DECISION

No. 21/03.09.2010

on approval of the Guideline on the writing of the marketing authorisation and annexes to the marketing authorisation

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), set up based on Order of the Minister of Public Health no. 1123/18.08.2010, as amended, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 03.09.2010, in accordance with Article 12(5) of Government Ordinance no. 734/2010 related to the set up, organisation and operation of the National Medicines Agency, agrees on the following

DECISION

Art. 1. - The Guideline on the writing of the marketing authorisation and annexes to the marketing authorisation is approved, in accordance with the Annexes which are integral part of this Decision.

Art. 2. – On the date of the coming into force of this Decision, the NMA Scientific Council Decision No. 1/02.06.2005 on approval of the new structure of the marketing authorisation and Norms for marketing authorisation writing is hereby repealed.

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

ANNEX I

Guideline on the writing of the marketing authorisation and annexes to the marketing authorisation

Art. 1. – (1) This Guideline is issued in accordance with the provisions of Law No. 95/2006 on the healthcare reform, Title XVII – The medicinal product (hereinafter "the Law") transposing Directive 2001/83/EC, as amended.

(2) This Guideline applies to medicinal products authorised for marketing in Romania through centralised/decentralised/mutual recognition procedure.

Art. 2. – In accordance with Art. 700 of the Law, transposing Art. 6. of Directive 2001/83/EC, no medicinal product may be placed on the market of Romania unless a marketing authorisation has been issued by the National Agency for Medicines and Medical Devices (ANMDM) or by the European Medicines Agency (EMA).

Art. 3. – This Guideline provides recommendations concerning the writing of the marketing authorisation and annexes to the marketing authorisation, replacing the previous related norms for medicinal products authorised by the NAMMD through national, decentralised or mutual recognition procedure.

Art. 4. – Under the heading referring to the legal basis of the marketing authorisation, a combination of the following legal bases is to be used, as required: <Art. 700 (1), <Art. 702 (4)>, <Art. 704 (1) and (2)>, <Art. 704 (3)>, <Art. 704 (4)>, <Art. 705>, <Art. 706>, <Art. 707>, <Art. 710>, <Art. 714>, <Art. 730 (2)>, <Art. 730 (5)>, <Art. 736 (2)>, <Art. 736 (3)> or <Art. 736 (4)>.

Art. 5. – (1) According to Art. 730 (1) of the Law, a marketing authorisation shall be valid for 5 years.

(2) The marketing authorisation shall contain the following specification: "This marketing authorisation is valid for 5 years as of the date of its issue".

Art. 6. – (1) In accordance with Art. 730. (5) of the Law, once renewed, the marketing authorisation is valid for an unlimited period, in which case the marketing authorisation shall not specify anything related to the validity of the marketing authorisation.

Art. 7. – (1) Under the heading "Registration name", the name, strength and pharmaceutical form of the medicinal product shall be specified.

(2) In accordance with Art. 695, point 20 of the Law, the name of the medicinal product "may be an invented name not liable to confusion with the common name/ a common name or a scientific name, accompanied by the trademark or the name of the Marketing Authorisation Holder";

(3) The strength is expressed in accordance with the "Guideline on the expression of strength in the name of centrally authorised medicinal products for human use", approved through Scientific Council Decision No. 11/07.06.2010;

(4) The registered mark symbol, ®, TM, for the medicinal product invented trade name is not entered;

(5) The pharmaceutical form shall be named in accordance with the Regulations in force concerning the Romanian standard terms for pharmaceutical forms, routes of administration, closure and administration systems, in accordance with those adopted by the European Pharmacopoeia Commission.

Art. 8. – (1) The following are entered in the marketing authorisation under the heading "Composition": active substance(s) in terms of quality and quantity and auxiliary substance(s) in terms of quality;

(2) The quantity of active substance is expressed per dosage unit, per volume unit or weight unit, depending on the type of pharmaceutical form;

(3) In the case of active substance(s) under the form of salt, ester, hydrated form etc., the quantity of the respective substance and its equivalent in anhydrous base are entered;

(4) Components are entered using the common name or the scientific name or the common standard name according to the European Pharmacopoeia or the Romanian Pharmacopoeia or some international pharmacopoeia giving official status to the respective component (the name of the components is to be entered in the mentioned order);

(5) For certain auxiliary substances, specifications have to be made on the following:

- the colour index (colouring matters, for instance, E_{171})
- granulometry (for instance: Lactose monohydrate 200mesh);

(6) For certain auxiliary substances, addition of the trade name next to the scientific name is allowed or the trade name may be written, in case no scientific name is available (for instance, Opadry code……..; under such circumstances, the composition of the filming mixture must be given in terms of quality).

Art. 9. – The heading "Marketing Authorisation Holder" shall contain the full name and address of the Marketing Authorisation Holder, according to the data stated in the marketing authorisation/marketing authorisation renewal dossier.

Art. 10. – The name and address of the manufacturer(s) responsible for the release of the concerned batch are specified in the marketing authorisation under the heading "Manufacturer(s)", in accordance with the data mentioned in the marketing authorisation/marketing authorisation renewal dossier.

Art. 11. - The ATC (Anatomic – Therapeutic – Chemical) code of the ATC Index in force elaborated by the World Health Organisation (WHO) is specified up to level 5 (chemical substance) under the heading "ATC Classification".

Art. 12. - Under the heading "Supply", the option is ticked which corresponds to medicinal product supply.

Art. 13. - Under the heading "Packaging", information should be included on immediate packaging (type of packaging, material, closure and administration system, pack size) and outer packaging;

a) For instance:

Carton with 2 blisters Al/PVC 10 tablets each

b) For instance:

Brown glass vial with child resistant closure system, containing 100ml syrup, in a box, together with a syringe for oral administration.

Art. 14. - Shelf life of the medicinal product after packaging for commercial use is mentioned under the heading "Shelf life" (specified in years and months where specification in years is not feasible), shelf life after the first opening (if necessary), shelf life after dilution or reconstitution (if necessary).

Art. 15. – (1) Under the heading "Storage conditions", medicinal product storage conditions are specified after packaging for commercial use, after the first opening, after dilution or reconstitution, as necessary;

(2) The marketing authorisation must mention the main storage statement as resulted from evaluation of stability studies developed with the finished product; mentioning other specific storage statements relevant for the medicinal product Package Leaflet and Label is not mandatory.

Art. 16. – Under the heading "Summary of Product Characteristics", when conducting studies in accordance with the Paediatric Investigation Plans, it shall be specified that "The paediatric studies mentioned in the Summary of Product Characteristics under point 5.1 have been performed in accordance with the paediatric investigation plan agreed by the EMA Paediatric Committee (PDCO)".

Art. 17. – Writing Annex 1 to the marketing authorisation (the leaflet) shall be done in accordance with Art. 769 of the Law, transposing Art. 59 of Directive 2001/83/EC, while mentioning that under the heading "Manufacturer" there are data included related to the name and address of the manufacturer(s) responsible for the release of the finished product batch;

Art. 18. – Writing annex 2 to the marketing authorisation (summary of product characteristics) takes into account Art. 708 of the Law, transposing Art. 11 of Directive 2001/83/EC.

Art. 19. – (1) Information mentioned in annex 3 to the marketing authorisation (Information related to the labelling and package leaflet) refers to the inner and outer packaging of medicinal products. Inscription of the inner and outer packaging takes into account Art. 763 and Art. 764 of the Law, transposing Art. 54 and Art. 55 of Directive 2001/83/EC;

(2) Should the trade name be an invented name for active substance, the name may be entered in Romanian or the international non-proprietary name (INN) may be inserted;

(3) Annex 3 to the marketing authorisation should include specifications regarding immediate packaging (for instance, blister, vial label) and outer packaging (for instance: carton box);

(4) For medicinal products subject to medical prescription, the type of medical prescription should be mentioned, according to SCD No. 12/07.06.2010;

(5) Small inner packagings shall contain the mark/logo of the Marketing Authorisation Holder.

Art. 20. – (1) Annex 4 to the marketing authorisation "Qualitative and quantitative composition of the medicinal product" includes the active substance(s) and excipient(s) in terms of quality and quantity as well as data on what the authorised medicinal product looks like;

(2) Components quantities entered are expressed per dosage unit, volume unit or weight unit, depending on type of pharmaceutical form; for instance:

- Qualitative and quantitative composition for one tablet (mg)
- Qualitative and quantitative composition for 5ml oral suspension (mg/5ml)
- Qualitative and quantitative composition for 1 g ointment (mg/g)
- Qualitative and quantitative composition for 1000ml solution for infusion (g/1000ml);

(3) Overdose components in forms must be specified (percentage, reason for overdose), whether the respective information has been included in the applicant's dossier, under the heading "Composition";

(4) Overfill must be specified, whether the respective information has been included in the applicant's dossier, under the heading "Composition"";

(5) When required, the compounds used for technological purposes shall be included as well, followed by an explanation (asterisk) "are eliminated during the manufacturing process, cannot be found in the finished product";

(6) Writing Annex 4 to the marketing authorisation "Data on qualitative and quantitative composition of the medicinal product" takes into account the requirements mentioned in this Annex, Art. 8, points 3 – 6.

(7) Under the heading "Description of the medicinal product" in Annex 4, the product's appearance shall be described (colours, marks, appearance of the product prior to reconstitution etc.); similarly, information shall be provided concerning the real dimension of an oral solid preparation, e.g.:

"Round, white, flat, bevelled-edged, 5-mm diameter tablets imprinted with "100" on one side"

Art. 21. – (1) Annex 5 to marketing authorisation “Manufacturing of the medicinal product” must mention information concerning every manufacturer involved in the manufacturing process of the finished product, including the manufacturer(s) of the active substance(s);

(2) Should the manufacturing process of the finished product involve a single manufacturer for the entire manufacturing process/batch release, Annex 5 to marketing authorisation includes the name of the respective manufacturer, as well as the address of the manufacturing site;

(3) Should the manufacturing process of the finished product involve several manufacturers, Annex 5 to marketing authorisation includes the name of all manufactures involved, specifying the address of the manufacturing site and all operations performed (acquisition of active substance(s), bulk product, immediate packaging, outer packaging, batch testing, batch release);

(4) Should certain manufacturing stages involve several manufacturers, Annex 5 to marketing authorisation must include the mention “Alternative manufacturing site”.

Art. 22. – The marketing authorisation number is made up of 3 groups of numbers, representing:

- the marketing authorisation number;
- the year of marketing authorisation issuance;
- the number of packaging sizes /presentation forms available, encoded as 01-02…

Art. 23. – The pharmaceutical form, immediate packaging, closure and administration system are named in agreement with the Regulations in force related to Romanian standard terms for pharmaceutical forms, administration routes, closure and administration system, in accordance with those adopted by the Commission of the European Pharmacopoeia.

ANNEX II

THE MARKETING AUTHORISATION

The National Agency for Medicines and Medical Devices, set up based on the Emergency Government Ordinance No. 72/2010 on the reorganisation of certain healthcare institutions, as well as on the modification of regulatory acts in the healthcare field, based on Art. 4 (2) b) of Government Decision No. 734/2010 on the set up and functioning of the National Agency for Medicines and Medical Devices, based on Art. 700 (1) and <Art. 702 (4)>, <Art. 704 (1) and (2)>, <Art. 704 (3)>, <Art. 704 (4)>, <Art. 705>, <Art. 706>, <Art. 707>, <Art. 710>, <Art. 714>, <Art. 730 (2), <Art. 730 (5)>, <Art. 736 (2)>, <Art. 736 (3)> or <Art. 736 (4)> of Law No. 95/28.04.2006 on healthcare reform, Title XVII – The medicinal product and based on the submitted documentation, decides the authorisation of the following medicinal product on the Romanian market:

Registration name

{Trade name, strength, pharmaceutical form}

Composition

{The following shall be specified: qualitative/quantitative data for active substance(s), qualitative data for excipient(s)}
{The quantity of active substance is specified per dose, volume or mass unit, depending on the type of the pharmaceutical form}

Marketing Authorisation Holder

{Name and address}

Manufacturer(s) responsible for the finished product batch release

{Name and address}

ATC Classification

{ATC code (Anatomical-Therapeutic-Chemical) up to level 5 (chemical substance), if possible}

Supply

<☑ **subject to medical prescription**
☐ not subject to medical prescription>

or

<☐ subject to medical prescription
☑ **not subject to medical prescription**>

Packaging

{Inner packaging (packaging type, nature of the material, closure and administration system, packaging size) and outer packaging}

Shelf life

{After packaging for commercial use expressed in X months/year(s)}
{ After first opening (if necessary)}
{ After dilution or reconstitution }

Storage conditions

{After packaging for commercial use}
{After first opening}
{After dilution or reconstitution}

Package leaflet

According to Annex 1

Summary of Product Characteristics
According to Annex 2
<The paediatric data mentioned in the Summary of Product Characteristics have been carried out in accordance with the paediatric investigation plan agreed by the Paediatric Committee of the EMA>

Labelling
According to Annex 3

Data on qualitative and quantitative composition of the medicinal product
According to Annex 4

Data on manufacturing of the medicinal product
According to Annex 5

Number of marketing authorisation
{NNNN/AAAA/01-02-..... }

The National Agency for Medicines and Medical Devices shall be informed on any modification of data in the marketing authorisation and annexes or data in the authorisation dossier, according to legislation in force.

<This marketing authorisation shall be valid for 5 years as of its issuance.>

PRESIDENT

{DD.MM.YYYY}

ANNEX II

MARKETING AUTHORISATION NO. NNNN/AAAA/01-02-	*Annex 1* **Leaflet**

LEAFLET: USER INFORMATION

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

<Please read carefully this leaflet in its entirety prior to <taking> <using> this medicinal product.
- Please keep this leaflet. You may need to reread it.
- For any additional information, please contact your <physician> <or> <pharmacist>.
- <This medicinal product has been prescribed for your needs. You should not give it to other persons. It may harm them, although they may suffer from the same symptoms as yours.>
- If any of the adverse reactions worsens or if you are dealing with any other type of adverse reaction unspecified in this leaflet, please contact your <physician ><or> <pharmacist>.>

Please read carefully this leaflet in its entirety, because it contains valuable information for you.
This medicinal product is an over the counter product. However, it is necessary to <take> <use> X cautiously, in order to obtain optimal results.
- Please keep this leaflet. You may need to reread it.
- Contact your pharmacist in case you need more information or advice.
- Please contact your physician if your symptoms worsen or improve <during the {number of} days.>
- If any of the adverse reactions worsens or if you are dealing with any other type of adverse reaction unspecified in this leaflet, please contact your <physician ><or> <pharmacist>.>

In this leaflet you shall find:

1. WHAT IS X AND WHAT IS IT USED FOR

<This medicinal product is only recommended for diagnosis.>
PRIOR TO <TAKING> <USING> X

Do not <take> <use> X
- <if you are allergic (hypersensitive) to {active substance(s)} or to any other compound of X.>

- <if ….>

Be particularly cautious when taking
- <If you…>
- <when…>
- <Prior to the treatment with X, …>

<Taking> <Using> other medicinal products
<Please contact your <physician> <or> <pharmacist> if you currently take or have recently taken any other medicinal product, including OTCs.>

<Taking> <Using> X in association with food and drink

Pregnancy and breastfeeding
<Please contact your <physician> <or> <pharmacist> for adequate recommendation prior to taking any type of medicinal product.>

Driving and using appliances
<Do not drive vehicles <because…>.>
<Do not use appliances.>

Valuable information concerning certain compounds of X

3. HOW TO <TAKE> <USE> X

<Always take> <use> <X following the exact recommendations of your physicians. You should talk to your <physician> <or> <pharmacist> if in doubt.> <The usual dose is …>

<Use in children>

If you have <taken> <used> more X than recommended

If you have forgotten to <take> <use> X

<Do not take a double dose to compensate for the forgotten <dose> <tablet>.

If you start <taking> <using> X

<If you have further questions related to this product, please contact your <physician> <or> <pharmacist>.>

4. POTENTIAL ADVERSE REACTIONS

As all medicinal products, X may cause adverse reactions, although they may not occur in all patients.

If any adverse reaction worsens or if you notice any adverse reaction not mentioned in this leaflet, please contact your <physician> <or> <pharmacist>.

5. STORAGE CONDITIONS FOR X

[For the terms to be used related to the storage conditions, please see Annex III of SCD No. 21/27.11.2009]

Keep out of the sight and reach of children.

Do not use X after the expiry date imprinted on the <label> <box> <vial> <…> <after {abbreviation used to express the expiry date}.> <The expiry date refers to the last day of the month in course.>

<Do not use X if you notice {description of visible deterioration signs}.>

<Medicinal products should not be should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicinal products which you no longer need. These measures will help protect the environment.>

6. ADDITIONAL INFORMATION

What does X contain?
- Active substance(s) are …
- Its other compound(s) is (are)…

What does X and the content of the package look like?

Marketing authorisation holder and manufacturer

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

<For any information related to this medicinal product, please contact the local representatives of the marketing authorisation holder:>

This leaflet was approved on {MM/YYYY}.

<----------
<The following information are solely meant for physicians and healthcare professionals:>

ANNEX II

MARKETING AUTHORISATION NO. NNNN/AAAA/01-02- *Annex 2*
Summary of Product Characteristics

SUMMARY OF PRODUCT CHARACTERISTICS

1. TRADE NAME OF THE MEDICINAL PRODUCT

{(Invented) name strength pharmaceutical form}

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<Excipient(s):>
For the entire list of excipients, see point 6.1.

3. PHARMACEUTICAL FORM

<The medial line has the sole purpose of ease the breaking of the tablet in order to be swallowed easily, not to divide into equal doses>
<The tablet may be divided into two equal parts.>

4. CLINICAL DATA

4.1 Therapeutic indication

<This medicinal product shall only be used in diagnosis.>
<{X} is recommended for <adults> <neonates> <nurselings> <children> <teenagers> <aged {between x and y}> <years> <months>>.>

4.2 Doses and method of administration

Doze

Children and teenagers

<The safety> <and> <efficacy> {X} in children aged {between x and y} <months> <years> {or any other subgroups, e.g. weight, teenage, gender} has/have <not yet> <been> established.>
<No available data.>

<Currently available data are described under point(s) <4.8> <5.1> <5.2>, however, no dose-related recommendation can be made.>

<{X should not be used in children aged {between x and y} <years> <months> {or any other subgroup, e.g. weight, teenage, gender}, due to <safety> <efficacy>-related issues.

<{X> does not imply a relevant use <in children and teenagers> <in children aged {between x and y} <years> <months> {or any other subgroup, e.g. weight, teenage, gender} <in the indication...>
<{X} is contraindicated in <children aged {between x and y} <years> <months> {or any other subgroup, e.g. weight, teenage, gender} <in the indication ...> (see point 4.3).>

Manner of administration
<Cautions to be taken prior to the handling or administration of the medicinal product>

<For instructions related to the <reconstitution> <dilution> of the medicinal product prior to administration, see point 6.6.>

4.3 Contraindications

<Hypersensibility to active substance(s) or to any of the excipients <or {name(s) of the waste(s)}>.>

4.4 Special warnings and precautions for use

<Children and teenagers>

4.5 Interactions with other medicinal products and other types of interaction

< Studies related to the interactions have not been carried out.>

<Children and teenagers>

< Studies related to the interactions can only be carried out in adults.>

4.6 Fertility, pregnancy and lactation
[For terms to be used, see Annex I of SCD No. .../2009]

<Women of childbearing potential>
<Contraception in men and women>
<Pregnancy>
<Lactation>
<Fertility>

4.7 Effects on the ability to drive vehicles or to use machinery

<{The (invented) name has no influence/ <has a negligible influence> <has a feeble influence> <has a moderate influence> <has a major influence> on the ability to drive vehicles or to use machinery.>
<Studies on the ability to drive vehicles or to use machinery have not been carried out.
<Not relevant.>

4.8 Adverse reactions
[For the MedDRA terminology to be used, see Annex II of SCD No. 21/27.11.2009]

<Children and teenagers>

3.9 Supradose

<*Children and teenagers*>

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamyc properties

Pharmacotherapeutic group: {group}, ATC code: <still unallocated> {code}

<Mechanism of action>
<Pharmacodynamic effects>
<Safety and efficacy>
<Children and teenagers>

5.2 Pharmacodynamic properties

<Children and teenagers>

5.3 Preclinical safety data

<Nonclinical data have not revealed any particular risk in men following conventional pharmacological studies on the evaluation of safety, toxicity after repeated doses, genotoxicity, carcinogenicity, toxicity upon the functions of reproduction and development.>
<Nonclinical studies have revealed effects only to exposures considered major enough compared to the maximum exposure in humans; this fact reveals a low relevance for clinical use.>
<Adverse reactions unobserved during clinical trials, but signalled in animals at the same exposure limits as those used in clinical trials and with a potential relevance for clinical use, have been the following:>

<Environmental risk assessment (ERA)>

6. PHARMACEUTICAL PROPERTIES

6.1 List of excipients

6.2 Incompatibilities

<Not required.>
<In the absence of compatibility studies, this medicinal product should not be mixed with other medicinal product.>
<This medicinal product should not be mixed with other medicinal products, except for those mentioned under 6.6.>

6.3 Shelf life

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

6.4 Special storage precautions

[For terms to be used related to the storage conditions, see Annex III of SCD No. 21/27.11.2009]

<For storage conditions of <reconstituted> <diluted> medicinal products, see point 6.3.>

6.5 Nature and content of the packaging <and special equipment for use, administration and implantation>

<Is it possible for all packaging sizes to be marketed?>

6.6 Special precautions for waste disposal

<No particular requirements.>
<Any unused product or waste material should be disposed in accordance with local regulations.>

7. MARKETING AUTHORISATION HOLDER

{Name and address}
<{telephone number}>
<{fax}>
<{e-mail}>

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION OR RENEWAL OF THE AUTHORISATION

<{DD/MM/YYYY}> <{DD month YYYY}>

10. DATE OF TEXT REVISION

{MM/YYYY}

11. DOSIMETRY>

12. INSTRUCTIONS ON THE MANUFACTURING OF RADIOPHARMACEUTICALS>

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

ANNEX II

MARKETING AUTHORISATION NO. NNNN/AAAA/01-02- *Annex 3*
Information on the labelling

INFORMATION ON THE LABELLING

INFORMATION WHICH SHOULD APPEAR ON THE <OUTER PACKAGING> <AND> <INNER PACKAGING>

{PACKAGING TYPE}

1. INVENTED NAME OF THE MEDICINAL PRODUCT

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

2. DECLARATION OF THE ACTIVE SUBSTANCE(S)

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENT

5. MANNER AND ROUTE(S) OF ADMINISTRATION

Please read the leaflet before use.

6. SPECIAL WARNING RELATED TO THE FACT THAT THE MEDICINAL PRODUCT SHOULD NOT BE STORED AT THE REACH AND SIGHT OF CHILDREN

Please keep away from the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF REQUIRED

8. EXPIRY DATE

[For terms to be used related to the manufacturing batch number and to the expiry date, see Annex IV of SCD No. 21/27.11.2009]

9. SPECIAL STORAGE CONDITIONS

[For terms to be used related to the storage conditions, see Annex III of SCD No. 21/27.11.2009]

10. SPECIAL PRECAUTIONS RELATED TO THE DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR TO THE WASTE PRODUCTS COMING FROM SUCH MEDICINAL PRODUCTS, IF REQUIRED

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

{Name and address}
<{telephone number}>
<{fax}>
<{e-mail}>

12. MARKETING AUTHORISATION NUMBER

13. MANUFACTURING BATCH

[For terms to be used related to the manufacturing batch number and to the expiry date, see Annex IV of SCD No. 21/27.11.2009]

14. CLASSIFICATION RELATED TO SUPPLY

[The expressions used for the sub classification for release of medicinal products are established through SCD No. 12/07.06.2010, as follows]

<Medicinal products released based on medical prescription – <PRF> <P6L> <PS> <PR>>
<Over the counter medicinal product>

15. INSTRUCTIONS FOR USE

16. BRAILLE INFORMATION

THE MINIMUM OF INFORMATION WHICH MUST APPEAR ON THE BLISTER OR ON THE BLISTER OR ON BRAILLE STRIPS

{PACKAGING TYPE}

1. TRADE NAME OF THE MEDICINAL PRODUCT

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

2. NAME OF THE MARKETING AUHTORISATION HOLDER

{Name}

3. EXPIRY DATE

[For terms to be used related to the manufacturing batch number and expiry date, see Annex IV of SCD No. 21/27.11.2009]

4. MANUFACTURING BATCH

[For terms to be used related to the manufacturing batch number and expiry date, see Annex IV of SCD No. 21/27.11.2009]

5. MISCELLANEA

THE MINIMUM OF INFORMATION WHICH MUST APPEAR ON SMALL INNER PACKAGING

{PACKAGING TYPE}

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

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

2. MANNER OF ADMINISTRATION

3. EXPIRY DATE

[For terms to be used related to the manufacturing batch number and expiry date, see Annex IV of SCD No. 21/27.11.2009]

4. MANUFACTURING BATCH

[For terms to be used related to the manufacturing batch number and expiry date, see Annex IV of SCD No. 21/27.11.2009]

5. MASS, VOLUME OR DOSE UNIT CONTENT

6. MISCELLANEA

[Brand/logo of the Marketing Authorisation Holder]

ANNEX II

MARKETING AUTHORISATION NO. NNNN/AAAA/01-02-.... *Annex 4*
Data on the qualitative and quantitative composition of the medicinal product

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

Qualitative and quantitative composition

{The following shall be entered: the active substance(s) and excipient(s) in terms of quantity and quality}
{The quantity of active substance is expressed as dose per unit/volume/weight, depending on the type of the pharmaceutical form}
{The compounds used for technological purposes shall also be specified, mentioning (asterisk) "disposed of during the manufacturing process, is/are not found in the finished product"}

Description of the medicinal product

{Description of the medicinal product's appearance (colour, bookmarks, appearance of the medicinal product prior to reconstitution etc.), also comprising data related to the real dimension of an oral solid dosage form}

ANNEX II

MARKETING AUTHORISATION NO. NNNN/AAAA/01-02-..... *Annex 5*
Data on the medicinal product manufacturing

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

Manufacturer(s) of active substance(s)

{Full name and address}

<Manufacturer(s) involved in the manufacturing process of the batch product>

<Manufacturer(s) involved in the <primary> and <secondary> packaging>

<Manufacturer(s) involved in batch testing>

<Manufacturer(s) involved in the finish product batch release>

{Full name and address}