Co-ordination Group for Mutual Recognition and Decentralised Procedures - Human

CMD(h) ANNOTATED QRD TEMPLATE FOR MR/DC PROCEDURES

(Based on version 7.2 of the QRD template for CP)

November 2005
Revision 3, October 2006

NOTE:

The CMD(h) 'Annotated' QRD Template provides guidance on how to present the SPC, Labelling and Package Leaflet for an application in the Mutual Recognition or Decentralised Procedure. The 'clean' QRD Template for use in a MRP, DCP or referral procedure is published in all languages on the website of the EMEA http://www.emea.europa.eu/htms/human/qrd/qrdtemplate.htm

SUMMARY OF PRODUCT CHARACTERISTICS

[NOTE: the following are those items of information required by Article 11 of Directive 2001/83/EC, as amended, for the Mutual Recognition Procedure and the Decentralised Procedure. This guidance should be read in conjunction with the relevant guidelines that can be found on the EMEA website (See also "Convention" for format and layout): http://www.emea.europa.eu/htms/human/qrd/docs/convention.pdf, in particular the "Guideline on Summary of Product Characteristics" as published on the Website of the European Commission in the Notice to Applicants, Volume 2C: http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev2.htm#2c

During the evaluation process, applicants may present SPCs for different strengths in one document, clearly indicating with grey-shaded titles the strength or presentation to which alternative text elements refer. Upon MS agreement with a combined SPC text, the text does not need to be separated in the national phase of marketing authorisation. However, in all other cases, a separate SPC per strength and per pharmaceutical form, containing all pack-sizes related to the strength and pharmaceutical form concerned will have to be provided by the applicant as follows:

- *English language version: immediately after agreement on final SPC.*
- *All other language versions: at latest 5 days after the end of the Mutual Recognition or Decentralised Procedure.*

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

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

1. NAME OF THE MEDICINAL PRODUCT

{(Invented) name strength pharmaceutical form}

[Name of the medicinal product in the RMS.]

[no ® ™ symbols attached here and throughout the text; "tablets" and "capsules" in the plural.]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

[Name of the active substance(s) in the language of the text.]
[Qualitative and quantitative composition in terms of the active substances and constituents of the excipient, knowledge of which is essential for proper administration of the medicinal product. The usual common name or chemical description shall be used. See also the "Guideline on excipients" as published on the Website of the European Commission in the Notice to Applicants, Volume 3B http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev3.htm#3b]

<Excipient(s):>

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

[The pharmaceutical form should be stated according to the full "Standard Terms" published by the Council of Europe, in the singular. Where the Council of Europe short standard term is used on small immediate packaging materials, the short term should be added in brackets.]

[Include here a description of the visual appearance of the product pharmaceutical form as marketed, including information on pH and osmolarity as required.
Information on appearance of reconstituted parenteral solution should appear under section 6.6.]

<The score line 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

[Specify, if appropriate <This medicinal product is for diagnostic use only.>
If applicable, results of clinical trials to appear under section 5.1.]

4.2 Posology and method of administration

[In case of restricted medical prescription start this section by specifying the conditions.
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.
Instructions for preparation are to be placed under section 6.6 or 12, and cross-referenced here.]

<{(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 Appendix I.]

[Results from reproduction toxicology to be included under section 5.3 and cross-referenced here, if necessary.]

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.> *[describe effects where applicable]*
<No studies on the effects on the ability to drive and use machines have been performed.>
<Not relevant.>

4.8 Undesirable effects

[MedDRA frequency convention and system organ class database, see Appendix II.]

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

4.9 Overdose

[Describe the symptoms, emergency procedures, and antidotes (if available) in case of overdose.]

<No case of overdose has been reported.>

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: {group *[lowest available level]*}, ATC code: {code}

[For products approved under "exceptional circumstances", include the following statement:]
<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 {name MS/Agency} will review any new information which may become available every year and this SPC will be updated as necessary>

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

[Each to be listed on a separate line according to the different parts of the product.]
[Name of the excipient(s) in the language of the text.]

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.>

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).]

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

6.4 Special precautions for storage

[For Storage condition statements see Appendix III.]

[General storage conditions of the finished product should appear here, together with a cross-reference to section 6.3 where appropriate: <For storage conditions of the <reconstituted> <diluted> medicinal product, see section 6.3>*]*

6.5 Nature and contents of container

[All pack sizes must be listed. If applicable, add:]

<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 product, where applicable, including disposal of the medicinal product, and waste materials derived from the used medicinal product.]

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

7. MARKETING AUTHORISATION HOLDER

<[To be completed nationally]>

[Country name in the language of the text. Telephone, fax numbers or-e-mail addresses may be included (no websites, no e-mails linking to websites).]

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

8. MARKETING AUTHORISATION NUMBER(S)

<[To be completed nationally]>

[Item to be completed by the Marketing Authorisation Holder once the Marketing Authorisation has been granted.]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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

<[To be completed nationally]>

[Item to be completed by the Marketing Authorisation Holder once the Marketing Authorisation has been granted or renewed.
The date should correspond to the initial authorisation of the medicinal product concerned. It should not reflect individual strength/presentation approvals introduced via subsequent variations and/or extensions.
Both the date of first authorisation and, if the authorisation has been renewed, the date of the (last) renewal should be stated in the format given in the following example:
Date of first authorisation: 3 April 1985.
Date of latest renewal: 3 April 2000.]

10. DATE OF REVISION OF THE TEXT

[Item to be completed by the Marketing Authorisation Holder at time of printing once a change to the SPC has been notified or approved.]

{MM/YYYY}

<[To be completed nationally]>

<11. DOSIMETRY>

[For radiopharmaceuticals, full details of internal radiation dosimetry.]

<12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS>

<Any unused product or waste material should be disposed of in accordance with local requirements.>
[For radiopharmaceuticals, additional detailed instructions for extemporaneous preparation and quality control of such preparation and, where appropriate, maximum storage time during which any intermediate preparation such as an eluate or the ready-to-use pharmaceutical will conform to its specifications.]

[It is recommended that the following reference is included:]
<Detailed information on this product is available on the website of: {name of MS/Agency}>

LABELLING AND PACKAGE LEAFLET

*[The lay-out of the labelling and package leaflet presented in this template is intended for the word document during the Mutual Recognition or Decentralised Procedure only. Guidance on how to best present the actual **printed** labelling and package leaflet (e.g. font size, use of colours, lay-out, etc.) is available in the "the Guideline on the Readability of the Label and Package Leaflet of Medicinal Products for Human Use" as published on the Website of the European Commission in the Notice To Applicants, Volume 2C http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev2.htm#2c]*

*[**N.B.**: boxed headings are provided to help applicants when completing the template. However, 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. Upon agreement between RMS and CMS on a combined labelling text, the text does not need to be separated in the national phase of marketing authorisation.
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. Upon MS agreement with a combined package leaflet text, the text does not need to be separated in the national phase of marketing authorisation. However, in all other cases, a separate package leaflet per strength and per pharmaceutical form, containing all pack-sizes related to the strength and pharmaceutical form concerned will have to be provided by the applicant as follows:

- *English language version: immediately after agreement on final package leaflet.*
- *All other language versions: at latest 5 days after the end of the Mutual Recognition or Decentralised Procedure.*

Text which will not appear in the final printed material is to be presented as shaded text.]

LABELLING

[NOTE: these are all mandatory items listed in Title V of Directive 2001/83/EC, as amended. 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 (e.g. top flap, front, back etc.). Blue-boxes and their contents should not be included.
Where the same text for outer and inner packaging is used, this should be clearly indicated in the 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; however, this should not appear in the Labelling text.]

[Boxed headings are provided to help applicants when completing the template. However, they are not to appear in the final printed packaging materials (mock-ups/specimens).]

PARTICULARS 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 SPC 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)

(invented) name 60 mg tablets
diltiazem hydrochloride
(since 60 mg corresponds to the hydrochloride salt)]

[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) shall be included, or, in absence of INN name, the common names should be used.
In addition, the different strengths of fixed-combination 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)" or "toremifene citrate equivalent to 60 mg toremifene";"60 mg diltiazem hydrochloride".]

3. LIST OF EXCIPIENTS

[Express qualitatively those excipients known to have a recognised action or effect and included in guideline on "Excipients in the Label and Package Leaflet of Medicinal Products for Human Use" (The rules governing medicinal products in the European Union, Volume 3B). However, if the medicinal product is a parenteral, a topical or an eye preparation or if used for inhalation, all excipients must be stated.
Additional excipients information (e.g. warnings) should be presented under this section and not under section 7.]

4. PHARMACEUTICAL FORM AND CONTENTS

[Pharmaceutical form according to the full "Standard terms" published by the Council of Europe.
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.). 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.

28 tablets
56 tablets
100 tablets]

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.

[Route of administration according to the "Standard terms" published by the Council of Europe.]

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 Appendix IV.]

[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.: February 2007, Feb 2007, 02-2007.]

[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 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 product".]

9. SPECIAL STORAGE CONDITIONS

[For Storage condition statements see Appendix III.]

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

[E.g. radiopharmaceuticals, cytostatics.]
[A reference to any appropriate collection system in place should be included in the 'Blue Box' on the outer packaging.]

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

To be completed nationally

[Including town, postal code (if available) and country name of the MAH in the language of the text (Telephone, fax numbers or e-mail addresses may be included (no websites, no e-mails linking to websites). [no ® ™ symbols attached here and throughout the text; "tablets" and "capsules" in the plural.]

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

12. MARKETING AUTHORISATION NUMBER(S)

<[To be completed nationally]>

[Item to be completed by the Marketing Authorisation Holder once the Marketing Authorisation has been granted.]

13. BATCH NUMBER

[For terms on Batch number and Expiry date see Appendix IV.]

14. GENERAL CLASSIFICATION FOR SUPPLY

[The prescription status is part of the 'Blue Box'.]

<[To be completed nationally]>

15. INSTRUCTIONS ON USE

*[Only for medicinal products **not subject** to medical prescription only, include:*
- *Indication(s).*
- *Dosage recommendations, contraindication(s) and warnings, if full details cannot be printed a reference to the package leaflet should be made, e.g. "Read the package leaflet before use".*
- *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 RMS or CMS.]*

<[To be completed nationally]>

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 "Guidance concerning the Braille requirements for labelling and the package leaflet" published by the European Commission: http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2005/04_05/braille_text20050411.pdf)]

[In cases where Braille is not included, according to the abovementioned guideline, the justification for such an exclusion should be provided in module 1.3.6. Upon agreement by the national competent authority, the following statement should be included in this section in grey shading:
< Justification for not including Braille accepted>]

<[To be completed nationally]>

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

1. NAME OF THE MEDICINAL PRODUCT

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

[Active substance – see guidance in section 1 of the outer packaging.]

[Pharmaceutical form short terms according to the current version of the "Standard terms" published by the Council of Europe may be used in case of space limitation, if consistently used in all language versions.]

2. NAME OF THE MARKETING AUTHORISATION HOLDER

<[To be completed nationally]>

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

3. EXPIRY DATE

[For terms on Batch number and Expiry date see Appendix IV.]

4. BATCH NUMBER

[For terms on Batch number and Expiry date see Appendix IV.]

5. OTHER

[Space permitting, any other information necessary for the correct use and administration of the product can be included here, e.g. calendar days.]

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 Competent Authority and will be based on the specific national legislation of the MS.]

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

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

[Pharmaceutical form short terms according to the current version of the "Standard terms" published by the Council of Europe may be used in case of space limitation, if consistently used in all language versions.]
[Where different labels apply to different constituents of the pharmaceutical form, 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).]

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 should be made, e.g. "Read the package leaflet before use".]

3. EXPIRY DATE

[For terms on Batch number and Expiry date see Appendix IV.]

[Where applicable, shelf life after reconstitution, dilution or after first opening the container.
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. BATCH NUMBER

[For terms on Batch number and Expiry date see Appendix IV.]

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

6. OTHER

[Space permitting, any other information necessary for the correct use and administration of the product can be included here, e.g. storage conditions.]

PACKAGE LEAFLET

*[**NOTE**: the following items must appear in the package leaflet as required by Title V of Directive 2001/83/EC, as amended. In exceptional cases, alternative headings may be acceptable, especially for those headings containing <take><use> or where a different wording would be more appropriate for the product concerned e.g. to better reflect the user of the product. This should not in any case impact on the content required for the section concerned. Applicants should justify the use of alternative headings (e.g. by reference to user testing results). For certain medicinal products not all items may be relevant, in this case the corresponding heading should not be included.*
The leaflet must be readable for the patient; please refer to the "Guideline on the Readability of the Label and Package Leaflet of Medicinal Products for Human Use" as published on the Website of the European Commission in the Notice To Applicants, Volume 2C:
http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev2.htm#2c
Throughout the text "X" stands for the (invented) name of the medicinal product.

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

Guidance notes in orange cross-refer to the section/information of the SPC which is to be reflected in that particular section of the package leaflet.

Applicants shall ensure that, on request from patients' organisations, the package leaflet is made available in formats appropriate for the blind and partially sighted.]

PACKAGE LEAFLET: INFORMATION FOR THE USER
[Heading to be printed]

{(Invented) name strength pharmaceutical form}
{Active substance(s)}
[The (invented) name of the medicinal product in the RMS (referred to as X throughout this document) followed by the strength and pharmaceutical form (i.e. as it appears in the SPC) 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.]

[For medicinal products available only on prescription:]
<**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>.>

[For medicinal products available without a prescription:]
<**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 effect not listed in this leaflet, please tell your <doctor> <or> <pharmacist>.>

<[To be completed nationally]>
[Include text for the RMS and amend at national level as necessary depending on the legal status]

In this leaflet:

1. What X is and what it is used for
2. Before you <take> <use> X
3. How to <take> <use> X
4. Possible side effects
5. How to store X
6. Further information

1. WHAT X IS AND WHAT IT IS USED FOR

[Pharmacotherapeutic group.]
[The pharmacotherapeutic group or type of activity should be stated here using patient understandable language.]

[Therapeutic indications.]
[The therapeutic indications should be stated here, using patient understandable language. If appropriate, specify that:]
<This medicine is for diagnostic use only.>

2. BEFORE YOU <TAKE> <USE> X

[Additional sub-headings within the headings given below may be included if needed to increase readability.]

[List of information necessary before taking the medicinal product.]
[The whole section 2 must take into account the particular condition of certain categories of users, e.g. children and the elderly (specify the age range; for children see CHMP Note for Guidance on Clinical Investigation of Medicinal Products in Children (CPMP/EWP/462/95)); special patient populations, e.g. patients with renal or hepatic impairment.]

[Contraindications.]
Do not <take> <use> X
- <if you are allergic (hypersensitive) to {active substance(s)} or any of the other ingredients of X.> *[include reference to residues, if applicable.]*
- <if...>

[Give information on absolute contraindications here in accordance with the SPC; this should be in patient understandable language and should be strictly limited to contraindications, including contraindications due to interactions with other medicinal products. Other precautions and special warnings should be made 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.]

[Appropriate precautions for use; special warnings.]
Take special care with X
- <if you ...>
- <when ...>
- < Before treatment with X, …>

[Information in patient understandable language, special warnings and appropriate precautions for use should be provided here.]

[Interaction with other medicinal products.]
<Taking> <Using> other medicines
[Describe the effects of other products on the product in question and vice versa. Reference should be made to the intensification/weakening and the extension/shortening of effects.]

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

[Interactions with herbal or alternative therapies should be addressed where necessary.]

[Interactions with food and drink.]
<Taking> <Using> X with food and drink
[Interactions not related to medicinal products should be mentioned here. For example, patients should not consume milk in combination with tetracyclines and no alcohol should be consumed during treatment with benzodiazepines. 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.]

[Use by pregnant or breast-feeding women.]
Pregnancy and breast-feeding
[Where the information is significantly different, pregnancy and breast-feeding information can be presented under separate headings.]

[Include conclusion summary of the information given in the SPC, in addition to the following optional statement:]
<Ask your <doctor> <or> <pharmacist> for advice before taking any medicine.>

[Information on teratogenicity in patient understandable language, should be included in the leaflet when the product is contra-indicated during pregnancy.]

[Effects on the ability to drive or to use machines.]
Driving and using machines
<Do not drive <because...>.>
<Do not use any tools or machines.>

[Excipients warnings.]
Important information about some of the ingredients of X
[If appropriate, details of those excipients knowledge of which is important for the safe and effective use of the medicinal product and included in the guideline on "Excipients in the Label and Package Leaflet of Medicinal Products for Human Use" (The rules governing medicinal products in the European Union, Volume 3B), including relevant warnings for residues from the manufacturing process.]

3. HOW TO <TAKE> <USE> X

[Additional sub-headings within the headings given below may be included if needed to increase readability.]

[Instructions for proper use.]
[The following 4 items can be combined as one paragraph.]

[Dosage.]
<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...>

[Method and/or route(s) of administration.]
[Method of administration: directions for a proper use of the medicinal product; e.g. "Do not swallow", "Do not chew", "Shake well before use".
Route(s) of administration according to "Standard Terms" published by the Council of Europe and an additional patient-friendly explanation may be given if necessary.
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.]

[Frequency of administration.]
[Specify if necessary the appropriate time(s) at which the medicinal product may or must be administered.]

[Duration of treatment.]
[If appropriate, especially for products 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.]*

[Symptoms in case of overdose and actions to be taken.]
If you <take> <use> more X than you should
[Describe how to recognise if someone has taken an overdose and what to do.]

[Actions to be taken when one or more doses have been missed.]
If you forget to <take> <use> X
[Make clear to patients what they should do after irregular use of a product; e.g.:]

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

[Indication of the risk of withdrawal effects.]
If you stop <taking> <using> X
[Indicate any effects of interrupting or ending the treatment early, if applicable.
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 or pharmacist should be included as appropriate in patient understandable language.
Indicate withdrawal effects when the treatment ends, when necessary.]
[As appropriate, close this section with:]

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

4. POSSIBLE SIDE EFFECTS

[Description of side effects (frequency according to MedDRA).]
[Begin this section with:]
Like all medicines, X can cause side effects, although not everybody gets them.

[Describe, if necessary, the actions to be taken. If the patient needs to seek help urgently, the use of the term <immediately> is recommended; for less urgent conditions, <as soon as possible> can be used.]

[Close this section with:]
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

Keep out of the reach and sight of children.

[Expiry date.]
[Where a specific abbreviation for Expiry date is used on the labelling, the full term should be mentioned here as well as the abbreviation.]
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.>

[Storage conditions.]
[For Storage condition statements see Appendix III.]

[Where applicable, shelf life after reconstitution, dilution or after first opening the container.]
[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).]

[Where appropriate, warning against certain visible signs of deterioration.]
<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

[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 the SPC and in the language of the text, e.g.]

- The active substance(s) is (are)… *[see guidance in section 2 of outer packaging.]*
- The other ingredient(s) is (are)... *[separate the excipients of the different parts of the medicinal product, e.g. tablet core/coating, capsule contents/shell; powder/solvent (e.g. water for injections).]*

[Pharmaceutical form, nature and contents of container in weight, volume or units of dosage.]

What X looks like and contents of the pack

[The pharmaceutical form should be stated according to the full "Standard Terms" published by the Council of Europe and an additional patient-friendly explanation may be given if necessary. Where the Council of Europe short standard term is used on small immediate packaging materials, the short term should be added in brackets.
It is recommended to include a physical description e.g. shape, colour, texture, imprint.]

[All pack sizes for this pharmaceutical form and strength should be detailed here; 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 manufacturing authorisation holder responsible for batch release, if different.]

Marketing Authorisation Holder and Manufacturer

<[To be completed nationally]>

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

[State the name and address of the Marketing Authorisation Holder and identify as such e.g. "Marketing Authorisation Holder: ABC Ltd, etc." (Full address: name of the country to be stated in the language of the text. Telephone, fax numbers or e-mail addresses may be included (no websites, no e-mails linking to websites).]
[State the name and address of the manufacturer responsible for batch release and identify as such e.g. "Manufacturer: DEF Ltd, etc." (Full address: name of the country to be stated in the language of the text. 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 in the EEA is designated, all should be listed here. However, 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 locally printed PL in each MS need only to include the manufacturing site(s)specific to that MS.]

[Information on local representative and/or co-promotion is part of the 'Blue Box'.]

[For information about the 'Blue Box' please refer to the Notice to Applicants, Volume 2A, Chapter 7 as published on the Website of the European Commission:
http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev2.htm#2a

[If the medicinal product is authorised in accordance with Articles 28 to 39 (Mutual Recognition, Decentralised Procedure, after referral according to Article 30 and Article 31 of Directive 2001/83/EC) under different names in the Member States concerned, a list of the names authorised in each Member State has to follow (Article 59 (1) g of Directive 2001/83/EC):]

<This medicinal product is authorised in the Member States of the EEA under the following names:>

< {Name of the Member State} > < {Name of the medicinal product} >
< {Name of the Member State} > < {Name of the medicinal product} >

[To be duplicated as necessary.]

This leaflet was last approved in {MM/YYYY}

<[To be completed nationally]>

[For products approved under "exceptional circumstances", include the following statement:]
<This medicine has been authorised under "Exceptional Circumstances".
This means that <because of the rarity of this disease> <for scientific reasons> <for ethical reasons> it has been impossible to get complete information on this medicine.
The {name MS/Agency} will review any new information on the medicine every year and this leaflet will be updated as necessary.>

[It is recommended that the following reference is included:]
<Detailed information on this medicine is available on the web site of: {name of MS/Agency}>

<----------

[Practical information on handling and/or administration of the medicinal product by the patient may be provided here, only where such information is too extensive to be included in section 3. A cross-reference to this information should be included in section 3.]

[For parenteral products or other products which are mainly used in hospitals, practical information on preparation and/or handling of the medicinal product for medical and healthcare professionals can be included in this section, WHERE RELEVANT and a cross-reference to section 3 should be included. In such case, start the section with:]

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

[If other additional scientific information is to be included in the package for the healthcare professional, this can be achieved by either:

- *providing the complete SPC as a separate document in the product package,*
- *adding the complete SPC as a tear-off section at the end of the printed PL,*

so that the information for the patient (i.e. the package leaflet) and the information for the healthcare professional (i.e. the SPC) are clearly differentiated.

The intention to include the complete SPC and the way in which this will be achieved must be justified by the applicant and indicated at the end of the package leaflet without actually repeating the complete latest SPC text.
Applicants should carefully consider whether including such scientific information in the pack is appropriate, taking into account the nature of the product.]