) visits by medical sales representatives to persons qualified to prescribe medicinal products;
d) supply of samples;
e) sponsorship of promotional meetings with participation of persons qualified for medicinal product prescription or distribution;
f) sponsorship of scientific congresses with participation of persons qualified for medicinal product prescription or distribution particularly with regard to payment of related travel and accommodation expenses;
23. *Reminder* – brief advert intended for the target audience, which may include the name of the medicinal product or the international non–proprietary name only, if any, the trademark of the medicinal product, the name of the company or image of the medicinal product. According to legislation in force, reminders may only be used in the frame of campaigns and use the same communication channel as the full advertising material;
24. *Essential information in the SmPC*: minimum information in the Summary of Product Characteristics required for accurate use of the medicinal product. This will generally include important information in sections 1–4 and 6–7 of the Summary of Product Characteristics: indications, doses and method of administration, contraindications, warnings, as well as adverse reactions. Abbreviation or removal of information deemed unessential of these sections may be acceptable;
25. *Comparative advertising* – any form of advertising explicitly or implicitly identifying a competitive product and/or comparative description;

26. *Misleading advertising* – any advertising which, under any form, presentation included, misleads or is liable to mislead any intended or unintended audience;
27. *Subliminal advertising* – advertising using adverts whose recipient is not aware thereof, for instance generated at low acoustic intensity or displayed briefly (under one second);
28. *Adverse reaction* – A response to a medicinal product which is noxious and unintended at doses currently used for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or adjustment of physiological functions;
29. *Serious adverse reaction* – an adverse reaction which results in death, is life–threatening, requires inpatient hospitalisation or prolonged hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly/birth defect.
30. *Unexpected adverse reaction* – an adverse reaction, the nature, severity or outcome of which is not consistent with the Summary of Product Characteristics;
31. *Representative of the marketing authorisation holder* – person, currently known as "local representative", appointed by the Marketing Authorisation Holder (MAH) for representation in Romania;
32. *Medical representative* – a person paying visits to healthcare professionals and/or appropriate administrative staff regarding promotion of medicinal products, such as but not limited to assigned sale managers, product managers, marketing directors etc. ;
33. *Risks related to use of the medicinal product*:
a) any risk for patient or public health, regarding the quality, safety or efficacy of the medicinal product; and/or
b) any risk of undesirable effects on the environment;
34. *Healthcare services* – the entirety of medical or pharmaceutical services provided by healthcare professionals for treatment or prevention of disease in humans.

SECTION 3
Scope
Article 5. – (1) These Rules apply to advertising of medicinal products for human use (whether innovators or generic, on prescription or OTC).

(2) These Rules relate to promotion and advertising aimed not only at physicians, but also at all other healthcare professionals who, within their professional activities, may prescribe, supply, administer a medicine or encourage its sale, distribution or use.

Article 6. – These Rules cover relates all promotion methods, i.e. those mentioned under Article 4 (21), as well as visits from medical representatives accompanied by supply of promotional material, advertising in newspapers or magazines, scientific publications, direct e–mail advertising, and other means of electronic communication (sites, web–pages, blogs, forums), use of audio–visual systems (such as films, video recordings, data storage services).

Article 7. – These Rules do not seek to limit or restrict supply of medical or scientific information to healthcare professionals or the public.

Article 8. – The following are outside the scope of these Rules:

a) summaries of product characteristics, as provided by relevant legislation, labelling and patient leaflets of medicinal products, if not promotional in nature;

b) mail exchanges, possibly accompanied by non–promotional material, in response to individual queries of healthcare professionals, only if exclusively related to the letter or the question subject and if non–promotional;

c) general, non–promotional information about companies (i.e. information for investors or current/prospective employees), including financial data, descriptions of research and development programmes and discussions on regulation affecting the company and its products.

Article 9. – These Rules apply not only to pharmaceutical companies *per se*, to their affiliated companies or representatives, but to any other partners as well (agents, agencies, MAH representatives) under contract for conduct of the any type of medicinal products advertising.

Article 10. – (1) Pharmaceutical companies and their representatives are responsible for compliance with these Rules, even for activities contracted out to third parties, such as promotional, advertising or implementation activities as well as involvement, on their behalf, in advertising activities subject to these Rules.

(2) Pharmaceutical companies shall ensure that any of the third parties to whom medicinal product advertising activities have been contracted out are compliant with provisions of these Rules.

SECTION 4

Rules

Article 11. – Medicinal product advertising means any type of organised activity aiming to provide information by direct/indirect means, as well as any type of promotion meant to encourage prescription, distribution, sale, administration, recommendation or use of one or several medicinal products for human use. Medicinal product advertising may target healthcare professionals or the general public.

Article 12. – (1) Medicinal product advertising shall:

a) be accurate, balanced, unbiased, objective and contain enough information to allow the target audience an opinion of their own concerning the therapeutic value of the medicinal product concerned;

b) rely on updated assessment of all relevant evidence and clearly reflect such evidence;

c) encourage reasonable use of the medicinal product, by objective presentation without undue exaggeration of its properties and therapeutic qualities;

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

e) not be misleading, subliminal or misleading by distortion, overstatement, unjustified emphasis, omission or in any other way etc. ;

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

g) not be detrimental to respect for human dignity and public morals;

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

i) not be detrimental to any person's image, reputation, dignity and private life.

(2) All information included in medicinal product advertising material shall be compliant with information stipulated in the SmPC.

Article 13. – (1) As a general rule, advertising to the public is prohibited for the following categories of medicinal products:

a) medicinal products without a marketing authorisation valid in Romania;

b) medicinal products released on medical prescription only;

c) substances defined as psychoactive or psychotropic, according to legal provisions in force;

d) medicinal products prescribed and dispensed in the frame of the health insurance system.

(2) Exceptionally, manufacturing companies or their representatives to Romania may disseminate

a) clearly specified information on new medicinal products or new methods of administration of medicinal products already authorised for marketing, with potentially substantial impact on associated costs, required for medium– and long–term planning of estimated healthcare costs, to healthcare authorities or authorities in Board of Directors of healthcare Institutions;
b) relevant information when specifically requested by healthcare authorities.

Article 14. – Responsible parties:

(1) MAHs or their representative are responsible for the content of advertising material developed for a given medicinal product.

(2) MAHs are responsible for the training and conduct of medical representatives concerning use and distribution of advertising/promotional material, as well as for use and distribution of advertising material.

(3) MAHs are responsible for the design, distribution and use of advertising material for activities contracted to third parties as well.

(4) Pharmaceutical companies set up internal training systems related to use of promotional material by their representatives in promotional campaigns.

(5) Within a company, final approval of all advertising/promotional material is delegated to a responsible person.

(6) The NAMMD may request MAHs or their representatives to notify the names of persons delegated for final approval of advertising/promotional material, as well as the names of their alternates.

(7) The main responsibility for ensuring compliance with regulations in force relating to all medicinal product advertising material lies with the respective MAH.

Article 15. - (1) MAHs are required to submit for NAMMD approval all advertising material to the general public/patients and only make them available after grant of advertising approval.

(2) Advertising material for OTC medicinal products, as well as educational material for the general public/patients are subject to Article 15 (1).

(3) Advertising material is submitted together with the application form for assessment of the material and the payment form.

(4) Payment of assessment fees is performed for each product included in the advertising material and each communication channel intended.

(5) NAMMD assessment of advertising material is only commenced after confirmation of respective fee payment; assessment may result in approval of advertising material submitted, request for their change or rejection.

(6) Requests for change or potential non–compliances are notified to the MAH or their appointed representatives, respectively, by e–mail.
(7) For compliance check reasons, when NAMMD approval is obtained for a changed proposal (from the one initially submitted), MAHs are required to submit a printed copy of the finally approved material (the actually marketed version) as well as a copy in unprintable electronic format.
(8) The NAMMD assesses advertising material for healthcare professionals, concerning on–prescription/non–prescription medicinal products after distribution, in a random manner or following complaints.
(9) MAH participation in medical events is notified to the NAMMD prior to the actual event.
(10) To check compliance, for both printed and electronic material, the NAMMD requires a 3–year period as a minimum mandatory period for MAH archiving of advertising material.
(11) The period mentioned under Article 16 (10) runs from date of the first use of the advertising material.
Article 16. – The main forms of advertising used are as follows:
1. Printed material (prints):
a) scientific/promotional material for healthcare professionals;
b) advertising material for the general public;
c) educational material for patients and patient organisations/associations;
d) posters, invitations;
e) reminding material (reminders);
2. Audio–visual advertising (radio, television)
3. Billboards, any other outdoor advertising or any other advertising using a different communication channel than pharmacies, medical practices, audio-visual media, written press, the internet;
(4) Advertising over the Internet (web pages, e–mail, forums, blogs or any other form of electronic support, except for social networks such as, for instance, Facebook and Twitter etc. , or android mobile applications);
(5) Provision of samples;
(6) Promotional objects (relevant for medical practice).

CHAPTER II
Misleading and comparative advertising, encouragement of reasonable use, compliance with SmPC content

SECTION 1

Misleading advertising

Article 17. – (1) Misleading advertising means any form of advertising which, in any way, by presentation method included, misleads or is likely to mislead any intended/unintended person.

(2) No form of advertising shall suggest that a medicinal product or an active ingredient has any special intrinsic worth, quality or property, unless scientifically documented.

(3) In order to determine the misleading character of advertising, all its characteristics are considered, particularly such components as:

a) medicinal product characteristics (irrespective of their nature), the extent of their compliance with their intended purpose and outcomes expected from its use;

b) omission of essential information regarding identification and description of that medicine in order to mislead the targeted audience.

c) accurately described information, likely to mislead because of the overall image derived from their contradicting the respective therapeutic indications. Examples may include advertising material showing images related to driving when the respective medicinal product can affect the ability to drive vehicles.

SECTION 2

Comparative advertising

Article 18. – (1) Comparative advertising means any form of advertising explicitly or implicitly identifying a competitor by its comparative description.

(2) Comparative advertising for the general public is prohibited.

(3) Comparative advertising for healthcare professionals is prohibited if:

a) the comparison is misleading, according to provisions Article 17;

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

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

d) no objective comparison is made between/among essential, relevant, verifiable and representative characteristics of medicinal products, price included;

e) confusion arises in the market between the advertising company and a competitor thereof or between/among the various trademarks, international non–

proprietary names or other distinctive marks of the advertising company and a competitor;
f) a competitor's trademark, non–proprietary name, other distinctive marks, activities or any other characteristics are discredited or blamed;
g) a competitor's reputed trademark, international non–proprietary name, distinctive marks or any other characteristics are unfairly taken advantage of, without evidence to support such allegations.

SECTION 3
Encouragement of reasonable use
Article 19. – (1) Any advertising material shall encourage accurate and adequate use of the medicinal product. Therefore, it is compulsory that any advertising material include information at least regarding:
a) the recommended dose/administration schedule/specific administration instructions, if any;
b) the exact indications of the medicinal product according to the SmPC;
c) special warnings according to the SmPC;
d) contraindications according to the SmPC.
(2) Any piece of information included in advertising material shall be supported by clear scientific reference, without scientifically unsubstantiated exaggerations or extrapolations.

SECTION 4
Compliance with SmPC content
Article 20. – (1) No advertising material shall promote use of the medicinal product outside the therapeutic indications listed in the SmPC approved for that medicine.
(2) No advertising material for a medicine shall promote its use by certain categories of patients missing from indications in the SmPC.

CHAPTER III
Advertising for healthcare professionals

SECTION 1
General provisions
Article 21. – (1) Any form of advertising shall be in compliance with provisions listed in the approved SmPC as well with marketing authorisation terms.

(2) Information regarding certain indications of a medicinal product not specified in the marketing authorisation (MA) ("off–label indications") may only be supplied in response to an appropriately documented query from a healthcare professional.

(3**)** Use of such information for promotion of the respective medicinal product for off–label indications or use under different conditions than included in the approved SmPC is prohibited.

(4**)** In this case, the MAH ensures that the material provided is purely informative, non–promotional, clearly specifying that the respective information regards "off–label" use.

Article 22. – All medicinal product promotion is prohibited prior to grant of a marketing authorisation. Likewise, promotion of off–label indications is prohibited.

Article 23. – (1) Any form medicinal product advertising for persons qualified to prescribe or supply such products shall include:

a) essential information compatible with the approved SmPC;

b) the classification for supply of the respective medicine;

c) specifications regarding the date of the latest set–up or revision of the documentation used for development of the advertising material or of any other form of advertising.

(2) All information included in the documentation under Article 23 (1) shall be accurate, updated, verifiable and comprehensive enough to allow the recipient to develop their own opinion regarding the therapeutic quality of the medicine concerned.

Article 24. – Quotations as well as tables and other illustrative material taken from medical literature or other scientific works for use in the above–mentioned documentation shall be faithfully reproduced, with exact indication of the source (references).

Article 25. – All illustrations in promotion material, including graphs, various images, photographs and tables, taken from published studies shall meet the following conditions:

a) clearly indicate their exact source/ sources;

b) be faithfully reproduced, except when adjustment or change is needed, in which case any such adjustment/change shall be clearly specified.

c) not be in any way misleading regarding the nature of the medicine.

Article 26. – Unless documented in the SmPC, such qualifiers as "adverse reaction–free", "toxicity–free" or "dependence–free" shall never be used to describe a medicinal product.

Article 27. – The design and presentation of advertising shall allow clear and effortless understanding. When footnotes are used, these shall be made obvious, be proper in size for readability.

Article 28. – Promise and offer of gifts, advantages in cash or in kind for prescription or supply is prohibited.

SECTION 2
Advertising forms

SUBSECTION 1
Printed advertising material for healthcare professionals

Article 29. – (1) Advertising material for on–prescription medicinal products shall be distributed to healthcare professionals only.

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

a) name of the medicinal product and active substance (INN = international non–proprietary name);

b) pharmaceutical form and strength;

c) dosage for each administration route and each therapeutic indication, as appropriate;

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

e) other essential information in the SmPC;

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

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

h) the classification for release and the type of prescription required for release;

i) SmPC information is printed in font minimum size *10*, irrespective of the font type.

(3) Liability for display of such promotional material to the general public is presumed to lie with the pharmaceutical company, which may prove the contrary with documents.

(4) Unless scientifically supported, all misleading allegations to the effect that a medicinal product is "better" or "safer" as compared to another are prohibited.

(5) Inclusion into printed advertising material of messages stating or suggesting that use of the respective medicine is risk–free is prohibited, except for the cases mentioned in the SmPC.
(6) Display of promotional material to the general public is prohibited in places accessible to the general public such as, but not limited to, pharmacies, waiting rooms of medical practices, hospital and clinic halls etc.

SUBSECTION 2
Posters, invitations to medical events
Article 30. – (1) Invitations to medical events organised for healthcare professionals may only include the name of the product or its international non–proprietary name or its trademark and possibly a plain statement of the indications meant to designate the therapeutic category of the product or its route of administration.
Otherwise, such material is subject to regulations provided in Article 29 (2).
(2) Posters as well as invitations aimed at promoting certain activities, scientific medical events, educational programmes, or meant to increase notoriety of certain pathology, displayed in public places, shall comply with regulations provided in Article 50.

SUBSECTION 3
Reminders
Article 31. – By way of exemption from provisions of Article 10, reminders in relation to advertising for healthcare professionals may only include the name of the medicinal product or its International Non–proprietary Name, if any, or its trademark.

SUBSECTION 4
International literature for healthcare professionals
Article 32. – Promotional material included in international literature to be distributed by the MAH or their representatives in Romania shall be in compliance with regulations in force.

SUBSECTION 5
Advertising over the Internet
Article 33. – (1) Internet advertising of on–prescription medicinal products is only allowed if compliant with the following conditions.

a) MAHs shall prove restriction of access to this information for all other persons except healthcare professionals, by a valid and verifiable system of password protection. A complete SmPC is mandatory for the information included.
b) Likewise, web–site providers shall ensure that the material posted on the site does not contain information non–compliant with national and international rules in force.
(2) Medical information shall be endorsed by scientific references compatible with the approved SmPC.
(3) When links are included on certain web–sites that are meant for foreign users, Romanian users shall be specifically informed thereof.
(4) The following represent good practice rules for medicinal product advertising for human use:
a) Romanian users have to be provided direct access to any web–page containing medicinal product related information (SmPC – for web–sites intended for healthcare professionals, Patient Leaflet – for web–sites intended for the general public);
b) the web–site shall mention the category of users it is intended for;
c) any information about web–sites targeting healthcare professionals representing an advertising form shall be compliant with legal provisions regulating the content and format of advertising, as well as the manner of medicinal product advertising.

SUBSECTION 6
Hospitality
Article 34. – Hospitality to healthcare professionals is allowed at scientific/professional events only under the terms provided by regulations in force. Therefore, hospitality shall be limited to the main objective of the meeting and may not be extended to other people outside the healthcare professional category or for whom the scientific field of the event has no professional relevance.

SUBSECTION 7
Sponsorship
Article 35. – (1) Any type of sponsorship provided to healthcare professionals shall not be correlated with the name of a medicinal product, regardless of its classification for release (on– prescription or OTC).

(2) Sponsorship activities shall not involve use of direct/indirect promotional messages for medicinal products, regardless of their classification for release (on– prescription or OTC).
(3) It is mandatory that manufacturers, MAH or their representatives to Romania as well as wholesale and retail distributors notify the NAMMD, before 31 March of the current year, all sponsoring activities as well as any other expenses undertaken the previous year, provided to healthcare professionals, patient organisations and any other type of organisations conducting healthcare activities, medical or pharmaceutical care.
(4) The obligation under (3) also lies with recipients of sponsoring activities, i.e. physicians, nurses, professional organisations, patient organisations, and any other type of organisations conducting healthcare activities, medical or pharmaceutical care.
(5) Notification of sponsoring activities and other expenses, other than sponsoring, conducted as per paragraphs (3) and (4) shall be performed in line with the templates as provided in Annexes 1 and 2 to these Rules.
(6) Information notified in templates specified in par. (5) is posted in the second term of the year for the previous year, on the NAMMD, the reporting entity's and their recipient's website, as appropriate.
(7) in 2015, notifications hall be submitted before 30 June, and information provided in templates under (5) is posted on the NAMMD, the reporting entity's and their recipient's website, as appropriate, before 30 September 2015.

SUBSECTION 8

Facilitation of access to educational programmes, scientific material, medical goods or services

Article 36. – (1) Programmes initiated by the MAH or their legal representatives, aimed at sponsoring scientific research activities, study visits etc. are allowed provided that:
a) they do not include promotional elements regarding a specific medicine;
b) they are not provided on condition of prescription or stimulation of prescription of a medicine.
(2) Supply of goods and services to hospitals or other healthcare institutions:
a) shall have as a sole aim the welfare of the patients;
b) shall not be provided on condition of prescription, stimulation of a prescription or distribution of a medicine;
c) shall not in general be related to a medicinal product.

SUBSECTION 9

Advertising in the frame of medical events

Article 38. – (1) Local, regional, national or international medical events are subject to this provision. These are forms of advertising intended for healthcare professionals only and therefore the MAH or their representatives shall notify the NAMMD with respect to the following aspects:

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

b) Materials to be distributed during or after the event;

c) Medical information supplied during these events – the set of slides only with reference to product characteristics and not the entire presentation;

d) Romanian specialists participating in international events, who provide medical information on certain product characteristics in the event, shall only submit the set of slides referring on product characteristics as such and, not to the entire presentation;

e) Promotional objects distributed (to be listed);

f) Specialisations of healthcare professionals for whom the information is intended.

(2) Irrespective of the information support, all advertising material used in this context shall be compliant with regulations in force. MAHs or their representatives shall ensure that all advertising material contain all recommended information.

(3) Should a single set of studies be used during a medicinal product advertising campaign, a single notification will suffice, submitted at the beginning of the campaign and accompanied by a plan of all events in the campaign.

(4) Should prizes be offered in such events, these shall be of no significant value and not be offered on condition of medicinal product prescription.

(5) Notification is to be made 10 days prior to the event.

SUBSECTION 10

Grant of samples

Article 38. – Exceptionally, free samples are only provided to persons qualified for prescription of such products and under the terms imposed by regulations in force.

SUBSECTION 11
Promotional objects

Article 39. – (1) Healthcare professionals may not be supplied with, offered or promised any gifts, financial advantages or in kind benefits as incentive for the prescription, purchase, supply, sale or administration of a medicinal product.

(2) Promotional objects may only be supplied or offered to healthcare professionals only if not costly (not exceeding RON 150, VAT included, prior to personalisation) and relevant for medicine or pharmacy practice.

(3) Promotional objects may only bear inscriptions of:

a) the name and logo of the pharmaceutical company;

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

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

CHAPTER IV
Advertising to the general public

SECTION 1
General considerations

Article 40. – (1) Advertisement to the general public is only allowed for those medicinal products, which, based on their composition and purpose, may be used without a physician's intervention for diagnosis, prescription or treatment monitoring, a pharmacist's advice sufficing in case of need.

(2) Pharmacies are allowed to present trade catalogues and lists of prices to the general public provided they are free from promotional offers whatsoever, and they are only displayed in pharmacies.

Article 41. – (1) Advertisement to the general public is prohibited for medicinal products which:

a) have no MA valid in Romania;

b) are released on medical prescription only;

c) contain substances defined as narcotic or psychotropic within the meaning established in legislation in force.

d) are prescribed and dispensed within the health insurance system, except for vaccination campaigns carried out by the pharmaceutical industry with approval by the Ministry of Health.

(2) Direct distribution of medicinal products to the general public by medicinal product manufacturers for promotional purposes is prohibited.

(3) Advertising to the general public by means of social networks or mobile applications is prohibited.

Article 42. – Advertisement for the general public by MAHs and contracted third parties acting on their behalf containing promotional offers or reference to discounts, price cuts, special prices is prohibited.

Article 43. – (1) Any form of medicinal product advertising to the general public shall be designed in such a way as to clearly emphasise that this is an advertising message and allow unambiguous identification of the product as a medicinal product;

(2) Any form of medicinal product advertising to the general public shall include at least the following information:

a) the name of the medicinal product, and the non–proprietary name should the medicine contain a single active substance;

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

c) an explicit and legible invitation to careful reading of instructions in the patient leaflet or the outer packaging, worded according to legislation in force;

d) 'reminder' material shall include the name of the medicinal product and the invitation to read the instructions in the patient leaflet or the outer package, as appropriate.

(3) Any form of medicinal product advertising to the general public shall be submitted to the NAMMD for approval; the NAMMD grants an approval valid for a 6 month/1 year period, depending on the applicant's request.

(4) Any form of medicinal product advertising to the general public approved by the NAMMD shall bear the number of the approval and the date of its grant.

(5) Further to grant of approval for advertising visa maintenance, the visa number inscribed may remain the same, except for TV spots and material authorised for the on–line communication channel.

(6) Small advertising material such as change trays, wobblers etc. are exempted from mandatory inscription of the visa number.

7) Advertising material shall not contain any information which:

a) infers that no medical advice, medical intervention or surgical procedure is necessary, especially by offering suggestions for remote diagnosis or treatment;

b) suggests that treatment with the medicine in question has *guaranteed* effect or is free from occurrence of adverse reactions;
c) suggests that the effect of the respective medicinal product is better or equivalent to that of a different treatment or active substance, unless scientifically grounds are provided for such statements;
d) suggests that the patient's health can only be improved by use of the respective medicinal product;
e) suggests that the patient's health may be harmed unless the respective medicinal product is used; such prohibition does not apply to vaccination campaigns;
f) targets children exclusively or especially;
g) relates to a recommendation by scientists, healthcare professionals or persons outside such categories, but whose celebrity may encourage use of medicinal products;
h) suggests that the medicinal product is some food, cosmetic or other product designed for consumption;
i) suggests that medicinal product safety or efficacy is owed to its being non–synthetic;
j) by detailed description or representation of a particular case, be likely to induce inaccurate self–diagnosis;
k) provide, in inadequate or misleading terms, insurance regarding cure;
l) inaccurately, alarmingly or misleadingly use visual representations of disease or lesion induced changes or medicinal product action on the human body as a whole or in part;
m) falsely allege that a valid marketing authorisation has been granted for that medicinal product;
n) expresses violence (even if not explicitly);
o) uses diminutives or other words (phrases) meant to trigger users' emotional response;
p) represents messages, images from campaigns related to other types of products (cosmetics, food supplements, medical devices etc.).

SECTION 2

Rules for allegations in advertising for the general public

Article 44. – Allegations suggesting the product is the more effective and efficient are prohibited because of their capacity to mislead users with respect to

therapeutic benefits of the medicinal product as compared to those associated to other medicinal products in the same category.

Article 45. – (1) Allegations on medicinal product manufacturing resulting in lower residual content or higher quality than similar products are prohibited.

Article 46. – Unless substantiated by the SmPC, advertising material shall not suggest that the medicinal product is completely free from adverse reactions.

Article 47. – Allegations on the high action or absorption rate are prohibited unless substantiated by the SmPC.

Article 48. – Advertising promoting use of medicinal products together with others with similar trade names is prohibited.

Article 49. – Manufacturing companies or their representatives in Romania shall not directly or indirectly communicate the idea that their product is better than others for having been granted a marketing authorisation.

SECTION 3
Advertising forms

SUBSECTION 1
Print advertising material for the general public

Article 50. – (1) Print advertising material for the general public may include:

a) the name of the pharmaceutical company supporting development of the material, free from any reference but its identification data;

b) non–promotional information regarding human health or diseases, provided there is no direct or indirect reference to specific medicinal products (educational material);

c) advice (recommendations) for a better life quality of patients, however free form reference to any medicinal product (educational material);

(d) information not encouraging self–medication or unreasonable use of medicinal products;

(e) objective, realistic, scientific based information, without exaggerating properties and curative effects of medicinal products;

(f) the design and presentation of advertising allowing for clear and easy understanding;

(2) Print advertising material for the general public shall be subject to NAMMD approval;

(3) Print advertising material for the general public shall contain the approval visa number and date of its grant.

SUBSECTION 2

Posters, invitations, catalogues

Article 51. – (1) Posters and invitations are subject to rules on print advertising material to the general public, including that regarding inscription of the approval number and date of grant.

(2) Catalogues in pharmacies:

a) may mention prescription/non–prescription medicinal products;

b) may include the shelf price of the products, without mention of promotional offers or reference to price discounts, sales, special prices.

SUBSECTION 3

Audio–visual advertising

Article 52. – (1) Medicinal product advertising broadcast on radio and television programmes, by radio–electric means, cable or any other assimilated technical system is subject to legal provisions regarding audio-visual advertising.

(2) Audio-visual medicinal product and medical treatment advertising shall mean any form of promotion performed in the frame of programmes services, meant to stimulate their distribution, sale or use.

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

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

(5) Promotion of medicinal products in audio-visual programmes shall include the following:

a) the name of the medicinal product;

b) the non–proprietary name, for medicinal products containing a single active ingredient;

c) the therapeutic indication or any other wording showing the therapeutic indication;

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

e) verbal warning: *"This is a medicinal product. Careful reading of the patient leaflet is recommended";*

f) approval number and date of its grant, printed at the end of the spot, with mandatory update after each advertising visa renewal.

(6) By exemption from provisions of d) and e) of paragraph (5), medicinal product advertising broadcast in abbreviated form (reminders) shall include a brief written warning.
(7) Warnings mentioned under d) and e) of paragraph (5) and paragraph (6) shall be broadcast under the following terms:
a) where the main TV advertisement is concerned, the warning text shall be presented at the end of the spot, visually, for a time long enough to ensure clear perception;
b) for reminders, the warning text is presented during the entire broadcast of the TV advertisement, allowing for clear perception of the message.
c) audio warning is presented at the end of the spot, allowing for full perception of the message.
(8) Broadcast of advertising of medicinal products or therapies presented or recommended by healthcare professionals, academic, scientific organisations, foundations, public personalities in cultural fields or persons who, on account of their fame, can encourage the use of these products or treatments is prohibited.
(9) Likewise, no broadcast of advertising and teleshopping is allowed showing healthcare professionals recommending or expressing approval for medicinal products.
(10) No broadcast of medicinal product advertising is allowed during children's shows or advertising breaks before or after such shows.
(11) Medicinal product manufacturers and distributors may not be sponsors of children's programmes or shows.
(12) Broadcast of advertising is prohibited suggesting the necessity that any person supplement their diet with vitamins and minerals and that such supplements can improve otherwise regularly good physical or mental functions.
(13) Advertising for any kind of medicinal product or treatment for weight loss or maintenance shall comply the following:
a) shall not address people under 18 years of age and shall warn the public thereof in writing and /or sound;
b) may not be broadcast during children's shows or advertising breaks before or after such shows;
c) shall not include exemplifications mentioning or showing formerly overweight people before using the products or services advertised for;
d) shall not suggest or assert that being underweight is adequate or desirable.

(14) The design and presentation of advertising shall allow for clear and easy understanding, transposing in terms understandable to patients/final users, of SmPC indications in the advertising material.

Article 53. – Outdoor advertising or any type of advertising using communication channels other than pharmacies, medical practices, the audio-visual, the written press, the internet is prohibited;

Article 54. – (1) Reminders shall include:

a) the name of the medicinal product;

b) an express, legible invitation to careful reading of instructions in the patient leaflet or the packaging.

(2) For TV advertisement, reminders mean advertising clips cumulatively meeting the following conditions:

a) they are a part, sequel and/or supplementation of the same advertising campaign for a certain medicinal product, carried out at the same time and by the same audio-visual media service;

b) they remind the audience of elements of the message broadcast in the main advertisement of the campaign;

c) they do not exceed 10 seconds in length;

d) they convey the same information and messages as the whole trade;

e) they contain the approval visa number and the date of its grant.

SUBSECTION 4

Advertising over the Internet

Article 55. – (1) As any other form of advertising, irrespective of its form, advertising over the Internet shall be subject to NAMMD assessment and approval.

(2) Web pages shall contain information related to at least:

a) the identity and material and electronic address of their sponsor(s);

b) full reference to the source(s) of all medical information provided;

c) target audience of the web–page;

d) approval visa number and date of its grant;

e) aspects of interest for investors, news media and the general public, including financial data, descriptions of programmes for development and research, the product portfolio, comments on regulatory provisions governing the company and its products, information for prospective employees;

f) non–promotional information related to health education, characteristics of diseases, prevention methods, screening and treatment methods and other

information aimed at promoting public health. These may relate to therapeutic alternatives in place, provided the discussion is balanced and accurate.
g) relevant information may be provided on therapeutic alternatives, including, if necessary, surgical procedures, diet, behavioural change and other interventions not requiring use of medicinal products;
h) the latest approved information – Patient Leaflet and SmPC – for medicinal products advertised,
i) non–promotional information for patients and the general public, regarding products in the pharmaceutical company's OTC portfolio;
j) links to a full, unaltered copy of any public evaluation report issued by the Committee for Medicinal Products of Human Use (CHMP) of the European Medicines Agency (EMA) or a relevant competent national authority;
k) the recommendation to visitors to seek further information from healthcare professionals.
(3) Information included in the webpage shall be updated on any relevant change of MA and/or medical practice and submitted for NAMMD approval; the date of the latest update shall be clearly indicated for each webpage and/or topic, as applicable.
(4) Information on health education shall always recommend visitors to seek further information from healthcare professionals.
(5) Promotional information shall always recommend visitors to seek further information from healthcare professionals as well as include an express, legible invitation to careful reading of instructions in the Patient Leaflet or Packaging, worded compliant with regulatory provisions in force.
(6) Advertising to the general public by means of social networks or phone text messaging is prohibited.
(7) Pharmaceutical companies and/or their representatives shall ensure revision of scientific and medical information posted on their web–sites.
(8) Web–sites shall be compliant with legislation and applicable codes of conduct regulating the private character, security and confidentiality of personal information.

SUBSECTION 5

Awareness raising and prevention campaigns concerning certain diseases

Article 56 – (1) Campaigns classified as 'medical education' are encouraged (campaigns targeting general public health education, awareness raising campaigns and campaigns for prevention of certain diseases).

(2) MAH shall ensure that the material included in the respective campaign is free from direct or indirect advertising messages for a medicinal product and does not encourage abusive or excessive use of the given medicinal products.
(3) Promotion of messages restricting the therapeutic range of a given disease is prohibited.
(4) MAH shall also ensure that patients and the general public clearly understand that the therapeutic decision lies with the physician, as well as that the campaign is only broadcast after NAMMD approval.

SUBSECTION 6
Sponsorship
Article 57. – (1) Sponsorship of any kind addressing the general public may not be related to the name of any on–/off–prescription medicinal product.
(2) Moreover, sponsorship actions shall not contain direct or indirect promotional messages concerning the medicinal products available without medical prescription.
(3) Mutual aid or charity programmes may not be performed in the name of a specific medicinal product.

SUBSECTION 7
Provision of samples
Article 58. – (1) MAHs and contracted persons/entities acting on their behalf are prohibited from providing the public with samples for advertising purposes.
(2) Trade companies (authorised pharmacies or third parties) are not allowed to provide samples to the public for advertising purposes.
(3) Supply of samples by means of publications delivered directly or by mail or addition of samples in the publication packaging, as well as distribution of vouchers or tickets for access to free medicinal products or discounted medicinal products is prohibited.

SUBSECTION 8
Promotional objects
Article 59. – (1) Promotional objects given to the general public shall be inexpensive and promote health and wellbeing.
(2) Promotional objects may only be offered for promoting non–prescription medicinal products (OTCs).

SUBSECTION 9
Promotion of medical and pharmaceutical services

Article 60. – (1) Clinics, medical practices, pharmacies or other healthcare service providers may not provide activities related to advertising of medicinal products.

(2) The appropriate therapeutic approach of any disease is the result of physician–pharmacist–patient cooperation.

Article 61. – (1) MAH or their representatives, entities conducting programmes for price cuts related to medicinal products for human use may not gather personal information on their patients or patients' prescriptions from pharmacies or prescribing physicians.

(2) The NAMMD approves and inspects programmes for price cuts related to costs covered by patients in treatments with medicinal products for human use.

CHAPTER V
Supervision

SECTION 1
General considerations

Article 62. – The NAMMD is the competent authority for assessment and monitoring of all forms of medicinal product advertising, as follows:

a) it approves all advertising for the general public, promoting non–prescription medicinal products;

b) it approves all educational material intended for patients;

c) it inspects all advertising material intended for healthcare professionals, promoting both on– and non– prescription medicinal products, further to dissemination, randomly or following complaints;

d) it approves all educational material intended for healthcare professionals.

Article 63. – (1) The deadline for assessment of all medicinal product advertising forms submitted for NAMMD approval is 30 days from confirmation of payment, excluding the time used by the MAH to respond to potential NAMMD requests.

(2) The 30–day deadline may be extended depending on the quality and/or complexity of the advertising material originally submitted for evaluation.

(3) If data submitted for assessment of the various forms of advertising are substantial and assessment is not possible within the specified deadline, the

NAMMD provides an estimate of the time necessary to complete the evaluation, however not exceeding 60 days.
(4) Responses to NAMMD requests shall be provided in no longer than 30 days; otherwise, the material submitted shall be deemed as rejected and the assessment fee shall not be returned.
(5) For advertising material submitted for re-approval, if NAMMD response/approval is not granted in 30 days, they shall be deemed as implicitly approved.
(6) Following re-approval, advertising material already printed need not be reprinted to include the approval visa number and date; check of compliance is performed based on the new approval granted by the NAMMD.
(7) As regards advertising material requiring re-approval, the application and fee shall be undertaken at least 30 days prior to expiry of approval.
Article 64. – In addition to the advertising form submitted for evaluation, the MAH shall indicate its target audience.
Article 65. – All advertising forms shall have already been submitted for evaluation by the internal scientific service responsible for monitoring of information concerning medicinal products marketed by the MAH.
Article 66. – On receipt of any type of advertising material, all units involved in medicinal product distribution are required to ascertain grant of a valid NAMMD approval.
Article 67. – The NAMMD may seek opinion from other bodies responsible for evaluation of various advertising forms.
Article 68. – Natural and legal persons with legitimate interest in prohibiting any medicinal product advertising noncompliant with legal provisions in force may notify the NAMMD in this respect, who shall respond in 60 days.

SECTION 2
Supervision
Article 69. – (1) To ensure implementation of proper, correct, unexaggerated advertising for medicinal products for human use marketed in Romania, in accordance with these rules, the NAMMD performs inspections and checks compliance with provisions on advertising, as follows:
a) at sites undertaking distribution of medicinal products for human use (community pharmacies, hospital pharmacies, druggist's shops, wholesale distributors), for check of promotional or educational material they hold or supply;

b) at hospital sites or general practices, for check of promotional or educational material they hold;
c) at MAH and their representatives' sites for check of both promotional/educational material they hold or supply and the training of staff who come into contact with healthcare professionals for medicinal product promotion purposes.
d) at scientific events (symposia, conferences, congresses, panels) attended by healthcare professionals;
e) online (webpages);
f) at the offices of contracted legal entities acting on MAH behalf for check of compliance of promotional or educational material they provide.
(2) The complaint shall be in writing and include the following:
a) claimant's contact data;
b) details regarding the type, time and place where the advertising in question has been found;
c) claimant's underlying reasons for concern;
d) a copy of advertising submitted for inquiry;
e) copies of any documents in proof of possible prior contact with the MAH or advertising agent for amiable resolution of the disagreement.
Article 70. – The NAMMD gives priority to complaints concerning cases of possible negative impact of advertising upon public health.
Article 71. – The NAMMD records all complaints submitted; should assessment find breaches of legal provisions on medicinal product advertising, the NAMMD takes all necessary steps for enforcement of the law.

SECTION 3
Article 72. – (1) In case of non–compliance with legal provisions related to advertisement of on-/off-prescription medicinal products for human use, the NAMMD applies penalties in accordance with provisions of Article 836 (1) y) of Law No. 95/2006 on healthcare reform – Title XVII – The medicinal product, as amended.
(2) In case of non–compliance with legal provisions related to training of staff who come into contact with healthcare professionals for promotion of medicinal products for human use, the NAMMD applies penalties in accordance with provisions of Article 836 (1) y) of Law No. 95/2006 on healthcare reform – Title XVII – The medicinal product, as amended.

CHAPTER VI
Final provisions

Article 73. – MAHs have the following obligations:

a) to keep available for or provide to the NAMMD a sample of all advertising material they have initiated, together with a statement as to its intended audience, the manner of notification and the date of the first notification;

b) to ensure that the advertising material drafted for its own medicinal products are in compliance with legal provisions on public information, providing clear and legible information, in sufficient detail to allow readers a correct opinion as regards the efficacy, safety and manner of administration of a medicinal product;

c) to check appropriate training of their medical representatives as well as proper conduct of their legal obligations;

d) to provide the NAMMD with information necessary for accomplishment of its responsibilities;

e) to ensure that NAMMD decisions are enforced immediately and fully.

Article 74. – The NAMMD takes adequate steps to ensure application of legal provisions in force on advertising of medicinal product for human use as well as checks conduct of the training of staff who come into contact with healthcare professionals for promotion of medicinal products for human use and apply penalties, according to law, for breach thereof.

Article 75. – (1) MAHs or their legal representatives have to ensure that prescribers are immediately and fully informed on any important or relevant change of available product information as used in promotional campaigns.

(2) In result of urgent restrictions required by changes in the safety profile or following a variation to MA terms for similar reasons, persons in charge of advertising campaigns shall take all necessary steps for advertising material subsequent to such change to fully reflect both the new form and, where necessary, the possible differences in a relevant and clear manner.

Article 76. – Annexes 1 and 2 are integral part of these Rules.

Annex 1
to the Rules

Statement Form

according to Article 799^1 (1) of Law No. 95/2006 for healthcare reform, as amended

No.	Healthcare professional name	IDS[1]/ODS[2] Name	Speciality of the health-care professional	Address of main activity	Sponsoring					Service fees					Other expenses				
					Nature of sponsoring	Activity	Amount	Contract date	Payment date/Date of delivery	Activity	Amount	Costs associated with conduct of services provided for in service contracts (transport and accommodation) (Amount)	Contract date	Payment date	Other expenses	Amount	Contract date	Payment date	Total

Glossary

IDS[1]: Healthcare institutions

ODS[2]: Healthcare organisations, professional organisations, patient organisations and any other type of healthcare organisation

Nature of sponsoring: Fill in financial means//

Activity: Description of activity according to contract

Examples of types of services (see Nature of services): Types of service contracts:

- "Conferences"
- "Consultant services, e.g.(but not limited to) advisory board, expert opinion, drafting of medical texts, training for company employees"
- "Transfer of copyright"

Annex 2
to the Rules

Statement Form

according to Article 799^1 (2) of Law No. 95/2006 for healthcare reform, as amended

No.	Declarer Sponsor Address	SPONSORING				OTHER EXPENSES				Total
		Nature of sponsoring	Activity	Amount	Contract date	Payment date / Date of delivery	Activity	Amount	Contract date	Payment date /Date of delivery	

Glossary
Amount: Net amount
Nature of sponsoring: Fill in:

- "Sponsoring of financial means"
- "Sponsoring of material means"

Activity: Fill in: "According to contract"
Examples of types of services (see Nature of services): Types of service contracts:

- "Conferences"
- "Consultant services, e.g.(but not limited to) advisory board, expert opinion, drafting of medical texts, training for company employees"
- "Transfer of copyright"

DECISION No. 1/26. 02. 2015
on approval of the Organisational Strategy of the National Agency for Medicines and Medical Devices 2015 - 2017

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 374/02. 04. 2014, convened on summons by the NAMMD President in the ordinary session of 26. 02. 2015, in accordance with provisions of Article 12 (5) of Decision of the Romanian Government No. 734/2010 on organisation and operation of the National Agency for Medicines and Medical Devices, as amended, hereby adopts the following

DECISION

Sole article - The Organisational Strategy of the National Agency for Medicines and Medical Devices 2015 - 2017, is 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
to Scientific Council Decision No. 1/2015

Organisational Strategy of the National Agency for Medicines and Medical Devices 2015 - 2017

The organisational strategy of the National Agency for Medicines and Medical Devices (THE NAMMD) is a reflection of the Agency's priorities and thematic focus for the next three years.

The NAMMD is a public institution under the Ministry of Health, established through Ordinance No. 72 of 30 June, 2010 for reorganisation of healthcare institutions and amending certain healthcare laws, in result of consolidation by merger of the National Agency Medicines and the Medical Devices Technical Office. THE NAMMD organisation and operation were approved through Government Decision No. 734 of 21July, 2010, as amended.

Government Decision No. 315 of 23 April 2014, amending Government Decision 734/2010 for organisation and operation of the NAMMD, redefine the main duties of the Agency in the field of medicinal products for human use (including assessment of documentation for marketing authorisation, safety surveillance by pharmacovigilance inspection of medicinal products already in the therapeutic circuit and authorisation of clinical trial sites and conduct, medicinal product regulation approved by the Ministry of Health) plus setup of the list of reimbursed and free of charge medicines. In 2014, the NAMMD became the competent national authority for assessment of health technologies.

Law No. 132 of 9 October 2014 for Approval of Emergency Government Ordinance No. 2/2014 for amendment of Law No. 95/2006 for healthcare reform, also amending certain other regulatory acts, designates the NAMMD as national competent and decision making authority for medical devices.

The NAMMD authorises conduct of clinical investigations of medical devices on human subjects, according to regulations in force; the NAMMD is responsible for monitoring the performance and safety of medical devices in use as well as for assessment of service providers' capability in this field.

The NAMMD drafts proposals for submission to the Minister of Health of regulatory acts transposing European directives or creating a framework for implementation of European Union (EU) regulations concerning medicinal products or medical devices, respectively.

This organisational strategy is developed and updated within the legislative framework establishing the relationship between the NAMMD and the Ministry of Health as well as stakeholders. The current document covers the period 2015 - 2017, providing for adjustment for the general and pharmaceutical legislative framework.

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

NAMMD MISSION, VISION AND STRATEGIC OBJECTIVES

An organisation's *Mission and Vision* are a well individualised set of values meant for adoption and implementation at organisational level, at the same time strongly reflecting and a reflexion of the management culture content.
They are an expression of the way forward and development opportunities.
Features of a powerful mission and vision are:

• Adequacy - appropriateness for their respective organisations, in the given context, in line with the history and values of the organisation as well as with its performance, at the same time providing assessment of desired situations, attainable on condition certain courses of action are taken;
• Characterising the organisational purpose - provide true meaning and significance to the purpose of the organisation and the role of its employees;
• Proficiency in initiation and maintenance of urges to employee uncompromised intellectual and emotional involvement in development of organisation's work;
• Proficiency in conveying messages in an accessible form, so as to guideline decisions and actions of individuals called to their implementation;
• Proficiency in stimulating employees to self-improvement, to ensure accomplishment of strategic objectives of the organisation;
• Nationally unique character, in the context of distinctive competencies characteristic to the field of medicinal products and medical devices.

NAMMD MISSION:

- **Assessment at the highest scientific competence** of documentation for authorisation for marketing of high quality, safe and effective medicinal products for human use;
- **Implementation of a mechanism for prompt assessment of health technologies**, based on analyses and assessment reports of EU member states, for decision-making, with approval from the Ministry of Health;
- **Surveillance of the safety of medicinal products for human use** in therapeutic use by means of inspection and pharmacovigilance activities;
- **Registration of medical devices marketed or set in operation** in Romania, of national manufacturers, authorised representatives and distributors of medical devices, according to regulations in force;
- **Set up and update of the national data base** in line with national legal provisions transposing European directive related to medical devices;
- **Authorisation of the programme** for implementation of the procedure for clinical investigation/assessment of performance with medical devices for clinical investigations;

- **Ensuring activities related to the Agency's duty for surveillance of the medical device market**, in line with legislation in force;
- **Registration and assessment of information on incidents and corrective action reported in relation with medical devices** and implementation of the vigilance procedure provided for in harmonised regulations in force;
- **Maintaining of a high level of performance and safety of medical devices in use 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 patient and healthcare professional access** to useful and accurate information on medicinal products for human use authorised for marketing in Romania as well as on medical devices;
- **Ensuring institutional administrative effectiveness, efficiency** and transparency of practices and procedures in use.

NAMMD vision:

- **Strengthening of Agency's status as reference national authority** in the field of medicinal products for human use and medical devices, of control of the performance and safety of medical devices in use.
- **Strengthening of Agency's status as expert and reliable source** of accurate and timely information in the field of medicinal products for human use, provided to stakeholders.

NAMMD strategic objectives

- **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, and warranty of compliance of medical devices 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 to warrant compliance by medical devices with mandatory standards, intended purpose and an acceptable safety level;
- Fulfilment of the NAMMD role of communication, as a permanent expert and reliable source of accurate and timely information related to the medicinal product for human use, by providing clear and timely information to healthcare professionals, patients, the pharmaceutical industry and the general public;
- **Contribution to the design of the future legal frame** in the field of medicinal products for human use, by promotion of more effective working relations on European and international level;

· **Contribution to the design of implementation rules** in the fields 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**.

Contents:

1. Introduction

1. 1. - Medicinal products

Since the time of its establishment in 1999, in its various stages of development, the Agency has undergone significant regulatory developments, both internally (by harmonisation of national and European legislation) and at European level (European legislation the Agency sought alignment with was subject to major transformations itself), i.e. :

• Gradual replacement of former national legislation with harmonised European legislation;
• Major revision of EU medicinal product legislation in its entirety (amendment of Directive 2001/83/EC);
• Introduction of regulations to harmonise procedures for authorisation and conduct of clinical trials across the EU (Directive on Good Clinical Practice);
• Introduction of regulations designed to increase availability of medicines specifically authorised for the treatment of children (the Paediatric Regulation);
• Introduction of provisions for regulation of herbal traditional medicines (by amending Directive 2001/83/EC);
• Introduction of a new system for regulating the safety and quality of homeopathic medicines (by amending Directive 2001/83/EC).
• Regulation of manufacture of tissue engineered products and their use (the Advanced Therapies Regulation);
• Introduction of new regulatory pharmacovigilance provisions (Regulation and Directives amending Directive 2001/83/EC)
• Introduction of new regulations to prevent falsified medicines from entering the legal supply chain (Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC)

Medical devices

Since its very establishment in 2005, by reorganisation of the former SVIAM and OTDM, now part of THE NAMMD, has taken active part in generation of national regulatory documents on medical devices by:

• Creation and revision of the legal framework for conduct of controls by periodic inspection of medical devices;
• Creation and revision in line with the European provisions of the legal framework for assessment of service providers in the field of medical devices;
• Creation and revision of the legislative frame for the finding of breaches of regulatory provisions in the field of medical devices and imposition of penalties thereof;
• Revision of the legislative framework for authorisation of conduct of clinical investigations of medical devices concerning human subjects;
• Revision of the legislative framework for registration of medical devices placed on the market and those put into service on Romania's territory;
1. 2 – The NAMMD has implemented a number of important initiatives to improve conduct of its core activities, to broaden its role, by embracing new spheres of activity and improving communication with healthcare professionals and the general public as well as the latter's communication with the Agency, namely:
• Major restructuring of operational departments related to medicines, leading to more consistent medicinal product surveillance throughout its life cycle;
• Major restructuring of operational departments related to medicines, leading to more effective market surveillance of medical devices, as well as to better use of personnel resources;
• Development of the department related to regulation, authorisation and market surveillance of medical devices;
• Introduction of a new and important information system to support decision making and work in electronic format within the Agency;
• Appointment of a larger number of the NAMMD experts for participation in committees and working groups of European bodies in the field of medicines and medical devices, to provide for the NAMMD ability to further active contribution to the legislative and decision-making process in the EU;
• Participation in ASRO committees for medical devices with the NAMMD experts, ensuring the NAMMD capacity to continue active contribution to the standardisation process;
• Organisation of vigilance activities related to medical devices;
• Improvement of the flow of information to healthcare professionals;
• Improvement of the NAMMD profile as a communicator.
1. 3. – The current organisational strategy takes account of views expressed by stakeholders during workshops, conferences, symposia, various forums, etc. and outlines the principles and guidelines of the NAMMD concerns and activities for the next three years.

2. Protection and promotion of public health

2. 1. - The protection and promotion of public health is the NAMMD overall objective and its core activity throughout surveillance of the development and

use of medicinal products for human use and control over the use of medical devices.
The NAMMD ensures assessment at the highest levels of scientific competence of documentation submitted for marketing authorisation of quality, safe and effective human medicines.
The NAMMD grants authorisations for special needs and authorisations for compassionate use of medicinal products for human use.
The NAMMD implements a mechanism for rapid assessment of health technologies, based on the criteria, methodology and methodological tools approved through Order of the Minister of Health no 861/July 2014, for grant of decisions on inclusion, extension of indication, non-inclusion into or exclusion of medicinal products from the List of reimbursed and free of charge medicines.
The NAMMD provides technical support to the Ministry of Health in preparation of annex lists to orders of the minister for amendment of Order of the Minister of Health No. 456/04. 02. 2013 for approval of the List of INNs at important shortage risk, a provided to insurants in the healthcare security system and measures to ensure their availability on the Romanian market.
The respective Order refers to temporary suspension, pursuant to Law 95/2006, of distribution outside Romania of medicinal products specified in the Annex List.
The NAMMD inspects all aspects related to medicinal product development and manufacturing, application of rules for good manufacturing practice and good practice for wholesale distribution of medicinal products, taking action against companies or individuals in breach of their respective obligations.
The NAMMD authorises clinical trial sites and conduct of clinical trials with medicinal products in different stages of development, whereas its specialised inspectors monitor observance of good clinical practice rules.
The NAMMD monitors safe use of medicines for human use over their entire life cycle, through a system of adverse reaction reporting (by both professionals and patients), therefore allowing for maintenance of acceptable risk/benefit for products concerned and careful information in this regard of stakeholders, patients and healthcare professionals.
The NAMMD provides centralised registering and assessment of all information received on reported incidents related to medical devices and takes action according to the law.
The NAMMD carries out assessment of all service provision aspects related to medical devices.
The NAMMD decides on infringements and takes measures against natural or legal persons found in violation of their obligations under Title XIX of Law No. 95/2006 for health reform, as amended.
2. 2. - In recent years, significant improvement has been achieved of NAMMD systems for safety monitoring, of legislation underlying this activity as well as

intensified efforts towards better understanding by patients and the public of the benefits and risks associated with medicinal product use.

In Romania, pharmacovigilance activities are undertaken based on European legislation transposed and implemented into national law.

According to official documents of the European Commission, pharmacovigilance can be defined as "the science and related activities concerned with the detection, assessment, and prevention of adverse reactions to medicines"

The NAMMD also acts as the National Pharmacovigilance Centre operating within the Pharmacovigilance and risk management service.

NAMMD pharmacovigilance activities include, among others, assessment and submission of adverse reactions to the EudraVigilance system (the European network for processing and management of pharmacovigilance data), assessment of Pharmacovigilance Safety Updated Reports (PSURs), of pharmacovigilance systems held by Marketing Authorisation Holders, of Management Plans Risk assessment, harmonisation of the Summaries of Product Characteristics (SmPC) by implementing decisions of the Committee for Human Medicinal Products (CHMP) of the European Medicines Agency (EMA) in sections on medicinal product safety

Since as early as 1976, the NAMMD is a member of the WHO Collaborative Centre for international monitoring of medicines.

The WHO has played an important role in the development of pharmacovigilance through its Monitoring centre of Uppsala-Sweden, which maintains an international database of adverse medicinal product reactions. There are now 98 national centres assigned as active members of the WHO programme for international medicinal product monitoring and the number of adverse reactions entered in the database has grown to over 5 million.

Starting with 2012, the new Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010, amending, as regards pharmacovigilance, Directive 2001/83/EC establishing a Community Code human medicines, has entered into force, as transposed through Emergency Ordinance No. 35/2012. This directive amended and supplemented legal duties incumbent on Member States as regards pharmacovigilance.

The NAMMD aims to develop the national pharmacovigilance system in line with the new directive and pay special attention to cooperation with European bodies and competent authorities in matters related to the safety of medicines.

The NAMMD seeks to further emphasise the value of reports submitted by providing rapid feedback to reporters and by ongoing development of public and patient understanding of decisions regarding the risk/benefit ratio in the field of medicinal products available in the Romanian pharmaceutical market.

At the same time, the Romanian competent authority also aims to continue efforts towards guidance and urge of healthcare professionals with regard to adverse reactions reporting.
In recent years there has been significant improvement of NAMMD systems for control of medical devices in use and monitoring of sites providing medical device services, of legislation underpinning such control operations as well as more resolute focus of Agency efforts towards better understanding by patients and users of the benefits and risks associated with medical devices.
By strengthened market surveillance activities, the NAMMD shall ensure that all necessary steps are taken required for placement on the Romanian market and/or putting into service of medical devices compliant with regulations only.
For the coming years, the NAMMD aims at further development of its operation systems so as to ensure throughout the country working in accordance with the law of medical devices and all prostheses, irrespective of type, as well as maintenance and repair of medical devices at the highest quality.
The NAMMD aims to continue its efforts for education of healthcare professionals and their strong advisement towards reporting of incidents in use of medical devices.
2. 3. - At the same time, the NAMMD seeks active involvement in the development of the European Community system for the monitoring of medicinal product safety, which, by bringing together information submitted by the 28 Member States in the EudraVigilance database will further enhance elements underpinning safety decisions.
The EudraVigilance is one of the main components of the *European Risk Management Strategy* related to medicinal products.
Risk Management is the joint action of the European Medicines Agency and national competent authorities of the European Union to strengthen pharmacovigilance activities.
The NAMMD communicate with the Commission and other Member States of the European Union on measures taken or envisaged to minimise the risk of incidents related to use of medical devices.
The NAMMD also aims at active involvement in the application of European Risk Management Strategy on medicinal products, whose priority actions are:
a) implementation of European Union law;
b) complementary initiatives to achieve a more intensive monitoring system of medicines regarding:
- Risk communication and initiatives in underdeveloped areas of pharmacovigilance (paediatric vaccines and medicines);
- Risk identification, assessment and minimisation.
c) Further strengthening of the European pharmacovigilance system;
d) Initiating a Plan for incident management in the EU regulatory system, meant to manage crises related to medicines in the EU, regardless of their authorisation procedure;

e) Implementation of the project on a European Network of Pharmacoepidemiology and Pharmacovigilance Centres ((ENCePP-European Network of Centres for Pharmacoepidemiology and Pharmacovigilance), coordinated by the European Medicines Agency.

2. 4. - The new Directive 2011/62/EU for the prevention of entry into the legal supply chain of falsified medicinal products, amending Directive 2001/83/EC on the Community code of human medicines has been implemented in national laws of the Member States since 2013. Key elements have been added by this Directive with regard to legal responsibilities incumbent to competent authorities, as well as to manufacturers, importers and distributors in activities directed against counterfeiting of medicines.

For better implementation of the new directive, the NAMMD will create a specialised structure within the Pharmaceutical Inspection Department, in charge of management and monitoring of complex issues related to preventing the entry into the legal supply chain of falsified medicines.

Given that falsified medicines are a matter of increasingly strong concern for both regulators and the public, the NAMMD has initiated and continued collaboration with national institutions involved in combating the sale of counterfeit medicinal products, in particular over the Internet, as well as with similar institutions of EU Member States or outside of the EU, for establishment of permanent liaison points, meant to limit such criminal phenomena.

Thus, one of the main objectives has been to establish the framework for bilateral cooperation and exchange of information with the Romanian General Police Inspectorate concerning falsification of medicinal products for human use. The main directions of cooperation of the NAMMD with the Romanian General Police Inspectorate are as follows:

• Observance of legislation in the field of medicinal products for human use and medical devices;

• Sharing of information to meet legal respective obligations;

• Conduct of studies and market analyses more accurate knowledge of the human medicines market in Romania, especially as concerns their manufacture, import and distribution;

• Supervision of markets operation to identify breaches of national and/or EU legislation relating to counterfeiting of medicinal products and legal provisions on human medicines, to take the necessary steps by the two authorities, according to their respective powers and their correlation;

• Information of the public and businesses operating in markets of medicinal products for human on measures taken for breach of national and/or EU legislation concerning falsification of medicines;

• Mutual support for effective functioning and safety of the medicinal product sector, necessary legislative changes included.

2. 5. - For the next three years, the NAMMD aims to:

• Ensure compliance of marketing medicinal products authorised by the appropriate standards of quality, safety and efficacy, and their approval within a period as short as possible;
• Ensure authorisation of changes/variations to marketing authorisations of medicinal products for human use (for new strengths or pharmaceutical forms etc.) within a period as short as possible, while safeguarding public health;
• Further authorisation of clinical trials and clinical investigations only providing adequate assurance for patients, according to harmonised EU rules;
• Further development of the National Pharmacovigilance Centre operating within the NAMMD and improvement of the system for reporting of adverse reactions/events ensuring the collection of information from the widest possible sources, a simple manner of reporting and prompt feedback, to encourage participation;
• Increased transparency and improved communication on the safety of medicinal products and medical devices;
• Take action to ensure effective supervision of medicinal products and medical devices all over Romania;
• Ensure full ownership of the NAMMD role in implementation of EU legislation to increase the number of medicinal products authorised specifically for the treatment of children;
• Support to government initiatives to address serious risks to public health (e.g., pandemics, bioterrorism) and accomplishment of NAMMD role to ensure availability of products relevant to cover any increased needs;
• Provision of public information/instructions on use of safe medicinal product use and warnings for safe use in risk situations, where appropriate, for both on-prescription and over-the-counter medicines (OTCs);
• Provision of information to the public on conditions to be met by medical devices sold through pharmacies and other distribution facilities;
• Best use of instruments available for support and strengthening of safety monitoring of medicines for human use;
• Promotion of a risk-based approach in inspections, consistent with NAMMD responsibilities relating to public health and optimum use of resources;
• Take prompt and effective measures to prevent falsified medicines from entering the legal supply chain in the context of NAMMD legal duties arising from Emergency Ordinance No. 91/2012, transposing Directive 2011/62/EU for preventing entry of falsified medicines into the legal supply chain.
• Development of relationships with other institutions and bodies involved in this activity and raising awareness on the dangers of counterfeit medicines.
• Reanalysis of regulations governing control work by periodic examination of medical devices, for consistency between the list of medical devices subject to control and frequency of and their risk degree.

• Continuous improvement of procedures for assessment and monitoring of organisations seeking the right to provide medical device-related services and imposition of European standard working conditions;
• Investigation together with in-charge authorities of all incidents involving medical devices in order to determine their causes and limitation of their number as much as possible.

3. Information and communication

The Agency aims to act as both a reactive and proactive communicator. The communication strategy is based on SWOT analysis and stakeholders' (professional colleges, media representatives, patients, the industry) feedback provided through regular questionnaires.

Communication activity in the field of medicines and medical devices aim at continuous adaptation to the constant dynamic of EU regulations in the field as well as at balance between current activity and difficulties facing the Agency.

Given the NAMMD main objective of public health protection and promotion, the Agency will engage in combat of public misinformation through the media with regard to medicines for human use.

3. 1. - Most regulatory actions resulting in communication of updated information about human medicines, in line with knowledge arising from their use. This is usually achieved either in the form of briefings to healthcare professionals or through revised versions of the Patient Leaflet.

The quality of information provided by the NAMMD is therefore crucial to exercise of its role in protecting public health.

Permanently increasing knowledge on human medicines and their regulation will also help understanding by the media and the general public of issues related to emergence of safety issues and exceptional circumstances requiring withdrawal of a product from the market.

3. 2. – Healthcare professionals need clear information and advice on as support for discussion with patients on treatment options and patients and the public require ready access to information about medicinal products used in their own care with respect to their action, benefits to be expected, risks associated with their use, as well as better understanding of the manner for establishing the benefit/risk ratio.

3. 3. - The NAMMD has developed a communication strategy for 2013 - 2015, describing the frame for internal and external communication in this period, setting out key actions to be taken to develop communication. The communication strategy can be updated according to the general and pharmaceutical legislative framework.

The overall objective of the communication strategy is to achieve a higher level of understanding regarding assessment of the benefit/risk as well as of the manner for NAMMD decision-making for exercise of its powers, and

stimulation of the activity for the reporting of adverse reactions/events by healthcare professionals (doctors, pharmacists, nurses) and directly by patients.
To achieve the most important strategic objective in protection and promotion of public health, the Agency must be able to constantly describe the content of its work in this regard. The communication strategy established by the NAMMD has set out fundamental messages defining Agency work, representing top level key messages at the highest level, continually relayed to meet objectives of this strategy.
Communication regarding medicinal product safety must submit:
- Clear and concise information;
- New important information;
- Rationale for publication/dissemination of information;
- Any recommendations for the patient and healthcare professionals.
Safety information should not be biased, misleading, promotional or aimed at boosting sales.
NAMMD safety communication will use the current communication tools and channels in the European Union Network:
- Direct health professionals communications (to take certain measures or to adapt their healthcare practices in the interest of public health);
- Communication with the media;
- Communications posted on the NAMMD website;
- “Questions and Answers” documents.
- Communication among authorities ("Lines to Take" -LTT);
- Newsletters;
- Scientific publications;
To conclude on safety communication as well as on its role in minimizing the risk, the following may be listed:
- Risk communication is a key element in the pharmacovigilance process:
- EMA coordination and communication with Member States on medicinal product safety issues is extremely important;
- Ensuring access to pharmacovigilance information and related decisions underpins stakeholder involvement;
- Involvement of stakeholders in effective communication is essential for risk minimisation;
- Measuring the impact of safety communication on risk management is vital.
3. 4. - NAMMD approach is characterised by openness and transparency, seeking to ensure highest public confidence possible in the regulatory system related to medicinal products and medical devices, the system acting in its support.
Much has been achieved in this direction in recent years, and the NAMMD will continue to improve the transparency of its work as well as its accessibility to the public. The NAMMD will also promote transparency in what concerns businesses in its regulatory domain.

3. 5. – An important NAMMD strategic priorities is the need for closer and more effective engagement with patient associations and the general public, as well as finding general means for introducing patient perspective in its work. As an activity initiated earlier, this will be continued and developed.
The NAMMD will further:
• Act for consolidation of its status as an expert and reliable source for latest information on human medicinal products on the market through implementation of the NAMMD Communication Strategy;
• Ensure that the information accompanying medicinal products are ready for use, in due observance of requirements set for Leaflet user testing;
• Identify ways for increased transparency in decision making, at both NAMMD and pharmaceutical industry level;
All the above objectives may only be achieved through organisation of workshops and meetings with representatives of patient organisations, professional associations, the academia, associations of medicinal product manufacturers, associations of wholesale distributors of medicinal products, to identify possible problems for more effective approach of pharmacovigilance, to find solutions to prevent entry of falsified medicines into the authorised distribution chain, to identify measures for reduction of the risk for medicinal product shortage, to create the national legal framework enabling implementation as of 2016 of the new Regulation No. 536 on clinical trials/April 2014, and others.

4. Design of a balanced regulatory framework

4. 1. - The NAMMD will continue to act in line with its role as national competent authority for medicinal products for human use and medical devices in Romania, as a EU member state, fully integrated into activities of EU Competent Authorities for Medicines and Medical Devices and work of committees and working groups of European bodies in the field of medicinal products and medical devices.
As of 2008, the NAMMD also acts as Reference Member State in coordinating assessments of applications for authorisation submitted for marketing authorisation through European procedures, mainly through the decentralised procedure, showing its expertise in continuous professional development of agency assessors.
Following ratification of the Convention for elaboration of the European Pharmacopoeia, within the Council of Europe, Romania has been a full member since 2003. The designated NAMMD representative as member of the European Pharmacopoeia Commission takes active part in its working sessions.
The Agency intends to further its very important contribution to the work of the European Network of competent authorities in the field of medicines and the work of the European Official Medicines Control Laboratories OMCL.

The Agency aims to increase its contribution to the joint work of competent authorities in the field of medical devices and working groups of the European Commission.

4. 2. - The NAMMD continues to:

• Ensure active participation in technical and scientific deliberations for development of new legislation concerning medicinal products and medical devices;

• Ensure effective operation of the current regulatory system related to medicinal products for human use and medical devices, as well as a prompt implementation of future regulatory changes in the European framework in these areas;

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

• Increase supervision of medical devices on the Romanian market and permanent cooperation with the competent authorities in this field;

• Provide knowledge and expertise to other signatories of the Agreement for cooperation of drug competent authorities of countries associated with the European Union [*Collaboration Agreement of Medicinal product Regulatory Authorities in European Union Associated Countries (CADREAC)]/New Collaboration Agreement between Medicinal product Regulatory Authorities in Central and Eastern European Countries (nCADREAC)]*.

4. 3. - Within the European pharmaceutical regulatory system the NAMMD cooperates with all national competent authorities of the European Union (EU), the European Economic Area (EEA) and the European Medicines Agency (EMA).

The NAMMD hopes to develop future and international connections through the EMA with the US Food and Medicinal product Administration (FDA) within the EMA/EU and FDA/US cooperation.

It is the NAMMD belief that, for effective accomplishment of its regulatory duties related to human medicines for the benefit of public health, good working relations with countries of outside the EU are also necessary, particularly with countries with capabilities for medicinal product development, increasingly acting as supply sources for the EU market.

4. 4. - The NAMMD considers it advisable for regulators worldwide to work jointly to develop harmonised standards applicable to overall relations with the pharmaceutical industry.

4. 5. - The Agency will continue to:

• Develop its international relations and cooperation with regard to antivirals for human use, in the context of a global medicinal product market;

• Support the effort for harmonisation of regulations of the International Conference for Harmonisation (ICH) relating to medicinal products;

• Develop cooperation established with competent authorities of countries of strategic importance, such as China, India, Korea, as increasingly important

source of development and manufacturing of medicines for human use, subject to NAMMD authorisation and supervision.
4. 6. - The NAMMD anticipates substantial progress in science and technology, of potential impact on regulation of medicinal products for human use in the following areas:
• Biotech products;
• Advances in molecular biology, genetics, gene and cell therapy;
• Use of new screening technologies and mechanisms for better adaptation of medicines to patients, development of "customised" and "niche" medicinal products and diagnostic tests for identification of suited patient;
• Development of products combining medicinal products with their own delivery system, in medicinal product/device associations;
• Use of nanotechnology, biomedical science, μ-electronics and computer technology;
• Tissue engineering.
4. 7. - The NAMMD can help develop effective treatments to benefit health by promoting a supportive environment for conduct of clinical trials in Romania, according to European legislation.
The Agency will continue its work with partner organisations and support European efforts towards implementation of EU Clinical Trial Regulation No. 536/April 2014, of harmonised approach to requirements of clinical trial authorisation, reducing inconsistencies and bureaucracy, while maintaining safety measures for enrolled subjects.
4. 8. - The NAMMD will further:
• Ensure, by contribution with appropriate expertise to debates of scientific committees of European bodies, the capability of the legislative frame to establish the right balance between precautionary approach of safety and the freedom of innovation;
• Establish liaisons with academic and professional centres of excellence in medical, pharmaceutical and legislative sciences, to ensure NAMMD capability to rely on optimal skills and knowledge to maintain its own expertise;
• Promote an internal environment encouraging clinical research and cooperation with European bodies for harmonisation of regulations on clinical trial authorisation.
4. 9 - The NAMMD will continue its active involvement in improving the regulatory framework in the field of medicinal products for human use:
4. 9. 1. – The NAMMD Scientific Council establishes the Agency’s scientific policy, in accordance with its powers.
Scientific Council sessions focus on discussion and approval, as Decisions of the Scientific Council, of drug regulatory provisions and rules professional operation of the Agency.
Ruling decisions of the NAMMD Scientific Council are subject to approval by the Minister of Health and published in the Official Gazette of Romania as

orders of the minister of health. As a result of its constant preoccupation with demands and expectations of its stakeholders (healthcare professionals, the pharmaceutical industry, patients, the general public, the media) the NAMMD will continue its efforts to ensure a policy of appropriate, responsible regulation in its area.

4. 9. 2. – It is the NAMMD obligation to ensure that medicinal product regulation is proportionate and properly reflects the current level of knowledge of benefits and risks.

This translates into NAMMD duty to continuous self-assessment of its own work, to ensure adequate reflection of stakeholders' needs, effective regulation of services and targeting activities towards accomplishment of the Agency's primary objective, protection of public health.

Given the scarcity of specialised personnel, the NAMMD is unable to be involved in provision of scientific advice, very frequently providing advice on regulatory issues instead.

4. 10. - The NAMMD aims to further addressing risk-based inspection work, allowing focus on challenges as well as full capitalisation of inspection resources.

The Agency is committed to investigation in greater depth of the scope of risk-based approach to NAMMD regulatory functions and seeking areas for improvement of regulatory practices, consistent with both legislation and the NAMMD role in protection of public health.

4. 11. - The NAMMD is also fully aware of the need to ensure clear and unambiguous legislation underpinning 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, subject to amendments in line with new European regulations.

4. 12. - The NAMMD will continue to:

• Develop risk-based approach to NAMMD inspection work and seek new opportunities to reduce unnecessary legal obligations as well as identify areas allowing it to meet the Agency's objective for risk and proportionality based regulation;

• Support the European Commission's initiative for better regulation and further contribution to the same at national and European level;

• Consolidate and rationalise legislation in the field of medicinal products for human use.

4. 13 - The NAMMD will continue to be actively involved in improvement of the regulatory framework for medical devices.

EU legislation in force (i.e. the three European directives for medical devices) has been transposed into national legislation by Government Decisions No.

54/2009, No. 55/2009 and No. 798/2003, as amended, providing a unified framework for the free movement of CE European certified medical devices.
Currently, the NAMMD takes active part in discussions for two draft regulations to replace the three Directives, intending elimination of shortcomings and gaps, strengthening of the current medical device regulation and increased patient safety. The aim is to establish a robust, transparent and sustainable, "fit for purpose" regulatory framework.

5. Running a successful organisation

5. 1. - Given the dynamic environment of its operation, the NAMMD must remain as influential in its own sector and maintain its flexibility and responsiveness to change.
Entry into force of the new European Directive has resulted in significant changes in workload, allowing the Agency to anticipate further development of specific activities, while other activities/areas may remain constant or reduce in size and importance.
The NAMMD will take the necessary steps to maintain its flexibility and ability to adjust to fluctuating workload and adapt to growth or reduction requirements, to the its own benefit as well as that of its stakeholders.
5. 2. - The NAMMD needs good working relationships with the industry within its regulatory scope, relying on effective dialogue with leading manufacturers' and trade associations as well as with healthcare professionals and patients using these medicinal products.
It is necessary to maintain good relationships with other government bodies, whose work is closely related to NAMMD work.
5. 3. - The Agency will continue to:
• Invest and develop effective management information systems to support its work and take an active role in the EU debate regarding development and implementation of appropriate and harmonised standards;
• Ensure reflection of stakeholders' needs in its own activities, thereby meeting its primary objective related to protection of public health;
• Maintain effective relationships with other governmental bodies;
• Maintain and improve collaboration and cooperation with the pharmaceutical industry as well as appropriate liaisons with major manufacturers' and trade.
• Maintain and improve collaboration and cooperation with the medical device industry and as well as appropriate liaisons with ASRO, the RENAR and Health Insurance Houses.

Agency personnel

5. 4. - NAMMD staff is its most important resource. Effective regulation to protect public health requires maintenance of a highly skilled workforce and a high degree of motivation.

This challenge is particularly difficult, given that current potential to reward employees in the public system is hardly able to compete with that of the private market, an option many Agency trained specialists have preferred.
Until evolvement of a favourable legislative frame allowing for and motivation with adequate salaries as reward for superior professional merits, the NAMMD will need to continue efforts to maintain personnel with scientific expertise available today, attempting motivation at least through proper evaluation of performance and acknowledgment of professional skills.
The NAMMD is intent on continued efforts to raise awareness of the main credit officer on personnel challenges encountered and their impact on the Agency‘s ability to meet duties assigned.
5. 5. - THE NAMMD aims at:
• Effective action for recruitment and selection of new staff (started at the end of 2013 and continued in 2014), aimed particularly at university graduates in the medical and pharmaceutical fields;
• Implementation of promotion policies to ensure NAMMD human resources in the, especially in what concerns areas with proven shortages of skilled manpower;
• Provision of ample opportunities for employee training and development meant to develop human resources.

Agency funding
5. 6. - In late 2009, the Agency was reorganised as a public institution financed from the state budget, according to Law No. 329/2009 for the reorganisation of public authorities and institutions, rationalisation of public expenditure, business support and compliance with framework agreements with the European Commission and the International Monetary Fund.
Given that, by 2009, the Agency was a self-financing institution, subsequent fiscal measures have had significant negative impact on management of human resource and therefore the financing of the entire Agency work.
The NAMMD aims to at least maintain financial stability through a balanced budget, within allocated funds, compliant with legislation in force.
5. 7. – The NAMMD periodically updates its fees according to changes in the organisation's activities.
The NAMMD means to further lucrative activities resulting *in* increased revenues, as for instance by giving training courses, organising conferences etc.

Conclusions
The NAMMD is a mature institution, able to cope with activities deriving from its status a competent authority of an EU Member State in the field of medicinal products for human use and medical devices.
Agency’s strategic objectives are defined in the context of the regulatory framework in force.

The NAMMD aims at continuous adaptation to national and European requirements. The Agency's top management envisages engaging its entire staff in permanent self-assessment for continued improvement in the two areas, i.e. human medicinal products and medical devices.
In the context of issues addressed in the Commission Communication for effective, accessible and resilient health systems - COM (2014) 215 final, the NAMMD aims at growing involvement in resolution of certain issues raised for:

1. Support to the strengthening of health systems effectiveness/quality of healthcare, patient safety included, by**:**

- Promotion of the new pharmacovigilance legislation with both professionals and patients;
- Constant call, by various means, on reporting of adverse reactions;
- Monitoring of accomplishment of the public service obligation by marketing authorisations holders/wholesalers;
- Monitoring of elimination of deficits in medicinal product supply to the Romanian public.

2. Increased affordability of healthcare systems:

As provided for in Government Decision No. 315/2014, the NAMMD is the competent national authority in the field of health technology assessment.
As such, the NAMMD works together with the Ministry of Health and the National Health Insurance House in setting up the list of medicinal products for human use in the Index of medicines provided to insurants based on medical proscription, irrespective of individual contribution.
Order of the Minister of Health No. 861 of 23 July 2014 on approval of the criteria and methodology of Health Technology Assessment (HTA), the documentation to be submitted by applicants, methodological tools used in the evaluation process for medicinal product inclusion/non-inclusion into/exclusion from the List of reimbursed and free of charge medicinal products, ensuring transparency of measures regulating medicinal product inclusion in the scope of national health insurance systems, makes legislative changes of utmost importance, such as:

- HTA for List amendment becomes an ongoing process
- As of 2015, the List is updated at least once a year, by approval through Government Decision.

3. Improved resilience of health systems

The European Commission estimates Health Technology Assessment (HTA) as a useful approach for improving the resilience of EU health systems.
The NAMMD intends that HTA become an effective tool for:

- Improving patient access to innovative technologies;
- Support more efficient budget allocation.

DECISION
No. 2/26. 02. 2015
on adoption of the Guideline for interpretation of the Union Format for manufacturer/importer authorisation

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 374/02. 04. 2014, convened on summons by the NAMMD President in the ordinary session of 26. 02. 2015, in accordance with provisions of Article 12 (5) of Decision of the Romanian Government No. 734/2010 on organisation and operation of the National Agency for Medicines and Medical Devices, as amended, hereby adopts the following

DECISION

Sole article – The Guideline for Interpretation of the Union Format for manufacturer/importer authorisation is adopted 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
to Scientific Council Decision No. 2/2015

GUIDELINE
for interpretation of the Union format for manufacturer/importer authorisation

Note:

The Annex to this Decision is a translation into Romanian and an adaptation of the EMA document EMA/572454/2014 Rev 17 on *Interpretation of the Union Format for manufacturer/importer authorisation*, published by the European Medicines Agency (EMA)

Adaptation consists in reference to respective Romanian healthcare regulatory provisions, transposing EU regulations.

Therefore, for the Annex to this Decision, please see the **Compilation of Community Procedures** on *Inspections and Exchange of Information*, page 144, available at
http://www. ema. europa. eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706. pdf

DECISION
No. 3/26. 02. 2015
for adoption of the Guideline on Conduct of inspections of pharmaceutical manufacturers or importers

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 374/02. 04. 2014, convened on summons by the NAMMD President in the ordinary session of 26. 02. 2015, in accordance with provisions of Article 12 (5) of Decision of the Romanian Government No. 734/2010 on organisation and operation of the National Agency for Medicines and Medical Devices, as amended, hereby adopts the following

DECISION

Article 1. – The Guideline on Conduct of inspections of pharmaceutical manufacturers or importers is adopted according to the Annex which is integral part of this decision.

Article 2. – On entry into force of this decision, Decision of the Scientific Council Decision No. 20/28. 09. 2007 for approval of the Guideline inspections of pharmaceutical manufacturers shall be repealed.

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

Annex
to Scientific Council Decision No. 3/2015

GUIDELINE
on conduct of inspections of pharmaceutical manufacturers or importers

Note:

The Annex to this Decision is a translation into Romanian and an adaptation of the EMA document EMA/572454/2014 Rev 17 on *Conduct of Inspections of Pharmaceutical Manufacturers or Importers*, published by the European Medicines Agency (EMA)

Adaptation consists in reference to respective Romanian healthcare regulatory provisions, transposing EU regulations.

Therefore, for the Annex to this Decision, please see the **Compilation of Community Procedures** on *Conduct of Inspections of Pharmaceutical Manufacturers or Importers*, page 30, available at
http://www. ema. europa.
eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706. pdf

DECISION
No. 4/26. 02. 2015
on adoption of the Guideline for interpretation of the Union Format for GMP certificate

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 374/02. 04. 2014, convened on summons by the NAMMD President in the ordinary session of 26. 02. 2015, in accordance with provisions of Article 12 (5) of Decision of the Romanian Government No. 734/2010 on organisation and operation of the National Agency for Medicines and Medical Devices, as amended, hereby adopts the following

DECISION

Sole article - The Guideline for interpretation of the Union Format for GMP certificate is adopted 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
to Scientific Council Decision No. 4/2015

GUIDELINE
for interpretation of the Union Format for GMP certificate

Note:

The Annex to this Decision is a translation into Romanian and an adaptation of the EMA document EMA/572454/2014 Rev 17 on *Union Format for a GMP Certificate*, published by the European Medicines Agency (EMA)

Adaptation consists in reference to respective Romanian healthcare regulatory provisions, transposing EU regulations.

Therefore, for the Annex to this Decision, please see the **Compilation of Community Procedures** on *Union Format for a GMP Certificate*, page 195, available at
http://www. ema. europa.
eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706. pdf

DECISION
No. 5/26. 02. 2015
for adoption of the Procedure for issue and update of GDP Certificates for 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. 374/02. 04. 2014, convened on summons by the NAMMD President in the ordinary session of 26. 02. 2015, in accordance with provisions of Article 12 (5) of Decision of the Romanian Government No. 734/2010 on organisation and operation of the National Agency for Medicines and Medical Devices, as amended, hereby adopts the following

DECISION

Sole article - The Procedure for issue and update of GDP Certificates for medicinal products for human use is adopted 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
to Scientific Council Decision No. 5/2015

Procedure
for issue and update of GDP Certificates
for medicinal products for human use

Note:

The Annex to this Decision is a translation into Romanian and an adaptation of the EMA document EMA/572454/2014 Rev 17 on the *Issue and Update of GDP Certificates (Medicinal Products for Human Use)*, published by the European Medicines Agency (EMA)

Adaptation consists in reference to respective Romanian healthcare regulatory provisions, transposing EU regulations.

Therefore, for the Annex to this Decision, please see the **Compilation of Community Procedures** on the *Issue and Update of GDP Certificates* (Medicinal Products for Human Use), page 139, available at http://www. ema. europa. eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706. pdf

DECISION
No. 6/26. 02. 2015
for adoption of the Guideline on circumstances requiring conduct of inspection by the National Agency for Medicines and Medical Devices at the premises of manufacturers, importers and distributors of active substances and manufacturers or importers of excipients used as starting materials

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 374/02. 04. 2014, convened on summons by the NAMMD President in the ordinary session of 26. 02. 2015, in accordance with provisions of Article 12 (5) of Decision of the Romanian Government No. 734/2010 on organisation and operation of the National Agency for Medicines and Medical Devices, as amended, hereby adopts the following

DECISION

Article 1. - The Guideline on circumstances requiring conduct of inspection by the National Agency for Medicines and Medical Devices at the premises of manufacturers, importers and distributors of active substances and manufacturers or importers of excipients used as starting materials is adopted according to the Annex which is integral part of this decision.

Article 2. – On entry into force of this decision, Decision of the Scientific Council Decision No. 55/15. 12. 2006 for approval of the Guideline on circumstances requiring conduct of inspections by the National Agency for Medicines and Medical Devices at the premises of manufacturers of active substances used as starting materials shall be repealed.

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

Annex
to Scientific Council Decision No. 6/2015

GUIDELINE
on circumstances requiring conduct of inspection by the National Agency for Medicines and Medical Devices at the premises of manufacturers, importers and distributors of active substances and manufacturers or importers of excipients used as starting materials

Note:

The Annex to this Decision is a translation into Romanian and an adaptation of the EMA document EMA/572454/2014 Rev 17 on *Guidance on the occasions when it is appropriate for competent authorities to conduct inspections at the premises of manufacturers, importers and distributors of active substances and manufacturers or importers of excipients used as starting materials*, published by the European Medicines Agency (EMA)

Adaptation consists in reference to respective Romanian healthcare regulatory provisions, transposing EU regulations.

Therefore, for the Annex to this Decision, please see the **Compilation of Community Procedures** on *Guidance on the occasions when it is appropriate for competent authorities to conduct inspections at the premises of manufacturers, importers and distributors of active substances and manufacturers or importers of excipients used as starting materials*, page 62, available at
http://www. ema. europa.
eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706. pdf

DECISION
No. 7/26. 02. 2015
for adoption of the GDP inspection procedure for 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. 374/02. 04. 2014, convened on summons by the NAMMD President in the ordinary session of 26. 02. 2015, in accordance with provisions of Article 12 (5) of Decision of the Romanian Government No. 734/2010 on organisation and operation of the National Agency for Medicines and Medical Devices, as amended, hereby adopts the following

DECISION

Sole article - The GDP inspection procedure for medicinal products for human use is adopted 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
to Scientific Council Decision No. 7/2015

GDP inspection procedure
for medicinal products for human use

Note:

The Annex to this Decision is a translation into Romanian and an adaptation of the EMA document EMA/572454/2014 Rev 17 on *GDP Inspection Procedure (Medicinal Products for Human Use)*, published by the European Medicines Agency (EMA)

Adaptation consists in reference to respective Romanian healthcare regulatory provisions, transposing EU regulations.

Therefore, for the Annex to this Decision, please see the **Compilation of Community Procedures** on *GDP Inspection Procedure (Medicinal Products for Human Use)*, page 131, available at
http://www. ema. europa.
eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706. pdf

DECISION
No. 8/26. 02. 2015
on adoption of the Procedure for dealing with serious GMP non-compliance requiring co-ordinated measures to protect public health

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 374/02. 04. 2014, convened on summons by the NAMMD President in the ordinary session of 26. 02. 2015, in accordance with provisions of Article 12 (5) of Decision of the Romanian Government No. 734/2010 on organisation and operation of the National Agency for Medicines and Medical Devices, as amended, hereby adopts the following

DECISION

Article 1. – The Procedure for dealing with serious GMP non-compliance requiring co-ordinated measures to protect public health is adopted according to the Annex which is integral part of this decision.

Article 2. – On entry into force of this decision, Decision of the Scientific Council Decision No. 8/22. 04. 2013 on approval of the Procedure for dealing with serious GMP non-compliance or revocation/suspension of Certificates of Suitability requiring coordinated administrative action shall be repealed.

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

Annex
to Scientific Council Decision No. 8/2015

PROCEDURE
for dealing with serious GMP non-compliance requiring co-ordinated measures to protect public health

Note:

The Annex to this Decision is a translation into Romanian and an adaptation of the EMA document EMA/572454/2014 Rev 17 on *Procedure for dealing with serious GMP non-compliance thus requiring co-ordinated measures to protect public or animal health*, published by the European Medicines Agency (EMA)

Adaptation consists in reference to respective Romanian healthcare regulatory provisions, transposing EU regulations.

Therefore, for the Annex to this Decision, please see the **Compilation of Community Procedures** on *Procedure for dealing with serious GMP non-compliance thus requiring co-ordinated measures to protect public or animal health*, page 96, available at
http://www. ema. europa. eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706. pdf

DECISION
No. 9/26. 02. 2015
for adoption of the Statement of non-compliance with GMP

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 374/02. 04. 2014, convened on summons by the NAMMD President in the ordinary session of 26. 02. 2015, in accordance with provisions of Article 12 (5) of Decision of the Romanian Government No. 734/2010 on organisation and operation of the National Agency for Medicines and Medical Devices, as amended, hereby adopts the following

DECISION

Sole article - The Form for the Statement of non-compliance with GMP in line with EU legislation (Compilation of Community Procedures on Inspections and Exchange of Information EMA/572454/2014 Rev 17) is adopted 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
to Scientific Council Decision No. 9/2015

FORM
for the Statement of non-compliance with GMP

Note:

The Annex to this Decision is a translation into Romanian and an adaptation of the EMA document EMA/572454/2014 Rev 17 on the *Statement of non-compliance with GMP*, published by the European Medicines Agency (EMA).

Adaptation consists in reference to respective Romanian healthcare regulatory provisions, transposing EU regulations.

Therefore, for the Annex to this Decision, please see the **Compilation of Community Procedures** on the *Statement of non-compliance with GMP*, page 216, available at
http://www. ema. europa.
eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706. pdf

DECISION
No. 10/26. 02. 2015
on adoption of the Guideline on Good Manufacturing Practice (GMP) for 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. 374/02. 04. 2014, convened on summons by the NAMMD President in the ordinary session of 26. 02. 2015, in accordance with provisions of Article 12 (5) of Decision of the Romanian Government No. 734/2010 on organisation and operation of the National Agency for Medicines and Medical Devices, as amended, hereby adopts the following

DECISION

Article 1. - The Guideline on Good Manufacturing Practice (GMP) for medicinal products for human use is adopted according to the Annex which is integral part of this decision.

Article 2. - On entry into force of this decision, Decision of the Scientific Council Decision No. 5/7. 03. 2012 on approval of the Guideline on Good Manufacturing Practice (GMP) for medicinal products for human use shall be repealed.

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

Annex
to Scientific Council Decision No. 10/2015

GUIDELINE
on good manufacturing practice (GMP) for medicinal products for human use

Note:

The Annex to this Decision is a translation into Romanian and an adaptation of the document "The rules governing medicinal products in the European Union", Volume 4, Good manufacturing practice (GMP) Guidelines, published by the European Commission.

Adaptation consists in reference to respective Romanian healthcare regulatory provisions, transposing EU regulations.

Therefore, for the Annex to this Decision, please see the "The rules governing medicinal products in the European Union", Volume 4, Good manufacturing practice (GMP) Guidelines, available at
http://ec. europa. eu/health/documents/eudralex/vol-4/index_en. htm

DECISION
No. 11/26. 02. 2015
on approval of the Form for *Patient report of adverse reactions to 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. 374/02. 04. 2014, convened on summons by the NAMMD President in the ordinary session of 26. 02. 2015, in accordance with provisions of Article 12 (5) of Decision of the Romanian Government No. 734/2010 on organisation and operation of the National Agency for Medicines and Medical Devices, as amended, hereby adopts the following

DECISION

Article 1. – The Form for *Patient report of adverse reactions to medicinal products for human use* is approved according to the annexes which are integral part of this decision.

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

Annex
to Scientific Council Decision No. 11/2015

Information on patient reporting of adverse reactions to medicinal products

The National Agency for Medicines and Medical Devices (NAMMD) encourages patients, patients' legal representatives, carers, healthcare professionals (physicians, pharmacists, nurses) to report suspected adverse reactions to medicinal products and vaccines. Reporting adverse reactions can help provide information on the safety of medicines and vaccines and thus protect your and other people's health.

Any patient, carer, parent or legal guardian may report suspected adverse reactions to medicinal products or vaccines using the **Form for patient reporting of spontaneous adverse reactions to medicinal products**, available on the NAMMD website, in the section Medicines for Human Use/Report an adverse reaction (http://www. anm. ro/anmdm/med. html) – the appropriate section.
Contact your doctor or pharmacist if you experience any adverse reaction to your medicines, vaccines included. Adverse reactions consist of any potential side effects, whether included in the Patient Leaflet or not. Your doctor or pharmacist will advise on medical treatment required or on treatment discontinuation or change, if necessary.
Pregnant women or women planning for pregnancy, under treatment, should seek medical advice on the need to discontinue or change their treatment.

What is an ADR?
An adverse reaction is „A response to a medicinal product which is noxious and unintended", which means occurrence of an undesirable or unintentional effect after using a medicinal product. Adverse reactions also include undesirable effects that following medicinal product overdose, misuse, abuse and medication errors or undesirable effects arising from occupational exposure.

How can I report an adverse reaction to medicinal products/vaccines?
Suspected adverse reaction to medicines (including vaccines) can be reported as follows:
• You can talk with your doctor or pharmacist, who will report the suspected adverse reaction to either the NAMMD, the National Pharmacovigilance Centre or the pharmaceutical company holding a marketing authorisation for the medicinal product.
• You can download the **Form for patient reporting of spontaneous adverse reactions to medicinal products** available on the website of the National

Agency for Medicines and Medical Devices (www. anm. ro). The printed Form is filled in with full information and submitted to either the NAMMD, using the contact data listed below or the pharmaceutical company authorised for marketing the medicinal product concerned, using the contact data provided in the Patient Leaflet.

• The filled-in form may be submitted to the NAMMD using the following contact details:

- **mail address**: National Agency for Medicines and Medical Devices, Str. Av. Sănătescu No. 48, sector 1, 011478 Bucharest;
- **fax**: 021 316 34 97
- **e-mail**: adr@anm. ro.
- if you have any questions or in need of clarifications or additional detail on the **reporting of suspected adverse reactions**, you may contact the National Pharmacovigilance Centre at the dedicated number for adverse reaction reporting: +40757117259.

Where can I find information about on adverse reactions?
The Patient Leaflet accompanying the medicinal product provides user information. In **section 4, POSSIBLE ADVERSE REACTIONS**, you can find information on possible adverse reactions associated with use of the medicinal product. **If you experience any adverse reaction not listed in this Leaflet, talk to your doctor or pharmacist. If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist**.

Read all of this leaflet carefully before you start using this medicinal product, because it contains important information for you.

For certain medicinal products, the Patient Leaflet contains the ▼ symbol. What does the ▼symbol mean?

The European Union (EU) has introduced a new manner to label medicines under particularly close monitoring. These medicines are identified with a a black inverted triangle displayed in their Patient Leaflet together with a short sentence explaining what the triangle means:

▼"This medicinal product is subject to additional monitoring."

The updated List of medicines under additional monitoring is reviewed every month and can be found on the NAMMD website under "Medicines subject to additional monitoring ▼"as well as on the website of the European Medicines Agency (Human Regulatory/Pharmacovigilance/Medicines under additional monitoring

http://www. ema.
europa.eu/docs/en_GB/document_library/Other/2013/04/WC500142453. pdf.
All medicines are subject to careful monitoring after placement on the EU market. However, medicines labelled with a black triangle are more intensively monitored than others.
For more information on medicines subject to additional monitoring, information is provided on the NAMMD website under "Medicine under additional monitoring".
(http://www. anm. ro/anmdm/med_farmaco_monitorizate. html).

THE NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES

Str. Av. Sănătescu nr. 48, sector 1
011478 - Bucharest
Tel. : 021. 317. 11. 01/0757 117 259
Fax: 021. 316. 34. 97
Email: adr@anm. ro

This is not a mere sheet of paper. This may save lives.
Please provide full information.
Fields marked * are mandatory.
Please use BLOCK LETTERS only.

FORM
FOR PATIENT REPORTING OF ADVERSE REACTIONS TO MEDICINAL PRODUCTS

CONFIDENTIAL

I. * PACIENT

Name/Surname (initials) _____ **Gender M** ☐ **F** ☐ **Age (years, months)**

Birthdate (day, month, year) **……/……. /…….** **Weight (kgs): ……** **Height (cm)** **…….**

II. * SUSPECTED ADVERSE REACTION

1. Describe suspect adverse reaction (s):

Date of occurrence

Date of remission

Reaction lasted (min/hrs/days)

2. Seriousness of adverse reaction (please tick the case best describing the symptoms)

Unpleasant, not affecting daily routine	☐
Unpleasant, affecting daily routine	☐
Required medical opinion	☐
Involved hospital care/prolonged inpatient hospital care	☐
Resulted in significant/persistent disability or incapacity	☐
Resulted in congenital anomaly/deformity	☐
Life threatening	☐
Lethal outcome	☐
Other	☐

3. Adverse reaction required treatment

YES ☐ **NO** ☐ **If yes, treatment consisted of ……**

4. The dose was reduced

YES ☐ **NO** ☐ **Please discuss …….**

5. Suspected medicinal product was discontinued

YES ☐ **NO** ☐ **Please discuss…….**

6. Suspected medicinal product was resumed

YES ☐ **NO** ☐ **Please discuss …….**

7. Progression of the adverse reaction

Full remission	☐	**Not remitted on reporting date**	☐
In remission	☐	**Remitted, with sequelae**	☐
		Unknown	☐

8. Other comments deemed necessary

9. The adverse reaction has been reported to a healthcare professional (physician, pharmacist, nurse)

YES ☐ **NO** ☐

10. I agree that the National Agency for Medicines and Medical Devices can contact the physician if in need of additional information or medical confirmation of this case (e.g., outcomes of medical investigations)

YES ☐ **NO** ☐

If YES, please provide the name and address of the physician

Physician's name, surname …….

Address of the medical unit, city, county, Postal code …….

Telephone/Fax number/e-mail address …….

III. * 1. The suspected medicinal product (including vaccines) (trade name, strength, pharmaceutical form, Marketing Authorisation Holder

Daily Dose **Administration route**

Lot (for vaccines) **Batch (for medicines)**

Date of initiation **Date of discontinuation**

2. The suspected medicinal product has been administered for

3. Other concomitant medication

Other medication	Daily dose	Administration route	Starting with	To	Used for

4. The suspected medicinal product has been used in line with the information in the Leaflet

YES ☐ **NO** ☐

5. The Leaflet of the suspected medicinal product included the ▼ symbol

YES ☐ **NO** ☐

6. Other important information (other conditions, allergies, if suspected medicinal product has been used previously)

……. …….

……. …….

……. …….

IV. * Information on the reporting patient/person filling in the Adverse Reaction Reporting Form
(adverse reactions may be reported by patients, carers, legal guardians)

Name, Surname …… ……
Address …… …… Postal code …… ……
Telephone number …… …… E-mail address …… ……

Please specify your relationship to the patient ……. ……. ……. ……

*** Please sign and date this From (I agree that the National Agency for Medicines and Medical Devices can contact me for additional information on the suspected adverse reaction, if required)**

DATE **SIGNATURE**

DECISION
No. 12/26. 02. 2015
on adoption of the Guideline on Good Pharmacovigilance Practice, Module II – Pharmacovigilance Master File

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 374/02. 04. 2014, convened on summons by the NAMMD President in the ordinary session of 26. 02. 2015, in accordance with provisions of Article 12 (5) of Decision of the Romanian Government No. 734/2010 on organisation and operation of the National Agency for Medicines and Medical Devices, as amended, hereby adopts the following

DECISION

Article 1. – The Guideline on Good Pharmacovigilance Practice, Module II – Pharmacovigilance Master File is adopted 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,
Prof. Dr. Leonida Gherasim

Annex
to Scientific Council Decision No. 12/2015

GUIDELINE
on Good Pharmacovigilance Practices
Module II – Pharmacovigilance System Master File

Note:

The Annex to this Decision is a translation into Romanian and an adaptation of the EMA document **Guideline on Good Pharmacovigilance Practices (GVP)** *Module II – Pharmacovigilance system master file* (Rev 1), published by the European Medicines Agency.

Adaptation consists in reference to respective Romanian healthcare regulatory provisions, transposing EU regulations.

Therefore, for the Annex to this Decision, please see the **Guideline on Good Pharmacovigilance Practices (GVP)** *Module II – Pharmacovigilance system master file* (Rev 1), available at
http://www. ema. europa. eu/docs/en_GB/document_library/Scientific_guideline/2012/06/WC500129133. pdf

DECISION
No. 13/26. 02. 2015
on approval of the Romanian version of Standard Terms approved by the European Pharmacopoeia Commission for routes of administration and uses of dose pharmaceutical forms for auricular, nasal, ocular, oropharyngeal and oral use

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 374/02. 04. 2014, convened on summons by the NAMMD President in the ordinary session of 26. 02. 2015, in accordance with provisions of Article 12 (5) of Decision of the Romanian Government No. 734/2010 on organisation and operation of the National Agency for Medicines and Medical Devices, as amended, hereby adopts the following

DECISION

Sole article - The Romanian version of Standard Terms approved by the European Pharmacopoeia Commission (available in the *fully revised database of the European Directorate for the Quality of Medicines – EDQM, the version of 14 November 2014*) for routes of administration and uses of dose pharmaceutical forms for auricular, nasal, ocular, oropharyngeal and oral use is approved according to the annexes which are 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
to Scientific Council Decision No. 13/2015

	ADMINISTRATION ROUTES AND METHODS		
No.	**Status**	**Standard term**	
		English	**Romanian**
1	Current	***Auricular use***	***Administrare auriculară***
2	Current	***Buccal use***	***Administrare bucală***
3	Current	***Cutaneous use***	***Administrare cutanată***
4	Current	***Dental use***	***Administrare dentară***
5	Current	***Endocervical use***	***Administrare endocervicală***
6	Current	***Endosinusial use***	***Administrare endosinusală***
7	Current	***Endotracheopulmonary use***	***Administrare endotraheopulmonară***
8	Current	***Epidural use***	***Administrare epidurală***
9	Current	***Epilesional use***	***Administrare lezională***
10	Current	***Extraamniotic use***	***Administrare extraamniotică***
11	Current - New	***Extracorporeal use***	***Administrare extracorporală***
12	Current	***Gastric use***	***Administrare gastrică***
13	Current	***Gastroenteral use***	***Administrare gastrointestinală***
14	Current	***Gingival use***	***Administrare gingivală***
15	Current	***Haemodialysis***	***Hemodializă***
16	Current	***Implantation***	***Implantare***
17	Current	***Infiltration***	***Infiltratie***

18	Current	***Inhalation use***	***Administrare prin inhalare***
19	Current	***Intestinal use***	***Administrare intestinală***
20	Current	***Intraamniotic use***	***Administrare intraamniotică***
21	Current	***Intraarterial use***	***Administrare intraarterială***
22	Current	***Intraarticular use***	***Administrare intraarticulară***
23	Current	***Intrabursal use***	***Administrare intrabursală***
24	Current	***Intracameral use***	***Administrare intracameralã***
25	Current	***Intracardiac use***	***Administrare intracardiacă***
26	Current	***Intracartilaginews use***	***Administrare intracartilaginoasa***
27	Current	***Intracavernews use***	***Administrare intracavernoasă***
28	Current	***Intracerebral use***	***Administrare intracelebrală***
29	Current	***Intracervical use***	***Administrare intracervicală***
30	Current - New	***Intracholangiopancreatic use***	***Administrare intracolangiopancreatică***
31	Current	***Intracisternal use***	***Administrare intracisternală***
32	Current	***Intracoronary use***	***Administrare intracoronariană***
33	Current	***Intradermal use***	***Administrare intradermică***
34	Current	***Intradiscal use***	***Administrare intradiscală***
35	Current	***Intraepidermal use***	***Administare intraepidermică***
36	Current -New	***Intraglandular use***	***Administrare intraglandulară***
37	Current	***Intralesional use***	***Administrare intralezională***
38	Current	***Intralymphatic use***	***Administrare intralimfatică***
39	Current	***Intramuscular use***	***Administrare intramusculară***

40	Current	***Intraocular use***	***Administrare intraoculară***
41	Current	***Intraosseous use***	***Administrare intraosoasă***
42	Current	***Intrapericardial use***	***Administare intrapericardica***
43	Current	***Intraperitoneal use***	***Administrare intraperitoneală***
44	Current	***Intrapleural use***	***Administrare intrapleurală***
45	Current -New	***Intraportal use***	***Administrare intraportală***
46	Current - New	***Intraprostatic use***	***Administrare intraprostatică***
47	Current	***Intrasternal use***	***Administrare intrasternală***
48	Current	***Intrathecal use***	***Administrare intratecală***
49	Current	***Intratumoral use***	***Administrare intratumorală***
50	Current	***Intrauterine use***	***Administrare intrauterină***
51	Current	***Intravenews use***	***Administrare intravenoasă***
52	Current	***Intravesical use***	***Administrare intravezicală***
53	Current	***Intravitreal use***	***Administrare intravitreana***
54	Current	***Iontophoresis***	***Iontoforeză***
55	Current	***Laryngopharyngeal use***	***Administrare faringolaringiană***
56	Rejected	***Nail use***	
57	Current	***Nasal use***	***Administrare nazală***
58	Current	***Ocular use***	***Administrare oftalmică***
59	Current	***Oral use***	***Administrare orală***
60	Current	***Oromucosal use***	***Administrare bucofaringiană***
61	Current	***Oropharyngeal use***	***Administrare orofaringiană***

62	Current	***Periarticular use***	***Administrare periarticulară***
63	Current	***Perineural use***	***Administrare perineurală***
64	Current	***Periodontal use***	***Administrare periodontală***
65	Current	***Periosseous use***	***Administrare periosoasă***
66	Current -New	***Peritumoral use***	***Administrare peritumorală***
67	Current	***Posterior juxtascleral use***	***Administrare juxtascleralăposterioară***
68	Current	***Rectal use***	***Administrare rectală***
69	Current - New	***Retrobulbar use***	***Administrare retrobulbară***
70	Current	***Route of administration not applicable***	***Administrare nespecifică***
71	Current	***Skin scarification***	***Administrare prin scarificarea pielii***
72	Current	***Subconjunctival use***	***Administrare subconjunctivală***
73	Current	***Subcutaneous use***	***Administrare subcutanată***
74	Current	***Sublingual use***	***Administrare sublinguală***
75	Current	***Submucosal use***	***Administrare submucoasă***
76	Current	***Transdermal use***	***Administrare transdermică***
77	Current	***Urethral use***	***Administrare uretrală***
78	Current	***Vaginal use***	***Administrare vaginală***

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included in the database in order to avoid the submission **to the PhEur Commission** of new requests for the term**.**

Pending = proposed term is being evaluated by the EDQM ST *Working Group*

PHARMACEUTICAL DOSAGE FORMS FOR AURICULAR USE

		Full Standard Term	
No.	**Status**	***English***	***Romanian***
1	Deprecated	***Cutaneous/ear drops suspension***	***Picaturi auriculare / cutanate, suspensie***
2	Current	***Ear cream***	***Crema auriculara***
3	Current	***Ear drops, emulsion***	***Picaturi auriculare emulsie***
4	Pending	***Ear drops, powder for suspension***	***Picaturi auriculare,pulbere pentru suspensie***
5	Current	***Ear drops, solution***	***Picaturi auriculare, solutie***
6	Current	***Ear drops, suspension***	***Picaturi auriculare, suspensie***
7	Current	***Ear gel***	***Gel auricular***
8	Current	***Ear ointment***	***Unguent auricular***
9	Current	***Ear powder***	***Pulbere auriculara***
10	Current	***Ear spray, emulsion***	***Spray auricular, emulsie***
11	Current	***Ear spray, solution***	***Spray auricular, solutie***
12	Current	***Ear spray, suspension***	***Spray auricular, suspensie***
13	Current	***Ear stick***	***Creion auricular***
14	Current	***Ear tampon***	***Tampon auricular***
15	Current	***Ear wash, emulsion***	***Emulsie pentru spalaturi auriculare***
16	Current	***Ear wash, solution***	***Solutie pentru spalaturi auriculare***
17	Current - New	***Ear/eye drops, solution***	***Picaturi auriculare / oftalmice, solutie***

18	Current	***Ear/eye drops, suspension***	***Picaturi auriculare / oftalmice, suspensie***
19	Current	***Ear/eye ointment***	***Unguent auricular / oftalmic***
20	Current	***Ear/eye/nasal drops, solution***	***Picaturi auriculare / oftalmice / nazale, solutie***
21	Deprecated	***Ear/eye/nose drops, solution***	***Picaturi auriculare / oftalmice / nazale, solutie***
22	Current	***Ear/nasal drops, suspension***	***Picaturi auriculare / nazale, suspensie***

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PHARMACEUTICAL DOSAGE FORMS CLASSIFIED ACCORDING TO INTENDED SITE			
	PHARMACEUTICAL FORMS FOR NASAL USE		
		Full Standard Term	
No.	**Status**	***English***	***Romanian***
1	Deprecated	***Cutaneous and nasal ointment***	***Unguent cutanat si nazal***
2	Current	***Cutaneous/nasal ointment***	***Unguent cutanat / nazal***
3	Current	***Ear/eye/nasal drops, solution***	***Picaturi auriculare / oftalmice / nazale, solutie***
4	Deprecated	***Ear/eye/****nose* ***drops, solution***	
5	Current	***Ear/nasal drops, suspension***	***Picaturi auriculare / nazale, suspensie***
6	Pending	***Endosinusial solution***	***Solutie endosinusala***
7	Current	***Endosinusial wash, suspension***	***Suspensie pentru spalaturi endosinusale***
8	Current	***Gargle/nasal wash***	***Solutie pentru gargarisme / spalaturi nazale***
9	Current	***Nasal cream***	***Crema nazala***
10	Current	***Nasal drops, emulsion***	***Picaturi nazale, emulsie***
11	Pending	***Nasal drops, powder for solution***	***Picaturi nazale, pulbere pentru solutie***
12	Current	***Nasal drops, solution***	***Picaturi nazale, solutie***
13	Current	***Nasal drops, suspension***	***Picaturi nazale, suspensie***

14	Current	***Nasal gel***	***Gel nazal***
15	Current	***Nasal ointment***	***Unguent nazal***
16	Current	***Nasal powder***	***Pulbere nazala***
17	Deprecated	***Nasal spray and oromucosal solution***	***Spray nazal si solutie bucofaringiana***
18	Current	***Nasal spray, emulsion***	***Spray nazal, emulsie***
19	Current	***Nasal spray, powder for solution***	***Spray nazal, pulbere pentru solutie***
20	Current	***Nasal spray, solution***	***Spray nazal, solutie***
21	Current	***Nasal spray, solution/oromucosal solution***	***Spray nazal, solutie / solutie bucofaringiana***
22	Current	***Nasal spray, suspension***	***Spray nazal, suspensie***
23	Current	***Nasal stick***	***Creion nazal***
24	Current	***Nasal wash***	***Solutie pentru spalaturi nazale***
25	Current	***Nasal/oromucosal solution***	***Solutie nazala / bucofaringiana***
26	Current	***Nasal/oromucosal spray, solution***	***Spray nazal/bucofaringian, solutie***
27	Pending	***Powder for endosinusial solution***	***Pulbere pentru solutie endosinusala***
28	Deprecated	***Powder for solution for nasal spray***	***Pulbere pentru solutie pentru spray nazal***

29	Current	***Solution for provocation test***	***Solutie pentru testul de provocare***
30	Rejected	***Solvent for nasal use***	

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PHARMACEUTICAL DOSAGE FORMS CLASSIFIED ACCORDING TO INTENDED SITE			
	PHARMACEUTICAL FORMS FOR OPHTHALMIC USE		
		Full Standard Term	
No.	**Status**	***English***	***Romanian***
1	Current - New	***Concentrate for solution for intraocular irrigation***	***Concentrat pentru solutie de irigare intraoculara***
2	Current - New	***Ear/eye drops, solution***	***Picături auriculare/oftalmice, soluţie***
3	Current - New	***Ear/eye drops, suspension***	***Picături auriculare/oftalmice, suspensie***
4	Current - New	***Ear/eye ointment***	***Unguent auricular/oftalmic***
5	Current - New	***Ear/eye/nasal drops, solution***	***Picături auriculare/oftalmice /nazale, solutie***
6	Deprecated	***Ear/eye/***nose ***drops, solution***	
7	Current	***Eye cream***	***Crema oftalmica***
8	Current	***Eye drops, emulsion***	***Picaturi oftalmice, emulsie***
9	Pending - New	***Eye drops, powder for solution***	***Picaturi oftalmice, pulbere pentru solutie***
10	Pending - New	***Eye drops, powder for suspension***	***Picaturi oftalmice, pulbere pentru suspensie***
11	Current	***Eye drops, prolonged-release***	***Picaturi oftalmice cu eliberare prelungita***
12	Current	***Eye drops, solution***	***Picaturi oftalmice, solutie***
13	Current	***Eye drops, solvent for reconstitution***	***Solvent oftalmic pentru reconstituire***
14	Current	***Eye drops, suspension***	***Picaturi oftalmice, suspensie***
15	Current	***Eye gel***	***Gel oftalmic***
16	Current	***Eye lotion***	***Solutie pentru baie oculara***
17	Current	***Eye lotion, solvent for reconstitution***	***Solvent pentru baie oculara***
18	Current	***Eye ointment***	***Unguent oftalmic***

19	Pending - New	***Intraocular instillation solution***	***Solutie pentru instilatie intraoculara***
20	Current	***Ophthalmic insert***	***Insert oftalmic***
21	Current	***Ophthalmic strip***	***Banda oftalmica***
22	Pending - New	***Powder for intraocular instillation solution***	***Pulbere pentru solutie pentru instilatie intraoculara***
23	Current - New	***Powder for solution for intraocular irrigation***	***Pulbere pentru solutie pentru irigare intraoculara***
24	Current - New	***Solution for intraocular irrigation***	***Solutie pentru irigare intraoculara***
25	Current - New	***Solution for provocation test***	***Solutie pentru testul de provocare***
26	Current - New	***Solvent for solution for intraocular irrigation***	***Solvent pentru solutie pentru irigare intraoculara***

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Pending = proposed term is being evaluated by the EDQM ST *Working Group*

PHARMACEUTICAL DOSAGE FORMS CLASSIFIED ACCORDING TO INTENDED SITE			
	PHARMACEUTICAL FORMS FOR OROMUCOSAL USE		
		Full Standard Term	
No.	**Status**	***English***	***Romanian***
1	Current	***Buccal film***	***Film bucal***
2	Current	***Buccal tablet***	***Comprimat bucal***
3	Current	***Compressed lozenge***	***Comprimat de supt***
4	Current	***Concentrate for gargle***	***Solutie concentrata pentru gargarisme***
5	Pending	***Concentrate for oromucosal solution***	***Solutie concentrata pentru solutii bucogaringiene***
6	Current - New	***Cutaneous solution/concentrate for oromucosal solution***	***Solutie cutanata / concentrat pentru solutie bucofaringiana***
7	Rejected	***Cutaneous/oromucosal spray***	***Spray cutanat / bucofaringian***
8	Rejected	***Cutaneous/oromucosal/oral solution***	***Solutie cutanata / bucofaringiana / orala***
9	Rejected	***Effervescent buccal tablet***	***Comprimate bucale efervescente***
10	Current	***Gargle***	***Solutie pentru gargarisme***
11	Current	***Gargle, powder for solution***	***Pulbere pentru solutie pentru gargarisme***
12	Current	***Gargle, tablet for solution***	***Comprimat pentru solutie pentru gargarisme***
13	Current - New	***Gargle/mouthwash***	***Solutie pentru gargarisme / apa de gura***
14	Current - New	***Gargle/nasal wash***	***Solutie pentru gargarisme / spalaturi nazale***
15	Current	***Gingival gel***	***Gel gingival***
16	Current	***Gingival paste***	***Pasta gingivala***
17	Current	***Gingival solution***	***Solutie gingivala***
18	Pending	***Laryngopharyngeal solution***	***Solutie faringolaringiana***

19	Pending	***Laryngopharyngeal spray, solution***	***Spray faringolaringian, solutie***
20	Current	***Lozenge***	***Pastila***
21	Current - New	***Medicated chewing-gum***	***Guma masticabila medicamentoasa***
22	Current	***Mouthwash***	***Apa de gura***
23	Current	***Mouthwash, powder for solution***	***Apa de gura, pulbere pentru solutie***
24	Current	***Mouthwash, tablet for solution***	***Apa de gura, comprimat pentru solutie***
25	Rejected	***Muco-adhesive buccal prolonged-release tablet***	
26	Current	***Muco-adhesive buccal tablet***	***Comprimat bucal mucoadeziv***
27	Deprecated	***Nasal spray and oromucosal solution***	***Spray nazal si solutie bucofaringiana***
28	Current - New	***Nasal spray, solution/oromucosal solution***	***Spray nazal, solutie / solutie bucofaringiana***
29	Current - New	***Nasal/oromucosal solution***	***Solutie nazala / bucofaringiana***
30	Current - New	***Nasal/oromucosal spray, solution***	***Spray nazal / bucofaringian, solutie***
31	Current - New	***Oromucosal capsule***	***Capsula bucofaringiana***
32	Current	***Oromucosal cream***	***Crema bucofaringiana***
33	Current	***Oromucosal drops***	***Picaturi bucofaringiene***
34	Current	***Oromucosal gel***	***Gel bucofaringian***
35	Current	***Oromucosal ointment***	***Unguent bucofaringian***
36	Current	***Oromucosal paste***	***Pasta bucofaringiana***
37	Current - New	***Oromucosal patch***	***Plasture bucofaringian***
38	Current	***Oromucosal solution***	***Solutie bucofaringiana***
39	Deprecated	***Oromucosal spray***	***Spray bucofaringian***
40	Current	***Oromucosal spray, emulsion***	***Spray bucofaringian, emulsie***

41	Current	***Oromucosal spray, solution***	***Spray bucofaringian, solutie***
42	Current	***Oromucosal spray, suspension***	***Spray bucofaringian, suspensie***
43	Current	***Oromucosal suspension***	***Suspensie bucofaringiana***
44	Current	***Oromucosal/laryngopharyngeal solution***	***Soluţie bucofaringiană /faringolaringiană***
45	Deprecated	***Oromucosal/laryngopharyngeal solution/spray***	***Soluţie bucofaringiană /faringolaringiană / spray***
46	Current - New	***Oromucosal/laryngopharyn geal solution/spray, solution***	***Spray bucofaringian / faringolaringian, soluţie***
47	Current	***Pastille***	***Pastila moale***
48	Current - New	***Pillules***	***Granule homeopate***
49	Pending	***Powder for gingival gel***	***Pulbere pentru gel gingival***
50	Deprecated	***Powder for mouth wash***	***Pulbere pentru apa de gura***
51	Current	***Sublingual film***	***Film sublingual***
52	Deprecated	***Sublingual spray***	***Spray sublingual***
53	Current	***Sublingual spray, emulsion***	***Spray sublingual, emulsie***
54	Current	***Sublingual spray, solution***	***Spray sublingual, solutie***
55	Current	***Sublingual spray, suspension***	***Spray sublingual, suspensie***
56	Current	***Sublingual tablet***	***Comprimat sublingual***

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included in the database in order to avoid the submission **to the PhEur Commission** of new requests for the term**.**

Pending = proposed term is being evaluated by the EDQM ST *Working Group*

PHARMACEUTICAL DOSAGE FORMS CLASSIFIED ACCORDING TO INTENDED SITE			
	PHARMACEUTICAL FORMS FOR ORAL USE		
		Full Standard Term	
No.	**Status**	***English***	***Romanian***
1.	Current	***Cachet***	***Caşetă***
2.	Current	***Capsule, hard***	***Capsulă***
3.	Current	***Capsule, soft***	***Capsulă moale***
4.	Current	***Chewable capsule, soft***	***Capsula moale masticabila***
5.	Current	***Chewable tablet***	***Comprimat masticabil***
6.	Current - New	***Chewable/dispersible tablet***	***Comprimat masticabil / dispersabil***
7.	Pending	***Coated granules***	***Granule***
8.	Current	***Coated tablet***	***Drajeu***
9.	Current	***Concentrate for oral solution***	***Concentrat pentru solutie orala***
10.	Current	***Concentrate for oral suspension***	***Concentrat pentru suspensie orala***
11.	Current - New	***Concentrate for oral/rectal solution***	***Concentrat pentru solutie orala / rectala***
12.	Rejected	***Cutaneous / oromucosal / oral solution***	
13.	Current	***Dispersible tablet***	***Comprimat pentru dispersie orala***
14.	Current - New	***Dispersible tablets for dose dispenser***	***Comprimate dispersabile pentru dozatoare***
15.	Current	***Effervescent granules***	***Granule efervescente***
16.	Pending	***Effervescent granules for oral suspension***	***Granule efervescente pentru suspensie orala***
17.	Current	***Effervescent powder***	***Pulbere efervescenta***
18.	Current	***Effervescent tablet***	***Comprimat efervescent***

19.	Rejected	***Film coated gastro-resistant tablet***	***Comprimat filmat gastrorezistent***
20.	Current	***Film-coated tablet***	***Comprimat filmat***
21.	Current	***Gastro-resistant capsule, hard***	***Capsula gastrorezistenta***
22.	Current	***Gastro-resistant capsule, soft***	***Capsula moale gastrorezistenta***
23.	Deprecated	***Gastro-resistant coated tablet***	***Drajeu gastrorezistent***
24.	Current	***Gastro-resistant granules***	***Granule gastrorezistente***
25.	Current - New	***Gastro-resistant granules for oral suspension***	***Granule gastrorezistente pentru suspensie orală***
26.	Deprecated	***Gastro-resistant prolonged-release tablet***	***Comprimat gastrorezistent cu eliberare prelungita***
27.	Current	***Gastro-resistant tablet***	***Comprimat gastrorezistent***
28.	Current	***Granules***	***Granule***
29.	Deprecated	***Granules for oral and rectal suspension***	***Granule pentru suspensie orala si rectala***
30.	Deprecated	***Granules for oral drops, solution***	***Granule pentru picaturi orale, solutie***
31.	Current	***Granules for oral solution***	***Granule pentru solutie orala***
32.	Current	***Granules for oral suspension***	***Granule pentru suspensie orala***
33.	Current - New	***Granules for oral/rectal suspension***	***Granule pentru suspensie orala / rectala***
34.	Current - New	***Granules for syrup***	***Granule pentru sirop***
35.	Rejected	***Hard capsule with gastro-resistant pellets***	***Capsula cu pelete gastrorezistente***
36.	Current	***Herbal tea***	***Produse vegetale pentru ceai***
37.	Current	***Instant herbal tea***	***Produs vegetal instant pentru ceai***
38.	Current	***Medicated chewing-gum***	***Guma masticabila medicamentoasa***
39.	Current	***Modified-release capsule, hard***	***Capsula cu eliberare modificata***
40.	Current	***Modified-release capsule, soft***	***Capsula moale cu eliberare modificata***

41.	Deprecated	***Modified-release film-coated tablet***	***Comprimat filmat cu eliberare modificata***
42.	Current	***Modified-release granules***	***Granule cu eliberare modificata***
43.	Current - New	***Modified-release granules for oral suspension***	***Granule cu eliberare modificată pentru suspensie orală***
44.	Current	***Modified-release tablet***	***Comprimat cu eliberare modificata***
45.	Current	***Oral drops, emulsion***	***Picaturi orale, emulsie***
46.	Current	***Oral drops, granules for solution***	***Picături orale, granule pentru soluţie***
47.	Current - New	***Oral drops, liquid***	***Picaturi orale, lichid***
48.	Current - New	***Oral drops, powder for suspension***	***Picaturi orale, pulbere pentru suspensie***
49.	Current	***Oral drops, solution***	***Picaturi orale, solutie***
50.	Current	***Oral drops, suspension***	***Picaturi orale, suspensie***
51.	Current	***Oral emulsion***	***Emulsie orala***
52.	Current	***Oral gel***	***Gel oral***
53.	Current	***Oral gum***	***Guma orala***
54.	Current	***Oral liquid***	***Lichid oral***
55.	Current	***Oral lyophilisate***	***Liofilizat oral***
56.	Current	***Oral paste***	***Pasta orala***
57.	Current	***Oral powder***	***Pulbere orala***
58.	Current	***Oral solution***	***Solutie orala***
59.	Current	***Oral solution/concentrate for nebuliser solution***	***Soluţie orală/concentrat pentru soluţie de inhalat prin nebulizator***
60.	Current	***Oral suspension***	***Suspensie orala***
61.	Current - New	***Oral/rectal solution***	***Solutie orala / rectala***
62.	Current - New	***Oral/rectal suspension***	***Suspensie orala / rectala***

63.	Current	***Orodispersible film***	***Film orodispersabil***
64.	Current	***Orodispersible tablet***	***Comprimat orodispersabil***
65.	Rejected	***Pill***	
66.	Current	***Pillules***	***Granule homeopate***
67.	Current	***Powder for oral solution***	***Pulbere pentru solutie orala***
68.	Current	***Powder for oral suspension***	***Pulbere pentru suspensie orala***
69.	Current - New	***Powder for oral/rectal suspension***	***Pulbere pentru suspensie orala / rectala***
70.	Current	***Powder for syrup***	***Pulbere pentru sirop***
71.	Current	***Prolonged-release capsule, hard***	***Capsula cu eliberare prelungita***
72.	Current	***Prolonged-release capsule, soft***	***Capsula moale cu eliberare prelungita***
73.	Rejected	***Prolonged-release film-coated tablet***	***Comprimat filmat cu eliberare prelungita***
74.	Current	***Prolonged-release granules***	***Granule cu eliberare prelungita***
75.	Current	***Prolonged-release granules for oral suspension***	***Granule cu eliberare prelungită pentru suspensie orală***
76.	Current	***Prolonged-release tablet***	***Comprimat cu eliberare prelungita***
77.	Current - New	***Soluble tablet***	***Comprimat solubil***
78.	Deprecated	***Solution for infusion and oral solution***	***Soluţie perfuzabilă şi soluţie orală***
79.	Pending	***Suspension for oral suspension***	***Suspensie pentru suspensie orala***
80.	Current	***Syrup***	***Sirop***
81.	Current	***Tablet***	***Comprimat***
82.	Deprecated	***Tablet for oral suspension***	***Comprimat pentru suspensie orala***

Current = standard term (ST) approved for use by the European Pharmacopoeia (PhEur) Commission;

Romanian version approved by the NMA/NAMMD Scientific Council.

Current – NEW = ST approved for use by the PhEur Commission;

Romanian version submitted for approval in the NAMMD Scientific Council meeting of 26.02.2015.

Deprecated = ST not approved for use by the PhEur Commission;

not physically removed from the database, maintained to cover legacy data ;

Rejected = proposed term ST rejected during evaluation and is not approved for use as a Standard Term **by the PhEur Commission**;

included in the database in order to avoid the submission **to the PhEur Commission** of new requests for the term**.**

Pending = proposed term is being evaluated by the EDQM ST *Working Group*

DECISION
No. 14/26. 02. 2015
on adoption of the Model for risk-based planning for inspections of pharmaceutical manufacturers

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 374/02. 04. 2014, convened on summons by the NAMMD President in the ordinary session of 26. 02. 2015, in accordance with provisions of Article 12 (5) of Decision of the Romanian Government No. 734/2010 on organisation and operation of the National Agency for Medicines and Medical Devices, as amended, hereby adopts the following

DECISION

Article 1. - The Model for risk-based planning for inspections of pharmaceutical manufacturers is adopted according to the Annex which is integral part of this decision.

Article 2. – On entry into force of this decision, Decision of the Scientific Council Decision No. 11/23. 05. 2008 on approval of the Guideline for risk-based planning of inspections of medicinal product manufacturers shall be repealed.

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

Annex
to Scientific Council Decision No. 14/2015

MODEL
for risk-based planning for inspections of pharmaceutical manufacturers

Note:

The Annex to this Decision is a translation into Romanian and an adaptation of the EMA document EMA/572454/2014 Rev 17 on *A Model for Risk Based Planning for Inspections of Pharmaceutical Manufacturers*, published by the European Medicines Agency (EMA).

Adaptation consists in reference to respective Romanian healthcare regulatory provisions, transposing EU regulations.

Therefore, for the Annex to this Decision, please see the **Compilation of Community Procedures** on *A Model for Risk Based Planning for Inspections of Pharmaceutical Manufacturers*, page 76, available at http://www. ema. europa. eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706. pdf

DECISION
No. 15/26. 02. 2015
on adoption of the Guideline on Good Pharmacovigilance Practices, Module III - Pharmacovigilance inspections

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 374/02. 04. 2014, convened on summons by the NAMMD President in the ordinary session of 26. 02. 2015, in accordance with provisions of Article 12 (5) of Decision of the Romanian Government No. 734/2010 on organisation and operation of the National Agency for Medicines and Medical Devices, as amended, hereby adopts the following

DECISION

Sole article – The Guideline on Good Pharmacovigilance Practice, Module III - Pharmacovigilance inspections is adopted 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
to Scientific Council Decision No. 15/2015

Guideline on Good Pharmacovigilance Practice,
Module III - Pharmacovigilance inspections

Note:

The Annex to this Decision is a translation into Romanian and an adaptation of the EMA document **Guideline on Good Pharmacovigilance Practices (GVP)** *Module III – Pharmacovigilance inspections*, published by the European Medicines Agency.

Adaptation consists in reference to respective Romanian healthcare regulatory provisions, transposing EU regulations.

Therefore, for the Annex to this Decision, please see the **Guideline on Good Pharmacovigilance Practices (GVP)** *Module II – Module III – Pharmacovigilance inspections*, available at http://www. ema. europa. eu/docs/en_GB/document_library/Scientific_guideline/2014/09/WC500172400. pdf

DECISION
No. 16/26. 02. 2015
for adoption of the Request Form for exchange of information on Marketing Authorisation Holders or Manufacturing Authorisation Holders between competent authorities in the European Economic Area

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 374/02. 04. 2014, convened on summons by the NAMMD President in the ordinary session of 26. 02. 2015, in accordance with provisions of Article 12 (5) of Decision of the Romanian Government No. 734/2010 on organisation and operation of the National Agency for Medicines and Medical Devices, as amended, hereby adopts the following

DECISION

Article 1. - The Request Form for exchange of information on Marketing Authorisation Holders or Manufacturing Authorisation Holders between competent authorities in the European Economic Area is adopted according to the Annex which is integral part of this decision.

Article 2. – On entry into force of this decision, Decision of the Scientific Council Decision No. 15/15. 06. 2007 for approval of the Guideline on exchange of information on authorisation of medicinal product manufacturers and wholesale distributors between competent authorities in the European Economic Area.

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

Annex
to Scientific Council Decision No. 16/2015

REQUEST FORM
for exchange of information on Marketing Authorisation Holders or Manufacturing Authorisation Holders between competent authorities in the European Economic Area

Note:

The Annex to this Decision is a translation into Romanian and an adaptation of the EMA document EMA/572454/2014 Rev 17 on the *Request Form for the Exchange of Information on Marketing Authorisation Holders or Manufacturing Authorisation Holders between the Competent Authorities in the EEA*, published by the European Medicines Agency (EMA).

Adaptation consists in reference to respective Romanian healthcare regulatory provisions, transposing EU regulations.

Therefore, for the Annex to this Decision, please see the **Compilation of Community Procedures** on *Request Form for the Exchange of Information on Marketing Authorisation Holders or Manufacturing Authorisation Holders between the Competent Authorities in the EEA*, page 239, available at http://www. ema. europa. eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706. pdf

DECISION
No. 17/26. 02. 2015
for adoption of the Procedure for co-ordinating GMP inspections for centrally authorised products

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 374/02. 04. 2014, convened on summons by the NAMMD President in the ordinary session of 26. 02. 2015, in accordance with provisions of Article 12 (5) of Decision of the Romanian Government No. 734/2010 on organisation and operation of the National Agency for Medicines and Medical Devices, as amended, hereby adopts the following

DECISION

Article 1. – The Procedure for co-ordinating GMP inspections for centrally authorised products is adopted according to the Annex which is integral part of this decision.

Article 2. – On entry into force of this decision, Decision of the Scientific Council Decision No. 13/23. 05. 2008 for approval of the Procedure for co-ordinating GMP inspections within and outside the Community prior to marketing authorisation shall be repealed.

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

Annex
to Scientific Council Decision No. 17/2015

PROCEDURE
for co-ordinating GMP inspections for centrally authorised products

Note:

The Annex to this Decision is a translation into Romanian and an adaptation of the EMA document EMA/572454/2014 Rev 17 on *Co-ordinating GMP Inspections for Centrally Authorised Products*, published by the European Medicines Agency (EMA).

Adaptation consists in reference to respective Romanian healthcare regulatory provisions, transposing EU regulations.

Therefore, for the Annex to this Decision, please see the **Compilation of Community Procedures** on *Co-ordinating GMP Inspections for Centrally Authorised Products*, page 246, available at
http://www. ema. europa. eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706. pdf

DECISION
No. 18/26. 02. 2015
on approval of the form for Report of adverse reactions to medicinal products for compassionate use

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 374/02. 04. 2014, convened on summons by the NAMMD President in the ordinary session of 26. 02. 2015, in accordance with provisions of Article 12 (5) of Decision of the Romanian Government No. 734/2010 on organisation and operation of the National Agency for Medicines and Medical Devices, as amended, hereby adopts the following

DECISION

Article 1. - The form for *Report of adverse reactions to medicinal products for compassionate use* is adopted 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,
Prof. Dr. Leonida Gherasim

Annex
to Scientific Council Decision No. 18/2015

National Agency for Medicines and Medical Devices
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REPORT OF ADVERSE REACTIONS TO MEDICINAL PRODUCTS FOR COMPASSIONATE USE

Confidential **This is not a mere sheet of paper. This may save lives!**

Patient initials	**No. F. O. /Reg. Cons.**	**Date of birth** dd/mm/yyyy	**Age**	**Gender**	**Weight (kg)**	**Height (cm)**	**Reaction occurred on** dd/mm/yyyy	**Outcome of adverse reaction (please tick as appropriate:**
	Describe suspect adverse reaction(s) (including signs, symptoms, relevant laboratory tests/results):							**□ Patient died** **□ Life threatening** **□ Involved in hospitalisation/prolonged inpatient hospitalisation** **□ Involved persistence or significant disability or incapacity** **□ Involved in congenital anomaly/ deformity**

Information on the medicinal product available for compassionate use (self-medication included)

<table>
<tr><td colspan="2">Medicinal product name/Code (including the name of the active substance)</td><td>Batch/Lot</td></tr>
<tr><td colspan="2"></td><td>Programme Authorisation No.</td></tr>
<tr><td>Daily Dose</td><td>Administration route</td><td rowspan="2">Treatment duration</td></tr>
<tr><td>Date of treatment initiation</td><td>Date of treatment discontinuation</td></tr>
<tr><td colspan="3">Indication for use</td></tr>
<tr><td colspan="3">The suspected medicinal product may have causes the adverse reaction
☐ YES ☐ NO</td></tr>
</table>

Concomitant medication (self-medication included)

No.	Medicinal product	Indication	Administration route	Daily Dose	From-To
1.					
2.					
3.					
4.					
5.					
6.					
7.					

The adverse reaction required treatment

☐ **YES** ☐ **NO**

If YES, please specify the treatment of the adverse reaction

The patient has recovered after adverse reaction (please tick as appropriate)

☐ Fully recovered ☐ Recovered with sequelae ☐ Recovery in progress
☐ Not recovered ☐ Death ☐ Unknown

Please discuss ……

The medicinal product has been discontinued.

☐ **YES** ☐ **NO**

The dose has been reduced.

☐ **YES** ☐ **NO**

Adverse reaction remitted after discontinuation.

☐ **YES** ☐ **NO**

Full remission

☐ **YES** ☐ **NO**

Please discuss the progression of the adverse reaction……. ……

The medicinal product has been resumed.

☐ **YES** ☐ **NO**

The adverse reaction has re-occurred after resuming use of the medicinal product.

☐ **YES** ☐ **NO**

In case of death, please specify the cause and the date of death and if an autopsy has been performed (if YES, please provide report).

Other relevant medical history data (e.g., diagnostics, allergic reactions, pregnancy, drug and/or alcohol abuse etc.)

Information on the reporting physician

Name and surname ……. **Address of the healthcare facility……**

Speciality …… **……**

Tel. No. …… **……**

Date ……. **Postal code ……**

Signature and stamp……

Tel. No. ……

…….. .

Fax. No. ……

……

Information on the manufacturing company

Name of the manufacturing company …… . .
…….. …….
……
……
……

Medicinal product batches recalled during the 1st quarter of 2015

N.	Product recalled	Pharm. form	Strength	INN	Manufacturer/ MAH	Batch No.	Grounds for recall	Action proposed	Date of recall
1	GEROVITAL H3	lozenges	100 mg	procainum	S. C. Zentiva SA, România	All batches	Renewal procedure suspended for MA No. 3796/2003/01	Voluntary recall and destruction	09. 02. 2015
2	COLDREX HOTREM LEMON	powder for oral suspension		combinations	Smithkline Beecham/GSK Consumer Healthcare SRL	2074, 2075, 2076	Expiry of the 2-year period after NAMMD approval on 08. 01. 2013 of change to MA No. 7276/2006/01-02 (change of product name)	Voluntary recall and destruction	09. 02. 2015
3	COLDREX MAXGRIP LEMON	powder for oral suspension		combinations	Smithkline Beecham/GSK Consumer Healthcare SRL	2058, 2054, 2055, 2056, 2057, 2067	Expiry of the 2-year period (as per MOH No. 279/2005) after NAMMD approval on 16. 01. 2013 of change to MA No 3868/2003/01-02 (change of design)	Voluntary recall and destruction	09. 02. 2015
4	SANDOSTATIN	solution for injection	0.1 mg/ml	octreotidum	Novartis Pharma GmbH, Germany	S0243, S0267, S0268, S0280, S0286, S0295, S0295A, S0304, S0322, S0325, S0345, S0359	Expiry of the 2-year period (as per MOH No. 279/2005) after MA renewal	Voluntary recall and destruction	16. 02. 2015

Applications for marketing authorisation/marketing authorisation renewal submitted to the NAMMD during the 4th quarter of 2014

During the 4th quarter of 2014, 240 applications for marketing authorisation/marketing authorisation renewal for medicinal products have been submitted, corresponding to the following therapeutic groups:

A02 - Drugs for acid related disorders
A07 – Antidiarrheals, intestinal anti-inflammatory/anti-infective agents
A10 – Drugs used in diabetes
A11 – multivitamins, combinations
B01 – Antithrombotic agents
B02 – Antihemorrhagics
C01 – Cardiac therapy
C02 – Antihypertensives
C03 – Diuretics
C05 – Vasoprotectives
C07 – Beta blocking agents
C09 – Agents acting on the renin-angiotensin system
C10 – Lipid modifying agents
D01 – Antifungals for dermatological use
G03 – Sex hormones and modulators of the genital system
G04 – Urologicals
H01 – Pituitary and hypothalamic hormones and analogues
H02 – Corticosteroids for systemic use
H03 – Thyroid therapy
H05 – Calcium homeostasis
J01 – Antibacterial for systemic use
J02 – Antimycotics for systemic use
J05 – Antivirals for systemic use
L01 – Antineoplastic agents
L02 – Endocrine therapy
L04 – Immunosuppressants
M01 – Anti-inflammatory and antirheumatic products
M05 – Drugs for treatment of bone diseases
N02 – Analgezics
N04 – Anti-parkinson drugs
N05 - Psycholeptics
N06 - Psychoanaleptics
N07 – Other nervous system drugs
R01 – Nasal preparations

R03 – Drugs for obstructive airway diseases
R05 – Cough and cold preparations
R06 – Antihistamines for systemic use
S01 – Ophthalmologicals
V03 – All other therapeutic products
V09 – Diagnostic radiopharmaceuticals

Medicinal products authorised for marketing during the 4th quarter of 2014

INN	Invented name	Pharm. form	Strength	MAH	Country	MA number		
ACECLOFENACUM	ACE-TAB 100 mg	film-coated tablets	100mg	LABORMED PHARMA SA	ROMÂNIA	7066	2014	01
ACECLOFENACUM	AFLAMIL 15 mg/g	cream	15mg/g	GEDEON RICHTER ROMANIA SA	ROMÂNIA	7247	2014	01
ACECLOFENACUM	AFLAMIL 100 mg	powder for oral suspension	100mg	GEDEON RICHTER ROMANIA SA	ROMÂNIA	7248	2014	01
ACETYLCYSTEINUM	ACC LAMAIE SI MIERE 600 mg	powder for oral suspension	600mg	HEXAL AG	GERMANY	7032	2014	01
ACETYLCYSTEINUM	ACC LAMAIE SI MIERE 200 mg	powder for oral suspension	200mg	HEXAL AG	GERMANY	7031	2014	01
ACIDUM ACETYLSALICYLICUM	ACID ACETILSALICILIC SOLACIUM 500 mg	tablets	500mg	SOLACIUM PHARMA SRL	ROMÂNIA	7067	2014	01
ACIDUM ALENDRONICUM	ACID ALENDRONIC AUROBINDO 10 mg	tablets	10mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	7183	2014	01
ACIDUM ALENDRONICUM	ACID ALENDRONIC AUROBINDO 70 mg	tablets	70mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	7184	2014	01
ACIDUM GADOTERICUM	DOTAGITA 0.5 mmol/ml	sol. for single dose injection	0.5mmol/ml	AGFA HEALTHCARE IMAGING AGENTS GMBH	GERMANY	7007	2014	01
ACIDUM GADOTERICUM	DOTAGITA 0.5 mmol/ml	sol. for multiple dose injection	0.5mmol/ml	AGFA HEALTHCARE IMAGING AGENTS GMBH	GERMANY	7008	2014	01
ACIDUM IBANDRONICUM	ACID IBANDRONIC POLIPHARMA 50 mg	film-coated tablets	50mg	POLIPHARMA INDUSTRIES SRL	ROMÂNIA	7234	2014	01
ACIDUM IBANDRONICUM	ACID IBANDRONIC POLIPHARMA 150 mg	film-coated tablets	150mg	POLIPHARMA INDUSTRIES SRL	ROMÂNIA	7235	2014	01

ACIDUM RISEDRONICUM	LORINE 35mg	film-coated tablets	35mg	ANTIBIOTICE SA	ROMÂNIA	7140	2014	01
ACIDUM ZOLEDRONICUM	ZENDRACTIN 4 mg/100 ml	sol. for infusion	4mg/100ml	PHARMASWISS CESKA REPUBLIKA S. R. O.	CZECH REP.	7233	2014	01
ALBUMINUM HUMANUM	ALBUMEON 200 g/l	sol. for infusion	200g/l	CSL BEHRING GMBH	GERMANY	7181	2014	01
ALITRETINOINUM	TOCTINO 10 mg	capsules, soft	10mg	GLAXOSMITHKLINE (GSK) SRL	ROMÂNIA	7258	2014	01
ALITRETINOINUM	TOCTINO 30 mg	capsules, soft	30mg	GLAXOSMITHKLINE (GSK) SRL	ROMÂNIA	7259	2014	01
AMISULPRIDUM	AMISAN 50 mg	tablets	50mg	PRO. MED. CS PRAHA A. S.	CZECH REP.	7141	2014	01
AMISULPRIDUM	AMISAN 200 mg	tablets	200mg	PRO. MED. CS PRAHA A. S.	CZECH REP.	7142	2014	01
AMISULPRIDUM	AMISAN 400 mg	film-coated tablets	400mg	PRO. MED. CS PRAHA A. S.	CZECH REP.	7143	2014	01
AMOROLFINUM	FUNTROL 50 mg/ml	medicated nail lacquer	50mg/ml	CHANELLE MEDICAL	IRELAND	7155	2014	01
ANASTROZOLUM	ARIMIDEX 1 mg	film-coated tablets	1mg	ASTRAZENECA UK LIMITED	UK	7053	2014	01
ATORVASTATINUM	ATORVASTATINA AUROBINDO 10 mg	film-coated tablets	10mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	7076	2014	01
ATORVASTATINUM	ATORVASTATINA AUROBINDO 20 mg	film-coated tablets	20mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	7077	2014	01
ATORVASTATINUM	ATORVASTATINA AUROBINDO 40 mg	film-coated tablets	40mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	7078	2014	01
ATORVASTATINUM	ATORVASTATINA AUROBINDO 80 mg	film-coated tablets	80mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	7079	2014	01

AZITHROMYCINUM	AZITROX 200 mg/5 ml	powder for oral suspension	200mg/5ml	ZENTIVA SA	ROMÂNIA	7105	2014	01
BENZYDAMINUM	TANTUM VERDE CU AROMA DE MENTA 3 mg	lozenges	3mg	CSC PHARMACEUTICALS HANDELS GMBH	AUSTRIA	7149	2014	01
BETAHISTINUM	BETASERC 24 mg	orodispers. tablets	24mg	ABBOTT LABORATORIES GMBH	GERMANY	7264	2014	01
BETAXOLOLUM	LOKREN 20 mg	film-coated tablets	20mg	SANOFI-AVENTIS FRANCE	FRANCE	7016	2014	01
BICALUTAMIDUM	BICALUTAMIDA ACTAVIS 50 mg	film-coated tablets	50mg	ACTAVIS GROUP PTC EHF.	ICELAND	7100	2014	01
BICALUTAMIDUM	BICALUTAMIDA ACTAVIS 150 mg	film-coated tablets	150mg	ACTAVIS GROUP PTC EHF.	ICELAND	7101	2014	01
BUTOCONAZOLUM	GYNOFORT 20 mg/g	vaginal cream	20mg/g	GEDEON RICHTER ROMANIA SA	ROMÂNIA	6972	2014	01
CARBAMAZEPINUM	CARBESIL 200 mg	tablets	200mg	SLAVIA PHARM SRL	ROMÂNIA	7276	2014	01
CEFALEXINUM	OSPEXIN 250 mg	caps.	250mg	SANDOZ GMBH	AUSTRIA	7014	2014	01
CEFALEXINUM	OSPEXIN 500 mg	caps.	500mg	SANDOZ GMBH	AUSTRIA	7015	2014	01
CEFTRIAXONUM	SEFTRION 500 mg	powder for sol. for inj. /inf.	500mg	E.I.P.I.CO. MED SRL	ROMÂNIA	6994	2014	01
CEFTRIAXONUM	SEFTRION 1 g	powder for sol. for inj. /inf.	1g	E.I.P.I.CO. MED SRL	ROMÂNIA	6995	2014	01
CHLORPHENAMINUM	CLORFENIRAMIN 4 mg	tablets	4mg	LABORMED PHARMA SA	ROMÂNIA	7197	2014	01
CLARITHROMYCINUM	CLARITROMICINA AUROBINDO 250 mg	film-coated tablets	250mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	7103	2014	01
CLARITHROMYCINUM	CLARITROMICINA AUROBINDO 500 mg	film-coated tablets	500mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	7104	2014	01
CLINDAMYCINUM	CLINDAMYCIN-MIP	film-coated	600mg	MIP PHARMA GMBH	GERMANY	7191	2014	01

	600 mg	tablets						
CLOPIDOGRELUM	EGITROMB 75 mg	film-coated tablets	75mg	EGIS PHARMACEUTICALS PLC.	HUNGARY	7119	2014	01
COMBINATIONS	ACECLOFEN 500 mg/50 mg	suppositories	500mg/50mg	ANTIBIOTICE SA	ROMÂNIA	7222	2014	01
COMBINATIONS	DERMOBACTER 5mg/2mg/ml	cutaneous solution	5mg/2mg/ml	LABORATOIRE INNOTECH INTERNATIONAL	FRANCE	7150	2014	01
COMBINATIONS	STREPSILS PLUS	lozenges		RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED	UK	7022	2014	01
COMBINATIONS	TRIDERM 0.5 mg+10 mg+1 mg/gr	cream	0.5mg+10mg+ 1mg/gr	MERCK SHARP & DOHME ROMANIA SRL	ROMÂNIA	7215	2014	01
COMBINATIONS	BANEOCIN 250 UI/5000 UI /gr	ointment	250UI/ 5000UI/gr	SANDOZ GMBH	AUSTRIA	7021	2014	01
COMBINATIONS	TRIDERM 0.5 mg+10 mg+1 mg/gr	ointment	0.5mg+10mg+ 1mg/gr	MERCK SHARP & DOHME ROMANIA SRL	ROMÂNIA	7214	2014	01
COMBINATIONS	IDEOS 500 mg/400 UI	chewable tablets	500mg/400UI	LABORATOIRE INNOTECH INTERNATIONAL	FRANCE	7138	2014	01
COMBINATIONS	PERIOLIMEL N4E	emulsion for infus.		BAXTER SAS	FRANCE	6980	2014	01
COMBINATIONS	OLIMEL N5E	emulsion for infus.		BAXTER SAS	FRANCE	6981	2014	01
COMBINATIONS	OLIMEL N7	emulsion for infus.		BAXTER SAS	FRANCE	6982	2014	01
COMBINATIONS	OLIMEL N7E	emulsion for infus.		BAXTER SAS	FRANCE	6983	2014	01
COMBINATIONS	OLIMEL N9E	emulsion for		BAXTER SAS	FRANCE	6985	2014	01

		infus.						
COMBINATIONS	OLIMEL N9	emulsion for infus.		BAXTER SAS	FRANCE	6984	2014	01
COMBINATIONS	CALCIU COLECALCIFEROL BERES 600 mg/400 UI	film-coated tablets	600mg/400UI	BERES PHARMACEUTICALS LTD.	HUNGARY	7060	2014	01
COMBINATIONS	SEPTOLETE PLUS 10 mg+2 mg/ml	oromucosal spray, sol.	10mg+2mg/ml	KRKA, D. D. , NOVO MESTO	SLOVENIA	7030	2014	01
COMBINATIONS	PHYSIONEAL 35 CLEAR-FLEX GLUCOZA 13.6 mg/ml	sol. for peritoneal dialysis	13.6mg/ml	BAXTER HEALTH CARE SRL	ROMÂNIA	7042	2014	01
COMBINATIONS	PHYSIONEAL 35 CLEAR-FLEX GLUCOZA 22.7 mg/ml	sol. for peritoneal dialysis	22.7mg/ml	BAXTER HEALTH CARE SRL	ROMÂNIA	7043	2014	01
COMBINATIONS	PHYSIONEAL 35 CLEAR-FLEX GLUCOZA 38.6 mg/ml	sol. for peritoneal dialysis	38.6mg/ml	BAXTER HEALTH CARE SRL	ROMÂNIA	7044	2014	01
COMBINATIONS	PHYSIONEAL 40 CLEAR-FLEX GLUCOZA 13.6 mg/ml	sol. for peritoneal dialysis	13.6mg/ml	BAXTER HEALTH CARE SRL	ROMÂNIA	7045	2014	01
COMBINATIONS	PHYSIONEAL 40 CLEAR-FLEX GLUCOZA 22.7 mg/ml	sol. for peritoneal dialysis	22.7mg/ml	BAXTER HEALTH CARE SRL	ROMÂNIA	7046	2014	01
COMBINATIONS	PHYSIONEAL 40 CLEAR-FLEX GLUCOZA 38.6 mg/ml	sol. for peritoneal dialysis	38.6mg/ml	BAXTER HEALTH CARE SRL	ROMÂNIA	7047	2014	01
COMBINATIONS	VICKS PLUS 500 mg/200 mg/10 mg	powder for oral sol.	500mg/200mg/ 10mg	TEVA PHARMACEUTICALS SRL	ROMÂNIA	7122	2014	01
COMBINATIONS	BIPHOZYL	sol. for haemod/ haemofiltr.		GAMBRO LUNDIA AB	SWEDEN	7177	2014	01

COMBINATIONS	VICKS LAMAIE 1000 mg/12.2 mg	powder for oral sol.	1000mg/12.2mg	TEVA PHARMACEUTICALS SRL	ROMÂNIA	7156	2014	01
COMBINATIONS	REGIOCIT	sol. for haemofiltr.		GAMBRO LUNDIA AB	SWEDEN	7260	2014	01
COMBINATIONS	SANADOR SINUS 500 mg/30 mg	film-coated tablets	500mg/30mg	LAROPHARM SRL	ROMÂNIA	7281	2014	01
COMBINATIONS	REVIGRIP SINUS 500 mg/30 mg	film-coated tablets	500mg/30mg	SOLACIUM PHARMA SRL	ROMÂNIA	7282	2014	01
COMBINATIONS (ETINILESTRADIOLUM + DROSPIRENONUM)	FELICITY 0.02 mg/3 mg	film-coated tablets	0.02mg/3mg	SANDOZ SRL	ROMÂNIA	7120	2014	01
COMBINATIONS (ETINILESTRADIOLUM + DROSPIRENONUM)	FELICITY 0.03 mg/3 mg	film-coated tablets	0.03mg/3mg	SANDOZ SRL	ROMÂNIA	7121	2014	01
COMBINATIONS (AMINOACIZI)	GAVISCON CU AROMA DE CAPSUNI	chewable tablets		RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED	UK	7163	2014	01
COMBINATIONS (BISOPROLOLUM+ AMLODIPINUM)	SOBYCOMBI 5 mg/5 mg	tablets	5mg/5mg	KRKA, D. D. , NOVO MESTO	SLOVENIA	6996	2014	01
COMBINATIONS (BISOPROLOLUM+ AMLODIPINUM)	SOBYCOMBI 5 mg/10 mg	tablets	5mg/10mg	KRKA, D. D. , NOVO MESTO	SLOVENIA	6997	2014	01
COMBINATIONS (BISOPROLOLUM+ AMLODIPINUM)	SOBYCOMBI 10 mg/5 mg	tablets	10mg/5mg	KRKA, D. D. , NOVO MESTO	SLOVENIA	6998	2014	01
COMBINATIONS (BISOPROLOLUM+ AMLODIPINUM)	SOBYCOMBI 10 mg/10 mg	tablets	10mg/10mg	KRKA, D. D. , NOVO MESTO	SLOVENIA	6999	2014	01
COMBINATIONS	ALOTENDIN 5 mg/5 mg	tablets	5mg/5mg	EGIS PHARMACEUTICALS	HUNGARY	7033	2014	01

(BISOPROLOLUM+ AMLODIPINUM)				PLC				
COMBINATIONS (BISOPROLOLUM+ AMLODIPINUM)	ALOTENDIN 5 mg/10 mg	tablets	5mg/10mg	EGIS PHARMACEUTICALS PLC	HUNGARY	7034	2014	01
COMBINATIONS (BISOPROLOLUM+ AMLODIPINUM)	ALOTENDIN 10 mg/5 mg	tablets	10mg/5mg	EGIS PHARMACEUTICALS PLC	HUNGARY	7035	2014	01
COMBINATIONS (BISOPROLOLUM+ AMLODIPINUM)	ALOTENDIN 10 mg/10 mg	tablets	10mg/10mg	EGIS PHARMACEUTICALS PLC	HUNGARY	7036	2014	01
COMBINATIONS (BUDESONIDUM + FORMOTEROLUM)	SYMBICORT TURBUHALER 80 µgr. /4.5 µgr. /inhal.	inhal. powder	80µgr. / 4.5µgr. /inhal.	ASTRAZENECA AB	SWEDEN	7050	2014	01
COMBINATIONS (BUDESONIDUM + FORMOTEROLUM)	SYMBICORT TURBUHALER 160 µgr. /4.5 µgr. /inhal.	inhal. powder	160µgr. / 4.5µgr. /inhal.	ASTRAZENECA AB	SWEDEN	7051	2014	01
COMBINATIONS (BUDESONIDUM + FORMOTEROLUM)	SYMBICORT TURBUHALER 320 µgr. /9 µgr. /inhal.	inhal. powder	320µgr. / 9µgr. /inhal.	ASTRAZENECA AB	SWEDEN	7052	2014	01
COMBINATIONS (CLOPIDOGRELUM+ ACIDUM ACETYLSALCYLICUM	CLOPIDOGREL/ACID ACETILSALICILIC BILLEV 75 mg/75 mg	film-coated tablets	75mg/75mg	BILLEV PHARMA APS	DENMARK	7002	2014	01
COMBINATIONS (CLOPIDOGRELUM+ ACIDUM ACETYLSALCYLICUM	CLOPIDOGREL/ACID ACETILSALICILIC BILLEV 75 mg/100 mg	film-coated tablets	75mg/100mg	BILLEV PHARMA APS	DENMARK	7003	2014	01
COMBINATIONS (DIENOGESTUM+ ETINILESTRADIOLUM)	VELBIENNE 2 mg/1 mg	film-coated tablets	2mg/1mg	LADEEPHARMA KFT.	HUNGARY	7271	2014	01

COMBINATIONS (DROSPIRENONUM+ ETINILESTRADIOLUM)	DAYLLA ZILNIC 3 mg/0.02 mg	film-coated tablets	3mg/00.2mg	GEDEON RICHTER ROMANIA SA	ROMÂNIA	6989	2014	01
COMBINATIONS (DROSPIRENONUM+ ETINILESTRADIOLUM)	MIDIANA ZILNIC 3 mg/0.03 mg	film-coated tablets	3mg/0.03mg	GEDEON RICHTER ROMANIA SA	ROMÂNIA	6990	2014	01
COMBINATIONS (EZETIMIBUM+ ATORVASTATINUM)	ATOZET 10 mg/10 mg	film-coated tablets	10mg/10mg	MERCK SHARP & DOHME LTD	UK	7169	2014	01
COMBINATIONS (EZETIMIBUM+ ATORVASTATINUM)	ATOZET 10 mg/20 mg	film-coated tablets	10mg/20mg	MERCK SHARP & DOHME LTD	UK	7170	2014	01
COMBINATIONS (EZETIMIBUM+ ATORVASTATINUM)	ATOZET 10 mg/40 mg	film-coated tablets	10mg/40mg	MERCK SHARP & DOHME LTD	UK	7171	2014	01
COMBINATIONS (EZETIMIBUM+ ATORVASTATINUM)	ATOZET 10 mg/80 mg	film-coated tablets	10mg/80mg	MERCK SHARP & DOHME LTD	UK	7172	2014	01
COMBINATIONS (FACTORI DE COAGULARE)	PROTHROMPLEX TOTAL 600 UI	powder+solv. for sol. for inj.	600UI	BAXTER AG	AUSTRIA	7176	2014	01
COMBINATIONS (IPRATROPII BROMIDUM+ SALBUTAMOLUM)	IPRATROPIU/SALBUTAMOL CIPLA 0.5 mg/2.5 mg	nebuliser sol.	0.5mg/2.5mg	CIPLA EUROPE NV	BELGIUM	7213	2014	01
COMBINATIONS (LATANOPROSTUM+ TIMOLOLUM)	LATANOPROST/TIMOLOL ALAPIS 50 µgr/ml+5 mg/ml	eye drops, sol.	50 µgr/ml+ 5 mg/ml	ALAPIS ROMANIA SRL	ROMÂNIA	7219	2014	01
COMBINATIONS (LEVODOPUM+ CARBIDOPUM)	DUODOPA 20 mg/ml+ 5 mg/ml	intestinal gel	20mg/ml+5mg/ml	ABBVIE DEUTSCHLAND GmbH & Co. KG	GERMANY	7217	2014	01

COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	LEVODOPA/CARBIDOPA/ENTACAPONA TEVA 50 mg/12.5 mg/200 mg	film-coated tablets	50mg/12.5mg/ 200mg	TEVA PHARMACEUTICALS SRL	ROMÂNIA	7112	2014	01
COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	LEVODOPA/CARBIDOPA/ENTACAPONA TEVA 75 mg/18.75 mg/200 mg	film-coated tablets	75mg/18.75mg/ 200mg	TEVA PHARMACEUTICALS SRL	ROMÂNIA	7113	2014	01
COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	LEVODOPA/CARBIDOPA/ENTACAPONA TEVA 100 mg/25 mg/200 mg	film-coated tablets	100mg/25mg/ 200mg	TEVA PHARMACEUTICALS SRL	ROMÂNIA	7114	2014	01
COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	LEVODOPA/CARBIDOPA/ENTACAPONA TEVA 125 mg/31.25 mg/200 mg	film-coated tablets	125mg/31.25mg/ 200mg	TEVA PHARMACEUTICALS SRL	ROMÂNIA	7115	2014	01
COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	LEVODOPA/CARBIDOPA/ENTACAPONA TEVA 150 mg/37.5 mg/200 mg	film-coated tablets	150mg/37.5mg/ 200mg	TEVA PHARMACEUTICALS SRL	ROMÂNIA	7116	2014	01
COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	LEVODOPA/CARBIDOPA/ENTACAPONA TEVA 175 mg/43.75 mg/200 mg	film-coated tablets	175mg/43.75mg/ 200mg	TEVA PHARMACEUTICALS SRL	ROMÂNIA	7117	2014	01
COMBINATIONS (LEVODOPUM+ CARBIDOPUM+ ENTACAPONUM)	LEVODOPA/CARBIDOPA/ENTACAPONA TEVA 200 mg/50 mg/200 mg	film-coated tablets	200mg/50mg/ 200mg	TEVA PHARMACEUTICALS SRL	ROMÂNIA	7118	2014	01
COMBINATIONS (MIFEPRISTONUM+ MISOPROSTOLUM)	MIFEGYNE COMBIKIT 600 mg/400 µgr.	tablets	600mg/ 400µgr.	EXELGYN	FRANCE	7153	2014	01

COMBINATIONS (PARACETAMOLUM+ PHENYLEPHRINUM)	LEKADOL 500 mg/12.2 mg	powder for oral suspension	500mg/12.2mg	SANDOZ SRL	ROMÂNIA	7209	2014	01
COMBINATIONS (PARACETAMOLUM+ PHENYLEPHRINUM)	LEKADOL 1000 mg/12.2 mg	powder for oral suspension	1000mg/12.2mg	SANDOZ SRL	ROMÂNIA	7210	2014	01
COMBINATIONS (PERINDOPRILUM+ AMLODIPINUM+ INDAPAMIDUM)	ARPLEXAM 2.5 mg/5 mg/0.625 mg	film-coated tablets	2.5mg/5mg/ 0.625mg	LES LABORATOIRES SERVIER	FRANCE	7095	2014	01
COMBINATIONS (PERINDOPRILUM+ AMLODIPINUM+ INDAPAMIDUM)	ARPLEXAM 5 mg/5 mg/1.25 mg	film-coated tablets	5mg/5mg/ 1.25mg	LES LABORATOIRES SERVIER	FRANCE	7096	2014	01
COMBINATIONS (PERINDOPRILUM+ AMLODIPINUM+ INDAPAMIDUM)	ARPLEXAM 5 mg/10 mg/1.25 mg	film-coated tablets	5mg/10mg/ 1.25mg	LES LABORATOIRES SERVIER	FRANCE	7097	2014	01
COMBINATIONS (PERINDOPRILUM+ AMLODIPINUM+ INDAPAMIDUM)	ARPLEXAM 10 mg/5 mg/2.5 mg	film-coated tablets	10mg/5mg/ 2.5mg	LES LABORATOIRES SERVIER	FRANCE	7098	2014	01
COMBINATIONS (PERINDOPRILUM+ AMLODIPINUM+ INDAPAMIDUM)	ARPLEXAM 10 mg/10 mg/2.5 mg	film-coated tablets	10mg/10mg/ 2.5mg	LES LABORATOIRES SERVIER	FRANCE	7099	2014	01
COMBINATIONS (RAMIPRILUM + AMLODIPINUM)	RAMIPRIL/AMLODIPINA ADAMED 2.5 mg/5 mg	caps.	2.5mg/5mg	ADAMED SP. Z. O. O.	POLAND	7199	2014	01
COMBINATIONS RAMIPRILUM + AMLODIPINUM)	RAMIPRIL/AMLODIPINA ADAMED 5 mg/5 mg	caps.	5mg/5mg	ADAMED SP. Z. O. O.	POLAND	7200	2014	01

COMBINATIONS (RAMIPRILUM + AMLODIPINUM)	RAMIPRIL/AMLODIPINA ADAMED 5 mg/10 mg	caps.	5mg/10mg	ADAMED SP. Z. O. O.	POLAND	7201	2014	01
COMBINATIONS (RAMIPRILUM + AMLODIPINUM)	RAMIPRIL/AMLODIPINA ADAMED 10 mg/5 mg	caps.	10mg/5mg	ADAMED SP. Z. O. O.	POLAND	7202	2014	01
COMBINATIONS (RAMIPRILUM + AMLODIPINUM)	RAMIPRIL/AMLODIPINA ADAMED 10 mg/10 mg	caps.	10mg/10mg	ADAMED SP. Z. O. O.	POLAND	7203	2014	01
COMBINATIONS (ROSUVASTATINUM+ EZETIMIBUM)	LIPOCOMB 10 mg/10 mg	caps.	10mg/10mg	EGIS PHARMACEUTICALS PLC	HUNGARY	7026	2014	01
COMBINATIONS (ROSUVASTATINUM+ EZETIMIBUM)	LIPOCOMB 20 mg/10 mg	caps.	20mg/10mg	EGIS PHARMACEUTICALS PLC	HUNGARY	7027	2014	01
COMBINATIONS (ROSUVASTATINUM+ EZETIMIBUM)	LIPOCOMB 40 mg/10 mg	caps.	40mg/10mg	EGIS PHARMACEUTICALS PLC	HUNGARY	7028	2014	01
COMBINATIONS (TAFLUPROSTUM+ TIMOLOLUM)	TAPTIQOM 15 µgr. /ml+5 mg/ml	eye drops sol. in single-dose vial	15µgr. /ml + 5mg/ml	SANTEN OY	FINLAND	7175	2014	01
COMBINATIONS (TRAMADOLUM+ PARACETAMOLUM)	DORETA 37.5mg/325mg	film-coated tablets	37.5mg/325mg	KRKA, D. D. , NOVO MESTO	SLOVENIA	6991	2014	01
COMBINATIONS (TRAMADOLUM+ PARACETAMOLUM)	DORETA 75 mg/650 mg	film-coated tablets	75 mg/650 mg	KRKA, D. D. , NOVO MESTO	SLOVENIA	6992	2014	01
COMBINATIONS (OLMESARTAN MEDOXOMIL+ AMLODIPINA)	INOVUM 20 mg/5 mg	film-coated tablets	20mg/5mg	MENARINI INTERNATIONAL OPERATIONS LUXEMBURG SA	LUXEMBOURG	7206	2014	01

COMBINATIONS (OLMESARTAN MEDOXOMIL+ AMLODIPINA)	INOVUM 40 mg/5 mg	film-coated tablets	40mg/5mg	MENARINI INTERNATIONAL OPERATIONS LUXEMBURG SA	LUXEMBOURG	7207	2014	01
COMBINATIONS (OLMESARTAN MEDOXOMIL+ AMLODIPINA)	INOVUM 40 mg/10 mg	film-coated tablets	40mg/10mg	MENARINI INTERNATIONAL OPERATIONS LUXEMBURG SA	LUXEMBOURG	7208	2014	01
CYCLOPHOSPHAMIDUM	CICLOFOSFAMIDA SANDOZ 500 mg	powder for sol. for inj. /infus.	500mg	SANDOZ SRL	ROMÂNIA	7088	2014	01
CYCLOPHOSPHAMIDUM	CICLOFOSFAMIDA SANDOZ 1000 mg	powder for sol. for inj. /infus.	1000mg	SANDOZ SRL	ROMÂNIA	7089	2014	01
CYCLOPHOSPHAMIDUM	CICLOFOSFAMIDA SANDOZ 2000 mg	powder for sol. for inj. /infus.	2000mg	SANDOZ SRL	ROMÂNIA	7090	2014	01
DEXAMETHASONUM	DEXAMETHASONE SODIUM PHOSPHATE 8 mg/2 ml	sol. for inj.	8mg/2ml	E.I.P.I.CO. MED SRL	ROMÂNIA	7220	2014	01
DEXRAZOXANUM	CYRDANAX 20 mg/ml	powder for sol. for infusion	20mg/ml	PHARMASELECT INTERNATIONAL BETEILIGUNGS GMBH	AUSTRIA	7000	2014	01
DICLOFENACUM	VIKLAREN 75 mg	gastroresistant caps.	75mg	PHARMASWISS CESKA REPUBLIKA S. R. O.	CZECH REP.	7001	2014	01
DICLOFENACUM	VOLTAREN FORTE 23.2 mg/g	gel	23.2mg/g	NOVARTIS CONSUMER HEALTH GMBH	GERMANY	7270	2014	01
DONEPEZILUM	DONECEPT 5 mg	film-coated tablets	5mg	ACTAVIS GROUP PTC EHF	ICELAND	7004	2014	01
DONEPEZILUM	DONECEPT 10 mg	film-coated tablets	10mg	ACTAVIS GROUP PTC EHF	ICELAND	7005	2014	01
DONEPEZILUM	DONEPEZIL STADA 5 mg	film-coated tablets	5mg	STADA HEMOFARM SRL	ROMÂNIA	7254	2014	01

DONEPEZILUM	DONEPEZIL STADA 10 mg	film-coated tablets	10mg	STADA HEMOFARM SRL	ROMÂNIA	7255	2014	01
DORZOLAMIDUM	TRUSOPT 20 mg/ml	eye drops, sol.	20mg/ml	MERCK SHARP&DOHME ROMANIA SRL	ROMÂNIA	7216	2014	01
DROTAVERINUM	NO-SPA 40 mg/2 ml	sol. for inj.	40mg/2ml	CHINOIN PRIVATE CO. LTD.	HUNGARY	6973	2014	01
DROTAVERINUM	ANTISPASMIN FORTE 80 mg	tablets	80mg	BIOFARM SA	ROMÂNIA	7277	2014	01
DUTASTERIDUM	AVODART 0.5 mg	capsules, soft	0.5mg	GLAXOSMITHKLINE (GSK) SRL	ROMÂNIA	7029	2014	01
DUTASTERIDUM	DUTASTERIDA CIPLA 0.5 mg	capsules, soft	0.5mg	CIPLA EUROPE NV	BELGIUM	7154	2014	01
DUTASTERIDUM	DUTASTERIDA TEVA PHARMA 0.5 mg	capsules, soft	0.5mg	TEVA PHARMA B. V.	THE NETHERLANDS	7173	2014	01
ESCITALOPRAMUM	ESCITALOPRAM ATB 5 mg	film-coated tablets	5mg	ANTIBIOTICE SA	ROMÂNIA	7164	2014	01
ESCITALOPRAMUM	ESCITALOPRAM ATB 10 mg	film-coated tablets	10mg	ANTIBIOTICE SA	ROMÂNIA	7165	2014	01
ESCITALOPRAMUM	ESCITALOPRAM ATB 15 mg	film-coated tablets	15mg	ANTIBIOTICE SA	ROMÂNIA	7166	2014	01
ESCITALOPRAMUM	ESCITALOPRAM ATB 20 mg	film-coated tablets	20mg	ANTIBIOTICE SA	ROMÂNIA	7167	2014	01
ESCITALOPRAMUM	ESCITASAN ODT 10 mg	orodispers. tablets	10mg	STADA HEMOFARM SRL	ROMÂNIA	7265	2014	01
ESOMEPRAZOLUM	ESOMEPRAZOL TERAPIA 20mg	gastroresistant tablets	20mg	TERAPIA SA	ROMÂNIA	7261	2014	01
ESOMEPRAZOLUM	ESOMEPRAZOL TERAPIA 40mg	gastroresistant tablets	40mg	TERAPIA SA	ROMÂNIA	7262	2014	01
ESOMEPRAZOLUM	ESOMEPRAZOL HOSPIRA 40 mg	powder for sol. for inj. /infus.	40mg	HOSPIRA UK LIMITED	UK	7075	2014	01

ESOMEPRAZOLUM	ESOMEPRAZOL CIPLA 20 mg	gastroresistant tablets	20mg	CIPLA EUROPE NV	BELGIUM	7274	2014	01
ESOMEPRAZOLUM	ESOMEPRAZOL CIPLA 40 mg	gastroresistant tablets	40mg	CIPLA EUROPE NV	BELGIUM	7275	2014	01
ETOPOSIDUM	VEPESID 50 mg	capsules, soft	50mg	BRISTOL-MYERS SQUIBB KFT.	HUNGARY	7279	2014	01
ETOPOSIDUM	VEPESID 100 mg	capsules, soft	100mg	BRISTOL-MYERS SQUIBB KFT.	HUNGARY	7280	2014	01
ETORICOXIBUM	ETORICOXIB CHANELLE MEDICAL 30 mg	film-coated tablets	30mg	CHANELLE MEDICAL	IRELAND	7266	2014	01
ETORICOXIBUM	ETORICOXIB CHANELLE MEDICAL 60 mg	film-coated tablets	60mg	CHANELLE MEDICAL	IRELAND	7267	2014	01
ETORICOXIBUM	ETORICOXIB CHANELLE MEDICAL 90 mg	film-coated tablets	90mg	CHANELLE MEDICAL	IRELAND	7268	2014	01
ETORICOXIBUM	ETORICOXIB CHANELLE MEDICAL 120 mg	film-coated tablets	120mg	CHANELLE MEDICAL	IRELAND	7269	2014	01
EVEROLIMUS	CERTICAN 0.5 mg	tablets	0.5mg	NOVARTIS PHARMA GMBH	GERMANY	7239	2014	01
EVEROLIMUS	CERTICAN 0.75 mg	tablets	0.75mg	NOVARTIS PHARMA GMBH	GERMANY	7240	2014	01
EVEROLIMUS	CERTICAN 1 mg	tablets	1mg	NOVARTIS PHARMA GMBH	GERMANY	7241	2014	01
EVEROLIMUS	CERTICAN 0.25 mg	tablets	0.25mg	NOVARTIS PHARMA GMBH	GERMANY	7238	2014	01
EVEROLIMUS	CERTICAN 0.25 mg	tablets for oral disp.	0.25mg	NOVARTIS PHARMA GMBH	GERMANY	7243	2014	01
EVEROLIMUS	CERTICAN 0.1 mg	tablets for oral disp.	0.1mg	NOVARTIS PHARMA GMBH	GERMANY	7242	2014	01

COAGULATION FACTOR VIII	CLUVOT 250 UI	powder+solv. for sol. for inj./infus.	250UI	CSL BEHRING GMBH	GERMANY	7157	2014	01
COAGULATION FACTOR VIII	CLUVOT 1250 UI	powder+solv. for sol. for inj./infus.	1250UI	CSL BEHRING GMBH	GERMANY	7158	2014	01
COAGULATION FACTOR VIII	OCTANATE LV 100 UI/ml	powder+solv. for sol. for inj.	100UI/ml	OCTAPHARMA (IP) LTD.	UK	7186	2014	01
COAGULATION FACTOR VIII	OCTANATE LV 200 UI/ ml	powder+solv. for sol. for inj.	200UI/ml	OCTAPHARMA (IP) LTD.	UK	7187	2014	01
COAGULATION FACTOR VIII AND VON WILLEBRAND FACTOR	WILATE 500 500 UI FVW/500 UI FVIII	powder+solv. for sol. for inj.	500 UI FVW/ 500 UI FVIII	OCTAPHARMA (IP) LTD.	UK	6978	2014	01
COAGULATION FACTOR VIII AND VON WILLEBRAND FACTOR	WILATE 1000 1000 UI FVW/1000 UI FVIII	powder+solv. for sol. for inj.	1000 UI FVW/ 1000 UI FVIII	OCTAPHARMA (IP) LTD.	UK	6979	2014	01
FLURBIPROFEN	STREPSILS INTENSIV 8.75 mg/dose	oromucosal spray, sol.	8.75mg/dose	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED	UK	7174	2014	01
FOSFOCREATININUM	NEOTON 1g PHLEBO	powder+solv. sol. for infusion	1g	ALFA WASSERMANN S. P. A.	ITALY	6986	2014	01
GABAPENTINUM	GABAGAMMA 600 mg	film-coated tablets	600mg	WORWAG PHARMA GMBH & CO. KG	GERMANY	7204	2014	01
GABAPENTINUM	GABAGAMMA 800 mg	film-coated tablets	800mg	WORWAG PHARMA GMBH & CO. KG	GERMANY	7205	2014	01
GANCICLOVIRUM	CYMEVENE 500 mg	powder for sol. for infus.	500mg	ROCHE ROMANIA SRL	ROMÂNIA	7024	2014	01
GEMCITABINUM	GEMCITABINA TEVA 40 mg/ml	conc. for sol. for infusion	40mg/ml	TEVA PHARMACEUTICALS SRL	ROMÂNIA	7041	2014	01

HEPARINUM	LIOTON GEL 100000U I /100 g	gel	100000U. I. / 100g	A. MENARINI INDUSTRIE FARMACEUTICHE RIUNITE SRL	ITALY	7283	2014	01
HOMEOPATE	MEDICAMENTE HOMEOPATICE UNITARE 2CH-200CH	granules	2CH-200CH	BOIRON	FRANCE	7224	2014	01
HOMEOPATE	MEDICAMENTE HOMEOPATICE UNITARE 3K-1000000K	granules	3K-1000000K	BOIRON	FRANCE	7284	2014	01
HYDROCORTISONUM	HYDROCORTISONE SUCCINAT SODIC E.I.P.I.CO 100 mg	powder+solv. for sol. for inj. / infus.	100mg	E.I.P.I.CO. MED SRL	ROMÂNIA	7221	2014	01
IBUPROFENUM	ADAGIN 200 mg	film-coated tablets	200mg	ACTAVIS GROUP PTC EHF	ICELAND	7161	2014	01
IBUPROFENUM	ADAGIN 400 mg	film-coated tablets	400mg	ACTAVIS GROUP PTC EHF	ICELAND	7162	2014	01
IBUPROFENUM	IBALGIN RAPID 400 mg	film-coated tablets	400mg	ZENTIVA, K. S.	CZECH REP.	7102	2014	01
IBUPROFENUM	ADVIL ULTRA FORTE 400 mg	capsules, soft	400mg	PFIZER CORPORATION AUSTRIA GMBH	AUSTRIA	7168	2014	01
IBUPROFENUM	NUROFEN EXPRESS 200 mg	capsules, soft	200mg	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED	UK	7253	2014	01
IBUPROFENUM	NUROFLEX CU AROMA DE PORTOCALE 40 mg/ml	oral susp.	40mg/ml	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED	UK	7256	2014	01
IBUPROFENUM	NUROFLEX CU AROMA DE CAPSUNI 40 mg/ml	oral susp.	40mg/ml	RECKITT BENCKISER HEALTHCARE INTERNATIONAL	UK	7257	2014	01

				LIMITED				
IMATINIBUM	IMATINIB KRKA 100 mg	film-coated tablets	100mg	KRKA ,D. D. , NOVO MESTO	SLOVENIA	6970	2014	01
IMATINIBUM	IMATINIB KRKA 400 mg	film-coated tablets	400mg	KRKA ,D. D. , NOVO MESTO	SLOVENIA	6971	2014	01
IMATINIBUM	IMATINIB FAIR-MED 100 mg	film-coated tablets	100mg	FAIR-MED HEALTHCARE GMBH	GERMANY	7229	2014	01
IMATINIBUM	IMATINIB FAIR-MED 400 mg	film-coated tablets	400mg	FAIR-MED HEALTHCARE GMBH	GERMANY	7230	2014	01
C1 ESTERASE INHIBITOR, HUMAN	BERINERT 500 UI	powder+solv. for sol. for inj. / infus.	500 UI	CSL BEHRING GMBH	GERMANY	7182	2014	01
ITRACONAZOLUM	MICOGAL 100 mg	caps.	100mg	ROMPHARM COMPANY SRL	ROMÂNIA	7080	2014	01
KETOROLACUM TROMETHAMIN	KETANOV 10 mg	film-coated tablets	10mg	TERAPIA SA	ROMÂNIA	7211	2014	01
LANSOPRAZOLUM	LANSOPRAZOL MOMAJA 15 mg	gastroresistant tablets	15mg	MOMAJA S. R. O.	CZECH REP.	7147	2014	01
LANSOPRAZOLUM	LANSOPRAZOL MOMAJA 30 mg	gastroresistant tablets	30mg	MOMAJA S. R. O.	CZECH REP.	7148	2014	01
LATANOPROSTUM	XALATAN 50 µg/ml	eye drops, sol.	50µg/ml	PFIZER EUROPE MA EEIG	UK	7107	2014	01
LATANOPROSTUM	XALOPTIC 0.05 mg/ml	eye drops, sol.	0.05 mg/ml	PHARMACEUTICAL WORKS POLPHARMA SA	POLAND	6969	2014	01
LETROZOLUM	LETROZOL STADA 2.5 mg	film-coated tablets	2.5mg	STADA ARZNEIMITTEL AG	GERMANY	7139	2014	01
LEUPRORELINUM	LEPTOPROL 5 mg	implant	5mg	SANDOZ SRL	ROMÂNIA	7133	2014	01
LEVETIRACETAMUM	LEVETIRACETAM POLIPHARMA 100 mg/ml	oral sol.	100mg/ml	POLIPHARMA INDUSTRIES SRL	ROMÂNIA	7025	2014	01
LEVOCETIRIZINUM	LEVOCETIRIZINA	film-coated	5mg	STADA	GERMANY	7188	2014	01

	STADA 5 mg	tablets		ARZNEIMITTEL AG				
LISINOPRILUM	LISINOPRIL ATB 10 mg	tablets	10mg	ANTIBIOTICE SA	ROMÂNIA	7192	2014	01
LISINOPRILUM	LISINOPRIL ATB 20 mg	tablets	20mg	ANTIBIOTICE SA	ROMÂNIA	7193	2014	01
LISINOPRILUM	LISINOPRIL ATB 40 mg	tablets	40mg	ANTIBIOTICE SA	ROMÂNIA	7194	2014	01
LOSARTANUM	LODIAL 50 mg	film-coated tablets	50 mg	ALKALOID-INT D.O.O.	SLOVENIA	7037	2014	01
LOSARTANUM	LODIAL 100 mg	film-coated tablets	100 mg	ALKALOID-INT D.O.O.	SLOVENIA	7038	2014	01
LOSARTANUM	LOSARTAN MYLAN 12.5 mg	film-coated tablets	12.5mg	MYLAN SAS.	FRANCE	6974	2014	01
LOSARTANUM	LOSARTAN MYLAN 25 mg	film-coated tablets	25mg	MYLAN SAS.	FRANCE	6975	2014	01
LOSARTANUM	LOSARTAN MYLAN 50 mg	film-coated tablets	50mg	MYLAN SAS.	FRANCE	6976	2014	01
LOSARTANUM	LOSARTAN MYLAN 100 mg	film-coated tablets	100mg	MYLAN SAS.	FRANCE	6977	2014	01
MEBEVERINUM	COLOSPASMIN 100 mg lozenges	lozenges	100mg	E.I.P.I.CO. MED SRL	ROMÂNIA	7198	2014	01
MEDROXY-PROGESTERONUM	SAYANA 104 mg	susp. for inj. in pre-filled syringe	104mg	PFIZER EUROPE MA EEIG	UK	7212	2014	01
MELOXICAMUM	MELOXICAM LPH 7.5 mg	tablets	7.5mg	LABORMED PHARMA SA	ROMÂNIA	7189	2014	01
MELOXICAMUM	MELOXICAM LPH 15 mg	tablets	15mg	LABORMED PHARMA SA	ROMÂNIA	7190	2014	01
MELOXICAMUM	MOVALIS 15 mg	tablets	15mg	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	GERMANY	7196	2014	01
MELOXICAMUM	MOVALIS 7.5 mg	tablets	7.5mg	BOEHRINGER INGELHEIM INTERNATIONAL	GERMANY	7195	2014	01

				GMBH				
MELOXICAMUM	MELOXICAM ROMPHARM 15 mg/1.5 ml	sol. for inj.	15mg/1.5ml	ROMPHARM COMPANY SRL	ROMÂNIA	7091	2014	01
MEMANTINUM	MELUTRIN 10 mg/ml	oral sol.	10mg/ml	NEOLA PHARMA SRL	ROMÂNIA	7059	2014	01
MEMANTINUM	MANTOMED 10 mg	film-coated tablets	10mg	MEDOCHEMIE LTD.	CYPRUS	7231	2014	01
MEMANTINUM	MANTOMED 20 mg	film-coated tablets	20mg	MEDOCHEMIE LTD.	CYPRUS	7232	2014	01
MEROPENEMUM	MEROPENEM HOSPIRA 500 mg	powder for sol. for inj. /inf.	500mg	HOSPIRA UK LIMITED	UK	7272	2014	01
MEROPENEMUM	MEROPENEM HOSPIRA 1 g	powder for sol. for inj. /inf.	1g	HOSPIRA UK LIMITED	UK	7273	2014	01
MESALAZINUM	PENTASA 2 g	prolonged release granules	2g	FERRING GMBH	GERMANY	7178	2014	01
METFORMINUM	GLUCOPHAGE XR 500 mg	prolonged release tablets	500mg	MERCK SANTE SAS.	FRANCE	7236	2014	01
METOPROLOLUM	BETALOC 5 mg/5 ml	sol. for i.v. inj. / infus.	5mg/5ml	ASTRAZENECA AB	SWEDEN	7137	2014	01
METOPROLOLUM	BETALOC ZOK 100 mg	prolonged release tablets	100mg	ASTRAZENECA AB	SWEDEN	7136	2014	01
METOPROLOLUM	BETALOC ZOK 50 mg	prolonged release tablets	50mg	ASTRAZENECA AB	SWEDEN	7135	2014	01
METOPROLOLUM	BETALOC ZOK 25 mg	prolonged release tablets	25mg	ASTRAZENECA AB	SWEDEN	7134	2014	01
METOPROLOLUM	METOPROLOL RETARD TERAPIA 100 mg	prolonged release tablets	100mg	TERAPIA SA	ROMÂNIA	7106	2014	01
METOPROLOLUM	EGILOK EP 25 mg	prolonged release tablets	25mg	EGIS PHARMACEUTICALS PLC	HUNGARY	6965	2014	01

METOPROLOLUM	EGILOK EP 50 mg	prolonged release tablets	50mg	EGIS PHARMACEUTICALS PLC	HUNGARY	6966	2014	01
METOPROLOLUM	EGILOK EP 100 mg	prolonged release tablets	100mg	EGIS PHARMACEUTICALS PLC	HUNGARY	6967	2014	01
METOPROLOLUM	EGILOK EP 200 mg	prolonged release tablets	200mg	EGIS PHARMACEUTICALS PLC	HUNGARY	6968	2014	01
METRONIDAZOLUM	METRONIDAZOL B 5 g/l	sol. for infusion	5g/l	INFOMED FLUIDS SRL	ROMÂNIA	7124	2014	01
MIDODRINUM	GUTRON 2.5 mg	tablets	2.5mg	TAKEDA AUSTRIA GMBH	AUSTRIA	7023	2014	01
MIFEPRISTONUM	MIFEGYNE 600 mg	tablets	600mg	EXELGYN	FRANCE	7152	2014	01
MONTELUKASTUM	MONTELUKAST CIPLA 5 mg	chewable tablets	5mg	CIPLA (EU) LIMITED	UK	7040	2014	01
MONTELUKASTUM	MONTELUKAST CIPLA 5 mg	chewable tablets	4mg	CIPLA (EU) LIMITED	UK	7039	2014	01
NALTREXONUM	NALTREXONA TORREX 50 mg	film-coated tablets	50mg	CHIESI PHARMACEUTICALS GMBH	AUSTRIA	6028	2014	01
NAPROXENUM	ETRIXENAL 250 mg	tablets	250mg	PROENZI S. R. O.	CZECH REP.	7263	2014	01
NIMESULIDUM	NIMELID 100 mg/sachet	granule for oral susp.	100mg/sachet	ROMPHARM COMPANY SRL	ROMÂNIA	7278	2014	01
OXYCODONUM	PANCOD 5 mg	prolonged release tablets	5mg	PHARMASWISS CESKA REPUBLIKA S. R. O.	CZECH REP.	7082	2014	01
OXYCODONUM	PANCOD 10 mg	prolonged release tablets	10mg	PHARMASWISS CESKA REPUBLIKA S. R. O.	CZECH REP.	7083	2014	01
OXYCODONUM	PANCOD 20 mg	tablets prolonged release	20mg	PHARMASWISS CESKA REPUBLIKA S. R. O.	CZECH REP.	7084	2014	01

OXYCODONUM	PANCOD 40 mg	tablets prolonged release	40mg	PHARMASWISS CESKA REPUBLIKA S. R. O.	CZECH REP.	7085	2014	01
PANTOPRAZOLUM	PANTOPRAZOL AUROBINDO 20 mg	gastroresistant tablets	20mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	7086	2014	01
PANTOPRAZOLUM	PANTOPRAZOL AUROBINDO 40 mg	gastroresistant tablets	40mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	7087	2014	01
PARACETAMOLUM	PARACETAMOL POLIPHARMA 500 mg	tablets	500mg	POLIPHARMA INDUSTRIES SRL	ROMÂNIA	7092	2014	01
PARICALCITOLUM	PARICALCITOL TEVA 1 µgr	capsules, soft	1µgr	TEVA PHARMACEUTICALS SRL	ROMÂNIA	7159	2014	01
PARICALCITOLUM	PARICALCITOL TEVA 2 µgr.	capsules, soft	2µgr.	TEVA PHARMACEUTICALS SRL	ROMÂNIA	7160	2014	01
PERINDOPRILUM	PRESTARIUM 5 mg	film-coated tablets	5mg	LES LABORATOIRES SERVIER	FRANCE	7057	2014	01
PERINDOPRILUM	PRESTARIUM 10 mg	film-coated tablets	10 mg	LES LABORATOIRES SERVIER	FRANCE	7058	2014	01
PLANTE	HERBION LICHEN DE PIATRA 6 mg/ml	syrup	6mg/ml	KRKA, D. D. , NOVO MESTO	SLOVENIA	7179	2014	01
PRAMIPEXOLUM	PRAMIPEXOL STADA 0.088 mg	tablets	0.088mg	STADA ARZNEIMITTEL AG	GERMANY	7144	2014	01
PRAMIPEXOLUM	PRAMIPEXOL STADA 0.18 mg	tablets	0.18mg	STADA ARZNEIMITTEL AG	GERMANY	7145	2014	01
PRAMIPEXOLUM	PRAMIPEXOL STADA 0.7 mg	tablets	0.7mg	STADA ARZNEIMITTEL AG	GERMANY	7146	2014	01
PROGESTERONUM	LUTINUS 100 mg	vaginal tablets	100mg	FERRING GMBH	GERMANY	7218	2014	01
PROPAFENONUM	RYTMONORM 150 mg	film-coated tablets	150mg	ABBOTT GMBH&CO. KG	GERMANY	7093	2014	01

PROPAFENONUM	RYTMONORM 70 mg/20 mg	sol. for inj.	70mg/20ml	ABBOTT GMBH&CO. KG	GERMANY	7094	2014	01
PROPOFOLUM	PROPOFOL HOSPIRA 10 mg/ml	emulsion for inj. / infus.	10mg/ml	HOSPIRA UK LIMITED	UK	7006	2014	01
QUETIAPINUM	SEROQUEL 100 mg	film-coated tablets	100mg	ASTRAZENECA UK LIMITED	UK	7048	2014	01
QUETIAPINUM	SEROQUEL 200 mg	film-coated tablets	200mg	ASTRAZENECA UK LIMITED	UK	7049	2014	01
QUETIAPINUM	SEROQUEL XR 200 mg	prolonged release tablets	200mg	ASTRAZENECA UK LIMITED	UK	7126	2014	01
QUETIAPINUM	SEROQUEL XR 300 mg	prolonged release tablets	300mg	ASTRAZENECA UK LIMITED	UK	7127	2014	01
QUETIAPINUM	SEROQUEL XR 50 mg	prolonged release tablets	50mg	ASTRAZENECA UK LIMITED	UK	7125	2014	01
QUETIAPINUM	SEROQUEL XR 400 mg	prolonged release tablets	400mg	ASTRAZENECA UK LIMITED	UK	7128	2014	01
QUETIAPINUM	SEROQUEL XR 150 mg	prolonged release tablets	150mg	ASTRAZENECA UK LIMITED	UK	7223	2014	01
RIBAVIRINUM	RIBAVIRINA AUROBINDO 200 mg	film-coated tablets	200mg	AUROBINDO PHARMA (MALTA) LIMITED	MALTA	7185	2014	01
RIVASTIGMINUM	RIVASTIGMINA STADA 1.5 mg	caps.	1.5mg	STADA ARZNEIMITTEL AG	GERMANY	7017	2014	01
RIVASTIGMINUM	RIVASTIGMINA STADA 3 mg	caps.	3mg	STADA ARZNEIMITTEL AG	GERMANY	7018	2014	01
RIVASTIGMINUM	RIVASTIGMINA STADA 4.5 mg	caps.	4.5mg	STADA ARZNEIMITTEL AG	GERMANY	7019	2014	01
RIVASTIGMINUM	RIVASTIGMINA STADA 6 mg	caps.	6mg	STADA ARZNEIMITTEL AG	GERMANY	7020	2014	01
RIVASTIGMINUM	RIVASTIGMINA TORRENT 1.5 mg	caps.	1.5mg	TORRENT PHARMA SRL	ROMÂNIA	7068	2014	01
RIVASTIGMINUM	RIVASTIGMINA	caps.	3mg	TORRENT PHARMA	ROMÂNIA	7069	2014	01

	TORRENT 3 mg			SRL				
RIVASTIGMINUM	RIVASTIGMINA TORRENT 4.5 mg	caps.	4.5mg	TORRENT PHARMA SRL	ROMÂNIA	7070	2014	01
RIVASTIGMINUM	RIVASTIGMINA TORRENT 6 mg	caps.	6mg	TORRENT PHARMA SRL	ROMÂNIA	7071	2014	01
ROPINIROLUM	ROPINIROL ARENA 0.25 mg	film-coated tablets	0.25mg	ARENA GROUP SA	ROMÂNIA	7009	2014	01
ROPINIROLUM	ROPINIROL ARENA 0.5 mg	film-coated tablets	0.5mg	ARENA GROUP SA	ROMÂNIA	7010	2014	01
ROPINIROLUM	ROPINIROL ARENA 1 mg	film-coated tablets	1mg	ARENA GROUP SA	ROMÂNIA	7011	2014	01
ROPINIROLUM	ROPINIROL ARENA 2 mg	film-coated tablets	2mg	ARENA GROUP SA	ROMÂNIA	7012	2014	01
ROPINIROLUM	ROPINIROL ARENA 5 mg	film-coated tablets	5mg	ARENA GROUP SA	ROMÂNIA	7013	2014	01
SALMETEROLUM+ FLUTICASONUM	SALMETEROL/PROPIONAT DE FLUTICAZONA MOMAJA 25 µgr. /125 µgr. /dose	pressurised susp. for inhal.	25µgr./125µgr./ dose	MOMAJA S. R. O.	CZECH REP.	6987	2014	01
SALMETEROLUM+ FLUTICASONUM	SALMETEROL/PROPIONAT DE FLUTICAZONA MOMAJA 25 µgr. /250 µgr. /dose	pressurised susp. for inhal.	25µgr. /250µgr. / dose	MOMAJA S. R. O.	CZECH REP.	6988	2014	01
SILDENAFILUM	ENAFILZIL 25 mg	film-coated tablets	25mg	SIGILLATA LIMITED	UK	7130	2014	01
SILDENAFILUM	ENAFILZIL 50 mg	film-coated tablets	50mg	SIGILLATA LIMITED	UK	7131	2014	01
SILDENAFILUM	ENAFILZIL 100 mg	film-coated tablets	100mg	SIGILLATA LIMITED	UK	7132	2014	01
SOMATROPINUM	GENOTROPIN 16 UI/ml (5.3 mg/ml)	powder + solv. for sol. for inj.	16UI/ml (5.3mg/ml)	PFIZER EUROPE MA EEIG	UK	7081	2014	01

SOMATROPINUM	ZOMACTON 10 mg/ml	powder+solv. pt. sol. for inj. in prefilled syringe	10mg/ml	FERRING GMBH	GERMANY	7151	2014	01
TAMSULOSINUM	FOKUSIN 0.4 mg	modif. release caps.	0.4mg	ZENTIVA, K. S.	CZECH REP.	7237	2014	01
TERBINAFINUM	TERBINARAN 250 mg	tablets	250mg	RANBAXY (U. K.) LIMITED	UK	7129	2014	01
TOPIRAMATUM	TOPRAN 25 mg	film-coated tablets	25mg	TERAPIA SA	ROMÂNIA	7062	2014	01
TOPIRAMATUM	TOPRAN 50 mg	film-coated tablets	50mg	TERAPIA SA	ROMÂNIA	7063	2014	01
TOPIRAMATUM	TOPRAN 100 mg	film-coated tablets	100mg	TERAPIA SA	ROMÂNIA	7064	2014	01
TOPIRAMATUM	TOPRAN 200 mg	film-coated tablets	200mg	TERAPIA SA	ROMÂNIA	7065	2014	01
TRAMADOLUM	MABRON RETARD 100 mg	prolonged release tablets	100mg	MEDOCHEMIE LTD.	CYPRUS	7244	2014	01
TRAMADOLUM	MABRON RETARD 150 mg	prolonged release tablets	150mg	MEDOCHEMIE LTD.	CYPRUS	7245	2014	01
TRAMADOLUM	MABRON RETARD 200 mg	prolonged release tablets	200mg	MEDOCHEMIE LTD.	CYPRUS	7246	2014	01
TRANDOLAPRILUM	TRANDOLAPRIL ARENA 0.5 mg	caps.	0.5mg	ARENA GROUP SA	ROMÂNIA	7108	2014	01
TRANDOLAPRILUM	TRANDOLAPRIL ARENA 1 mg	caps.	1mg	ARENA GROUP SA	ROMÂNIA	7109	2014	01
TRANDOLAPRILUM	TRANDOLAPRIL ARENA 2 mg	caps.	2mg	ARENA GROUP SA	ROMÂNIA	7110	2014	01
TRANDOLAPRILUM	TRANDOLAPRIL ARENA 4 mg	caps.	4mg	ARENA GROUP SA	ROMÂNIA	7111	2014	01
TRAVOPROSTUM	TRAVOPROST PHARMATHEN 40 µgr. /ml	eye drops, sol	40µgr. /ml	PHARMATHEN SA	GREECE	6993	2014	01

TRIMETAZIDINUM	MODUXIN MR 35 mg	prolonged release tablets	35mg	GEDEON RICHTER ROMANIA SA	ROMÂNIA	7061	2014	01
VACCIN GRIPAL INACTIVAT	AFLURIA	susp. for inj. in pre-filled syringe		BIOCSL GMBH	GERMANY	7123	2014	01
ZIPRASIDONUM	ZIXADOX 20 mg	caps.	20mg	ZENTIVA, K. S.	CZECH REP.	7249	2014	01
ZIPRASIDONUM	ZIXADOX 40 mg	caps.	40mg	ZENTIVA, K. S.	CZECH REP.	7250	2014	01
ZIPRASIDONUM	ZIXADOX 60 mg	caps.	60mg	ZENTIVA, K. S.	CZECH REP.	7251	2014	01
ZIPRASIDONUM	ZIXADOX 80 mg	caps.	80mg	ZENTIVA, K. S.	CZECH REP.	7252	2014	01

Medicinal products authorised through centralised procedure by the EMA for which a marketing price was established in Romania during the 4th quarter of 2014

INN	Trade Name	Pharm. form	Strength	MAH	Country	MA number		
ACLIDINIUM BROMIDUM+ FORMOTEROLUM FUMARAT	DUAKLIR GENUAIR 340 µgr/12 µgr	powder for inhal.	340 µgr / 12 µgr	ASTRAZENECA AB	SWEDEN	964	2014	01
DULAGLUTIDUM	TRULICITY 0.75 mg/0.5ml	sol. for inj. in prefilled pen	0.75 mg/0.5ml	ELI LILLY NEDERLAND BV	THE NETHERLANDS	956	2014	01
DULAGLUTIDUM	TRULICITY 1.5 mg/0.5ml	sol. for inj. in prefilled pen	1.5 mg/0.5ml	ELI LILLY NEDERLAND BV	THE NETHERLANDS	956	2014	06
OLAPARIBUM	LYNPARZA	caps.	50mg	ASTRA ZENECA AB	SWEDEN	959	2014	01
RAMUCIRUMABUM	CYRAMZA	conc. for sol. for infus.	10 mg/ml	ELI LILLY NEDERLAND BV	THE NETHERLANDS	957	2014	01