DECISION

No. 12/22.04.2013

on approval of new templates of package leaflet, summary of product characteristics and label information for medicinal products authorised for marketing through national procedure in Romania, in accordance with European models

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 158/18.02.2013, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 22.04.2013, in accordance with Article 12(5) of Government Decision no. 734/2010 on establishment, organisation and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following

DECISION

Art. 1. - The new templates of package leaflet, summary of product characteristics and label information for medicinal products authorised for marketing through national procedure in Romania, in accordance with European models are approved, in accordance with Annexes I–IV which are integral part of this Decision.

Art. 2. – (1) Provisions of this decision concern applications for marketing authorisation/marketing authorisation renewal and the applications for approval of variations to MA terms related to information concerning this medicinal product, submitted to the NAMMD following the entry into force of this Decision.

(2) For medicinal products not undergoing MA renewal procedure, provisions of this decision are applied throughout 3 years as of the entering into force of this procedure;

(3) Provisions of this decision do not concern the applications for approval of a variation to MA terms, other than a variation referring to the product information.

Art. 3. – This Decision shall enter into force on the date of its repeal, through:

- Order of the Minister of Health no. 1450/24.11.2010 on amendment of Annexes I-III to Order of the Minister of Health no. 399/2006 on

approval of European templates of package leaflet, summary of product characteristics and label information for medicinal products authorised for marketing in Romania (which lead to the approval of NMA Scientific Council Decision no. 20/27.11.2009);

- Order of the Minister of Health no. 399/10.04.2006 on approval of European templates of package leaflet, summary of product characteristics and label information for medicinal products authorised for marketing in Romania (which lead to the approval of NMA Scientific Council Decision no. 2/27.01.2006).

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

Acad. Prof. Dr. Leonida Gherasim

ANNEX 1
to SCD no. 12/22.04.2013

Package leaflet: Information for the <patient><user>

{ (Invented) name strength pharmaceutical form}
{Active substance(s)}

< ▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects. >

<**Read all of this leaflet carefully before you start <taking> <using> this medicine because it contains important information for you.>**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your <doctor> <or> <pharmacist>.
- <This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.>
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your <doctor> <or> <pharmacist>.> See Section 4.>

<**Read all of this leaflet carefully before you start <taking> <using> this medicine because it contains important information for you.>**
Always <take> <use> this medicinal product in accordance with the indications listed in this leaflet or with the indications provided by your <doctor> <or> <pharmacist>.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your <doctor> <or> <pharmacist>.> See Section 4.
- You must contact a doctor if your symptoms worsen or do not improve <after {number of} days.>

In this leaflet:

1. What is X and what it is used for

- You must contact a doctor if your symptoms worsen or do not improve <after {number of} days.>

2. Before you <take> <use> X

Do not <take> <use> X <:>

- <if you are allergic (hypersensitive) to {active substance(s)} or any of the other ingredients of X (mentioned at point 6).>

Special warnings and precautions for use
Before you <take> <use> X, please contact your <doctor> <or> <pharmacist>.

Children <and teenagers>
<**Athletes**>

<Taking> <Using> other medicines

<Please tell your <doctor> <or> <pharmacist> if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.>

<Taking> <Using> X with <food> and <drink> and <alcohol>

<Pregnancy> and <breast–feeding>

<If you are pregnant or if you breastfeed, think you might be pregnant or intend to, ask your <doctor > <or> <pharmacist> for advice before taking this medicine.>

Driving and using machines

<X contains {name(s) of excipient(s)}>

3. How to <take> <use> X

<Always <take> <use> X exactly as your doctor <or pharmacist> has told you. You should check with your <doctor> <or> <pharmacist> if you are not sure.>

<The usual dose is …>

<Always <take> <use> X as described in this leaflet or exactly as your doctor <or pharmacist><or nurse> has told you. You should check with your <doctor> <or> <pharmacist> if you are not sure.>

<The usual dose is …>

<Use in children <and teenagers>>

<The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.>
<The tablet can be divided into equal halves.>
<The scoreline is not meant for the division of the tablet.>

<If you <take> <use> more X than you should>

<If you forget to <take> <use> X>
<Do not take a double dose to make up for a forgotten <dose> <tablet>.>

<If you stop <taking> <using> X>
<If you have any further questions on the use of this product, ask your <doctor> <or> <pharmacist>.>

4. Possible side effects

Like all medicines, X can cause side effects, although not everybody gets them.

<Additional side effects in children <and teenagers>>

Reporting of side effects
If you encounter any side effects, please tell your <doctor> or <pharmacist>. These include any type of side effects not listed in this leaflet.
You could also report side effects via the national reporting system, whose details are published on the website of the National Agency for Medicines and Medical Devices, http://www.anm.ro/. By reporting the side effects, you could help with the supply of additional information related to the safety of this medicinal product.

5. How to store X

Keep out of the reach and sight of children.

Do not use X after the expiry date which is stated on the <label> <carton> <bottle> <...> <after {abbreviation used for expiry date}.> <The expiry date refers to the last day of that month.>

[For terms to be used in accordance with the storage conditions see Annex III to the Order of the Minister of Health no. 1446/2010]
<Do not use X if you notice {description of the visible signs of deterioration}.>

<Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.>

6. Further information

What X contains
- The active substance(s) is (are)…
- The other ingredient(s) excipient(s) is (are)...

What X looks like and contents of the pack

Marketing Authorisation Holder and Manufacturer

{Name and address}
<{tel}>
<{fax}>
<{e–mail}>

For any information about this medicinal product, please contact the local representatives of the Marketing Authorisation Holder:

Romania
{Name}
<{Address}
{City} {Postal code} – RO>
Tel: + {Telephone number}
<{e-mail}>

This leaflet was last approved in < {**MM/YYYY**}.>

<This medicinal product has been authorised under „special circumstances".
This means that, <due to the scarceness of the disease> <due to scientific reasons> <due to ethical reasons>, complete information about the product couldn't be gathered.
The National Agency for Medicines and Medical Devices shall yearly revise any new available information about this medicinal product and this leaflet is updated, as required.>

<Other sources of information>

You can find detailed information about this product on the website of the National Agency for Medicine and Medical Devices, http://www.anm.ro/

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< The following information is intended for medical or healthcare professionals only:>>

ANNEX 2
to SCD no. 12/22.04.2013

SUMMARY OF PRODUCT CHARACTERISTICS

< ▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.>

1. NAME OF THE MEDICINAL PRODUCT

{(Invented) name strength pharmaceutical form}

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<Excipient(s):>

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

<The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.>
<The scoreline is not meant for the division of the tablet>
<The tablet can be divided into equal doses.>

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

<This medicinal product is for diagnostic use only.>

<{X} is indicated in <adults> <neonates> <infants> <children> <adolescents> <aged {x to y}> <years> <months>.>

4.2 Posology and method of administration

Posology

Children and teenagers

<The <safety> <and> <efficacy> of {X} in children aged {x to y} <months> <years> {or any other relevant subsets, e.g. weight, pubertal age, gender} <has> <have> not <yet> been established.>
<No data are available.>
<Currently available data are described in section <4.8> <5.1> <5.2> but no recommendation on a posology can be made.

<{X} should not be used in children aged {x to y} <years> <months> {or any other relevant subsets e.g. weight, pubertal age, gender} because of <safety> <efficacy> concern(s).>

<There is no relevant use of {X} <in the paediatric population> <in children aged {x to y} <years> <months> {or any other relevant subsets, e.g. weight, pubertal age, gender} <in the indication...>.

<{X} is contraindicated in children aged {x to y} <years> <months> {or any other relevant subsets, e.g. weight, pubertal age, gender} <in the indication...> (see Section 4.3).>

Method of administration

<Precautions to take prior to handling or administration of the medicinal product>
<For instructions on the <reconstitution> <dilution> of the medicinal product before administration, see Sections <6.6> <and> <12>.>

4.3 Contraindications

<Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1 <or {name of the residue(s)}>.>

4.4 Special warnings and precautions for use

<Children and teenagers>

<Athletes>

4.5 Interaction with other medicinal products and other forms of interaction

<No interaction studies have been performed.>

<Children and teenagers>

<Interaction studies have only been performed in adults.>

4.6 Pregnancy, lactation and fertility
[For Pregnancy and lactation statements see Annex I of the Order of the Minister of Health no. 1446/2010]

<Pregnancy>
<Lactation>
<Fertility>

4.7 Effects on ability to drive and use machines

<{Invented name} has <no <or negligible> influence> <minor or moderate influence> <major influence> on the ability to drive and use machines.>

<Not relevant.>

4.8 Side effects

<Children and teenagers>

Reporting suspected adverse reactions
It is important to report adverse reactions suspected after the product's authorisation. This allows a continual monitoring of the product's risk-benefit balance. Healthcare professionals are asked to report any adverse reaction suspected via the national reporting system, whose details are published on the website of the National Agency for Medicines and Medical Devices http://www.anm.ro.

4.9 Overdose

<Children and teenagers>

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: {group}, ATC code: {code} <blank>

<{Invented name} is a biosimilar medicinal product. You can find detailed information about this product on the website of the National Agency for Medicines and Medical Devices, http://www.anm.ro .>

<Mechanism of action>
<Pharmacodynamic effects>
<Clinical efficacy and safety>
<Children and teenagers>

<The European Medicines Agency has waived the obligation to submit the results of studies with {(Invented) Name} [or with generic medicinal products: <reference medicinal product containing {name of the active substance(s)}>] in all subsets of the paediatric population in {condition as per Paediatric Investigation Plan (PIP) decision, in the granted indication} (see section 4.2 for information on paediatric use).>

<The European Medicines Agency has deferred the obligation to submit the results of studies with {(Invented) Name} [or with generic medicinal products: <reference medicinal product containing {name of the active substance(s)}>] in one or more subsets of the paediatric population in {condition as per Paediatric Investigation Plan (PIP) decision, in the granted indication} (see section 4.2 for information on paediatric use).>

<This medicinal product has been authorised under 'exceptional circumstances'.
This means that <due to the rarity of the disease> <for scientific reasons> <for ethical reasons> it has not been possible to obtain complete information on this medicinal product.
The National Agency for Medicines and Medical Devices shall yearly review any new available information and this SPC is updated, if applicable.>

5.2 Pharmacokinetic properties

<Absorption>
<Distribution>
<Metabolisation>
<Disposal>
<Linearity/Nonlinearity >
<Pharmacokinetic/pharmacodynamic relationship(s)>

5.3 Preclinical safety data

<Non–clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.>
<Effects in non–clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.>
<Adverse reactions not observed in clinical studies, but seen in animals at exposure levels similar to clinical exposure levels and with possible relevance to clinical use were as follows:>

<Environmental Impact Assessment (EIA)>

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

<Not applicable.>

6.2 Incompatibilities

<Not applicable.>

<In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.>

<This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6 and section 12.>

6.3 Shelf life

<...> <6 months> <...> <1 year> <18 months> <2 years> <30 months> <3 years> <...>

6.4 Special precautions for storage

[For storage conditions statements see Annex III to the Order of the Minister of Health no. 1446/2010]
< For storage conditions of the <reconstituted> <diluted> medicinal product, see section 6.3.>

6.5 Nature and contents of container

<Not all pack sizes may be marketed.>

6.6 Special precautions for disposal <and other handling>

<Use in children and teenagers>

<No special requirements for disposal.>

<Any unused product or waste material should be disposed of in accordance with local requirements.>

7. MARKETING AUTHORISATION HOLDER

{Name and address}
<{tel}>
<{fax}>
<{e–mail}>

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<Date of first authorisation: <{month YYYY }>
<Date of most recent authorisation renewal: <{month YYYY }>

10. DATE OF REVISION OF THE TEXT

{MM/YYYY}

<11. DOSIMETRY>

<12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS >

< Any unused product or waste material should be disposed of in accordance with local requirements.>

You can find detailed information about this product on the website of the National Agency for Medicine and Medical Devices, http://www.anm.ro/

ANNEX 3
to SCD No.12/22.04.2013

Labelling

PARTICULARS TO APPEAR ON THE <OUTER PACKAGING> <AND> <THE IMMEDIATE PACKAGING>

{NATURE/TYPE}

{(Invented) name strength pharmaceutical form}
{Active substance(s)}

1. NAME OF THE MEDICINAL PRODUCT

{(Invented) name strength pharmaceutical form}
{Active substance(s)}

2. STATEMENT OF ACTIVE SUBSTANCE(S)

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

<Warnings for athletes – see Leaflet!>

<Pictogram (triangle shape – in accordance with the Order of the Minister of Health no. 759/2003**)**
(see leaflet for more information)


>]

8. EXPIRY DATE

[For terms on Expiry date see Annex IV to the Order of the Minister of Health no. 400/2006]

9. SPECIAL STORAGE CONDITIONS

[For terms on Storage condition see Annex III to the Order of the Minister of Health no. 1446/2010]

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

{Name and address}
<{Telephone number}>
<{Fax number}>
<{e-mail}>

12. MARKETING AUTHORISATION NUMBER(S)

{...../YYYY/01-...}

13. BATCH NUMBER

[For terms on Batch number see Annex IV to the Order of the Minister of Public Health no. 400/2006]

14. GENERAL CLASSIFICATION FOR SUPPLY

<Medicinal product subject to medical prescription -<PRF> <P6L> <PR> <PS>.>
< Medicinal product not subject to medical prescription.>

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

<Justification accepted for not including the information in Braille>

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS
{NATURE/TYPE}

{(Invented) name strength pharmaceutical form}
{Active substance(s)}

1. NAME OF THE MEDICINAL PRODUCT

{(Invented) name strength pharmaceutical form}
{Active substance(s)}

2. NAME OF THE MARKETING AUTHORISATION HOLDER

{Trade name}

3. EXPIRY DATE

[For terms on Expiry date see Annex IV to the Order of the Minister of Public Health no. 400/2006]

4. BATCH NUMBER

[For terms on Batch number, see Annex IV to the Order of the Minister of Public Health no. 400/2006]

5. OTHER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{NATURE/TYPE}

{(Invented) name strength pharmaceutical form}
{Active substance(s)}

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

{(Invented) name strength pharmaceutical form}
{Active substance(s)}
{Route of administration}

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

[For terms on Expiry date, see Annex IV to the Order of the Minister of Public Health no. 400/2006 ("Terms on Batch number and Expiry date, both on the inner and outer packaging")]

4. BATCH NUMBER

[For terms on Batch number, see Annex IV to the Order of the Minister of Health no. 400/2006]

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

6. OTHER

{Name/stamp of the Marketing Authorisation Holder}

ANNEX 4
to SCD No.12/22.04.2013

SUMMARY OF PRODUCT CHARACTERISTICS

[NOTE: the following are those items of information required by Article 708 of Law no. 95/2006 on healthcare reform, Title XVII – The medicinal product, as amended, transposing the amended Directive 2001/83/EC.
For the full information to be included in each section and subsection of the SmPC, please refer to Scientific Council Decision no. 22/27.11.2009 on approval of the Guideline on Summary of Product Characteristics, published on the NAMMD website:
http://www.anm.ro/anmdm/med_legislatie_hcs.html, which is a translation into Romanian and a transposition of the Guideline EC/2009 on the Summary of Product Characteristics (SmPC). This Guideline should also be read in conjunction with other relevant Guidelines (a cross-reference is made in this document), published on the NAMMD website and/or on the European Medicines Agency (EMA) website, http://www.ema.europa.eu (e.g. "QRD Convention to be followed for the EMA-QRD templates",
http://www.ema.europa.eu/htms/human/qrd/docs/convention.pdf)

During the evaluation process, applicants may present SmPCs for different strengths in one document, clearly indicating with grey-shaded titles the strength or presentation to which alternative text elements refer.
However, the final printed material shall contain a separate SmPC per strength and per pharmaceutical form, containing all pack-sizes related to the strength and pharmaceutical form concerned.

Standard statements are given in the European template, which must be used whenever they are applicable. If the applicant needs to deviate from these statements to accommodate medicinal product-specific requirements, alternative or additional statements will be considered on a case-by-case basis.

Text colour convention:
Violet text: recommendations referring to the information to be included in each section and subsection.
Black text: standard mentions/text to be or not to be included, as required/information to be filled out.

Bracketing convention:
{text}: Information to be filled in
<text>: Text to be selected or deleted as appropriate.]

[ONLY for medicinal products subject to additional monitoring:
The black symbol and the specifications should precede Section 1. The black symbol should be an equilateral triangle oriented downwards: the symbol should be proportional to the size of the characters used in the text and each side of the triangle should be no longer than 5 mm. In view of submitting the information about the medicinal product, the black triangle shown here is used (see below).]

< ▼ This medicinal product is subject to an additional monitoring. This shall allow a rapid identification of new safety information. Healthcare professionals are asked to report any suspected adverse reaction. See Section 4.8 on the manner of reporting adverse reactions.>

1. NAME OF THE MEDICINAL PRODUCT

[The Guideline on the expression of strength in the trade name of medicinal products for human use, approved through Scientific Council Decision no. 11/07.06.2010, is available on the NAMMD website: http://www.anm.ro/anmdm/med_legislatie_hcs.html]

[The pharmaceutical form is stated in accordance with the Scientific Council Decisions concerning the approval of Romanian Standard Terms for pharmaceutical forms, starting materials, closure and administrative systems, in accordance with the European Standard Terms approved by the European Pharmacopoeia Commission, available on the NAMMD website: http://www.anm.ro/anmdm/med_legislatie_hcs.html]

{(Invented) name strength pharmaceutical form}

[No ® ™ symbols is attached here and throughout the text.]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

[The name(s) of the active substance(s) is written in Romanian.]

<Excipient(s) with known effect :>
<For the full list of excipients, see section 6.1.>

3. PHARMACEUTICAL FORM

<The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.>
<The score line is not intended for breaking the tablet.>
<The tablet can be divided into equal doses.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

[Specify, if appropriate, <This medicinal product is for diagnostic use only.>]

<{X} is indicated in <adults> <neonates> <infants> <children> <adolescents> <aged {x to y}> <years> <months>.>

4.2 Posology and method of administration

Posology
[Additional subheadings such as “Elderly patients” or “Patients with renal impairment” can be stated if necessary.]

Paediatric population

<The <safety> <and> <efficacy> of {X} in children aged {x to y} <months> <years> {or any other relevant subsets, e.g. weight, pubertal age, gender} <has> <have> not <yet> been established.> [One of the following statements should be added:
<No data are available.>
or]<Currently available data are described in section <4.8> <5.1> <5.2> but no recommendation on a posology can be made.>

<{X} should not be used in children aged {x to y} <years> <months> {or any other relevant subsets e.g. weight, pubertal age, gender} because of <safety> <efficacy> concern(s).> [concern(s) to be stated with cross-reference to sections detailing data (e.g. 4.8 or 5.1).]

<There is no relevant use of {X} <in the paediatric population> <in children aged {x to y} <years> <months> {or any other relevant subsets, e.g. weight, pubertal age, gender} <in the indication...>.> [specify indication(s).]

<{X} is contraindicated in children aged {x to y} <years> <months> {or any other relevant subsets, e.g. weight, pubertal age, gender} <in the indication...> [specify indication(s).] (see section 4.3).>

Method of administration

<Precautions to be taken before handling or administering the medicinal product>

[Method of administration: directions for proper use by healthcare professionals or by the patient. Further practical details for the patient can be included in the package leaflet, e.g. in the case of inhalers, subcutaneous self-injection. Explanatory illustrations may be included, if necessary.]

<For instructions on <reconstitution> <dilution> of the medicinal product before administration, see section <6.6> <and> <12>.

4.3 Contraindications

[In case the active substance(s) is/are included on the List of the substances contraindicated to drivers, approved through Order of the Minister of Health no. 87/2003 supplemented through Order of the Minister of Health no. 759/2003, this subsection shall also state the fact that their use is contraindicated in drivers, with cross-reference to subsection 4.7.]

<Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1 <or {name of the residue(s)}>.

4.4 Special warnings and precautions for use

[Sub-headings (e.g. "Interference with serological testing" "Hepatic impairment", "QT prolongation") should be used where necessary to facilitate readability (i.e. identification of information in lengthy section).]

<Paediatric population>

<Athletes>
[State the active substance(s) included on the list of forbidden substances from the World Anti-doping Code in force established by the World Anti-doping Agency, http://www.wada-ama.org/en/ .]

<This medicinal product contains an <active substance(s)> which might determine whether anti-doping tests turned positive.>

[For excipients with a known effect, warnings is enforced in accordance with the Order of the Minister of Health no. 1202/02.10.2006, available on the NAMMD website: http://www.anm.ro/anmdm/med_legislatie_ordine.html]

4.5 Interaction with other medicinal products and other forms of interaction

<No interaction studies have been performed.>

<Paediatric population>

<Interaction studies have only been performed in adults.

4.6 Fertility, pregnancy and lactation

[For standard statements referring to pregnancy and lactation, see Annex 1 to the Order of the Minister of Health no. 1446/2010, available on the NAMMD website, http://www.anm.ro/anmdm/med_legislatie_ordine.html]

<Pregnancy>
<Breastfeeding>
<Fertility>

[Additional sub-headings such as "Women of childbearing potential", "Contraception in males and females" can be stated, as appropriate.]

4.7 Effects on the ability to drive and use machines

< {Invented name} has <no or negligible influence> <minor influence> <moderate influence> <major influence> on the ability to drive and use machines.> <and its use is forbidden for drivers and those using machines (see Section 4.3.)
[Describe effects where applicable.]

<Not relevant.>

4.8 Undesirable effects

[For MedDRA frequency convention and system organ class database, see Annex II to the Order of the Minister of Health no. 1446/2010, available on the NAMMD website, http://www.anm.ro/anmdm/med_legislatie_ordine.html]

[Subheadings should be used to facilitate identification of information on each selected adverse reaction and on each relevant special population, e.g.: "Summary of the safety profile", "Tabulated list of adverse reactions", "Description of selected adverse reactions" (alternatively the subsection could be named with the name of the relevant adverse reaction), "Other special populations".]

<Paediatric population>

[For all medicinal products:
The following subtitle should also appear in the end of Section 4.8]

Reporting suspected adverse reactions
It is important to report adverse reactions suspected after the product's authorisation. This allows a continual monitoring of the product's risk-benefit balance. Healthcare professionals are asked to report any adverse reaction suspected via the national reporting system, whose details are published on the website of the National Agency for Medicines and Medical Devices http://www.anm.ro.

4.9 Overdose

[Additional sub-headings, such as "Symptoms" or "Management" can be stated, if necessary.]
<Paediatric population>

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: {group}, ATC code: {code} <not yet assigned>

[For medicinal product authorised as similar biological medicinal product, include the following statement:]
<{(Invented) Name} is a biosimilar medicinal product. Detailed information is available on the website of the National Agency for Medicines and Medical Devices, http://www.anm.ro/>.

[Tabular presentation of clinical efficacy and safety information may be used.]

<Mechanism of action>
<Pharmacodynamic effects>
<Clinical efficacy and safety>
<Paediatric population>

[If the European Medicines Agency has waived or deferred the obligation to submit the outcomes of the performed trials, the information should be given as follows:]

<The European Medicines Agency has waived the obligation to submit the results of studies with {(Invented) Name} [or with generic medicinal products: <reference medicinal product containing {name of the active substance(s)}>] in all subsets of the paediatric population in {condition as per Paediatric Investigation Plan (PIP) decision, in the granted indication} (see section 4.2 for information on paediatric use).>

<The European Medicines Agency has deferred the obligation to submit the results of studies with {(Invented) Name} [or with generic medicinal products: <reference medicinal product containing {name of the active substance(s)}>] in one or more subsets of the paediatric population in {condition as per Paediatric Investigation Plan (PIP) decision, in the granted indication} (see section 4.2 for information on paediatric use).>

<This medicinal product has been authorised under 'exceptional circumstances'.
This means that <due to the rarity of the disease> <for scientific reasons> <for ethical reasons> it has not been possible to obtain complete information on this medicinal product.
The National Agency for Medicines and Medical Devices will review any new information which may become available every year and this SmPC will be updated as necessary.>

5.2 Pharmacokinetic properties

<Absorption>
<Distribution>
<Biotransformation>
<Elimination>
<Linearity/non-linearity>
<Pharmacokinetic/pharmacodynamic relationship(s)>

[Additional sub-heading(s), such as "Renal impairment", "Hepatic impairment", "Elderly", "Paediatric population" or "Other special populations" (to be specified) should be used, where appropriate.]

5.3 Preclinical safety data

[Additional subheadings such as "Juvenile animal studies" can be included when necessary.]
<Nonclinical data have not shown any special risk in humans based on conventional pharmacological studies concerning safety assessment, toxicity after repeated doses, genotoxicity, carcinogenicity, toxicity on reproduction and development.>
<Effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.>
<Adverse reactions not observed in clinical studies, but seen in animals at exposure levels similar to clinical exposure levels and with possible relevance to clinical use were as follows:>

<Environmental Risk Assessment (ERA)>

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

[Name of the excipient(s) in Romanian.]
<None>

6.2 Incompatibilities

<Not applicable.> [if appropriate, e.g. for solid oral pharmaceutical forms.]

<In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.> [e.g. for parenterals.]

<This medicinal product must not be mixed with other medicinal products except those mentioned in section <6.6> <and> <12>.>

6.3 Shelf life

[Information on the finished product shelf life and on the in-use stability after 1st opening and/or reconstitution/dilution should appear here. Only one overall shelf life for the finished product is to be given even if different components of the product may have a different shelf life (e.g. powder & solvent). For example, if the powder's shelf life is 2 years, and the solvent's, 3 years, the medicinal product's shelf life is 2 years.]
<...> <6 months> <...> <1 year> <18 months> <2 years> <30 months> <3 years> <...>

6.4 Special precautions for storage

[For standard statements referring to storage conditions, see Annex III to the Order of the Minister of Health no. 1446/2010, available on the NAMMD website, http://www.anm.ro/anmdm/med_legislatie_ordine.html]

[General storage conditions of the finished medicinal product should appear here, together with a cross-reference to section 6.3 where appropriate:
<For storage conditions after <reconstitution> <dilution> <first opening> of the medicinal product, see section 6.3.>

6.5 Nature and contents of container

<Not all pack sizes may be marketed.>

6.6 Special precautions for disposal <and other handling

[Include practical instructions for preparation and handling of the medicinal product, where applicable, including disposal of the medicinal product, and waste materials derived from the used medicinal product. Presentation of practical information using pictograms in addition to text may be considered, if necessary.]

<Use in the paediatric population>

<No special requirements <for disposal>.>

<Any unused medicinal product or waste material should be disposed of in accordance with local requirements.>

7. MARKETING AUTHORISATION HOLDER

[Country name in Romanian.]
{Name and address}
<{tel.}>
<{fax}>
<{e-mail}>

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[As per SmPC guideline, the date should be stated in the following format:]
<Date of first authorisation: {DD month YYYY}>
<Date of latest renewal: {DD month YYYY}
[The date should correspond to the initial authorisation of the medicinal product concerned.]

10. DATE OF REVISION OF THE TEXT

< {month YYYY}>

<11. DOSIMETRY>

<12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS>

<Any unused medicinal product or waste material should be disposed of in accordance with local requirements.>

Detailed information on this medicinal product is available on the website of the National Agency for Medicines and Medical Devices: http://www.anm.ro

LABELLING AND PACKAGE LEAFLET

[The lay-out of the labelling and package leaflet presented in this template is only intended for Annex I "Leaflet" and for Annex III "Labelling information" of the marketing authorisation. Recommendations about the optimal manner of conceiving and organising the information on the package and leaflet are available in the Scientific Council Decision no. 8/26.06.2009, available on the NAMMD website,
http://www.anm.ro/anmdm/med_legislatie_hcs.html]

[**B**oxed headings in Annex III are provided to help applicants when completing the European template; they are not to appear in the final printed packaging materials (mock-ups/specimens).
A separate text for outer and inner packaging labelling should be completed per strength and per pharmaceutical form. Different pack sizes of the same strength can be presented in one document.
A separate package leaflet should be provided per strength and per pharmaceutical form. During the evaluation process however, applicants may present package leaflets for different strengths in one document, clearly indicating the strength or presentation to which alternative text elements refer. Where applicants consider marketing a combined printed package leaflet, a detailed justification for such a combined package leaflet will have to be included at submission of the marketing authorisation/renewal application. The justification shall take into account the recommendations of the "Compilation of QRD decisions on stylistic matters", published on the website of the European Medicines Agency, http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004442.pdf.
Text which will not appear in the final printed material is to be presented as grey-shaded text].

[Patient alert card:
In case a patient alert card is to be included in the carton, then the text itself will have to be part of the product information (at the end of the inner packaging).]

LABELLING

[NOTE: these are all mandatory items listed in Title V, Labelling and leaflet of Law no. 95/2006 – Title XVII "The medicinal product", transposing Title V of Directive 2001/83/EC.
The data should be presented according to the template below, irrespectively of their sequence on the actual labelling and their position and possible repetition on the individual sides/flaps of the packaging.
Where the same text for outer and inner packaging is used, this should be clearly indicated in the first heading and in {nature/type}. Text which is identical for different presentations should be provided only once, e.g. text of inner vial label where such vial is part of different pack-sizes.

On the printed outer packaging material, an empty space should be provided for the prescribed dose.]

REGULARS TO APPEAR ON <THE OUTER PACKAGING> <AND> <THE IMMEDIATE PACKAGING>

{NATURE/TYPE}

1. NAME OF THE MEDICINAL PRODUCT

{(Invented) name strength pharmaceutical form} [as it appears in the SmPC under section 1.]
{Active substance(s)}

[The reference to the active substance should correspond to the strength expressed in the name,
e.g. (invented) name 60 mg capsules toremifene
(since 60 mg corresponds to toremifene, even if the active substance is actually present as toremifene citrate).]

[The Guideline on the expression of strength and trade name of medicinal products for human use, approved through Scientific Council Decision no. 11/07.06.2010, is available on the NAMMD website:
http://www.anm.ro/anmdm/med_legislatie_hcs.html]

[For mock-ups and specimens, this information may be presented on different lines of text or in different font sizes if necessary, provided that the appearance of the name is as an integrated item,
e.g. (invented) name Z mg/ml
solution for injection]

[The international non-proprietary name (INN) of the active substance(s) is included.

In addition, the different strengths of fixed-combination medicinal products should be presented separated by a "/". The names of the active substances should be presented separated by a "/" and in the same order relating to the strength,
e.g. (invented) name 150 mg/12.5 mg tablets
irbesartan/hydrochlorothiazide]

2. STATEMENT OF ACTIVE SUBSTANCE(S)

[Expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight. Where the active substance is present as a salt, this should be clearly indicated, e.g. for the examples given above: "60 mg toremifene (as citrate)", "60 mg diltiazem hydrochloride". The statement should be based on the information on the active substance given in section 2 of the SmPC.]

3. LIST OF EXCIPIENTS

[Express qualitatively those excipients known to have a recognised action or effect and included in the Order of the Minister of Health no. 1202/02.10.2006, published on the NAMMD website, http://www.anm.ro/anmdm/med_legislatie_ordine.html . However, if the medicinal product is a parenteral, a topical or an eye preparation or if used for inhalation, all excipients must be stated.]

4. PHARMACEUTICAL FORM AND CONTENTS

[The pharmaceutical form is expressed in accordance with the Scientific Council Decisions related to the approval of Romanian Standard Terms for pharmaceutical forms, primary packages, closure and administrative systems, in accordance with the European Standard Terms approved by the European Pharmacopoeia Commission, published on the NAMMD website, http://www.anm.ro/anmdm/med_legislatie_hcs.html. The full form of the Standard Terms is used. Pharmaceutical form patient-friendly terms will be considered on a case-by-case basis, in case of space constraints. If used, the pharmaceutical form patient-friendly term should be added in brackets in section 3 of the SmPC.
Contents by weight, by volume or by number of doses or number of units of administration of the medicinal product (i.e. pack size, including a reference to any ancillary items included in the pack such as needles, swabs, etc.). The information should be as simple and descriptive as possible using terms used in section 3 and 6.5 of the SmPC. Since the pharmaceutical form is already mentioned as part of the name of the medicinal product in section 1, it should be repeated here in grey shading, so that it will not appear several times on the final printed material.
In case of a combined labelling text covering different pack sizes of the same strength, each pack size should be listed on a separate line in grey shading,
e.g. 14 film-coated tablets
28 film-coated tablets
42 film-coated tablets]

[In case of a treatment initiation pack, please follow the below example:
"Treatment initiation pack
Each pack of 28 film-coated tablets for a 4 week treatment schedule contains:
7 film-coated tablets of X 5 mg
7 film-coated tablets of X 10 mg
7 film-coated tablets of X 15 mg
7 film-coated tablets of X 20 mg"]

5. METHOD AND ROUTE(S) OF ADMINISTRATION

[Method of administration: directions for proper use of the medicinal product, e.g. "Do not swallow", "Do not chew", "Shake well before use". In all cases, and especially if full details cannot be included on the outer packaging itself, a reference to the package leaflet must be made:]

Read the package leaflet before use.

[The Standard terms approved through the Scientific Council Decisions related to the approval of Romanian Standard Terms for pharmaceutical forms, primary packages, closure and administrative systems is used for the routes of administration, in accordance with the European Standard Terms approved by the European Pharmacopoeia Commission, published on the NAMMD website, http://www.anm.ro/anmdm/med_legislatie_hcs.html.]

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. SPECIAL WARNING(S), IF NECESSARY

[Special warnings on labelling should be reserved:

- To cases where they are considered very important in order to fulfil a risk minimisation objective (e.g. "Cytotoxic: Handle with caution", "May cause birth defects", etc.).]

- To cases where the active substance(s) of the medicinal product is/are included on the list of forbidden substances from the World Anti-doping Code in force established by the World Anti-doping Agency, http://www.wada-ama.org/en/, when the leaflet shall state:

<Warning for Athletes – see leaflet!>]

[If the active substance(s) is/are included on the List of substances contraindicated to drivers, approved through Order of the Minister of Health no. 87/2003 supplemented through Order of the Minister of Health no. 759/2003, this section shall contain the following statement and pictogram:

<Pictogram (a triangle, in accordance with the Order of the Minister of Health no. 759/2003**)**
(see leaflet for more information)

8. EXPIRY DATE

[For terms on Expiry date, see Annex IV to the Order of the Minister of Health no. 400/2006, published on the NAMMD website, http://www.anm.ro/anmdm/med_legislatie_ordine.html]

[The expiry date printed on medicinal products stating only month and year should be taken to mean the last day of that month. Expiry dates should be expressed with the month given as 2 digits or at least 3 characters and the year as 4 digits, e.g.: January 2012, Jan 2012, 02-2012.]

[Where applicable, shelf life after reconstitution, dilution or after first opening the container.
Please refer to CHMP "Note for Guidance on Maximum Shelf Life for Sterile Products for Human Use after First Opening or Following Reconstitution" (CPMP/QWP/159/96/corr). If however the maximum in-use shelf life for the reconstituted medicinal product varies, depending on how, or with what, it is reconstituted, then there should be a statement on the label, such as: "Read the leaflet for the shelf life of the reconstituted medicine".]

9. SPECIAL STORAGE CONDITIONS

[The statement(s) should reflect special precautions recommended in section 6.4 of the SmPC. For Storage condition statements, see Annex III to the Order of the Minister of Health no. 1446/2010, available on the NAMMD website.]
http://www.anm.ro/anmdm/med_legislatie_ordine.html]

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

[The statement(s) should reflect special precautions recommended in section 6.6 or 12 of the SmPC, e.g. radiopharmaceuticals, cytostatics.]

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[Including town, postal code (if available) and country name of the MAH in Romanian. Telephone, fax numbers or e-mail addresses may be included (no MAH websites, no e-mails linking to MAH websites)].

{Name and address}
<{tel}>
<{fax}>
<{e-mail}>

12. MARKETING AUTHORISATION NUMBER(S)

[Item to be completed by the NAMMD once the Marketing Authorisation has been granted.]
[In case of a combined Annex III covering different pack sizes of the same strength, the respective pack sizes should be included in grey shading after the corresponding MA number and listed on a separate line,

e.g.

...../AAAA/01	14 film-coated tablets
...../AAAA/02	28 film-coated tablets
...../AAAA/03	42 film-coated tablets

13. MANUFACTURING BATCH

[For the terms to be used related to the number of the manufacturing batch, see Annex IV to the Order of the Minister of Health no. 400/2006, published on the NAMMD website,
http://www.anm.ro/anmdm/med_legislatie_ordine.html]

14. GENERAL CLASSIFICATION FOR SUPPLY

[The classification for release is done in accordance with the Order of the Minister of Health no. 1602/31.12.2010 published on the NAMMD website, http://www.anm.ro/anmdm/med_legislatie_ordine.html]

< Medicinal product subject to medical prescription - <PRF> <P6L> <PR> <PS>.>
<Medicinal product not subject to medical prescription.>

15. INSTRUCTIONS ON USE

[Only for medicinal products **not subject** to medical prescription, include, in accordance with the available space and with provisions of Scientific Council Decision no. 8/26.06.2009:
- Therapeutic indication(s)

- Dose recommendations, contraindication(s) and warnings;
- General warnings and overdose warnings are not routinely required, but for certain medicinal products such warnings may be added during the procedure at the request of the NAMMD.]

16. INFORMATION IN BRAILLE

[Information that will appear in Braille on the printed outer packaging material should be mentioned here in normal text format; see also the Scientific Council Decision no. 12/15.07.2007, published on the NAMMD website, http://www.anm.ro/anmdm/med_legislatie_hcs.html]
[In cases where Braille is not included, according to the above mentioned guideline, the justification for such exclusion should be provided in module 1.3.6. Upon agreement by the NAMMD, the following statement should be included in this section in grey shading: <Justification for not including Braille accepted>.]

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{NATURE/TYPE}

1. NAME OF THE MEDICINAL PRODUCT

{(Invented) name strength pharmaceutical form}
{Active substance(s)}

[The active substance is mentioned in accordance with the provisions in section 1 of the outer packaging.]

[Pharmaceutical form patient-friendly terms may be used in case of space limitation]

2. NAME OF THE MARKETING AUTHORISATION HOLDER

{Name} [Full/short name of the Marketing Authorisation Holder.]

3. EXPIRY DATE

[For terms on Expiry date, see Annex IV to the Order of the Minister of Health no. 400/2006, published on the NAMMD website, http://www.anm.ro/anmdm/med_legislatie_ordine.html]

4. MANUFACTURING BATCH

[For terms on Batch number, see Annex IV to the Order of the Minister of Health no. 400/2006, published on the NAMMD website, http://www.anm.ro/anmdm/med_legislatie_ordine.html]

5. OTHER

[Space permitting, any other information necessary for the correct use and administration of the medicinal product can be included here, e.g. Calendar days may be included if the product is taken as a single dose and that is packaged in blister strips that comprise multiples of seven.]

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{NATURE/TYPE}

[Small immediate packaging units are defined as containers sized up to and including 10 ml. On a case-by-case basis the minimum particulars could also be considered for other containers where it is not feasible to include all the information. Such exceptional cases have to be justified, discussed and agreed with the NAMMD.
In case of radiopharmaceuticals, vials should be labelled in accordance with Art. 776 (3) of Law no. 95/2006, Title XVII – The medicinal product.]

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

{(Invented) name strength pharmaceutical form}
{Active substance(s)}
{Route of administration}

[In case of space-related limitations, patient-friendly terms may be used for the pharmaceutical forms; moreover, the abbreviations in the QRD table (containing standard abbreviations), published on the EMA website, http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004439.pdf, may be used as well.
Abbreviations should also be explained and stated in full in the relevant section of the package leaflet.]

[Where different labels apply to different constituents of the medicinal product, the pharmaceutical form in the name on the specific label should only refer to the constituent concerned (e.g. separate label for powder vial and solvent ampoule).]

[In case of a solvent container, section 1 should read:
"Solvent for X" (identify medicinal product name)
< {Route of administration}>]

2. METHOD OF ADMINISTRATION

[Method of administration: directions for proper use of the medicinal product, e.g. "Do not swallow", "Do not chew", "Shake well before use". If full details cannot be included on the immediate packaging itself, a reference to the package leaflet can be made, e.g. "Read the package leaflet before use".]

3. EXPIRY DATE

[For terms on Expiry date, see Annex IV to the Order of the Minister of Health no. 400/2006, published on the NAMMD website, http://www.anm.ro/anmdm/med_legislatie_ordine.html].

[Where applicable and if space permitting, shelf life after reconstitution, dilution or after first opening the container.
For medicinal products which have a limited shelf life after opening or reconstitution, space and a statement inviting to record the date of opening or reconstitution is recommended, e.g. "reconstituted on: …", "EXPIRY DATE: …".
Please refer to "Note for Guidance on Maximum Shelf Life for Sterile Products for Human Use after First Opening or Following Reconstitution" (CPMP/QWP/159/96/corr).]

4. MANUFACTURING BATCH

[For terms on Batch number, see Annex IV to the Order of the Minister of Health no. 400/2006, published on the NAMMD website, http://www.anm.ro/anmdm/med_legislatie_ordine.html]

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

6. OTHER

{Name/stamp of the Marketing Authorisation Holder}

[If space permitting, any other information related to the proper use and administration of the medicinal product, e.g. storage conditions, may be included.]

PACKAGE LEAFLET

[**NOTE**: the following items must appear in the package leaflet as required by Chapter V Labelling and Leaflet of Law no. 95/2006, Title XVII – The medicinal product, transposing Title V of Directive 2001/83/EC.
The package leaflet must be readable for the patient; see Scientific Council Decision no. 21/07.11.2008 and Scientific Council Decision no. 8/26.06.2009, published on the NAMMD website, http://www.anm.ro/anmdm/med_legislatie_hcs.html .
The package leaflet should be written in a language understandable by the patient and should reflect the terminology the patient is likely to be familiar with.
Throughout the text "X" stands for the (invented) name of the medicinal product.

The headings of the sections and subsections given in the European template must be used whenever they are applicable. If the applicant needs to deviate from these headings/statements to accommodate medicine-specific requirements (e.g. for medicines administered by healthcare professionals, "take"/"use" could be replaced by "are given" or "are administered"), alternative or additional headings/subheadings/statements different from those specified in the European template will be considered on a case-by-case basis (please also consider this for contraceptives).
When requested, applicants should justify the use of alternative headings/subheadings, different from European ones (e.g. by reference to user testing results).
For certain medicines not all items may be relevant, in this case the corresponding heading should not be included.

The purpose of the formats is to ensure that all the information required by Art. 769 of Law no. 95/2006, Title XVII – The medicinal product is included in the text versions of all packaging components in the order specified. Design and layout are key elements for the readability of the final printed material. Marketing authorisation holders will still need to format the resulting texts into the relevant full colour mock-ups for all packaging components.
European formats ensure the consistency of the presentation of information across medicinal products authorised through national procedure, and between these and the products authorised through European procedure.
Concerning the conception and organization of the information, as well as to the size, type and colour of characters from the printed leaflet, see Scientific Council Decision no. 8/26.06.2009.
The green recommendations refer to the sections/information in the SmPC corresponding to that section of the leaflet.
In accordance with Art. 14 (4) of Scientific Council Decision no. 12/15.07.2007, published on the NAMMD website, http://www.anm.ro/anmdm/med_legislatie_hcs.html, it is the responsibility of the Marketing Authorisation Holders to provide the leaflet at the request of patient organisations, in an adequate format and in its current version for blind people and for people suffering of visual impairment. As a consequence, MAHs are encouraged to include a statement at the end of each leaflet in view of informing the public about the availability of such formats.]

Package leaflet: Information for the <patient><user>
[Heading to be printed]

{(Invented) name strength pharmaceutical form}
{Active substance(s)}

[The (invented) name of the medicine (referred to as "this medicine" throughout the package leaflet, wherever practical) followed by the strength and pharmaceutical form (i.e. as it appears in section 1 of the SmPC) should be stated here in bold. This should be followed by the active substance(s) (as stated on the label section 1), which may be written on the line below. In the remainder of the document the invented name should appear in lower case without bold or underline and should not be used excessively throughout the text.]

[ONLY for medicinal products subject to additional monitoring:
The black symbol and the specifications should precede Section 1. The black symbol should be an equilateral triangle oriented downwards: the symbol should be proportional to the size of the characters used in the text and each side of the triangle should be no longer than 5 mm. In view of submitting the information about the medicinal product, the black triangle shown here is used (see below).]

< ▼ This medicinal product is subject to an additional monitoring. This shall allow a rapid identification of new safety information. Healthcare professionals are asked to report any suspected adverse reaction. See last part of Section 4 on the manner of reporting adverse reactions.>

[For medicinal products available ONLY on prescription:]
<**Read all of this leaflet carefully before you start <taking> <using> this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your <doctor> <,> <or> <pharmacist> <or nurse>.
- <- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.> [Do not include this statement in case of hospital use.]
- If you get any side effects, talk to your <doctor> <,> <or> <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet.> See Section 4.>

[For medicinal products available without prescription:]
<**Read all of this leaflet carefully before you start <taking> <using> this medicinal product because it contains important information for you.**
Always <take> <use> this medicine exactly as described in this leaflet or as your <doctor> <,> <or> <pharmacist> <or nurse> <has> <have> told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your <doctor> <,> <or> <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet. See Section 4.
- You must talk to a doctor if you do not feel better or if you feel worse <after {number of} days>.>

What is in this leaflet:
[User testing to date has indicated that most patients value a content listing in the package leaflet. In order for this to be most useful it needs to be prominently displayed where it appears. The content listing would normally reflect the six main sections of the leaflet, where a flat leaflet is prepared. However, if a booklet format is used, or the flat leaflet contains many subsections, a more detailed content listing may be used (page numbers or column numbers may be added to enable readers to quickly find the information they are seeking).]

1. What X is and what it is used for

[Invented name, active substance(s) and pharmacotherapeutic group]

[You should first of all include the invented name of the medicinal product and the active substance(s) included in it, as per section 2 of the SmPC, e.g. "X contains the active substance Y". The pharmacotherapeutic group and/or type of activity, as per section 5.1 of the SmPC should also be stated (e.g. statins (used to lower cholesterol).]

[Therapeutic indications]
[The therapeutic indications in line with section 4.1 of the SmPC should be stated here. It should be stated in which age group the medicine is indicated, specifying the age limits, e.g. "X is used to treat {specify indication} in <adults> <new-born babies> <babies> <children> <adolescents> <aged {x to y}> <years> <months>".]

[Information on the benefits of using this medicinal product]
[On a case-by-case basis, information on the benefits of the treatment could be included in this section, as long as it is compatible with the SmPC, useful for the patient, and to the exclusion of any element of a promotional nature. This could be included under a separate subheading, e.g. entitled "How X works".
The information should be depicted in a clear and condensed way. For example, information could relate to:

- signs and symptoms of the target disease, in particular for non-prescription medicines, but also for medicines to be taken "on-demand" (e.g. treatment of migraine);
- the benefit(s) of taking the medicine could be summarised (e.g. "this medicine reduces pain associated with arthritis", "this medicine has been shown to reduce blood sugar, which helps to prevent complications from your diabetes"). This would be particularly important to encourage adherence to the treatment, e.g. for long-term and prevention treatment. Benefit may be described in terms of prevention of disease complications (e.g. anti-diabetic), if established. The timing of the effect may also be described if useful. In any case, information must be compatible with the SmPC, in particular section 5.1;
- information on the amount of time the medicine usually takes to work may be presented if relevant for the patient (pain-killer, antidepressant, etc.).

<You must talk to a doctor if you do not feel better or if you feel worse <after {number of} days>.>.]

2. What you need to know before you <take> <use> X

[This section should include information which patients/users should be aware of before they start taking the medicine and while using it. This section of the package leaflet is the one which in user testing patients have most difficulty with due to its overall size. The inclusion of additional sub-headings (e.g. for information to particular category of users) with a clear hierarchy is therefore critical in helping patients to navigate this information.]

[Contraindications]
Do not <take> <use> X <:>
[All contraindications mentioned in section 4.3 of the SmPC should be included here in the same order as presented in the SmPC. Other precautions and special warnings should be presented in the next section.
Care must be taken to ensure that complex details are not omitted.
It is not acceptable to state only the common or major contraindications. Belief that a patient cannot understand a contraindication is not a reason for omitting it.]

- <if you are allergic to {active substance(s)} or any of the other ingredients of this medicine (listed in section 6).>

[Appropriate precautions for use; special warnings]
Warnings and precautions
Talk to your doctor <or> <pharmacist> <or nurse> before <taking> <using> X
[All warnings and precautions for use included in section 4.4 of the SmPC should be provided here (as in the SmPC, the order should be in principle determined by the importance of safety information provided) and it should also be made clear for each warning or precaution for use, what action the patient should take to minimise the potential risk. Detailed information on warnings and precautions relating to side effects that could occur while a patient is taking the medicine should be presented in section 4, with an appropriate cross-reference in section 2.]

[Warnings relating to interactions, fertility, pregnancy and breast-feeding, the ability to drive and use machines, or excipients should be presented in the relevant subsequent subsections, unless they are of major safety importance (contraindication) in which case they should also be highlighted in the subsection "Do not take/use X", above.]

[An additional sub-heading could be included for information on additional monitoring tests that the patient will be required to undergo during treatment.]

Children <and adolescents>
[When the medicine is indicated in children, the warnings and precautions which are specific to this population (and identified as such in section 4.4 of the SmPC) should be included under this sub-heading. Where relevant, parents/carers should also be alerted in this section of potential children/teenager specific warnings included under "driving and using machines".]

[If there is no indication in some or all subsets of the paediatric population, information should reflect those in subsection *Paediatric population* (section 4.2 of the SmPC), e.g. "Do not give this medicine to children between the ages of x and y <years> <months>, because of the <risk of [....]> <it does not work> <the potential benefits are not greater than the risks>, <it is unlikely to be safe>".]

<**Athletes**>
[State the active substance(s) included on the list of forbidden substances from the World Anti-doping Code in force established by the World Anti-doping Agency, http://www.wada-ama.org/en/ .]
<This medicinal product contains an <active substance(s)> which might determine whether anti-doping tests turned positive.>

[Interactions with other medicinal products]
Other medicines and X
<Tell your <doctor> <or> <pharmacist> if you are <taking> <using>, have recently <taken> <used> or might <take> <use> any other medicines.>

[Describe the effects of other medicines on the medicine in question and vice versa as per section 4.5 of the SmPC. Refer to other medicines by their pharmacotherapeutic group/type of activity and by their INN(s) (including the lay terms first and the INNs in brackets unless the interaction is only with one active in a class, e.g. „statin (medicine used to lower cholesterol)".]

[In some cases, where it may be helpful to the patient, you should describe in brief terms the consequence of the interaction. One possibility could be to distinguish the medicine which must not be used with the medicine, e.g.: "Do not take X with Y (a medicine used for Z) as this may result in the <loss of its effect> <side effect>", those for which the combination should be avoided and those for which the combination would require some precaution (e.g. dose adjustment; in such a case please cross-refer to section 3 of this leaflet). For example, if hormonal oral contraceptives are likely to become ineffective as a result of an interaction, patients should also be advised to use additional forms of contraceptives (e.g. barrier contraceptives).]

[Interactions with herbal or alternative therapies should be addressed if mentioned in section 4.5 of the SmPC.]

[Interactions with food and drink]
X with <food> <and> <,> <drink> <and> <alcohol>
[Interactions not related to medicines should be mentioned here if reference is made in section 4.5 of the SmPC. For example, patients should not consume milk in combination with tetracyclines and no alcohol should be consumed during treatment with benzodiazepines. This section should not be used to tell patients whether or not their medicine should be taken before, during or after meals as this should only be addressed in section 3 (below), but a cross-reference to section 3 can be included.]

[Use by pregnant or breastfeeding women, information on fertility]

Pregnancy <and> <,> breast-feeding <and fertility>
[Where the information is significantly different, pregnancy, breast-feeding and fertility information can be presented under separate sub-headings.]

[Include conclusion summary of the information given in section 4.6 of the SmPC, in addition to the following optional statement:]
<If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your <doctor> <or> <pharmacist> for advice before taking this medicine.>

[Please note that if the medicine is contraindicated in pregnancy and/or breast-feeding the same information should be presented in both subsections ("Do not take/use X" & "Pregnancy, breast-feeding and fertility") of the leaflet and should include information on teratogenicity where this is known.]

[Effects on the ability to drive or to use machines]
Driving and using machines
[Where there is cautionary advice in section 4.7 of the SmPC related to the affectation of the ability to drive or use equipment, this should be translated into meaning colloquial language for the patient, in this section.
MAHs should bear in mind that medicines taken by children may need specific advice. For example, regarding road safety, children who may not be old enough to drive may nevertheless cycle.
The advice should include an explanation as to why the patient is advised not to drive or undertake these tasks, and whether or not they should discuss this with their doctor if they wish to do so.]

[Excipient warnings]
<X contains {name the excipient(s)}>
[Warnings referring to known excipients is included, in accordance with the Order of the Minister of Health no. 1202/02.10.2006, available on the NAMMD website: http://www.anm.ro/anmdm/med_legislatie_ordine.html]
This subsection should be omitted when the medicine does not contain any excipients of known effect. In case the information relates to another section of the package leaflet (e.g. alcohol), a cross reference to this section should be made. It will also be necessary to refer back to the excipients warning from those sections relating to the effects (e.g. pregnancy and breast-feeding, paediatric information, ability to drive and use equipment).]

3. How to <take> <use> X

[Dose (SmPC Section 4.2)]
[For medicines available on prescription only:]
<Always <take> <use> this medicine exactly as your doctor <or pharmacist> has told you.
Check with your <doctor> <or> <pharmacist> if you are not sure.>

<The recommended dose is …>

[For medicines available without prescription:]
<Always <take> <use> this medicine exactly as described in this leaflet or as your <doctor> <,> <or> <pharmacist> <or nurse> <has> <have> told you. Check with your <doctor> <or> <,> <pharmacist> <or nurse> if you are not sure.>

<The recommended dose is …>

[When available, information on maximum single, daily and/or total dose should also be included. Additional sub-headings may be included where the posology varies for different indications or for different populations (e.g. elderly, hepatic impairment, renal impairment). Include the recommended dose and specify, if necessary, the appropriate time(s) at which the medicine may or must be administered.]

<Use in children <and adolescents>>
[When the medicine is indicated in different age groups with a different dose, method of administration, frequency of administration or duration of treatment, specific instructions for use for each age group should be clearly identified.
If there are more appropriate strength(s) and/or pharmaceutical form(s) for administration in some or all subsets of the paediatric population (e.g. oral solution for infants), these should be mentioned, e.g. "Other form(s) of this medicine may be more suitable for children; ask your doctor or pharmacist.".]

[Route(s) of administration (SmPC section 4.2)]
[The route(s) of administration is/are given in accordance with the Scientific Council Decisions on approval of the Romanian Standard Terms for pharmaceutical forms, primary packages, closure and administration systems, in accordance with the European Standard Terms approved by the European Pharmacopoeia Commission, available on the NAMMD website: http://www.anm.ro/anmdm/med_legislatie_hcs.html. An additional patient-friendly explanation may be given if necessary.
Method of administration: directions for a proper use of the medicine, e.g. "Do not swallow", 'Do not chew", "Shake well before use" (user testing experience has shown it is useful to state the reasons for the inclusion of such a statement, e.g. "Do not break or crush the tablet(s). If you do, there is a danger you could overdose because this medicine will be absorbed into your body too quickly").

When applicable, there should be descriptions (if useful with illustrations) of opening techniques for child-resistant containers and other containers to be opened in an unusual way.
Where relevant, guidance should always be included to clarify if the medicine must be taken with food, during/before meals, or clearly state if food/meals have no influence, etc.]
<The score line is only there to help you break the tablet if you have difficulty swallowing it whole.>
<The tablet can be divided into equal doses.>
<The score line is not intended for breaking the tablet.>

[Duration of treatment (SmPC section 4.2)]
[If appropriate, especially for medicines available without prescription, precise statements should be included on:
- the usual duration of the therapy;
- the maximum duration of the therapy;
- the intervals with no treatment;
- the cases in which the duration of treatment should be limited.]
[For some medicines it may be necessary to include some additional information in this section although this need not be covered in all cases.]

<If you <take> <use> more X than you should>
[Describe how to recognise symptoms if someone has taken an overdose and what to do as per SmPC section 4.9.]

<If you forget to <take> <use> X>
[Make clear to patients what they should do after irregular use of a medicine, e.g.: if information is available, try to include information on the maximum interval the missed dose can be caught up as per SmPC section 4.2.]

<Do not take a double dose to make up for a forgotten <tablet> <dose> <…>.>

<If you stop <taking> <using> X>
[Indicate withdrawal effects and how to minimise them as per SmPC section(s) 4.2 and/or 4.4.
A statement on the potential consequences of stopping the treatment before finishing the course of treatment and the need for a prior discussion with the treating physician, for medicines released on prescription, and with the pharmacist or nurse, for medicines released without prescription should be included as appropriate.]
[Close this section with:]

<If you have any further questions on the use of this medicine, ask your <doctor> <,> <or> <pharmacist> <or nurse>.>

4. Possible side effects

[Description of side effects]
[Begin this section with:]
Like all medicines, this medicine can cause side effects, although not everybody gets them.

[The section should generally be divided into two sections bearing in mind that there should be sufficient patient-friendly description of the overt clinical signs and symptoms to enable the patient to recognise all side effects which may occur as set out in section 4.8 of the SmPC:

1) summary safety profile as per section 4.8 of the SmPC: the most serious side effects need to be listed prominently first with clear instructions to the patients on what action to take (e.g. to stop taking the medicine and/or seek urgent medical advice; the use of the words "straight away" or "immediately" may be helpful in this context), together with the most frequently occurring side effects.

2) then a list of all other side effects (without repeating the most serious and most frequent included above).

Within each section, side effects should be arranged by frequency. The following frequency convention is recommended:

Very common: may affect more than 1 in 10 people
Common: may affect up to 1 in 10 people
Uncommon: may affect up to 1 in 100 people

Rare: may affect up to 1 in 1,000 people
Very rare: may affect up to 1 in 10,000 people
Not known: frequency cannot be estimated from the available data

This frequency convention should not appear before the list of side effects as this takes up space and has shown in user testing to be misleading to patients.

In any case, when expressing the likelihood of side effects it is important to include verbal terms and numerical data, as far as possible. Bear in mind that user testing has shown that double sided expressions such as "affects more than 1 in 100 but less than 1 in 10" are not well understood and should not be used.
System organ class listings should not be used. However, patient-friendly terms for parts of the body may be used as headings where the frequency is not known (e.g. for older medicines) in order to break up an otherwise long list, e.g. skin, stomach and gut, etc.]

<Additional side effects in children <and teenagers>>
[If appropriate (and in line with information stated in section 4.8 of the SmPC), a subsection should highlight any clinically relevant differences in terms of side effects in any relevant subset of the paediatric population compared to another or to the adult population.]

[For all medicinal products:
The following subtitle should show up in the end of Section 4]

Reporting of side effects
If you encounter any side effects, please tell your <doctor> or <pharmacist>. These include any type of side effects not listed in this leaflet.
You could also report side effects via the national reporting system, whose details are published on the website of the National Agency for Medicines and Medical Devices, http://www.anm.ro/. By reporting the side effects, you could help with the supply of additional information related to the safety of this medicinal product.

5. How to store X

Keep this medicine out of the sight and reach of children.

[Expiry date]
[Where a specific abbreviation for Expiry date is used on the labelling, it should be mentioned here.] Do not use this medicine after the expiry date which is stated on the <label> <carton> <bottle> <...> <after {abbreviation used for expiry date}.> <The expiry date refers to the last day of that month.>

[Storage conditions]
[Information should be compliant with section 6.4 of the SmPC; for storage condition statements, see Annex III to the Order of the Minister of Health no. 1446/2010, available on the NAMMD website, http://www.anm.ro/anmdm/med_legislatie_ordine.html]

[Where applicable, shelf life after reconstitution, dilution or after first opening the container]
[Information should be in accordance with section 6.3 of the SmPC; please also refer to "Note for Guidance on Maximum Shelf Life for Sterile Products for Human Use after First Opening or Following Reconstitution" (CPMP/QWP/159/96/corr).]

[Where appropriate, warnings against certain visible signs of deterioration]
<Do not use this medicine if you notice {description of the visible signs of deterioration}.>

< Do not throw away any medicines via wastewater <or household waste>. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.>

6. Contents of the package and other information

[Full statement of the active substance(s) and excipient(s)]
What X contains
[The active substance(s) (expressed qualitatively and quantitatively) and the other ingredients (expressed qualitatively) should be identified using their names as given in sections 2 and 6.1 of the SmPC and in Romanian.]

- The active substance(s) is (are)… [e.g. “Each <tablet> <capsule> contains x <gram> <milligram>…{active substance}”.]
- The other <ingredient(s)> <(excipient(s))> is (are)... [A cross-reference to section 2 “X contains {name the excipients}” should be included when applicable.]

[Pharmaceutical form, nature and contents of container in weight, volume or units of dose]
What X looks like and contents of the package
[The pharmaceutical form should be stated according to the Scientific Council Decisions referring to the approval of the Romanian Standard Terms for pharmaceutical forms, primary packages, closure and administrative systems, in accordance with the European Standard Terms approved by the European Pharmacopoeia Commission, available on the NAMMD website: http://www.anm.ro/anmdm/med_legislatie_hcs.html
It is recommended to include a physical description, e.g. shape, colour, imprint, etc. as per section 3 of the SmPC.]

[All pack sizes for this pharmaceutical form and strength should be detailed here as per section 6.5 of the SmPC, including the reference to any ancillary items included in the pack such as needles, swabs etc.
If appropriate, indicate that not all pack sizes may be marketed. A cross-reference to other pharmaceutical forms and strengths may be included.]

[Name and address of the marketing authorisation holder and of the manufacturer responsible for batch release, if different]

Marketing Authorisation Holder and Manufacturer

{Name and address}
<{tel}>
<{fax}>
<{e-mail}>
[State the name and address of the Marketing Authorisation Holder as per section 7 of the SmPC and identify as such, e.g. “Marketing Authorisation Holder: ABC Ltd, etc.” State the full address of the MAH, including the city, postal code (if available) and Member State in Romanian. Telephone, fax numbers or e-mail addresses may be included. The inclusion of the holding companies’ websites and links sent via e-mails to the websites of holding companies are forbidden.]

[State the name and address of the manufacturer responsible for batch release, e.g. „Manufacturer: ABC …. etc”. Please specify the full address of the manufacturer responsible for batch release, including the city, postal code (if available) and name of the Member State in Romanian. Telephone or fax numbers, e-mail addresses or websites are not allowed.]

[If MAH and manufacturer are the same, the general heading “Marketing Authorisation Holder and Manufacturer” can be used.]
[In cases where more than 1 manufacturer responsible for batch release is designated, all should be listed here (with or without grey-shading, depending on the option chosen for the printed package leaflet).
The printed package leaflet of the medicinal product must clearly identify the manufacturer responsible for the release of the concerned batch or mention only the specific manufacturer responsible for the release of that batch.]

[The local representative may be stated, without this being a mandatory requirement, when appropriate. There are cases in which the local representative and the MAH are one and the same. In such cases, nothing is stated.]

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder:

Romania
{Name}
<{Address}
{City} {Postal code} – RO>
Tel: + {Telephone number}
<{e-mail}>

This leaflet has been revised in <{month YYYY}.>

[The date of the release of the marketing authorisation/approval of the most recent variation implying changes in the leaflet or in the transfer of a Marketing Authorisation Holder.]

<This medicinal product has been authorised under 'exceptional circumstances'.
This means that <for scientific reasons> <for ethical reasons> it has not been possible to obtain complete information on this medicinal product.
The National Agency for Medicines and Medical Devices shall yearly revise any new available information about this product and this leaflet is updated, as required.>

<Other information sources>
[This subsection should include references to other information sources which are useful for the patient. These information sources should be compatible with the Summary of Product Characteristics and should not be promotional:
- Details referring to the manner in which patients can access this information randomly, e.g. Braille, audio, CD-ROM, for blind people or in adequate written format (e.g. font size: Sans serif, 16-20 points; contrast: black letters on white background; word spacing, text alignment, row spacing, aspect, quality of the paper) for blind persons (see Scientific Decision no. 12/2007. These details should have a larger font, so that blind persons are aware of the availability of information.]

Detailed information related to this medicinal product is available on the website of the National Agency for Medicines and Medical Devices, http://www.anm.ro/

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[For parenteral medicinal products, other products particularly used in the hospital or in the exceptional case of extemporaneous preparation (when a product is not suitable for use in children and when an adequate formulation for children has not been developed (based on justified scientific reasons)), practical information relevant for healthcare professionals, e.g. preparation and/or handling, non-compliances, doses, overdosage or monitoring measures and laboratory investigations can be added in this section, when applicable, and a cross-reference to section 3 should also be included. In this case, the section shall start with the following statement:

<The following information is only meant for healthcare professionals>

[If additional scientific information must be included in the leaflet at the request of healthcare professionals, this can be done:

- either by providing a full SmPC as a separate document in the package;
- or by adding the entire SmPC as a document which can be attached at the end of the printed leaflet, so that the information meant for patients (in other terms, the leaflet) and the information meant for healthcare professionals (namely the SmPC) can be easily differentiated.

The intention of including a complete SmPC and the manner in which this issue will be solved should be explained by the applicant and indicated in the end of Annex 1 "Leaflet", without overtly repeating the last SmPC approved. Applicants must decide whether the inclusion of scientific information on the package is proper, given the type of the medicinal product.]