DECISION

No. 20/27.11.2009

on approval of amended European templates for package leaflet, summary of product characteristics and label information for medicinal products authorised for marketing in Romania, approved through SCD No. 2/27.01.2006

The Scientific Council of the National Medicines Agency,set up based on Order of the minister of public health No. 1027/22.05.2008, reunited on summons of the National Medicines Agency President in the ordinary meeting of 27.11.2009, in accordance with Article 10 of Government Ordinance No. 125/1998 related to the set up, organisation and operation of the National Medicines Agency, approved with changes and supplementations through Law No. 594/2002, as amended, agrees on the following

DECISION

Art. 1. – Approval of amended European templates for package leaflet, summary of product characteristics and label information for medicinal products authorised for marketing in Romania, according to the Annexes which are integral part of this decision.

Art. 2. – The present decision is to be approved through Order of the Minister of Health and shall be published in the Official Gazette of Romania, Part I.

Art. 3. – On the date of this Decision coming into force, NMA Scientific Council Decision No. 2/27.01.2006, approved through Order of the Minister of Public Health No. 399/2006 is amended.

PRESIDENT
of the Scientific Council
of the National Medicines Agency,

Acad. Prof. Dr. Victor Voicu

ANNEX 1
(Annex I to Order No. 399/2006)

Package leaflet: information for the user
{(Invented) name strength pharmaceutical form}
{Active substance(s)}
<Read all of this leaflet carefully before you start <taking> <using> this medicine.
- Keep this leaflet. You may need to read it again.
- For further questions, please contact your <physician> <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>.>
<<Read all of this leaflet carefully because it contains important information for you.>
This medicinal product is available without prescription. However, you still need to <take> <use> X carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your pharmacist.
- You must contact a doctor if your symptoms worsen or do not improve <after {number of} days.>
- 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>.>

In this leaflet:

1. **What X is and what it is used for**
<This medicinal product is for diagnostic use only>
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.>
- <if ….>
Take special care with X
- <if you…>
- <when…>

- <Before treatment with X, …>

<Taking> <Using> other medicinal products

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

<Taking> <Using> X with food and drink

Pregnancy and breast-feeding

<Ask your <doctor> <or> <pharmacist> for advice before taking any medicinal product.>

Driving and using machines

<Do not drive <because…>.>

<Do not use any tools or machines.>

Important information about some of the ingredients of X

3. **How to <take> <use> X**

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

<Use in children>

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 <tablet> <dose> <…>.>

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.

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>.

5. **How to store X**

[For storage condition statements see Annex III of Scientific Council Decision No. 21/27.11.2009]

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.>

<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) is (are) …

What X looks like and contents of the pack

Marketing Authorisation Holder

{Name and address}

<{telephone number}>

<{fax number}>

<{e-mail}>

<For further information on this medicinal product, please contact the local representative of the Marketing Authorisation Holder:>

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

<……
…...

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

ANNEX 2
(Annex II to Order No. 399/2006)

Summary of Product Characteristics

1. **Trade 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 tablet can be divided into equal halves.>

4. **Clinical particulars**

4.1 **Therapeutic indications**

<This medicinal product is for diagnostic use only.>

<{X} is recommended for use in <adults> <neonates> <sucklings> <children> <teenagers> <aged {between x and y}> <years> <months>.>

4.2 **Posology and method of administration**

Doses

Children and teenagers

<Safety> <and> <efficacy> {X} in children aged {between x and y} <months> <years> {or any other subgroup, e.g. weight, teenage, gender} <has> <have> not <yet> been established.>

<No available data.>

<Presently available data are described under sections <4.8> <5.1> <5.2>, but no dose-related recommendation can be done.>

<{X} is not recommended for use in children aged {between x and y} <years> <months> {or any other subgroup, e.g. weight, teenage, gender}, due to (a) <safety> <efficacy> issue(s).

<There is no relevant indication for use of {X} in <children and teenagers> <in children aged {between x and y} <years> <months> {or any other subgroup, e.g. weight, teenage, gender} <...>

<{X} is not recommended for use in <children aged {between x and y} <years> <months> {or any other subgroup, e.g. weight, teenage, gender} >...<(see section 4.3).>

Method of administration

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

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

4.3 **Contraindications**

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

4.4 **Special warnings and precautions for use**

<*Children and teenagers*>

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 and lactation**

[For Pregnancy and lactation statements see Annex I of Scientific Council Decision No. …/2009]

<Women of childbearing potential>

<Contraception in males and females>

<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.>

<No studies on the effects on the ability to drive and use machines have been performed.>

<Not relevant.>

4.8 **Undesirable effects**

Undesirable effects *[For recommended MedDRA terminology, see Annex II of Scientific Council Decision No. 21/27.11.2009]*

<*Children and teenagers*>

4.9 **Overdose**

<*Children and teenagers*>

5. **Pharmacological properties**

5.1 **Pharmacodynamic properties**

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

<Action mechanism>

<Pharmacodynamic effects>

<Safety and efficacy>

<Children and teenagers>

5.2 **Pharmacokinetic properties**

<*Children and teenagers*>

5.3 **Pre-clinical 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.>

<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 hazard assessment (EHA)>

6. **Pharmaceutical properties**

6.1 **List of excipients**

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.>

6.3 **Shelf life**

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

6.4 **Special precautions for storage**

[For special conditions statements see Annex III of Scientific Council Decision No. 21/27.11.2009]

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

6.5 **Nature and contents of container <and special equipment for use, handling or implementation>**

<Not all packaging sizes may be marketed.>

6.6 **Special precautions for disposal of residues**

<No special requirements.>

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

7. **Marketing Authorisation Holder**

{Name and address}

<{telephone number}>

<{fax number}>

<{e-mail}>

8**. Marketing authorisation number(s)**

9**. Date of first authorisation/renewal of the authorisation**

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

Annex 3
(Annex III to Order No. 399/2006)

LABELLING INFORMATION

Particulars to appear on the <outer packaging> <and> <the outer packaging>

{Nature/Type}

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

8. Expiry date

[For terms on Batch number and Expiry date see Annex IV of Scientific Council Decision No. 12/27.11.2009]

9. Special storage conditions

[For storage conditions statements see Annex III of scientific council decision No. 21/27.11.2009]

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}

<{tel}>
<{fax}>
<{e–mail}>

12. Marketing authorisation number

13. Manufacturing batch

[For terms on Batch number and Expiry date see Annex IV of Scientific Council Decision No. 21/27.11.2009]

14. General classification for supply

< Medicinal product subject to medical prescription – P–RF/P–6L/S/P–TS>
< Medicinal product not subject to medical prescription.>

15. Instructions on use

16. Information in Braille

Minimum particulars to appear on blisters or strips
{Nature/Type}

1. International Non-proprietary Name

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

2. Name of the marketing authorisation holder

{Trade name}

3. Expiry date

[For terms on Batch number and Expiry date see Annex IV of Scientific Council Decision No. 21/27.11.2009]

4. Manufacturing batch

[For terms on Batch number and Expiry date see Annex IV of Scientific Council Decision No. 21/27.11.2009]

5. Other

Minimum particulars to appear on small immediate packaging units
{Nature/Type of packaging}

1. International Non-proprietary 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 Batch number and Expiry date see Annex IV of Scientific Council Decision No. 21/27.11.2009]

4. Manufacturing batch

[For terms on Batch number and Expiry date see Annex IV of Scientific Council Decision No. 21/27.11.2009]

5. Contents by weight, by volume or by unit

6. Other