NOTE:
The CMDh ‘Annotated’ QRD Template provides guidance on how to present the SmPC, 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 European Medicines Agency [URL].

SUMMARY OF PRODUCT CHARACTERISTICS

[NOTE: the following are those items of information required by Article 11 of Directive 2001/83/EC. For the full information to be included in each section, please refer to the “Guideline on Summary of Product Characteristics” as published on the Website of the European Commission in the Notice to Applicants, Volume 2C: [URL]. This guidance should also be read in conjunction with other relevant guidelines that can be found on the European Medicines Agency website (“QRD Convention to be followed for the EMA-QRD templates”: [URL]).

During the evaluation process, applicants may present SmPCs for different strengths in one document, clearly indicating with grey-shaded titles the strength or presentation to which alternative text elements refer. Upon MS agreement with a combined SmPC, the text does not need to be separated in the national phase of marketing authorisation. However, in all other cases, a separate SmPC 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 SmPC.
- All other language versions: at the 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 medicinal 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]
[For medicinal products subject to additional monitoring ONLY:
The black symbol and the statements should only appear preceding section 1. The black symbol shall be a
black inverted equilateral triangle: the symbol shall be proportional to the font size of the subsequent
standardised text and in any case each side of the triangle shall have a minimum length of 5 mm. For the
purpose of preparing the product information annexes please use the black triangle as presented in this
template (see below).]

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

1. NAME OF THE MEDICINAL PRODUCT

{(Invented) name strength pharmaceutical form}[For MRP/DCP procedures]

{{(Invented) name and associated names (see Annex I) strength pharmaceutical form}
[See Annex I - To be completed nationally]} [For referral procedures]

[Name of the medicinal product in the RMS.]

[No ® ™ symbols attached here and throughout the text; “tablets” and “capsules” in the plural.]

[For Referrals: according to the type of referral procedure the (invented) name should be presented as
follows:
Art. 29 => the (invented) name approved in the Reference Member State
Art. 30 => the (invented) name used in the referral notification to CHMP
Art.31 => INN (or common name) - containing medicinal products (see Annex I)

Similar pharmaceutical forms (e.g. capsules, tablets, film-coated tablets) can be presented in a combined
document. In case of combined texts, all strengths/forms should be presented on a separate line, e.g.:
X and associated names (see Annex I) 2 mg/ml solution for infusion
X and associated names (see Annex I) 10 mg/ml solution for infusion
X and associated names (see Annex I) 20 mg/ml solution for infusion
[see Annex I - To be completed nationally]]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

[Name of the active substance(s) in the language of the text.]

<Excipient(s) with known effect>

<For the full list of excipients, see section 6.1.>
<[To be completed nationally]> [For referral procedures, as appropriate]

[Art. 29 => the whole section should be filled in; the statement “[To be completed nationally]” is not to be
included.
Art. 30 => if the quality part is harmonised then the principles of article 29 (see above) apply. If not, the
section should be left empty and the statement “[To be completed nationally]” should be included
Art.31 => the section should be left empty and the statement “[To be completed nationally]” should be
included]

3. PHARMACEUTICAL FORM
<[To be completed nationally]> [For referral procedures, as appropriate]

[Art. 29 => the whole section should be filled in (both standard terms and the visual description should be given here); the statement “[To be completed nationally]” is not to be included.
Art. 30 => if the quality part is harmonised then the principles of article 29 (see above) apply. If not, the full standard term of the pharmaceutical form(s) should be listed; the rest of the section should be left empty and the statement “[To be completed nationally]” should be included
Art.31 => the section should be left empty and the statement “[To be completed nationally]” should be included]

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

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

[Specify, if appropriate <This medicinal product is for diagnostic use only.>] [Art. 29 => the whole section should be filled in (both standard terms and the visual description should be given here); the statement “[To be completed nationally]” is not to be included.
Art. 30 => if the quality part is harmonised then the principles of article 29 (see above) apply. If not, the full standard term of the pharmaceutical form(s) should be listed; the rest of the section should be left empty and the statement “[To be completed nationally]” should be included
Art.31 => the section should be left empty and the statement “[To be completed nationally]” should be included]

4.2 Posology and method of administration

Posology
[Additional sub-headings such as “Elderly” or “Renal impairment” can be stated if necessary.]

Paediatric population

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

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

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

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

Method of administration

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

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

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1 or [name of the residue(s)].

4.4 Special warnings and precautions for use

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

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

[For pregnancy and lactation statements, see Appendix I.]

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

4.7 Effects on ability to drive and use machines

{Invented name} has <no or negligible influence> <minor influence> <moderate influence> <major influence> on the ability to drive and use machines. [describe effects where applicable.]

4.8 Undesirable effects

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

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

4.8 Undesirable effects

[For ALL medicinal products:
The following sub-heading should appear at the end of section 4.8]

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.*

[*For the printed materials: The actual details of the national reporting system (as listed within the Appendix V) of the concerned Member State(s) shall be displayed on the printed version and may also be
displayed in the electronic national translation, published or not published. No reference to the Appendix V should be included in the printed materials. Linguistic adjustments may also be necessary depending on the grammatical rules of the languages used.
For Referrals: Refer to the guidance in the annotated QRD template for centralised procedures.]

4.9 Overdose

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

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

[For medicinal product authorised as similar biological medicinal products, include the following statement:]<{(Invented) Name} is a biosimilar medicinal product. Detailed information is available on the website of: {name of MS/Agency}>

[Tabular presentation of clinical efficacy and safety information may be used.]<Mechanism of action><Pharmacodynamic effects><Clinical efficacy and safety><Paediatric population>

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

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

[For medicinal 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 SmPC will be updated as necessary>

5.2 Pharmacokinetic properties

<Absorption><Distribution><Biotransformation>
<Elimination>
<Linearity/non-linearity>

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

<Pharmacokinetic/pharmacodynamic relationship(s)>

5.3 Preclinical safety data

[Additional sub-headings such as “Juvenile animals studies” can be included when necessary.]
<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 and development.>
<Adverse reactions not observed in clinical studies, but seen in animals at exposure levels similar to clinical exposure levels and with possible relevance to clinical use were as follows:>

<Environmental Risk Assessment (ERA)>

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

[Name of the excipient(s) in the language of the text.]

<[To be completed nationally]> [For referral procedures, as appropriate]
<None.>

[Art. 29 => the whole section should be filled in; the statement “[To be completed nationally]” is not to be included.
Art. 30 => if the quality part is harmonised then the principles of article 29 (see above) apply. If not, the section should be left empty and the statement “[To be completed nationally]” should be included
Art.31 => the section should be left empty and the statement “[To be completed nationally]” should be included]

6.2 Incompatibilities

<Not applicable.> [if appropriate, e.g. for solid oral pharmaceutical forms.]
<In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.> [e.g. for parenterals.]<This medicinal product must not be mixed with other medicinal products except those mentioned in section <6.6> <and> <12>.>]

<[To be completed nationally]> [For referral procedures, as appropriate]

[Art. 29 => the whole section should be filled in; the statement “[To be completed nationally]” is not to be included.
Art. 30 => if the quality part is harmonised then the principles of article 29 (see above) apply. If not, the section should be left empty and the statement “[To be completed nationally]” should be included
Art.31 => the section should be left empty and the statement “[To be completed nationally]” should be included]

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> <...>

<[To be completed nationally]> [For referral procedures, as appropriate]

[Art. 29 => the whole section should be filled in; the statement “[To be completed nationally]” is not to be included.
Art. 30 => if the quality part is harmonised then the principles of article 29 (see above) apply. If not, the section should be left empty and the statement “[To be completed nationally]” should be included
Art.31 => the section should be left empty and the statement “[To be completed nationally]” should be included]

6.4 Special precautions for storage

[For Storage condition statements, see Appendix III.]

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

[Art. 29 => the whole section should be filled in; the statement “[To be completed nationally]” is not to be included.
Art. 30 => if the quality part is harmonised then the principles of article 29 (see above) apply. If not, the section should be left empty and the statement “[To be completed nationally]” should be included
Art.31 => the section should be left empty and the statement “[To be completed nationally]” should be included]

6.5 Nature and contents of container

[All pack sizes must be listed. If applicable, add:
<Not all pack sizes may be marketed.>
[Multipack presentations should also be listed in this section, e.g. “multipacks containing 180 (2 packs of 90) film-coated tablets”.]

<[To be completed nationally]> [For referral procedures, as appropriate]

[Art. 29 => all pack-sizes should be listed here; the statement “Not all pack-sizes may be marketed” should be added; the statement “[To be completed nationally]” is not to be included.
Art. 30 => if the quality part is harmonised then the principles of article 29 (see above) apply. If not, the section should be left empty and the statement “[To be completed nationally]” should be included
Art.31 => the section should be left empty and the statement “[To be completed nationally]” should be included]

6.6 Special precautions for disposal <and other handling>

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

<Use in the paediatric population>

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

[This section should always be filled in for all referrals]

7. MARKETING AUTHORISATION HOLDER

[To be completed nationally] [For MRP/DCP procedures]

[See Annex I - To be completed nationally] [For referral procedures]

[This statement should always be included for all types of referrals]

[Country name in the language of the text.]
[Name and address]

[For all types of referrals the above fields (name, tel, fax, etc.) should not be completed but kept as stated above.]

8. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

[This statement should always be included for all types of referrals]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[As per SmPC guideline, the date should be stated in the following format:]

<Date of first authorisation: {DD month YYYY}>
<Date of latest renewal: {DD month YYYY}>

[To be completed nationally]

[This statement should always be included for all types of referrals]

[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.]

10. DATE OF REVISION OF THE TEXT

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

[To be completed nationally]

[This statement should always be included for all types of referrals]

<11. DOSIMETRY>

<12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS>
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

It is recommended that the following reference is included:
Detailed information on this medicinal 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/PdF 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 “Guideline on the Readability of the Labelling 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/vol2_en.htm.]

[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, 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 the 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 **grey-shaded text**.]

[Patient alert card:
In case where a patient alert card is to be included in the carton, then the text itself will have to be part of the product information (at the end of the last labelling component (e.g. vial)).]
LABELLING

[NOTE: these are all mandatory items listed in Title V of Directive 2001/83/EC. The data should be presented according to the template below, irrespectively of their sequence on the actual labelling and their position and possible repetition on the individual sides/flaps of the packaging (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}
[In case of multipack presentations the outer and inner labelling should be presented as separate labelling components, i.e. the outer label should indicate under this boxed area that it contains Blue Box; the inner label should indicate under this boxed area that no Blue Box is included. In cases where a product is also supplied as an individual presentation in addition to a multipack one, this should be presented separately and not be combined with either the outer or inner carton label of the multipack presentation.]

1. NAME OF THE MEDICINAL PRODUCT

{(Invented) name strength pharmaceutical form} [For MRP/DCP procedures] [as it appears in the SmPC under section 1.]
{(Invented) name and associated names (see Annex I) strength pharmaceutical form}
[See Annex I - To be completed nationally] [For referral procedures]
[See guidance in section 1 of the SmPC]

{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)]

[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 medicinal products should be presented separated by a “/” . The names of the active substances should be presented separated by a “/” and in the same order relating to the strength, e.g. (invented) name 150 mg/12.5 mg tablets irbesartan/hydrochlorothiazide]

2. STATEMENT OF ACTIVE SUBSTANCE(S)

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

<To be completed nationally> [For referral procedures, as appropriate]
[See guidance in section 2 of the SmPC]
3. LIST OF EXCIPIENTS

[Express qualitatively those excipients known to have a recognised action or effect and included in the 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.]

<[To be completed nationally]> [For referral procedures, as appropriate]
[See guidance in section 6.1 of the SmPC]

4. PHARMACEUTICAL FORM AND CONTENTS

[Pharmaceutical form according to the full “Standard terms” published by the Council of Europe. Pharmaceutical form patient-friendly terms will be considered on a case-by-case basis in case of space constraints. If used, the pharmaceutical form patient-friendly term should be added in brackets in section 3 of the SmPC.

Contents by weight, by volume or by number of doses or number of units of administration of the medicinal product (i.e. pack size, including a reference to any ancillary items included in the pack such as needles, swabs, etc.). The information should be as simple and descriptive as possible using terms used in section 3 and 6.5 of the SmPC. Since the pharmaceutical form is already mentioned as part of the name of the medicinal product in section 1, it should be repeated here in grey-shading (so that it will not appear several times on the final printed material).

In case of a combined labelling text covering different pack sizes of the same strength, each pack size should be listed on a separate line in grey-shading,
e.g. 28 film-coated tablets
     56 film-coated tablets
     100 film-coated tablets]

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

[In case of multipacks presentation, please follow the below example:
On the outer carton: “Multipack: 180 (2 packs of 90) film-coated tablets.”
On the inner carton (without blue box): “90 film-coated tablets. Component of a multipack, can’t be sold separately.”.]

<[To be completed nationally]> [For referral procedures, as appropriate]
[See guidance in sections 3 and 6.5 of the SmPC]

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

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

[Special warnings on labelling should be reserved to cases where they are considered very important in order to fulfil a risk minimisation objective (e.g. “Cytotoxic: Handle with caution”, “May cause birth defects”, etc.).]

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 medicinal product varies, depending on how, or with what, it is reconstituted, then there should be a statement on the label, such as: “Read the leaflet for the shelf life of the reconstituted medicine”.]

9. SPECIAL STORAGE CONDITIONS

[The statement(s) should reflect special precautions recommended in section 6.4 of the SmPC. For Storage condition statements, see Appendix III.]

<To be completed nationally> [For referral procedures, as appropriate]
[See guidance in section 6.4 of the SmPC]

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

[The statement(s) should reflect special precautions recommended in section 6.6 or 12 of the SmPC, e.g. radiopharmaceuticals, cytostatics.]
[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] [<See Annex I - To be completed nationally>] [For referral procedures] [This statement should be included for all types of referrals]

[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 MAH websites, no e-mails linking to MAH websites).]

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

[See guidance in section 7 of the SmPC]

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.]

[For multipacks, clearly indicate the pack content for each marketing authorisation number, e.g. XXX 180 film-coated tablets (2 packs of 90).]

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] [this statement should be included for all types of referrals]

15. INSTRUCTIONS ON USE

[Only for medicinal products not subject to medical prescription include:
- Indication(s).
- Dose 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 “Guideline on the Readability of the Labelling and Package leaflet of Medicinal Products for Human Use” as published by the European Commission in the Notice to Applicants, Volume 2C).]
[In cases where Braille is not included, according to the above mentioned 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]> [For referral procedures]

17. UNIQUE IDENTIFIER – 2D BARCODE

<2D barcode carrying the unique identifier included.>

<Not applicable.>

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

< PC: {number} [product code]
SN: {number} [serial number]
NN: {number} [national reimbursement number or other national number identifying the medicinal product]>

<Not applicable.>
## MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

**[NATURE/TYPE]**

### 1. NAME OF THE MEDICINAL PRODUCT

{(Invented) name strength pharmaceutical form} [For MRP/DCP procedures]

{(Invented) name and associated names (see Annex I) strength pharmaceutical form} [See Annex I - To be completed nationally] [For referral procedures] [See guidance in section 1 of the SmPC]

{Active substance(s)}

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

[Pharmaceutical form patient-friendly 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] [For MRP/DCP procedures]

[See Annex I - To be completed nationally] [For referral procedures]

This statement should be included for all types of referrals

{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 medicinal product can be included here, e.g. calendar days may be included if the product is taken as a single dose and is packaged in blister strips that comprise multiples of seven.]
MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

[NATURE/TYPE]
[Small immediate packaging units are defined as containers sized up to and including 10 ml. On a case-by-case basis the minimum particulars could also be considered for other containers where it is not feasible to include all the information. Such exceptional cases have to be justified, discussed and agreed with the Competent Authority and will be based on the specific national legislation of the MS. In case of radiopharmaceuticals the vial should be labelled in accordance to the article 66(3) of Directive 2001/83.]

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

{(Invented) name strength pharmaceutical form} [For MRP/DCP procedures]
{(Invented) name and associated names (see Annex I) strength pharmaceutical form}
[See Annex I - To be completed nationally] [For referral procedures]
[See guidance in section 1 of the SmPC]
[Active substance(s)]
(Route of administration)

[Pharmaceutical form patient-friendly 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. In case of space limitation you can also refer to the “QRD Table of non-standard abbreviations” where you can find the list of abbreviations to be used for Route of Administration. Abbreviations should also be explained and stated in full in the relevant section of the Package Leaflet.]

[Where different labels apply to different constituents of the medicinal product, the pharmaceutical form in the name on the specific label should only refer to the constituent concerned (e.g. separate label for powder vial and solvent ampoule).]
[In case of a solvent container, section 1 should read: “Solvent for X” (identify medicinal product name; X can be omitted provided safety concerns are not raised)
{(Route of administration)}]

2. METHOD OF ADMINISTRATION

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

3. EXPIRY DATE

[For terms on Batch number and Expiry date, see Appendix IV.]
[Where applicable, and space permitting, shelf life after reconstitution, dilution or after first opening the container.
For medicinal products which have a limited shelf life after opening or reconstitution, space and a statement inviting to record the date of opening or reconstitution is recommended, e.g. “reconstituted on: …”, “expiry date: …”.
Please refer to “Note for Guidance on Maximum Shelf Life for Sterile Products for Human Use after First Opening or Following Reconstitution” (CPMP/QWP/159/96/corr).]
4. BATCH NUMBER

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

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

<[To be completed nationally]> [For referral procedures, as appropriate]

6. OTHER

[Space permitting, any other information necessary for the correct use and administration of the medicinal 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.]

The package leaflet must be readable for the patient; please refer to the “Guideline on the Readability of the Labeling 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:

The package leaflet should be written in a language understandable by the patient and should reflect the terminology the patient is likely to be familiar with. Throughout the text “X” stands for the (invented) name of the medicine.

Headings and standard statements given in the template must be used whenever they are applicable. If the applicant needs to deviate from these headings/statements to accommodate medicine-specific requirements (e.g. for medicines administered by healthcare professionals, “take”/”use” could be replaced by “are given” or “are administered”), alternative or additional headings/statements will be considered on a case-by-case basis.

When requested, applicants should justify the use of alternative headings (e.g. by reference to user testing results). For certain medicines not all items may be relevant, in this case the corresponding heading should not be included.

The purpose of the templates is to ensure that all the information required by Directive 2001/83/EC is included in the text versions of all packaging components in the order specified (where order is a requirement of the legal provisions).

Design and layout are key elements for the readability of the final printed material. Having used the templates provided, marketing authorisation holders will still need to format the resulting texts into the relevant full colour mock-ups for all packaging components. This template ensures a certain degree of consistency across centrally authorised medicines, however the formatting should not be transferred to the printed material (especially the font and text size).

Guidance notes in orange cross-refer to the section/information of the SmPC 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. Marketing authorisation holders are therefore encouraged to include a statement at the end of the package leaflet to inform about the availability of such alternative formats.]
Package leaflet: Information for the <patient> <user>

[Heading to be printed]

{(Invented) name strength pharmaceutical form} For MRP/DCP procedures

{(Invented) name and associated names (see Annex I) strength pharmaceutical form}
[See Annex I - To be completed nationally] [For referral procedures]
[See guidance in section 1 of the SmPC]

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

[For medicinal products subject to additional monitoring ONLY:
The black symbol and the statements should only appear here. The black symbol shall be a black inverted equilateral triangle: the symbol shall be proportional to the font size of the subsequent standardised text and in any case each side of the triangle shall have a minimum length of 5 mm. For the purpose of preparing the product information annexes please use the black triangle as presented in this template (see below).]

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

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

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

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

[For referral procedures: if legal status known, please select the appropriate option above. If legal status unknown or if likely to be different between MSs both options should appear together with the statement “[To be completed nationally]”.]
What is in this leaflet
[User testing to date has indicated that most patients value a content listing in the package leaflet. In order for this to be most useful it needs to be prominently displayed where it appears. The content listing would normally reflect the six main sections of the leaflet, where a flat leaflet is prepared. However, if a booklet format is used, or the flat leaflet contains many subsections, a more detailed content listing may be used (page numbers or column numbers, which enable readers to quickly find the information they are seeking, can only be included in the mock-up).]

1. What X is and what it is used for
2. What you need to know before you <take> <use> X
3. How to <take> <use> X
4. Possible side effects
5. How to store X
6. Contents of the pack and other information

1. What X is and what it is used for

[Invented name, active substance(s) and pharmacotherapeutic group]
[You should first of all include the invented name of the medicinal product and the active substance(s) included in it, if necessary, as per section 1 and 2 of the SmPC, e.g. “X contains the active substance Y”. The pharmacotherapeutic group and/or type of activity, as per section 5.1 of the SmPC should also be stated, e.g. “statins (used to lower cholesterol)”.

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

[Information on the benefits of using this medicine]
[On a case-by-case basis, information on the benefits of the treatment could be included in this section, as long as it is compatible with the SmPC, useful for the patient, and to the exclusion of any element of a promotional nature (in accordance with art 62 of Directive 2001/83/EC). This could be included under a separate sub-heading, e.g. entitled “How X works”.
The information should be depicted in a clear and condensed way. For example, information could relate to:
- signs and symptoms of the target disease, in particular for non-prescription medicines, but also for medicines to be taken “on-demand” (e.g. treatment of migraine);
- the benefit(s) of taking the medicine could be summarised (e.g. “this medicine reduces pain associated with arthritis”, “this medicine has been shown to reduce blood sugar, which helps to prevent complications from your diabetes”). This would be particularly important to encourage adherence to the treatment, e.g. for long-term and prevention treatment. Benefit may be described in terms of prevention of disease complications (e.g. anti-diabetic), if established. The timing of the effect may also be described if useful. In any case, information must be compatible with the SmPC, in particular section 5.1;
- information on the amount of time the medicine usually takes to work may be presented if relevant for the patient (pain-killer, antidepressant, etc).
You must talk to a doctor if you do not feel better or if you feel worse <after \{number of\} days>.

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

[This section should include information which patients/users should be aware of before they start taking the medicine and while using it. This section of the package leaflet is the one which in user testing patients have most difficulty with due to its overall size. Inclusion of additional sub-headings (e.g. for information to particular category of users) with a clear hierarchy is therefore critical in helping patients to navigate this information.]
[Contraindications]
Do not <take> <use> X::<>
[All contraindications mentioned in section 4.3 of the SmPC should be included here in the same order as presented in the SmPC. Other precautions and special warnings should be presented in the next section. Care must be taken to ensure that complex details are not omitted. It is not acceptable to state only the common or major contraindications. Belief that a patient cannot understand a contraindication is not a reason for omitting it.]

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

[Appropriate precautions for use; special warnings]

Warnings and precautions
Talk to your doctor <or> <pharmacist> <or nurse> before <taking> <using> X [in case of long bulleted list, book-ends (i.e. whereby the statement recommending the action to talk to your doctor or pharmacist is repeated after each warning or precaution) are recommended.]

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

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

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

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

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

[Interaction with other medicines]

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

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

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

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

[Interactions with food and drink]

X with food and drink

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

[Use by pregnant or breast-feeding women, information on fertility]

Pregnancy and breast-feeding

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

[Include conclusion summary of the information given in section 4.6 of the SmPC, in addition to the following optional statement:]

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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

[Effects on the ability to drive or to use machines]

Driving and using machines

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

[Excipients warnings]

X contains excipient(s)

[If appropriate, warnings of those excipients knowledge of which is important for the safe and effective use of the medicine 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), as per section 4.4 of the SmPC, should be mentioned here. This subsection should be omitted when the medicine does not contain any excipients of known effect. In case the information relates to another section of the package leaflet (e.g. alcohol), a cross reference to this section should be made; it will be necessary to refer back to the excipients warning from those sections relating to the effects (e.g. ability to drive, pregnancy and breast-feeding, paediatric information).]

[To be completed nationally] [For referral procedures, as appropriate]

[See guidance in section 6.1 of the SmPC]
3. How to \textit{take} \textit{use} X

[In simple cases, the following 3 items can be combined as one paragraph.]

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

<The recommended dose is ...>

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

<The recommended dose is ...>

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

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

[Route(s) and/or method of administration (SmPC section 4.2)]
[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.
Method of administration: directions for a proper use of the medicine, e.g. “Do not swallow”, “Do not chew”, “Shake well before use” (user testing experience has shown it is useful to state the reasons for the inclusion of such a statement, e.g. “Do not break or crush the tablet(s). If you do, there is a danger you could overdose because this medicine will be absorbed into your body too quickly”).
When applicable, there should be descriptions (if useful with illustrations) of opening techniques for child-resistant containers and other containers to be opened in an unusual way.
Where relevant, guidance should always be included to clarify if the medicine must be taken with food, during/before meals, or clearly state if food/meals have no influence, etc.]
<The score line is only there to help you break the tablet if you have difficulty swallowing it whole.>
<The tablet can be divided into equal doses.>
<The score line is not intended for breaking the tablet.>

[Duration of treatment (SmPC section 4.2)]
[If appropriate, especially for medicines available without prescription, precise statements should be included on:
• the usual duration of the therapy;
• the maximum duration of the therapy;
• the intervals with no treatment;
• the cases in which the duration of treatment should be limited.]

[For some medicines it may be necessary to include some additional information in this section although this need not be covered in all cases. The following headings can be used as a guide:]
<If you <take> <use> more X than you should>
[Describe how to recognise symptoms if someone has taken an overdose and what to do as per SmPC section 4.9.]

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

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

<If you stop <taking> <using> X>
[Indicate withdrawal effects and how to minimise them as per SmPC section(s) 4.2 and/or 4.4. A statement on the potential consequences of stopping the treatment before finishing the course of treatment and the need for a prior discussion with the treating physician, pharmacist or nurse should be included as appropriate. Close this section with:]

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

4. Possible side effects

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

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

1) the most serious side effects need to be listed prominently first with clear instructions to the patients on what action to take (e.g. to stop taking the medicine and/or seek urgent medical advice. The use of the words “straight away” or “immediately” may be helpful in this context).

2) then a list of all other side effects, listed by frequency and starting with the most frequent (without repeating the most serious and most frequent included above).

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

Very common: may affect more than 1 in 10 people
Common: may affect up to 1 in 10 people
Uncommon: may affect up to 1 in 100 people
Rare: may affect up to 1 in 1,000 people
Very rare: may affect up to 1 in 10,000 people
Not known: frequency cannot be estimated from the available data

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

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

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

[For ALL medicinal products:  
The following sub-heading should appear at the end of section 4]

Reporting of side effects
If you get any side effects, talk to your <doctor> <or> <,> <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via the national reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

[*For the printed materials:  
The actual details of the national reporting system (as listed within the Appendix V) of the concerned Member State(s) shall be displayed on the printed version and may also be displayed in the electronic national translation, published or not published. No reference to the Appendix V should be included in the printed materials. Linguistic adjustments may also be necessary depending on the grammatical rules of the languages used.
For Referrals: Refer to the guidance in the annotated QRD template for centralised procedures.

• The examples below are not exhaustive; the design and layout chosen for the package leaflet should drive the display of the details. Linguistic adjustments may also be necessary depending on the grammatical rules of the languages used. In case the details of the national reporting system are short, e.g. website only, you may wish to integrate the details within the text as per the example below:

“If you get any side effects, talk to your <doctor> <or> <,> <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via www.xxx.xx.xx. By reporting side effects you can help provide more information on the safety of this medicine.”

• In case the details of the national reporting system are long, e.g. website + alternative reporting details and/or leaflet addressed to more than one Member States, you may wish to follow the example below:

“If you get any side effects, talk to your <doctor> <or> <,> <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
{Name}  
<{Address}>  
{Town} {Postal code} – UK
Tel: + {Telephone number}
<website>

Ireland
{Name}  
<{Address}>  
IRL - {Town} {Code for Dublin}>
Tel: + {Telephone number}
<website>
<{e-mail}>

Malta
5. **How to store X**

<[To be completed nationally]> [For referral procedures, as appropriate]

[See guidance in section 6.4 of the SmPC]

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

**[Expiry date]**

[Where a specific abbreviation for Expiry date is used on the labelling, it should be mentioned here.]

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

**[Storage conditions]**

[Information should be in accordance with section 6.4 of the SmPC; for storage condition statements, see Appendix III.]

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

[Information should be in accordance with section 6.3 of the SmPC; please also refer to “Note for Guidance on Maximum Shelf Life for Sterile Products for Human Use after First Opening or Following Reconstitution” (CPMP/QWP/159/96/corr).]

[Where appropriate, warnings against certain visible signs of deterioration]

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

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

6. **Contents of the pack and other information**

**[Full statement of the active substance(s) and excipient(s)]**

**What X contains**

[The active substance(s) (expressed qualitatively and quantitatively) and the other ingredients (expressed qualitatively) should be identified using their names as given in section 2 and 6.1 of the SmPC and in the language of the text.]

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

<[To be completed nationally]> [For referral procedures, as appropriate]

[See guidance in section 2 of the SmPC]

**[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 patient-friendly term is used on small immediate packaging materials, the patient-friendly term should be added in brackets.]
It is recommended to include a physical description e.g. shape, colour, texture, imprint, etc as per section 3 of the SmPC.

[All pack sizes for this pharmaceutical form and strength should be detailed here as per section 6.5 of the SmPC, including a reference to any ancillary items included in the pack such as needles, swabs, etc. For multipacks, clearly indicate the pack content, e.g. “X is available in packs containing Y, Z or W tablets and in multipacks comprising N cartons, each containing M tablets”. If appropriate indicate that not all pack sizes may be marketed. A cross-reference to other pharmaceutical forms and strengths may be included.]

<To be completed nationally> [For referral procedures, as appropriate]

[See guidance in sections 3 and 6.5 of the SmPC]

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

**Marketing Authorisation Holder and Manufacturer**

<To be completed nationally> [For MRP/DCP procedures]

<See Annex I - To be completed nationally> [For referral procedures]

[This statement should be included for all types of referrals]

{Name and address}

<{tel}>

<{fax}>

<{e-mail}>

[For the MAH: See guidance in section 7 of the SmPC.

For the Manufacturer: Art. 29 => include details of the Manufacturer responsible for batch release of the RMS.

Art. 30 => if the quality part is harmonised then the principles of article 29 (see above) apply. If not, the fields (name, tel, fax, etc.) should not be completed but kept as stated above.

Art.31 =>. The fields (name, tel, fax, etc.) should not be completed but kept as stated above.]

[State the name and address of the Marketing Authorisation Holder as per sectin 7 of the SmPC 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 or 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 (with or without grey-shading, depending on the option chosen for the printed package leaflet). However, the printed package leaflet of the medicine 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 Articles 29 and 30 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.]

<[See Annex I - To be completed nationally] [For referral procedures, as appropriate]

[According to the type of the referral procedure this section should be completed as follows:

Art. 29 & Art 30 => if names are different between Member States, the whole section should be filled in, listing the names of all member states concerned with the invented names of the product.]

[In addition, the following approach is recommended when the same name applies to several Member States:

*List the names of the MSs to which a certain name applies on one line, followed by the next group of MSs to which another name applies.*

For instance:

Belgium, Greece, Spain: <Name 1>
Estonia, France, Italy:  <Name 2>
Ireland, Malta, UK: <Name 3>
etc.]

This leaflet was last revised in <{MM/YYYY}> <{month YYYY}>.

[To be completed nationally]

[For medicines 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 this medicine every year and this leaflet will be updated as necessary.]*

**Other sources of information**

[This section should include references to other sources of information which will be useful for the patient. Such sources of information must be compatible with the SmPC and non-promotional:

- Details of how patients can access the information in alternative formats such as Braille, audio, cd-rom or large print. Normally, this should appear in a large font to ensure visually impaired patients are aware of the service.

[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}*

<----------------------------------------------------------------------------------------------------------------------------->

[For parenteral products, other medicines which are mainly used in hospitals or in the exceptional cases of extemporaneous preparations (where a medicine is indicated in children and where no adequate paediatric formulation can be developed (based on duly justified scientific grounds)), practical information relevant for healthcare professionals, such as on preparation and/or handling, incompatibilities, posology of the medicine,
overdose or monitoring measures and laboratory investigations can be included in this section, WHERE RELEVANT, and a cross-reference to section 3 should be included. In such a case, start the section with:

<The following information is intended for 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 SmPC as a separate document in the medicine pack, or
- adding the complete SmPC 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 SmPC) are clearly differentiated.

The intention to include the complete SmPC 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 SmPC text.

Applicants should carefully consider whether including such scientific information in the pack is appropriate, taking into account the nature of the medicine.]