MINISTRY OF HEALTH

ORDER
on approval of European models of package leaflet, summary of product characteristics and label information for medicinal products authorised for marketing in Romania

Taking into account provisions of Government Ordinance No. 152/1999 on medicinal products for human use, approved with changes and completions through Law No. 336/2002, with further changes and completions and of Government Ordinance No. 125/1998 1998 related to the set up, organisation and functioning of the National Medicines Agency, approved with changes and completions through Law No. 594/2002, with further changes and completions,

on seeing The Approval Report of the General Pharmaceutical and Medical Devices Directorate No. E.N. 9.277/2006,

based on Government Decision No. 168/2005 on organisation and functioning of the Ministry of Health, with further changes and completions,

the minister of health hereby issues the following order:

Article 1. – Approval of European models of package leaflet, summary of product characteristics and label information for medicinal products authorised for marketing in Romania, according to Annexes I–III which are integral part of this order.

Article 2. – Provisions of this order apply to applications for marketing authorisation submitted to the National Medicines Agency following this order entry into force, except for the provision on marketing authorisation number, to be applied after Accession.

Article 3. – The National Medicines Agency shall carry out provisions of the present order.

Article 4. – The present order is to be published in the Official Gazette of Romania, Part I.

Minister of health,
Gheorghe Eugen Nicolăescu

Bucharest, 12 April 2006.
No. 399.

ANNEX I

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.
- 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>.>

<**Read all of this leaflet carefully because it contains important information for you.**
This medicine 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.
- Ask your pharmacist if you need more information or advice.
- 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 medicine 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 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

Pregnancy and breast–feeding
<Ask your <doctor> <or> <pharmacist> for advice before taking any medicine.>

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...>

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 conditions statements see Annex III of Scientific Council Decision No. 3/27.01.2006]

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 and Manufacturer

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

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

<———————————————————————————————————

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

Annex II

SUMMARY OF PRODUCT CHARACTERISTICS

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 tablet can be divided into equal halves.>

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

<This medicinal product is for diagnostic use only.>

4.2 Posology and method of administration

<{(Invented) name} is not recommended for use in children <above> <below> {age Y} due to <a lack of> <insufficient> data on <safety> <and> <or> <efficacy> <(see section <5.1> <5.2>).>
<The experience in children is limited.>
<There is no experience in children> <(see section <4.4> <5.2>).>
<There is no relevant indication for use of {(Invented) name} in children.>
<{(Invented) name} is contraindicated in children (see section 4.3).>

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

4.5 Interaction with other medicinal products and other forms of interaction

<No interaction studies have been performed.>
<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. 3/27.01.2006]*

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 *[For recommended MedDRA terminology, see Annex II of Scientific Council Decision No. 3/27.01.2006]*

Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

4.9 Overdose

<No case of overdose has been reported.>

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: {group}, ATC code: {code}
5.2 Pharmacokinetic properties
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.>
<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:>

6. PHARMACEUTICAL PARTICULARS

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 storage conditions statements see Annex III of Scientific Council Decision No. 3/27.01.2006]

< 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>

<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}
<{tel}>
<{fax}>
<{e–mail}>

8. MARKETING AUTHORISATION NUMBER(S)

{RO/1/AA/00000/000}
(RO/Medicinal product for human use/AA/No. in the Register of authorized medicinal products/Pharmaceutical Form, strength and packaging)

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 III

LABELLING AND PACKAGE LEAFLET

PARTICULARS TO APPEAR ON THE <OUTER PACKAGING> <AND> <THE IMMEDIATE 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. 3/27.01.2006]

9. SPECIAL STORAGE CONDITIONS

[For storage conditions statements see Annex III of scientific council decision No. 3/27.01.2006]

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

{RO/1/AA/00000/000}
(RO/Medicinal product for human use/AA/No. in the Register of authorized medicinal products/Pharmaceutical Form, strength and packaging)

13. BATCH NUMBER

[For terms on Batch number and Expiry date see Annex IV of Scientific Council Decision No. 3/27.01.2006]

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. NAME A 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 Batch number and Expiry date see Annex IV of Scientific Council Decision No. 3/27.01.2006]

4. MANUFACTURING BATCH

[For terms on Batch number and Expiry date see Annex IV of Scientific Council Decision No. 3/27.01.2006]

5. OTHER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
{NATURE/TYPE}
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 Batch number and Expiry date see Annex IV of Scientific Council Decision No. 3/27.01.2006]

4. BATCH NUMBER

[For terms on Batch number and Expiry date see Annex IV of Scientific Council Decision No. 3/27.01.2006]

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

6. OTHER