ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

[NOTE: the following are those items of information required by Article 11 of Directive 2001/83/EC, as amended, and current practice in the centralised procedure. In the case of advanced therapy medicinal products, these items are listed in Annex II of Regulation (EC) 1394/2007.

For the full information to be included in each section, please refer to ~~This guidance should be read in conjunction with the relevant guidelines that can be found on the European Medicines Agency website, 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/vol2_en.htm

This guidance should also be read in conjunction with other relevant guidelines that can be found on the European Medicines Agency website (e.g. ~~(See also~~ "QRD Convention to be followed for the EMA-QRD templates" ~~for format and layout~~: http://www.ema.europa.eu/htms/human/qrd/docs/convention.pdf).

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. However, 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 adoption of the opinion.
- All other language versions: at the latest 25 days after adoption of the opinion (i.e. at the latest after incorporation of Member States comments).

See also: "The Product Information linguistic review process for new applications in the Centralised Procedure": http://www.ema.europa.eu/pdfs/human/regaffair/554202en.pdf

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:

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<text>: Text to be selected or deleted as appropriate.]

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1. NAME OF THE MEDICINAL PRODUCT

[Guidance on the expression of strength is available in the "QRD Recommendations on the Expression of Strength in the Name of Centrally Authorised Human Medicinal Product (as stated in section 1 of SmPC and in the name section of labelling and PL".]

{(Invented) name strength pharmaceutical form}

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

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2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

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[For Advanced Therapy Products ONLY:
Where an advanced therapy medicinal product contains cells or tissues, a detailed description of these cells or tissues and of their specific origin shall be provided, including the species of animal in cases of non-human origin. The following subheadings shall be included:
<2.1 General description> (For Advanced Therapy Products only)

<2.2 Qualitative and quantitative composition> (For Advanced Therapy Products only)
Moreover, in the case of advanced therapy medicinal products, explanatory illustrations may be included, if necessary.]

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<Excipient(s) with known effect:>
<For ~~a~~ the full list of excipients, see section 6.1.>

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3. PHARMACEUTICAL FORM

<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 ~~halves~~doses.>

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

[Specify, if appropriate <This medicinal product is for diagnostic use only.> .]

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<{X} is indicated in <adults> <neonates> <infants> <children> <adolescents> <aged {x to y}> <years> <months>~~>~~.>

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4.2 Posology and method of administration

Posology
[Additional subheadings such as "Elderly patients" or "Patients with renal impairment" can be stated if necessary.]

Paediatric population

<The <safety> <and> <efficacy> of {X} in children aged {x to y} <months> <years> {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} <in the indication...>.> [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} <in the indication...>.> [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. Explanatory illustrations may be included, if necessary, especially for advanced therapy medicinal products.]

<For instructions on <reconstitution> <dilution> of the medicinal product before administration, see section <6.6.> <and> <12>.>

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).]

<Paediatric population>

4.5 Interaction with other medicinal products and other forms of interaction

<No interaction studies have been performed.>

<Paediatric population>

<Interaction studies have only been performed in adults.>

4.6 Fertility, pregnancy and lactation

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

~~<Women of childbearing potential>~~

~~<Contraception in males and females>~~

<Pregnancy>

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<Breast-feeding>
<Fertility>
[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.]
<Not relevant.>

4.8 Undesirable effects

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

[Subheadings 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".]
<Paediatric population>

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 product, include the following statement:]
<{(Invented) Name} is a biosimilar medicinal product. Detailed information is available on the website of the European Medicines Agency http://www.ema.europa.eu.>

[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:]

[For waivers applying to all subsets:]
<The European Medicines Agency has waived the obligation to submit the results of studies with {(Invented) Name} in all subsets of the paediatric population in {condition as per Paediatric ~~Implementation~~ Investigation Plan (PIP) decision, in 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} in one or more subsets of the paediatric population in {condition as per Paediatric

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~~Implementation~~ Investigation Plan (PIP) decision, in the granted indication} (see section 4.2 for information on paediatric use).>

[For medicinal products approved under "conditional approval", include the following statement:]
<This medicinal product has been authorised under a so-called 'conditional approval' scheme.
This means that further evidence on this medicinal product is awaited.
The European Medicines Agency will review new information on ~~the~~ this medicinal product at least every year and this SmPC will be updated as necessary.>

[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 European Medicines Agency will review any new information which may become available every year and this SmPC will be updated as necessary.>

5.2 Pharmacokinetic properties

~~*<Paediatric population>*~~

<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 subheadings 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 and development.>
<Effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.>
<Adverse reactions not observed in clinical studies, but seen in animals at exposure levels similar to clinical exposure levels and with possible relevance to clinical use were as follows:>

<Environmental Risk Assessment (ERA)>

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

[Name of the excipient(s) in the language of the text.]
[For advanced therapy medicinal products, preservative systems should be described.]
<None.>

6.2 Incompatibilities

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<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>.>

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 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 ~~<reconstituted> <diluted>~~ medicinal product, see section 6.3.>

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

[The proposed optional heading "~~-~~and special equipment for use, administration or implantation"~~-~~is for Advanced Therapy Products only.]
Explanatory illustrations may be included, if necessary.]
[Multipack presentations should also be listed in this section, e.g. "multipacks containing 180 (2 packs of 90) film-coated tablets".]

<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 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.>

7. MARKETING AUTHORISATION HOLDER

[Country name in the language of the text.]
{Name and address}
<{tel}>
<{fax}>
<{e-mail}>

8. MARKETING AUTHORISATION NUMBER(S)

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

[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.]

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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 SmPC has been notified or printed.
For type IA variations affecting the product information, the date of revision of the text should be the date of implementation of the change by the MAH. For more details please consult the post-authorisation Q&A guidance - Type IA variations.]
<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

<11. DOSIMETRY>

<12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS>

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

Detailed information on this medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu.

ANNEX II

A. <MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND> MANUFACTURER~~ING AUTHORISATION HOLDER~~(S) RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE~~OF THE MARKETING AUTHORISATION~~

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<C. OTHER CONDITIONS AND REQUIREMENTS OF ~~SPECIFIC OBLIGATIONS TO BE FULFILLED BY~~ THE MARKETING AUTHORISATION ~~HOLDER~~>

[Annex II will be completed in English by the European Medicines Agency at the time of adoption of the Opinion, ~~and will reflect the manufacturing site(s), legal status, specific obligations and other conditions (if any) as agreed by the CHMP.~~ ~~T~~Therefore, applicants are not to provide the Annex II in the English version of the Annexes as part of a new marketing authorisation~~product~~ application.

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Translations of the adopted Annex II in all languages are however to be included in the full set of translated Annexes as provided by the Applicant after Opinion, reflecting the adopted English Annex II.

~~Section C of Annex II is only applicable to Opinions adopted by the CHMP under "Exceptional Circumstances" or under "conditional approval" and for which Specific Obligations are to be fulfilled by the MAH.~~]

A. <MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND> MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

<Name and address of the manufacturer(s) of the biological active substance(s)

{Name and address}>

Name and address of the manufacturer(s) responsible for batch release

{Name and address}

[In cases where more than 1 manufacturer responsible for batch release is designated: , list all and add the following statement:]
<The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.>

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE OF THE MARKETING AUTHORISATION

- **CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IMPOSED ON THE MARKETING AUTHORISATION HOLDER**

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<Medicinal product subject to medical prescription.>
<Medicinal product not subject to medical prescription.>
<Medicinal product subject to special medical prescription.>
<Medicinal product subject to restricted medical prescription (See see Annex I: Summary of Product Characteristics, section 4.2).>
<Medicinal product subject to special and restricted medical prescription (see Annex I: Summary of Product Characteristics, section 4.2).>

- **<Official batch release** (only for Vaccines and Blood products)

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In accordance with Article 114 of Directive 2001/83/EC, the official batch release will be undertaken by a state laboratory or a laboratory designated for that purpose.>

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C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

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[If additional risk minimisation activities (e.g. controlled distribution, educational material, pregnancy prevention programmes) are proposed beyond those addressed in the product information, these should be listed here and, as required to ensure correct implementation by the Member States, also in an Annex IV addressed to the Member States. Any exception to this rule (e.g. set up of surveillance programmes in only a few MS) should be discussed and reflected in the CHMP AR]

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<Not applicable.>

- **OTHER CONDITIONS**

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Pharmacovigilance system

The MAH must ensure that the system of pharmacovigilance, ~~as described in version {insert version reference}~~ presented in Module 1.8.1~~.~~ of the Marketing Authorisation ~~<Application>~~, is in place and functioning before and whilst the medicinal product is on the market.

~~[Where outstanding items need to be resolved in the pharmacovigilance system before the medicinal product is put on the market, these should be listed as FUMs in the CHMP AR]~~

[Where a risk management plan has been submitted,]

~~<~~Risk Management Plan (RMP)~~>~~

<The MAH ~~commits to performing~~shall perform the ~~studies and additional~~ pharmacovigilance activities detailed in the Pharmacovigilance Plan <and the Efficacy Follow-up Plan>, as agreed in ~~version {insert version reference} of~~ the ~~Risk Management Plan (~~RMP~~)~~ presented in Module 1.8.2~~.~~ of the Marketing Authorisation ~~<Application>~~ and any subsequent updates of the RMP agreed by the Committee for Medicinal Products for Human Use (CHMP).~~>~~

[The actual studies and/or any additional pharmacovigilance activities to be performed by the MAH as part of the Pharmacovigilance Plan~~,~~ should be listed as FUMs in the CHMP AR.]

As per the CHMP Guideline on Risk Management Systems for medicinal products for human use, ~~any~~ the updated RMP should be submitted at the same time as the ~~following~~ next Periodic Safety Update Report (PSUR).

In addition, an updated RMP should be submitted:

- When new information is received that may impact on the current Safety Specification, Pharmacovigilance Plan or risk minimisation activities
- Within 60 days of an important (pharmacovigilance or risk minimisation) milestone being reached
- At the request of the European Medicines Agency.>

[Where no risk management plan has been submitted, this should be discussed and reflected in the CHMP AR.]

<Not applicable.>

<PSURs>

[~~e.g.~~ [PSURs: ~~Specify~~ specify requirements only if different from the normal PSUR cycle. For biosimilars and generics, it is required to specify the PSUR cycle.]

<The PSUR cycle for the medicinal product should follow the <standard requirements> <a <half->yearly cycle> until otherwise agreed by the CHMP.>

[For generics]

<The PSUR submission schedule should follow the PSUR submission schedule for the reference medicinal product.>

[For multiple MA not being a generic, as appropriate]

<The PSUR submission schedule should follow the PSUR submission schedule for the {cross-referred product}.>

~~[It is recommended that whenever possible the submission of the updated RMP be aligned with the PSUR cycle. Should this not be the case then the additional RMP update(s) request should be listed as FUMs in the CHMP AR]~~

~~[Where no risk management plan has been submitted, this should be discussed and reflected in the CHMP AR]~~

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~~[Vaccines and Blood products] <Official batch release: in accordance with Article 114 of Directive 2001/83/EC as amended, the official batch release will be undertaken by a state laboratory or a laboratory designated for that purpose.>~~

- **CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT**

[If additional risk minimisation activities (e.g. controlled distribution, educational material, pregnancy prevention programmes) are proposed beyond those addressed in the product information, these should be listed here and, as required to ensure correct implementation by the Member States, also in an Annex 127a addressed to the Member States. Any exception to this rule (e.g. set up of surveillance programmes in only a few MS) should be discussed and reflected in the CHMP AR.]

<Not applicable.>

- **<SPECIFIC OBLIGATION TO COMPLETE POST-AUTHORISATION MEASURES FOR <THE CONDITIONAL MARKETING AUTHORISATION> <THE MARKETING AUTHORISATION UNDER EXCEPTIONAL CIRCUMSTANCES>>**

[Conditions in relation to the conditional MA status should be distinguished from other conditions. List here all conditions in relation to the conditional MA, i.e. specific obligations subject to the annual renewal review. Please note that once these measures are considered fulfilled, the conditional MA will be 'switched' to a standard MA.]
<This being a conditional marketing authorisation and pursuant to Article 14(7) of Regulation (EC) No 726/2004, the MAH shall complete, within the stated timeframe, the following measures:>

[Conditions in relation to the MA under exceptional circumstances status should be distinguished from other conditions. List here all conditions in relation to the MA under exceptional circumstances ie specific obligations subject to annual re-assessment.]
<This being an approval under exceptional circumstances and pursuant to Article 14(8) of Regulation (EC) No 726/2004, the MAH shall conduct, within the stated timeframe, the following measures:>

Description	Due date

- **<OBLIGATION TO CONDUCT POST-AUTHORISATION MEASURES>**

[Conditions in relation to the conditional MA / MA under exceptional circumstances status should be distinguished from other conditions and should not be listed here. List here all conditions to the MA that are NOT related to the conditional MA / MA under exceptional circumstances.]
The MAH shall complete, within the stated timeframe, the following measures:

Description	Due date

~~**<C. SPECIFIC OBLIGATIONS TO BE FULFILLED BY THE MARKETING AUTHORISATION HOLDER**~~

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~~The Marketing Authorisation Holder shall complete the following programme of studies within the specified time frame, the results of which shall form the basis of the annual reassessment of the benefit/risk profile.~~

~~<Chemical, pharmaceutical and biological aspects>~~
~~<Toxicological and pharmacological aspects>~~
~~<Clinical aspects>~~

ANNEX III

LABELLING AND PACKAGE LEAFLET

[The lay-out of the labelling and package leaflet presented in this template is intended for the word document (Commission Decision Annex) 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 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.]

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[**N.B**.: boxed headings in Annex IIIA are provided to help applicants when completing the template; they should remain in the opinion/decision. 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 adoption by CHMP of a combined labelling text, the text does not need to be separated after adoption of the opinion.
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. Where applicants consider ~~to also~~ marketing a combined printed package leaflet, a detailed justification for such a combined package leaflet will have to be included ~~after the PL text and included~~ in the application at submission or at the latest at Day 121. The justification should take into account the QRD guidance as published in the "Compilation of QRD decisions on stylistic matters". Upon CHMP agreement (on a case-by-case basis) with a combined package leaflet text, the text does not need to be separated after adoption.
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 adoption of the opinion.
- All other language versions: at the latest 25 days after adoption of the opinion (i.e. at the latest after incorporation of Member States comments).

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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 ~~cart~~ card is to be included in the carton, then the text itself will have to be part of the product information (~~either~~ at the end of the last labelling component (e.g. vial)).] ~~or at the end of the package leaflet, whichever the MAH choice);~~

~~- In case where a patient alert cart is not to be included in the carton, then the text should not be part of the product information but only an appropriate reference in the SmPC and package leaflet should be included informing the doctor and the patient that such a card will be provided.]~~

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A. 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 (Annex IIIA).]

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

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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 SmPC under section 1.]
{Active substance(s)}

[The reference to the active substance should correspond to the strength expressed in the name~~.~~
~~E~~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).~~]

[Guidance on the expression of strength is available in the "QRD Recommendations on the Expression of Strength in the Name of Centrally Authorised Human Medicinal Product (as stated in section 1 of SmPC and in the name section of labelling and PL".]

[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~~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~~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~~e.g. for the examples given above: "60 mg toremifene (as citrate)" or "toremifene citrate equivalent to 60 mg toremifene"; "60 mg diltiazem hydrochloride". The statement should be based on the information on the active substance given in section 2 of the SmPC.]

[Where the advanced therapy medicinal product contains cells or tissues, the statement "~~"~~This ~~product~~ medicine contains cells of human/animal {as appropriate} origin"~~"~~ together with a short description of these cells or tissues and of their specific origin, including the species of animal in cases of non-human origin.]
<This ~~product~~ medicine contains cells of <human>~~ ~~<animal> origin.>

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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.
~~Additional excipients information (e.g. warnings) should be presented under this section and not under section 7.~~]

[For advanced therapy medicinal products, preservative systems should be described.]

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 or label: "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.".]

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.]

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

Keep out of the sight and reach ~~and sight~~ 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.).]

[In the case of advanced therapy medicinal products for autologous use, the unique patient identifier and the statement "~~-~~For autologous use only"~~-~~ shall be included.]

<For autologous use only.>

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~~e.g.: February 2007, Feb 2007, 02-2007. For advanced therapy medicinal products, the expiry date may specify the day.]

[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~~ Read the leaflet for the shelf life of the reconstituted medicine~~product~~".]

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.]

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~~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

[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)). Local representatives of the MAH, if mentioned in the leaflet, may be included in the 'Blue~~-~~Box' on the outer packaging.]

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

12. MARKETING AUTHORISATION NUMBER(S)

[Item to be completed by the Marketing Authorisation Holder once the Marketing Authorisation has been granted.]
[In case of a combined labelling text covering different pack sizes of the same strength, the respective pack size should be included in grey shading after the corresponding EU Sub-~~Number~~ number and listed on a separate line~~.~~

~~e.g.~~
e.g. EU/0/00/000/001 28 film-coated tablets
EU/0/00/000/002 56 film-coated tablets
EU/0/00/000/003 100 film-coated tablets]
For multipacks, clearly indicate the pack content for each marketing authorisation number, e.g. EU/X/XX/XXX/XXX 180 film-coated tablets (2 packs of 90).]

EU/0/00/000/000

13. BATCH NUMBER<, DONATION AND PRODUCT CODES>

[For terms on Batch number and Expiry date, see Appendix IV.]
[The proposed optional heading "~~-~~DONATION AND PRODUCT CODES"~~-~~ is for Advanced Therapy Products only.]
[For Advanced Therapy Products, Donation and Product codes should be included.]

14. GENERAL CLASSIFICATION FOR SUPPLY

[The following statements are optional. This section may be left blank.]

<Medicinal product subject to medical prescription.>
<Medicinal product not subject to medical prescription.>

15. INSTRUCTIONS ON USE

[Only for medicinal products **not subject** to medical prescription, include:
~~5.~~ Indication(s).
~~6.~~ Dos~~ag~~e 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".
~~s~~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 CHMP
~~-~~]

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~~ see also the "Guideline on the Readability of the Labelling and Package Leaflet of

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Medicinal Products for Human Use" as published by the European Commission in the Notice ~~To~~ to Applicants, Volume 2C) ~~; http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol2_en.htm~~.]

[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 CHMP, the following statement should be included in this section in grey shading:

<Justification for not including Braille accepted>.]

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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 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

{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<, DONATION AND PRODUCT CODES>

[For terms on Batch number and Expiry date, see Appendix IV.]
[The proposed optional heading "DONATION AND PRODUCT CODES" is for Advanced Therapy Products only.]
[For Advanced Therapy Products, Donation and Product codes should be included.]

5. OTHER

[Space permitting, any other information necessary for the correct use and administration of the medicinal product can be included here, e.g. Cealendar days may be included if the product is taken as a single dose and that is packaged in blister strips that comprise multiples of seven.]

[In the case of advanced therapy medicinal products for autologous use, the unique patient identifier and the statement "For autologous use only" shall be included.]
<For autologous use only.>

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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 ~~be~~ feasible to include all the information. Such exceptional cases have to be justified, discussed and agreed with the Competent Authority/European Medicines Agency.
In case of radiopharmaceuticals the vial should be labelled in accordance to the article 66(3) of Directive 2001/83.]

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

{(Invented) name strength pharmaceutical form}
{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 "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.]

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[Where different labels apply to different constituents of the ~~pharmaceutical form~~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).]

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[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}>]

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

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3. EXPIRY DATE

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

[Where applicable and if 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).]

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4. BATCH NUMBER<, DONATION AND PRODUCT CODES>

[For terms on Batch number and Expiry date see Appendix IV.]
[The proposed optional heading "DONATION AND PRODUCT CODES" is for Advanced Therapy Products only.]
[For Advanced Therapy Products, Donation and Product codes should be included]

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 medicinal product can be included here, e.g. storage conditions.]

[In the case of advanced therapy medicinal products for autologous use, the unique patient identifier and the statement "For autologous use only" shall be included.]
<For autologous use only.>

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B. 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 the case of advanced therapy ~~medicinal products~~medicines, these items are listed in Annex IV of Regulation (EC) 1394/2007.

~~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 package leaflet must be readable for the patient; please refer to 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~~ to Applicants, Volume 2C:
http://ec.europa.eu/health/files/eudralex/vol-2/c/2009_01_12_readability_guideline_final_en.pdf
~~http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol2_en.htm~~
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 ~~medicinal product~~medicine.

Headings and ~~Standard~~ standard statements ~~are~~ given in the template ~~which~~ must be used whenever they are applicable. If the applicant needs to deviate from these headings/statements to accommodate ~~product~~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).

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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).

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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 alternatives formats.]

Package leaflet: Information for the <patient> <user>
~~**PACKAGE LEAFLET: INFORMATION FOR THE USER**~~

[Heading to be printed]

{(Invented) name strength pharmaceutical form}

{Active substance(s)}

[The (invented) name of the medicine~~nal product~~ (referred to as "this medicine" ~~X~~ throughout ~~this document~~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 in lower case without bold or underline and should not be used excessively throughout the text.]

[For medicines~~nal products~~ 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 ~~symptoms~~ are the same as yours.> [Do not include this statement in case of hospital use.]
- If you get any ~~of the~~ side effects ~~gets serious, or if you notice any~~, talk to your <doctor> <,> <or> <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet~~, please tell your <doctor> <or> <pharmacist>~~.>

[For medicines~~nal products~~ 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.

~~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 you get any ~~of the~~ side effects ~~gets serious, or if you notice any~~, talk to your <doctor> <,> <or> <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet~~, please tell your <doctor> <or> <pharmacist.>~~.>
- You must talk to a doctor if you do not feel better or if you feel worse <after {number of} days>.>

What is ~~I~~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).]

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6. Contents of the pack and other ~~Further~~ information

1. What X is and what it is used for~~HAT X IS AND WHAT IT IS USED FOR~~

[Invented name, active substance(s) and ~~[P~~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).]
~~here using patient understandable language.]~~

[Therapeutic indications~~.~~]
[The therapeutic indications in line with section 4.1 of the SmPC should be stated here~~, using patient understandable language~~. 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>".]

[If appropriate, specify that:~~]~~
~~<This medicine is for diagnostic use only.>~~
~~- [i~~If the medicine is an advanced therapy ~~medicinal product~~medicine which contains cells or tissues, a description of those cells or tissues and of their specific origin, including the species of animal in cases of non-human origin, should be provided in line with section 2.1 of the SmPC.~~]~~
~~[- i~~If the medicine is an advanced therapy ~~medicinal product~~medicine which contains medical devices or active implantable medical devices, a description of those devices and their specific origin~~,~~ should be provided in line with section 2.2 of the SmPC.]

[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 subheading, 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>.>.]

~~1.~~2. What you need to know before you <take> <use> X ~~BEFORE YOU <TAKE> <USE> X~~

~~*[Additional sub-headings within the headings given below may be included if needed to increase readability, e.g. for information to particular category of users .]*~~

~~*[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 according to information given in the SmPC); special patient populations, e.g. patients with renal or hepatic impairment.]*~~
[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

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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 ~~(hypersensitive)~~ to {active substance(s)} or any of the other ingredients of this medicine (listed in section 6)~~X~~.> [include reference to residues, if applicable.]

~~- <if...>~~

~~*[Give information on absolute contraindications here in accordance with the SmPC; 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.]

Warnings and precautions ~~Take special care with X~~

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, 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.]

~~- <if you ...>~~

~~- <when ...>~~

~~- < Before treatment with X, …>~~

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

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/teenager 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>".]

[Interactions with other medicinesnal products.]
<Taking> <Using> oOther medicines and X
[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 tTell your <doctor> <or> <pharmacist> if you are <taking> <using>, or have recently <taken> <used> or might <take> <use> any other medicines., including medicines obtained without a prescription.>

[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><side 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 SmPCwhere necessary.]

[Interactions with food and drink.]
<Taking> <Using> X with <food> <and> <,> <drink> <and> <alcohol>
[Interactions not related to medicinal productsmedicines 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.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, information on fertility.]
Pregnancy <and> <,> breast-feeding <and fertility>
[Where the information is significantly different, pregnancy, and 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, Aask your <doctor> <or> <pharmacist> for advice before taking any 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 iInformation on teratogenicity in patient understandable language, should be included in the leaflet when the product is contra-indicated during pregnancywhere 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.]
~~<Do not drive <because...>.>~~
~~<Do not use any tools or machines.>~~

[Excipients warnings~~.~~]
~~**Important information about some of the ingredients of <**~~**X contains {name the excipient(s)}>**
[If appropriate, warnings~~details~~ of those excipients knowledge of which is important for the safe and effective use of the ~~medicinal product~~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), ~~including relevant warnings for residues from the manufacturing process~~ 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).]

2.3. How to <take> <use> X~~OW TO <TAKE> <USE> X~~
~~[Additional sub-headings within the headings given below may be included if needed to increase readability.]~~

~~[Instructions for proper use.]~~
[In simple cases, t~~T~~he following ~~4~~ 3 items can be combined as one paragraph.]

[Dose~~age.~~ (SmPC section 4.2)]
[For medicines available on prescription only:]
<Always <take> <use> ~~X~~ this medicine exactly as your doctor <or pharmacist> has told you. ~~You should e~~Check with your <doctor> <or> <pharmacist> if you are not sure.> ~~<The usual dose is...>~~

<The recommended dose is ...>

[For medicines available without prescription:]
<Always <take> <use> this medicine exactly as described in this leaflet or as your <doctor> <,> <or> <pharmacist> <or nurse> <has> <have> told you. Check with your <doctor> <or> <,> <pharmacist> <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 ~~Method and/or route(s)~~ of administration (SmPC section 4.2)~~.~~]

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[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 ~~medicinal product~~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").
~~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.]
<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.>

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

[Duration of treatment (SmPC section 4.2)~~.~~]
[If appropriate, especially for ~~products~~ 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:]
~~[Symptoms in case of overdose and actions to be taken.]~~
<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.]

~~*[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 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.]
~~*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 withdrawal~~any~~ effects and how to minimise them as per SmPC section(s) 4.2 and/or 4.4.
~~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 or nurse should be included as appropriate ~~in patient understandable language~~.]
~~[Indicate withdrawal effects when the treatment ends, when necessary.]~~
[~~As appropriate, c~~Close this section with:]

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

4. Possible side effects~~OSSIBLE SIDE EFFECTS~~

[Description of side effects.]
[Begin this section with:]
Like all medicines, ~~X~~ 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) summary safety profile as per section 4.8 of the SmPC: 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), together with the most frequently occurring side effects.

2) then a list of all other side effects (without repeating the most serious and most frequent included above).

Within each section, 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.]
~~*[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 you get any ~~of the~~ side effects, ~~gets serious, or if you notice any~~ talk to your <doctor> <or> <,> <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet~~, please tell your <doctor> <or> <pharmacist>~~.

5. How to store X~~OW TO STORE X~~

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

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[Expiry date.]
[Where a specific abbreviation for Expiry date is used on the labelling, the full termit should be mentioned here as well as the abbreviation.]
Do not use X 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; fFor Storage 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 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 X this medicine if you notice {description of the visible signs of deterioration}.>

< Do not throw away any medicines Medicines should not be disposed of via wastewater <or household waste>. Ask your pharmacist how to throw away dispose of medicines you no longer requireduse. These measures will help to protect the environment.>

6. Contents of the pack and other information 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 sections 2 and 6.1 of the SmPC and in the language of the text, e.g.]
- The active substance(s) is (are)… [e.g. "Each <tablet> <capsule> contains x <gram> <milligram>…{active substance}".]
- [see guidance in section 2 of outer packaging.]
- The other <ingredient(s)> <(excipient(s))> is (are)... [A cross-reference to section 2 "X contains {name the excipients}" should be included when applicable.] 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 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.]

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

Marketing Authorisation Holder and Manufacturer

{Name and address}
<{tel}>
<{fax}>
<{e-mail}>
[State the name and address of the Marketing Authorisation Holder as per section 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, 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 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 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.]

[List of local representatives, where applicable.

- Listing of local representatives is not a requirement, but where used they must be stated for all Member States. However, a representative may be designated for more than one country and may also be the MAH where no other local representative is indicated.
  In cases where the same representative is designated for more than one country, the representative's details may be listed only once below the names of the countries concerned.
- Where a local representative is located outside the country concerned and where an address is given, the country name must be included in the address of the local representative and must be given in the language(s) of the country(ies) for which the local representative is designated.
- ISO country codes* may be used to replace the full name of the country heading. ISO codes together with the respective names of EU/EEA countries can be found at the following web site: http://publications.europa.eu/code/en/en-370100.htm
- In order to save space in the printed package leaflet, local representatives may be presented sequentially rather than in a tabulated format. In case of multi-lingual leaflets, the list of local representatives can be printed only once at the end of the printed leaflet.
- The local representative may be indicated by name, telephone number and electronic e-mail address (optional) only. Postal address may be added space permitting. Website addresses or e-mails linking to websites are not allowed.
- If a representative is outside the relevant country, indicate the name of the country.
- For Belgium (Brussels) and Finland (Swedish speaking Finland) addresses may appear in two languages, respectively Dutch/French and Finnish/Swedish.
- For Greece and Cyprus, the address must appear in Greek.

Telephone numbers: international dialling code followed by the area code and telephone number, e.g. European Medicines Agency Tel: + 44-(0)20 7418 8400.]

*[except for the United Kingdom, for which UK is recommended (instead of the ISO code GB).]

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

België/Belgique/Belgien
{Nom/Naam/Name}
<{Adresse/Adres/Anschrift }

Luxembourg/Luxemburg
{Nom}
<{Adresse}

B-0000 {Localité/Stad/Stadt}>
Tél/Tel: + {N° de téléphone/Telefoonnummer/ Telefonnummer}
<{e-mail}>

България
{Име}
<{Адрес}
{Град} {Пощенски код}>
Тел.: + {Телефонен номер}
<{e-mail}>

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Tel: + {Teléfono}
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France
L-0000 {Localité/Stadt}>
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Italia
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{Ime}
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SI-0000 {Mesto}>
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{Meno}
<{Adresa}
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S-000 00 {Stad}>
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This leaflet was last revised in~~approved in~~ <{MM/YYYY}> <{month YYYY}.>
[Date of granting of the Marketing Authorisation/approval of latest variation or transfer (as per section 9 or 10 of the SmPC), e.g. the latest Commission Decision, implementation date of the Urgent Safety Restriction or date of ~~the~~ European Medicines Agency letter/notification. Item to be completed by the Marketing Authorisation Holder at time of printing.]

[For ~~products~~ medicines approved under "conditional approval", include the following statement:]

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<This medicine has been given ‘‘conditional approval’’.
This means that there is more evidence to come about this medicine.
The European Medicines Agency will review new information on the this medicine at least every year and this leaflet will be updated as necessary.>

[For products medicines approved under “exceptional circumstances”, include the following statement:]
<This medicine has been authorised under ‘‘Eexceptional cCircumstances’’.
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 European Medicines Agency will review any new information on the 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.
- Reference to the European Medicines Agency website:

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu. <There are also links to other websites about rare diseases and treatments.> [tThe last part of the statement is applicable to orphan medicinal medicinesproducts only.]

[For medicines having been granted an exemption of having English only labelling/package leaflet according to Art 63 of Directive 2001/83/EC, as amended, the following statement translated in all EU languages should be included here:
<This leaflet is available in all EU/EEA languages on the European Medicines Agency website.>
this information should appear prominently in the printed material.]

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

[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:

~~[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 SmPC as a separate document in the product medicine package, 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.

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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 Annex III B 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~~product~~. The product information must be presented in an identical way in all EU languages.]

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