ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

[NOTE: the following are those items of information required by Article 11 of Directive 2001/83/EC 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 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/health/files/eudralex/vol-2/c/smpc_guideline_rev2_en.pdf
This guidance should also be read in conjunction with other relevant guidelines that can be found on the European Medicines Agency website (e.g. "QRD Convention to be followed for the EMA-QRD templates":
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500005091.pdf).

The use of combined SmPCs for different strengths of the same pharmaceutical form is encouraged (for evaluation and after the adoption of the opinion for all languages) when the SmPCs are completely identical, except for the few strength-specific details (e.g. if the indications are different for the different strengths, the SmPCs cannot be combined). In case of combined terms, only the primary pharmaceutical form should be considered, e.g. "solution for injection in a vial" and "solution for injection in a pre-filled syringe" can be combined. No justification will be required, provided the above conditions are met. See "Policy on combined SmPCs" for full details of the process:
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2015/06/WC500187787.pdf.

For different strengths not meeting the criteria above (e.g. if the indications are different for the different strengths), applicants may present SmPCs for different strengths in one document for the evaluation process only, clearly indicating with 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 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/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004182.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:
{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

[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 Products (as stated in section 1 of SmPC and in the name section of labelling and PL".]

{(Invented) name strength pharmaceutical form}

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

[For advanced therapy medicinal 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 sub-headings shall be included:

<2.1 General description> [For advanced therapy medicinal products only]

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

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

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 doses.>

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

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

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} <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] <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. 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

[For biological medicinal products, include the following statement:]
<Traceability
In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.>

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

<Pregnancy>
<Breast-feeding>
<Fertility>

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.]

[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".]

<Paediatric population>

[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: No reference to Appendix V should be included in the printed materials. The above grey-shaded terms will only appear in the published version of the approved product information annexes on the European Medicines Agency website. The actual details of the national reporting system (as listed in Appendix V) of the concerned Member State(s) shall be displayed on the printed version. Linguistic adjustments may also be necessary depending on the grammatical rules of the languages used.]

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 products 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 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}> [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 "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 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.>

[For generic medicinal products, if the reference medicinal product has been approved under "exceptional circumstances", include the following statement:]
<The reference medicinal product containing {active substance} 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 the reference 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 accordingly to the reference medicinal product SmPC.>

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 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

<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 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 medicinal 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)

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}>

[For the initial authorisation, the date should correspond to the initial date of the Commission Decision on the marketing authorisation of the medicinal product concerned. It should not reflect individual strength/presentation approvals introduced via subsequent variations and/or extensions.

For the (conditional) renewal, the date should correspond to the actual date of the Commission Decision on the (conditional) renewal of the marketing authorisation.]

10. DATE OF REVISION OF THE TEXT

[Item to be completed by the Marketing Authorisation Holder (MAH) 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 type II variations listed in Article 23(1a)(a), the date of revision of the text should be the date of the Commission Decision amending the marketing authorisation.
For type II variations not listed in Article 23(1a)(a), which follow a yearly timeframe for update of the respective Commission Decision, the date of revision of the text should be the date of the adoption of the positive CHMP opinion on the variation to the terms of the marketing authorisation. For more details, please consult the post-authorisation Q&A guidance.]

<{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<, and on the website of {name of Member State Agency (link)}>.*

[*The last part of the statement is optional, and **it is only to be displayed on the final printed materials**. It will not be included in the product information annexes as applicants may choose to include it for one or more Member States but not for all of them.]

ANNEX II

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

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

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

[Annex II reflects the CHMP opinion on conditions and specific obligations, if/as applicable, to be imposed on the marketing authorisation. To facilitate the review, applicants should complete this Annex and present a draft together with the SmPC, labelling and package leaflet when submitting their product information as part of the marketing authorisation application. The final content of Annex II will be determined by the CHMP as a result of the assessment of the application.]

A. <MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND> MANUFACTURER(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

<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 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)

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.>

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

- **Periodic safety update reports (PSURs)**

[For medicinal products authorised as conditional marketing authorisation (CMA), please use the below statement.]

<The requirements for submission of PSURs for this medicinal product are set out in Article 9 of Regulation (EC) No 507/2006 and, accordingly, the marketing authorisation holder (MAH) shall submit PSURs every 6 months.>

[For all medicinal products, including CMA in addition to the above paragraph, please use the below statement.]
The requirements for submission of PSURs for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

[In addition, for initial MAA for which the 1st PSUR has a data lock point within 6 months after the Commission Decision, please select the below statement as well.]
<The marketing authorisation holder (MAH) shall submit the first PSUR for this product within 6 months following authorisation.>

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

- **Risk management plan (RMP)**

The marketing authorisation holder (MAH) shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the marketing authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:

- At the request of the European Medicines Agency;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

[When justified on a proportional risk-based approach, the CHMP could specify the deadline for the submission of the next update to the RMP. In that case, please include:]
<An updated RMP shall be submitted by {CHMP agreed deadline}.>

- **<Additional risk minimisation measures>**

[All additional risk minimisation measures and their key messages to be added here. The template for this section is included in the *Guidance on the format of the risk management plan (RMP) in the EU - in integrated format - Annex 6 - Details of proposed additional risk minimisation activities* on the European Medicines Agency website at https://www.ema.europa.eu/human-regulatory/marketing-authorisation/pharmacovigilance/risk-management/risk-management-plans).
Leave blank if no additional risk minimisation measures are proposed in the RMP.]

- **<Obligation to conduct post-authorisation measures**

The MAH shall complete, within the stated timeframe, the below measures:
[All post-authorisation measures that are imposed as a condition to the marketing authorisation to be listed here.
Where appropriate, please specify any proposed post-authorisation measure and whether the measure is a post-authorisation efficacy study (PAES) in accordance with the Commission Delegated Regulation (EU) No 357/2014.
For a post-authorisation safety study (PASS), please state clearly in the study description if non-interventional.
Due date: please only include the projected time point of the final study report. The exact milestones regarding protocol submission/agreement and interim reports should be detailed in the RMP.]

Description	Due date
<Post-authorisation efficacy study (PAES): [study title or description] >	
<Non-interventional post-authorisation safety study (PASS): [study title or description]>>	

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

[To be filled in only in case a conditional marketing authorisation or marketing authorisation under exceptional circumstances is being applied for.]
<This being a conditional marketing authorisation and pursuant to Article 14-a of Regulation (EC) No 726/2004, the MAH shall complete, within the stated timeframe, the following measures:

<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:
[All specific obligations to be listed here.
For a PASS, please state clearly in the study description if non-interventional.
Due date: please only include the projected time point of the final study report. The exact milestones regarding protocol submission/agreement and interim reports should be detailed in the RMP.]

Description	**Due date**
<Non-interventional post-authorisation safety study (PASS: [study title or description]>>	

ANNEX III

LABELLING AND PACKAGE LEAFLET

[The lay-out of the labelling and package leaflet presented in this template is intended for the Word/PDF 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 "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/health/files/eudralex/vol-2/c/2009_01_12_readability_guideline_final_en.pdf.]

[**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 the 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 marketing a combined printed package leaflet, a detailed justification for such a combined package leaflet will have to be 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).

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)).]

[Mobile technologies:
A mobile technology feature may be included in the packaging material and/or the package leaflet, and its location should take into account the overall readability.
Reference to the mobile technology should be made in Annex IIIA and/or IIIB as "name of the mobile technology" (grey-shaded text) and followed by the corresponding URL, i.e. "{name of mobile technology} + {URL}".
The actual information provided through the mobile technology feature will determine the specific section of the Annexes IIIA and/or IIIB where the reference above should be made (e.g. under 'method of administration' in the case of a video showing how the medicinal product should be administered).]

A. 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. The order of presentation of the different packaging labelling elements should be sequential, i.e. for each strength and pharmaceutical form the outer packaging component should be included first followed by its corresponding inner packaging component.
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).]

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} [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.g. (invented) name 60 mg capsules
toremifene
(since 60 mg corresponds to toremifene, even if the active substance is actually present as toremifene citrate).]

[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.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 also be presented separated by a "/". The order of active substances and corresponding strengths should follow the order of the WHO classification,
e.g. (invented) name 150 mg/12.5 mg tablets
irbesartan/hydrochlorothiazide]

2. STATEMENT OF ACTIVE SUBSTANCE(S)

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

[The pharmaceutical form patient-friendly term can be used in case of space constraints, e.g. "Each tablet contains…" instead of "Each film-coated tablet contains…".]

[Where the advanced therapy medicinal product contains cells or tissues, the statement "This 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 medicine contains cells of <human> <animal> origin.>

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.
The list of excipients can be merged with the statement of active substance in the printed materials if this helps improve readability, e.g. "Each capsule contains 60 mg toremifene (as citrate) and lactose monohydrate".]

[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.]

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.).]

[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.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 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.]

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

[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.]

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

12. MARKETING AUTHORISATION NUMBER(S)

[Item to be completed by the MAH 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 and listed on a separate line,
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 medicinal products only.]
[For advanced therapy medicinal products, donation and product codes should be included.]

14. GENERAL CLASSIFICATION FOR SUPPLY

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 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. There is no need to include the pharmaceutical form if there is only one (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 exclusion should be provided in module 1.3.6. Upon agreement by the CHMP, the following statement should be included in this section in grey-shading:
<Justification for not including Braille accepted.>.]

17. UNIQUE IDENTIFIER – 2D BARCODE

[A 2D barcode carrying the unique identifier has to be included on the packaging of products in order to fulfil the requirement of Article 54a(1) or Article 54a(5) of Directive 2001/83/EC. The following statement should be included in this section in grey-shading:
<2D barcode carrying the unique identifier included.>]

[For those products not required to have the unique identifier as per Article 54a(1) or Article 54a(5) of Directive 2001/83/EC, the following statement should be included in this section in grey-shading:
<Not applicable.>]

[When this template is used for immediate labelling, this section must be included and left blank.]

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

[The data elements of the unique identifier should be printed in human readable format on the packaging of products in order to fulfil the requirement of Article 54a(1) or Article 54a(5) of Directive 2001/83/EC. The abbreviations to be used, if applicable, are provided below:]

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

[For those products not required to have the unique identifier as per Article 54a(1) or Article 54a(5) of Directive 2001/83/EC, the following statement should be included in this section in grey-shading:
<Not applicable.>]

[When this template is used for immediate labelling, this section must be included and left blank.]

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 MAH.]

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 medicinal products only.]
[For advanced therapy medicinal 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. calendar 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.>

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/European Medicines Agency.
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}
{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":
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_proceduralguideline/2009/10/WC500004439.pdf where you can find the list of abbreviations to be used for the 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 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).]

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 medicinal products only.]
[For advanced therapy medicinal 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.>

B. PACKAGE LEAFLET

[**NOTE**: the following items must appear in the package leaflet as required by Title V of Directive 2001/83/EC. In the case of advanced therapy medicines, these items are listed in Annex IV of Regulation (EC) 1394/2007.
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 Applicants, Volume 2C:
http://ec.europa.eu/health/files/eudralex/vol-2/c/2009_01_12_readability_guideline_final_en.pdf
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, MAHs 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. MAHs 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}
{active substance(s)}

[The (invented) name of the medicine (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>.>

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).]

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>".]

[If appropriate, specify that:
- if the medicine is an advanced therapy 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.
- if the medicine is an advanced therapy 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 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 (painkiller, 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/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 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><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 SmPC.]

[Interactions with food and drink]
X with <food> <and> <,> <drink> <and> <alcohol>
[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 <and fertility>
[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 {name the 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).]

3. How to <take> <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 <take> <use> this medicine exactly as your doctor <or pharmacist> has told you. Check with your <doctor> <or> <pharmacist> if you are not sure.>

<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 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 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: No reference to Appendix V should be included in the printed materials. The above grey-shaded terms will only appear in the published version of the approved product information annexes on the European Medicines Agency website. The actual details of the national reporting system (as listed in Appendix V) of the concerned Member State(s) shall be displayed on the printed version.
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.

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

Malta
{Isem}
<{Indirizz}
MT-0000 {Belt/Raħal}>
Tel: + {Numru tat-telefon}
<website>
<{e-mail}>]

5. How to store X

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 sections 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.]

[Pharmaceutical form, nature and contents of container in weight, volume or units of dose]
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 MAH and of the manufacturer 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 MAH 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 if included in the product information annexes, the full list for all Member States must be stated. 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.
- In the printed package leaflet, only the concerned local representative can be mentioned provided the whole list has been included in the product information annexes.
- 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: + 31 (0)88 781 6000.]

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

Lietuva
{pavadinimas}
<{adresas}
LT {pašto indeksas} {miestas}>
Tel: + {telefono numeris}
<{e-mail}>

България
{Име}
<{Адрес}

Luxembourg/Luxemburg
{Nom}
<{Adresse}

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

Česká republika
{Název}
<{Adresa}
CZ {město}>
Tel: +{telefonní číslo}
<{e-mail}>

Danmark
{Navn}
<{Adresse}
DK-0000 {by}>
Tlf: + {Telefonnummer}
<{e-mail}>

Deutschland
{Name}
<{Anschrift}
D-00000 {Stadt}>
Tel: + {Telefonnummer}
<{e-mail}>

Eesti
{Nimi}
<{Aadress}
EE - {Postiindeks} {Linn}>
Tel: + {Telefoninumber}
<{e-mail}>

Ελλάδα
{Όνομα}
<{Διεύθυνση}
GR-000 00 {πόλη}>
Τηλ: + {Αριθμός τηλεφώνου}
<{e-mail}>

España
{Nombre}
<{Dirección}
E-00000 {Ciudad}>
Tel: + {Teléfono}
<{e-mail}>

France
{Nom}
<{Adresse}
F-00000 {Localité}>
Tél: + {Numéro de téléphone}
<{e-mail}>

Hrvatska
{Ime}
<{Adresa}
{Poštanski broj} {grad}>

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

Magyarország
{Név}
<{Cím}
H-0000 {Város}>
Tel.: + {Telefonszám}
<{e-mail}>

Malta
{Isem}
<{Indirizz}
MT-0000 {Belt/Raħal}>
Tel: + {Numru tat-telefon}
<{e-mail}>

Nederland
{Naam}
<{Adres}
NL-0000 XX {stad}>
Tel: + {Telefoonnummer}
<{e-mail}>

Norge
{Navn}
<{Adresse}
N-0000 {poststed}>
Tlf: + {Telefonnummer}
<{e-mail}>

Österreich
{Name}
<{Anschrift}
A-0000 {Stadt}>
Tel: + {Telefonnummer}
<{e-mail}>

Polska
{Nazwa/ Nazwisko:}
<{Adres:}
PL – 00 000{Miasto:}>
Tel.: + {Numer telefonu:}
<{e-mail}>

Portugal
{Nome}
<{Morada}
P-0000–000 {Cidade}>
Tel: + {Número de telefone}
<{e-mail}>

România
{Nume}
<{Adresă}
{Oraş} {Cod poştal} – RO>

Tel: + {Telefonski broj}
<{e-mail}>

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

Ísland
{Nafn}
<{Heimilisfang}
IS-000 {Borg/Bær}>
Sími: + {Símanúmer}
<{Netfang }>

Italia
{Nome}
<{Indirizzo}
I-00000 {Località}>
Tel: + {Numero di telefono}
<{e-mail}>

Κύπρος
{Όνομα}
<{Διεύθυνση}
CY-000 00 {πόλη}>
Τηλ: + {Αριθμός τηλεφώνου}
<{e-mail}>

Latvija
{Nosaukums}
<{Adrese}
{Pilsēta}, LV{pasta indekss }>
Tel: + {telefona numurs}
<{e-mail}>

Tel: + {Număr de telefon}
<{e-mail}>

Slovenija
{Ime}
<{Naslov}
SI-0000 {Mesto}>
Tel: + {telefonska številka}
<{e-mail}>

Slovenská republika
{Názov}
<{Adresa}
SK-000 00 {Mesto}>
Tel: + {Telefónne číslo}
<{e-mail}>

Suomi/Finland
{Nimi/Namn}
<{Osoite/Adress}
FIN-00000 {Postitoimipaikka/Stad}>
Puh/Tel: + {Puhelinnumero/Telefonnummer}
<{e-mail}>

Sverige
{Namn}
<{Adress}
S-000 00 {Stad}>
Tel: + {Telefonnummer}
<{e-mail}>

United Kingdom (Northern Ireland)
{Name}
<{Address}
{Town} {Postal code} – UK>
Tel: + {Telephone number}
<{e-mail}>>

This leaflet was last revised 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 or the latest favourable CHMP opinion, as applicable, implementation date of the Urgent Safety Restriction or date of European Medicines Agency letter/notification. Item to be completed by the MAH at time of printing. If the regulatory procedure does not affect the leaflet, this date does not need to be changed.]

[For medicines approved under "conditional approval", include the following statement:]
<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 this medicine at least every year and this leaflet will be updated as necessary.>

[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 European Medicines Agency will review any new information on this medicine every year and this leaflet will be updated as necessary.>

[For generic medicines, if the reference medicinal product was approved under "exceptional circumstances", include the following statement:]
<X contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU. The reference medicine for X has been authorised under 'exceptional circumstances'. This means that <because of the rarity of this disease><due to scientific reasons> <due to ethical reasons> it has been impossible to get complete information on the reference medicine. The European Medicines Agency will review any new information on the reference medicine every year and any updates for the reference medicine will also be included as appropriate in the information for X, such as this leaflet.>

<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<, and on the website of {name of Member State Agency (link)}>.* <There are also links to other websites about rare diseases and treatments.> [the last part of the statement is applicable to orphan medicines only.]

[*This statement is optional, and **it is only to be displayed on the final printed materials**. It will not be included in the product information annexes as applicants may choose to include it for one or more Member States but not for all of them.]

[For medicines having been granted an exemption of having English only package leaflet according to Art 63 of Directive 2001/83/EC, the following statement translated in all EU/EEA 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:

<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 package leaflet,

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 Annex IIIB 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. The product information must be presented in an identical way in all EU/EEA languages.]