EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 August 2025

Submission of comments on draft QRD annotated template v11

Comments from:

Name of organisation or individual
Inter-association Task force on ePI (IATF) (Collaboration of AESGP, EFPIA and Medicines for Europe)

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.
When completed, this form should be sent to qrd@ema.europa.eu electronically, in Word format (not PDF).

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1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	**Outcome (if applicable)** ***(To be completed by the Agency)***
	We appreciate that many of the recommendations shared by the IATF, based on interactions with patients, patient representatives, carers and user testing companies, were reflected in the proposal for the revision of the template.	
	We see this current revision as an interim update, awaiting more holistic revision in future to further reduce the length of the package leaflet to improve readability and patient experience as well as to support implementation of multilingual packs to support supply and access to medicines. We acknowledge that this revision must comply with the current Directive and that not all improvements envisaged were possible to introduce at this time. We welcome public consultation on a further revision to the QRD template once the revised pharmaceutical legislation is adopted. This next revision would be expected to include proposals for the information for patients on antimicrobial resistance (AMR) and appropriate use and disposal of antimicrobials. Standard statements should be proposed, and it should also be clarified in the QRD template that the AMR awareness statements for patients are optional for products for hospital use only or administered by health care professionals only. It should also be clarified how to integrate this information into the package leaflet to avoid duplication.	
	Some of the changes proposed may not be possible within the current legislative framework, but we are supportive of these changes and aim to make these possible with the change of the pharmaceutical legislation.	

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	Length of PL The length of the PL has been identified as a recurrent issue. We therefore welcome the two proposals which aim to address this (deletion of introductory bullets, optional table of contents). However, these proposals do not fully address the issue. Additional opportunities to reduce the length of the PL by removing repetitions which do not provide value should also be considered. See for example our comment on line 1409-1412. At the same time, proposals to add or lengthen sentences in the QRD template (now and in future) should be limited to those that provide added value for the patient, and they should be carefully formulated to minimize their impact on the length of the PL. See for example our comment on line 1384-1386. Further work on the QRD template is still required to reduce the length of the PL to contribute to improved readability of the PL and patient experience, as well as to aid implementation of multilingual packs to support supply and access to medicines.	

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	With the anticipated release and implementation of EMA's ePI development, the QRD template's role in structuring information will become even more critical. A future revision of the QRD template once the revised pharmaceutical legislation is adopted should further advance usage and standardization of structured data elements including standard statements, subheadings, and further choices of standard terms (meaning those choices currently given in <> brackets). QRD template and ePI could be further developed to support structured data elements for national information (e.g. reporting contact points and other blue box requirements). Lastly, under the revised pharmaceutical legislation the requirements for providing access to the electronic package leaflet and these digital requirements can be considered in the future QRD template revision. For the time being while we await finalization of the legislation it is important that the existing policy for mobile and digital scanning is maintained and kept flexible to support a smooth transition.	

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	Implementation: In light of the several upcoming changes impacting product information in the near to mid-term, pragmatic transitional arrangements are needed for this QRD template revision. Further changes are foreseen with the adoption of the revised pharmaceutical legislations, the EMA ePI development as well as legislation such as the Packaging and Packaging Waste Regulation. Management of deadlines for requirements is highly critical for product information changes, especially printed materials and can have an impact on supply. It is important to have sufficient time for implementation, with avoidance of the need for a large number of notifications or variations. Products referring to a reference product should be allowed to await the change of the reference product to avoid duplication of assessment. The implementation of ePI should be taken into consideration, and options for a more automated update should be explored. As mentioned, the revision of the General Pharmaceutical Legislation (GPL) may also lead to changes in the template, sufficient transitional time should be given to avoid a significant version update shortly after implementation of the update to Version 11. In light of the above and to avoid repeated update of the leaflet, notably for older products which leaflet does not often change, we propose to adopt a 5 year timeline for the implementation by which time all leaflets will have had to be brought into conformity with the QRD template rev 11, or when already available, allow for direct change into version 12 (due to the revised GPL). To support supply continuity, batch release of medicinal products with package leaflets printed according to the previous QRD templates should be permitted to continue until stocks have been exhausted.	

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	Formatting Consider the use of a sans serif font as these improve readability. • Please see the following resource for legibility considerations related to typeface: https://legibility.info/characters/typeface Also, consider avoiding use of all capital lettering for main headings as they have a negative effect on readability. We acknowledge that these suggestions would also require an update to the quality-review-documents-qrd-convention-be-followed-european-medicines-agency-qrd-templates_en.pdf.	
	PL Question-based approach Consider the option to allow a question-based format for subheadings within flexibility possibilities or within section content where useful and applicable. This format engages the patient and focuses their attention. ~~Some examples are included in section 2 for consideration~~.	
	Excipient guidance – Labelling text Please consider revising templated labelling statements in the Excipient guidance to: - develop more patient-friendly wording - Adding standardised wording for use in the **SmPC**	
	Gender sensitive languages In some languages, emphasis is placed on gender-sensitive language, for example, German. However, this is not always compatible with understandable language and accessible versions. To maintain readability of the SmPC and PL only one gender form should be used. Therefore, we propose to have standard text (greyed out to keep this optional) in SmPC and PIL to have this possible for these languages, such as: <This text is intended to be gender-inclusive. However, for ease of reading, only one gender form is used.>	

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	**Outcome (if applicable)** ***(To be completed by the Agency)***
	QRD Template Translations Please consider involving national authorities and industry stakeholders in the review of the translations once the English language version of the template has been finalized. Consideration should be given to translation of numbers (spacing, use of "," or ".") and units (e.g. mL or ml) as well as to cultural nuances.	
	Headings - subheadings Some proposals are made for flexibility in the headings or subheadings. This is much appreciated. However, this should be taken into consideration with the development of ePI and which flexibilities are possible in that system.	
	Clarity of text Give clear instructions if something is a "must" and try to avoid the word "should" in the instructions in these cases. Translations of this wordings can often be an issue, so it needs to be clarified what is meant by "should" and then "should" and "must" have to be correctly used in the text. Align to 2024 EMA updated their Compilation of stylistic matters in Product Information with the following footnote on p.1: "The use of 'must' vs 'should' has been revised throughout to avoid confusion between 'obligation' and 'recommendation"	
	Cross-References To improve readability and reduce length of the leaflet, it is advisable to keep relevant information together and to avoid duplication or too many cross-references in the leaflet.	
	User-testing – the revised QRD template should be user tested (all the black standard statements including options and suggested statements in the green statements) before finalisation as such to ensure the language speaks to patients, carers and users. As the primary focus of the leaflet is patients, carers and users, the leaflet should be using lay-terms and be patient-centric, taking into account user testing feedback results.	

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	Review the QRD template holistically in conjunction with all other relevant documents and guidance documents mentioned as reference in the annotated template. Changes to the QRD template must also be reflected accordingly in these associated documents, if necessary. The guidance documents can be found on the EMA website listing the product information requirements: Product-information requirements | European Medicines Agency (EMA) For consistency we recommend in particular the smpc_guideline_rev2_en.pdf (A GUIDELINE ON SUMMARY OF PRODUCT CHARACTERISTICS) and the 2009_01_12_readability_guideline_final_en.pdf (GUIDELINE ON THE READABILITY OF THE LABELLING AND PACKAGE LEAFLET OF MEDICINAL PRODUCTS FOR HUMAN USE) should be updated at the same time as to reflect the changes as well. Other changes are appreciated (eg moving the revision date upfront) but not in line with the current nor future legislation and therefore the future Annex VI should be modified accordingly.	
	Consistency in the explanatory text in green for the annotated version of the template Suggesting to have consistency across the QRD on how to word the green text when the section applies to "only" some products. For instance, in these sections is newly added in capitals and with a dot at the end, whether in existing green text (119, 148) is just in capitals and in other instances is "body" text (153). This also adds clarity to the text as referred above.	

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	The consultation document shows the proposed version 11 with tracked changes compared to QRD template version 10.3 (09/2022). When the final version 11 is published it must be ensured that the small changes introduced in version 10.4 (02/2024) do not get overridden. Additionally, some discrepancies between the two consultation documents (tracked version versus clean version) have been observed. Comments have been made on the clean version.	
	As a general comment, we welcome and appreciate the introduction of hyperlinks for referenced documents. A reference with hyperlink to the pharmacovigilance guidance GVP module XVI (rev3), section XVI.B.2.1 should be added in the QRD template in green guidance text. This refers to the requirement to mention, if applicable, the existence of additional RMM (Risk minimisation materials) materials for a specific risk in the SmPC, and if relevant the PL. However, the guidance's direct applicability to new MAAs and RMMs and not to existing RMMs must be taken into account: *The revised final guidance is applicable to new applications for marketing authorisation, new risk minimisation measures and new studies evaluating risk minimisation measures for authorised medicinal products but not immediately applicable to existing risk minimisation measures and ongoing activities regarding risk minimisation measures.*	

Please add more rows if needed.

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted here using 'track changes')*	Outcome *(To be completed by the Agency)*
Lines 115-116	**Comment:** This should apply to "normal" text only, e.g. "Excipient(s) with known effect" or "The active substance(s) is (are)…". All the section headings in the templates (e.g., 8. MARKETING AUTHORISATION NUMBER(S) in the SmPC, all in ANNEX II, all in ANNEX IIIA) should be exempted. There is no added value in deleting or inserting them depending on singular or plural. **Proposed change (if any):** (S)/(s): brackets to be deleted if term is in plural form, and brackets and 'S'/'s' to be deleted if term is in singular form**; headings are exempted from this requirement**.]	
148	**Comment:** As there is a separate QRD template for ATMP products, we suggest that all such comments which apply only to ATMP products be removed and appear only in the ATMP template. This would avoid confusion and provide clarity. **Proposed change (if any):** Ensure comments that apply to ATMPs appear only in the ATMP template.	
158	**Comment**: The first reference to excipients with known effect is SmPC section 2 but the first inclusion of the link to the excipient guidance appears only in PL section 2 (What you need to know before you <take> <use> {(Invented) name}). **Proposed change (if any):** Propose to add the link to the excipient guidance and high-level guidance in green text for declaring and providing warnings for excipients with known effect in the SmPC sections 2 and 4.4.	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted here using 'track changes')*	Outcome *(To be completed by the Agency)*
168-170	**Comment**: While the physical description of the score line is a part of the description of the pharmaceutical form, the information in the standard sentences in line 168 to 170 is relevant for posology and method of administration so it is proposed to move these to line 222. **Proposed change (if any):** ~~<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.>~~	
Lines 184, 186, 190, 210	**Comment:** "Posology" and "Method of administration" headings should have a different format of the sub-headings underneath Posology (Special population & Paediatric population) to make it clear that the information pertains to posology. **Proposed change (if any):** Change "Special population" and "Paediatric population" sub-headings format to not underlined and add <> at the beginning and end of each.	
Line 212	**Comment:** Repetition of the invented name is redundant here. It would be more concise to state "For {route of administration}" only. **Proposed change (if any):** ~~{(Invented) name} is f~~**F**or {route of administration}.	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted here using 'track changes')*	Outcome *(To be completed by the Agency)*
Line 222	**Comment**: Propose to relocate score line text options from SmPC 3 to SmPC 4.2 as this information is relevant for posology and method of administration. **Proposed change (if any):** Delete line 168-170 and add after line 222: **<The score line on the tablet is only to facilitate breaking for ease of swallowing and not to divide into equal doses.>** **<The score line on the tablet is not intended for breaking the tablet.>** **<The tablet can be divided into equal doses.>**	
Line 241	**Comment:** Inclusion of an explanatory note that additional optional sub-headings for the excipient(s), according to the Annex of the Excipients Guideline, can be included as appropriate, e.g. <Lactose>, <Invert sugar>.	
249-257	**Comment:** For alignment with the new PL subsection on contraception, propose to revise this section header title as shown. Also in SmPC to use the word 'lactation' in the sub-heading and in the PL 'Breastfeeding' (normally not hyphenated for easier readability). **Proposed change (if any):** 4.6 ~~Fertility, p~~**P**regnancy **<,> <**and**>** lactation **<,> <**and**> <fertility> <and contraception>** [For pregnancy and lactation statements, see Appendix I.] [Additional sub-headings such as "Women of childbearing potential" can be included, as appropriate.] <Pregnancy> <~~Breast feeding~~**Lactation**> <Fertility> **<Contraception><in males> <and><in females>**	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted here using 'track changes')*	Outcome *(To be completed by the Agency)*
268	**Comment:** As this format is not feasible in general for all products, the following sub-headlines should be used only if applicable. We understand the Tabulated list of adverse reactions should be standard and applied in most cases, however in some instances this may not feasible. **Proposed change (if any):** **<**Summary of the safety profile**>** **<**Tabulated list of adverse reactions**>**	
284	**Comment:** According to "Stylistic matters" italics are to be used for terms taken from another language such as in vivo, in vitro, Helicobacter pylori. Appendix V should appear as normal text. **Proposed change (if any):** Revert "Appendix V" text back to non-italic and avoid the use of italics for general text throughout SmPC and PL as readability is negatively impacted.	
259-262	**Comment:** Consider revising the heading as shown below based to in line with the updated guidance related to impact on concentration. This would also require updates to the headings/subheadings as proposed for PIL (see revision for QRD rows 1487-1498 below to reference related PL comment). **Proposed change (if any):** Effect on ability to drive**,** ~~and using~~ **use** machines **and concentrate** <{Invented) name} has <no or negligible influence> <minor influence> <moderate influence> <major influence> on the ability to drive**,** ~~and~~use machines **and effect on concentration**.> [describe effects where applicable.]	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted here using 'track changes')*	Outcome *(To be completed by the Agency)*
319	**Comment:** The new proposed text "under a relevant subheading" appears out of place in the sentence related to paediatric development, as these statements should appear under the heading "Paediatric population" which is already stated above. Assuming the intention is to introduce relevant subheadings for the other statements following the paediatric statements (conditional approval/exceptional circumstances), the subheading statement should be moved to those examples. Alternatively, recommended text for the optional subheading(s) should be included in the template, for consistency, see proposal below. **Proposed change (if any):** Line 318-319: [If the European Medicines Agency has waived or deferred a paediatric development, the information should be given as follows ~~under a relevant subheading~~:] Add before line 334: **<Conditions of approval>**"	
382	**Comment:** Consider to specifically refer to section 7 (Labelling and risk mitigation) of the linked Guideline on the environmental risk assessment of medicinal products for human use for standard text to be included.	
389-390	**Comment**: Consider adding a convention about the use of E numbers here, have an agreement on this for all languages.	
Line 389	**Comment:** According to the guideline "Excipients in the labeling and package leaflet of medicinal products for human use", page 2 (Nomenclature), several options are provided for naming an excipient (not limited to Ph.Eur.). The appropriate naming depends on the specific excipient. Therefore, referring to the guideline might be more appropriate here. **Proposed change (if any):** [Name of the excipient(s) in the language of the text, ~~according to~~ **in accordance with the guideline on "Excipients in the label and package leaflet of medicinal products for human use"** ~~European Pharmacopoeia~~ and listed in separate lines.]	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted here using 'track changes')*	Outcome *(To be completed by the Agency)*
410	**Comment:** Propose to remove: Full years must be stated as such and not in months (e.g. 2 years rather than 24 months). For Section 6.3, this is an unnecessary statement added requiring full years instead of months for shelf life when months can be used and the time frames provided (6 months, 18 months, 30 months, etc.) **Proposed change (if any):** [Information on the finished product shelf life and on the in-use stability after first 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 medicinal product may have a different shelf life (e.g. powder and solvent). ~~Full years must be stated as such and not in months (e.g. 2 years rather than 24 months).]~~	
414	**Comment:** The title of the section could be simplified and only state "Storage". **Proposed change (if any):** 6.4 ~~Special precautions for s~~torage	
436	**Comment:** For injectable products with preparation, it would be more logical that the title reads <Preparation and other handling> <and> Precautions for disposal. In all cases the term "special" seems unnecessary in the title. **Proposed change (if any):** 6.6 ~~Special precautions for disposal~~ <**Preparation** and other handling> **<and> Precautions for disposal**	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted here using 'track changes')*	Outcome *(To be completed by the Agency)*
452	**Comment:** In our experience 'Town/city' should be determined on a case-by-case basis. Often an official translation is available but is in fact not widely used and would therefore be inappropriate to include. In addition, there may be a space issue for multi-language packs. **Proposed change (if any):** [~~Town/city and c~~**C**ountry name in the language of the text.]	
453	**Comment:** "It remains unclear whether "address" could be just the town (with postal code) or whether the street name must also be provided. Not including the street name would save space on the materials. **Proposed change (if any):** {Name and address**(town) (and postal code, if available)**}	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted here using 'track changes')*	Outcome *(To be completed by the Agency)*
478	**Comment:** The green guidance text should add clarity on when this field will be completed by the MAH considering that the SmPC is not routinely printed. It is important that the meaning of date of revision for type IA/IAIN changes continues to be specifically mentioned in the QRD template for the package leaflet. A link to post-authorisation guidance for full details should be provided. **Proposed change (if any)** [Item to be completed by the Marketing Authorisation Holder (MAH) at time of ~~printing~~ **finalization of the SmPC. It should not be included in the submitted product information annexes.** For type IA**/IAIN** variations affecting the SmPC, the date of revision of the SmPC 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 other procedures, the date of revision should be the date of the Commission decision, date of adoption of the positive CHMP opinion, date of notification of the Agency, or date of approval by the RMS, as applicable.** For ~~more~~ details, please consult the **post-authorisation procedural advice for users of the centralised procedure**. **For MRP/DCP please consult the CMDh Procedural guidance on variation procedure and CMDh Q&A - List for the submission of variations for human medicinal products according to Commission Regulation (EC) 1234/2008 as amended].**	

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503-509	**Comments:** 1. Propose to add a new section (e.g., section 13) to include the *Detailed information on medicinal […]* as this information is not specifically related to the Section 12 content (instructions for preparing radiopharmaceuticals). 2. Please consider including links to 3rd party hosted compendia for example . Grey shading could be used as necessary for such links. An appendix could be created for acceptable websites as felleskatalogen, Rote Liste etc.	
Lines 710-714	**Comment:** We suggest clarifying the context in which a patient card is needed **Proposed change:** " In case where a patient card is to be placed inside the carton or is affixed to the outer side of the carton as a **RMM in light of GVP module XVI** then the text itself will have to be part of the product information (at the end of the last labelling 713 component of Annex IIIA (e.g. vial)). For further information, please refer to 714 "Guideline on good pharmacovigilance practices".]	
Lines 722-724	**Comment:** Depending on the complexity of the product the location of the mobile technology reference may depend on several considerations (e.g. more than one feature included; for CMDh annotated QRD template for MR/DC procedures (Based on versions of the QRD template for CP) -> different contents in different countries within one MRP/DCP, size/shape of the packaging material, etc.) **Proposed change (if any):** Introduction of a new section for the mobile technology within the labelling (instead of adding it content dependent to e.g. `method of administration`): e.g. <19. Mobile technology> <{QR code}> <{other 2D bar code}> <{NFC}> <{URL}>	
Line 756	**Comment:** For ease of reference: Addition of link to "Blue Box" requirements (although content should only be included in printed material) Bue boxes and their contents (*Guideline on the packaging information of medicinal products for human use authorised by the union*) should not be included.	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted here using 'track changes')*	Outcome *(To be completed by the Agency)*
761-767	**Comment:** As with SmPC and package leaflet, it is highly efficient for preparation and assessment to prepare one combined document for all strengths. This combined labelling text should not need to be separated after adoption by the CHMP. **Proposed change (if any):** ~~[A separate text for outer and inner packaging labelling should be completed per strength and per pharmaceutical form. However,~~**Applicants may prepare the outer and inner packaging labelling for different strengths in one document, clearly indicating the strength to which alternative text elements refer.**	
776	**Comment:** Sentence "Text which will not appear in the final printed material is to be presented as grey-shaded text" does not express the various ways in which grey-shading is utilized and is not in line with the QRD of stylistic matters. Grey-shading is used in a way to allow printing or not printing of alternative text but choosing the correct text at implementation stage. e.g. in the QRD of stylistic matters it states: "One of the IFU set should be grey-shaded to show that only the relevant one will be printed." e.g. in the QRD of stylistic matters it states: "When the applicant agrees with the Agency that short terms and/or abbreviations can be used on multilingual packs, this will be reflected in Annex IIIA in the language(s) concerned, i.e. the term as per the adopted English PI will be written in normal text, followed by the agreed short term/abbreviation in grey-shading. Grey-shading is also used to express for e.g. pack size options **Proposed change (if any):** ~~[Text which will not appear in the final printed material is to be presented as grey-shaded text.]~~**[Grey-shading can be used to indicate alternative text for printing, or text which will not appear in the final printed material]**	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted here using 'track changes')*	Outcome *(To be completed by the Agency)*
822	**Comment:** We acknowledge the addition of this statement, but it must be kept as optional due to limited space on packaging items (in particular multilingual packs). **Proposed change (if any):** Ensure statement is optional.	
847-849	**Comment:** Text added stating that excipients with known effect "*must be followed by the statement 'See leaflet for further information', which can be grey-shaded if it is not going to appear on the final printed materials due to space constraints".* We propose to remove the statement because it is a repetition as it is already stated that the leaflet must be read before use of the medicine. **Proposed change (if any):** ~~They must be followed by the statement "See leaflet for further information", which can be grey-shaded if it is not going to appear on the final printed materials due to space constraints.~~	
862-863	**Comment:** The guidance to support use of patient-friendly terms on labelling should be consistent across the template for SmPC, labelling and package leaflet. **Proposed change (if any):** If used, the pharmaceutical form patient-friendly term should be added in brackets in section 3 of the SmPC **and section 6 of the package leaflet**	
886	**Comment:** We appreciate the attempt to improve the language here, but feel that the following standard statement "Component of a multipack. Not to be sold separately." is linguistically and factually preferable. **Proposed change (if any):** On the inner carton (without blue box): "90 film-coated tablets. Component of a multipack**.**~~, cannot~~ **Not to** be sold separately.".]	

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904	**Comment**: We propose making this warning optional for products administered by HCPs only, provided they are not stored by the patient, or for hospital products, similar to the leaflet. **Proposed change (if any):** **<**Keep out of the sight and reach of children.**>** **[optional for products stored in hospitals or for products administered by health care professionals only]**	
Lines 920/979	**Comment:** We propose to adjust sections 8 "EXPIRY DATE" and 13 "BATCH NUMBER<, DONATION AND PRODUCT CODES>" by recommending consistent use of "EXP" and "Lot" instead of respective locale language translations. This would be supporting to - reduce complexity for production and consequently reduce production timelines (as there will be no need anymore to maintain different configurations at packaging lines) - reduce manual/human errors - increase readability on the printed packaging components Although many countries already allow using EXP/Lot in the European Union, we understand that including this recommendation to QRD template supports further discussion at local levels for countries who currently are not allowed to consistently use the abbreviated international terms. **Proposed change (if any):** [For terms on ~~batch number and~~ expiry date **and batch number**, **it is recommended to use respectively "EXP" and "Lot" instead of local language translations. Alternatively, terms could be used as mentioned in** ~~see~~ Appendix IV.]	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted here using 'track changes')*	Outcome *(To be completed by the Agency)*
952-953	**Comment:** In our experience the translation of 'town' should be determined on a case-by-case basis. Often an official translation is available but is in fact not widely used and would therefore be inappropriate to include. In addition, there may be a space issue for multi-language packs. We therefore propose to have the information of the MAH based on the language where the MAH is located, and have only the country in the language of the text **Proposed change (if any):** [Including town **(in local language of the location of the MAH)**, postal code (if available) and country in the language of the text (telephone numbers	
953	**Comment:** "It remains unclear whether "address" could be just the town (with postal code) or whether the street name must also be provided. Not including the street name would save space on the materials. **Proposed change (if any):** {Name and address **(town) (and postal code, if available)**}	
1055 -1057	**Comment:** The guidance to support use of patient-friendly term on labelling should be consistent across the template for SmPC, labelling and package leaflet. **Proposed change (if any):** [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 and included in section 3 of the SmPC **and section 6 of the package leaflet**.]	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted here using 'track changes')*	Outcome *(To be completed by the Agency)*
1094	**Comment:** To ensure consistency with the QRD approach applied in other sections, it would be helpful to explicitly reference Annex I **Proposed change:** "therefore a request with a detailed justification must be provided **(see Annex 1 - Information to be provided as part of the exemption request in Recommendations for the implementation of the exemptions to the labelling and package leaflet obligations in the centralised procedure")**	
1196 - 1200	**Comment:** As with package leaflet, it should be possible to market a combined patient card for all strengths, provided that the 3 conditions described in the stylistic matters are met (e.g posology foresees at least 2 dosages, the patient cards are identical except for few strength-specific details, a combined alert cards doesn't create risk of confusion/misuse). **Proposed change (if any):** **Applicants may prepare a patient card for different strengths in one document, clearly indicating the strength or presentation to which alternative text elements refer.**	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted here using 'track changes')*	Outcome *(To be completed by the Agency)*
1232-1234	**Comment:** Some medication risks, like abnormal lab results, can't be spotted by patients on their own. These need to be checked by a doctor before starting treatment in case they are a contraindication. Patient instructions should clearly say when a medical check is needed. This helps patients know what they can and can't figure out themselves. It also keeps the information simple and safe to follow. We propose to expand the following statement to include this concept formally at the beginning of the Patient Information. **Proposed revision:** **Write** ~~T~~**t**he ~~package leaflet~~**Patient information** ~~should be written in a~~**using simple, familiar** language ~~understandable by the~~ **t****hat will help a** patient **understand the content and related instructions** ~~and should reflect the terminology the patient is likely to be familiar with~~. **Provide patient-friendly descriptions of clinical signs and symptoms of medical conditions and clearly state what action the patient should take. For medical conditions that cannot be identified by patients alone, such as abnormal liver enzyme levels, clearly explain when medical checks are necessary, so the patient knows when to talk to their healthcare provider.**	
1236-1239	**Comment:** We would have appreciated the addition of standard statements within the template for this text: *"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 "is given", "is injected", etc.); alternative or additional headings/statements will be considered on a case-by-case basis."* **Proposed change (if any):** Inclusion of standard text in all relevant parts of the leaflet.	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted here using 'track changes')*	Outcome *(To be completed by the Agency)*
1241-1243	**Comment:** Regarding the last paragraph "When requested, applicants should…" - please add clarification to indicate if this is for all subheadings. Currently, it is not clear, for example in advice for children's section. **Proposed change (if any):** When requested, applicants should justify the use of alternative headings **or subheadings** (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.	
1266	**Comment:** To improve patient friendly wording, we propose to delete "Package leaflet;" from the naming convention for the Information for the patient as shown below. The "Package leaflet" this terminology does not give an indication as to the nature of the contents of the leaflet, so it is not informative. **Proposed change:** ~~Package leaflet: ~~Information for the <patient> <user>	
Lines 1286-1288	**Comment:** Improve patient-friendly rewording. As the length of the PI is one of the biggest issues, third and fourth sentence can be deleted, because they are already stated at the end of section 4. **Proposed change (if any):** ▼ 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.~~	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted here using 'track changes')*	Outcome *(To be completed by the Agency)*
1290	**Comment:** The green guidance text should clearly explain when this field will be completed by the MAH. It is also important that the meaning of date of revision of the leaflet for type IA/IAIN changes is specifically mentioned in the QRD template for the package leaflet. Guidance text should be consistent with that given in the SmPC. A link to post-authorisation guidance for full details should be provided. **Proposed change:** 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.~~] **[The placeholder <{MM/YYYY}> or <{month YYYY}> is to be completed by the Marketing Authorisation Holder (MAH) at time of ~~printing~~ finalization of the leaflet for printing. It should not be included in the submitted product information annexes.** **For type IA/IAIN variations affecting the leaflet, the date of revision of the leaflet should be the date of implementation of the change by the MAH. For other procedures, the date of revision should be the date of granting of the marketing authorisation, date of Commission decision, date of adoption of the positive CHMP opinion, date of notification of the Agency, or date of approval by the RMS, as applicable. If the regulatory procedure does not affect the leaflet, this date does not need to be changed. For details, please consult the post-authorisation procedural advice for users of the centralised procedure.** **For MRP/DCP please consult the CMDh Procedural guidance on variation procedure and CMDh Q&A - List for the submission of variations for human medicinal products according to Commission Regulation (EC) 1234/2008 as amended].**	

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1299-1301	**Comment:** Although the statement was already included in the previous QRD version, and the reference to other sources and information in alternative formats such as Braille, audio, and large print enhances patient focus, the space constraints should still be taken into account. We propose to change the large font size to having information in a prominent way. **Proposed change (if any):** Normally, this should appear ~~in a large font~~ **prominently** to ensure visually impaired patients are aware of the service.	
Lines 1312-1314	**Comment:** A more neutral wording is proposed for information available via URL or mobile scanning. **Proposed change (if any):** [If relevant, a statement can be included here to inform the patient that the leaflet is available electronically, e.g. "You can access ~~the most up-to-date version of this leaflet~~ **the latest approved information** electronically <via {URL}><by scanning the **<**QR**>** code on the packaging>".] **[additional green guidance of what can be referred to]** **In addition:** There should be flexibility regarding the order of references to other webpages. The option to reference third party non-promotional websites should be added to the green guidance text. The option to include reference to educational materials should be provided in the green guidance text.	
1328-1329	**Comment:** It is ambiguous as to which leaflets would be eligible for omission of the content listing. For the correct application of the content listing requirement, short leaflet should be defined in guidance.	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted here using 'track changes')*	Outcome *(To be completed by the Agency)*
1339-1344	**Comment:** 1. The statement does not fit logically under the heading What {(Invented) name} is and what it is used for. To improve readability it should be placed at the start of section 2 (What you need to know before you <take> <use> {(Invented) name}) instead. 2. It should be clarified in the green guidance text that this statement can be omitted if the product is only used in hospitals or is only administered by health care professionals (e.g. vaccines outside of the hospital). 3. Revise to more patient friendly wording as shown below. **Proposed change (if any):** 1. Move the statement to beginning of section 2 (What you need to know before you <take> <use> {(Invented) name}) 2. Reword the statement: <This medicine has been prescribed for you only. Do not **give it to someone else** ~~pass it on to others~~. It may harm them, even if **they have the same symptoms as you** ~~their signs of illness are the same as yours~~.> [Do not include this statement in case the medicine is for hospital use **only or administered by health care professionals only**.]	
1346-1350	**Comment:** Please consider how this can be added using plain language. We suggest to create standard patient friendly explanations of therapeutic groups.	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted here using 'track changes')*	Outcome *(To be completed by the Agency)*
1352-1356	**Comment:** General terms like children, babies etc. are not sufficient for the patients/care givers as those terms can be associated with different age ranges in different countries. In such cases the age range always needs to be specified in the leaflet and SmPC which will make the information easier to understand for patients and avoid misunderstanding and misuse. **Proposed change (if any):** 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 **in months/years**, e.g. "{(Invented) name} is used to treat {specify indication} in <adults> <new-born babies **aged {x to y} <weeks> <months>**> <babies **aged {x to y} months**> <children **aged {x to y} years**> <adolescents~~>~~ aged {x to y} years> ~~<months>~~"	
1381-1382	**Comment:** Information on the time expected to observe a clinical effect are described in section 4.2 of the SmPC. Referring to information on pharmacokinetic properties provided in section 5.2 will be less useful to the patient. **Proposed change (if any):** - information on the amount of time the medicine usually takes to work may be presented if relevant for the patient (painkiller, antidepressant, etc), in line with section ~~5.2~~ **4.2** of the SmPC.	
Lines 1384-1386	**Comment:** Two sentences make this statement too long. The repetition of "talk to your doctor or pharmacist" at the end of the statement is superfluous and can be removed if the sentences are connected with "or if". In accordance with patients' preference, please keep it once and do not repeat it; this would help keeping the leaflet concise. **Proposed change:** [For medicines available without a prescription, the following statement can be included:] <You must talk to your doctor or pharmacist if you do not feel better <after {x} days> **or** if you feel worse after taking this medicine~~, talk to your doctor or pharmacist~~>.]	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted here using 'track changes')*	Outcome *(To be completed by the Agency)*
1389-1395	**Comment:** Recommend that the template be improved to distinguish better between contraindications and warnings/precautions. Users find it difficult to distinguish between these sections, this is often a finding in tests according to testing companies.	
1389, 1398, 1410, etc...	**Comment:** Available options <take> and <use> are options to be selected in numerous headings, sub-headings and standard statements are most suitable for pharmaceutical forms like tablets. When used for other pharmaceutical forms such as injectable products in syringes or pens, the meaning is less understood, also when translated. Additional options which are more suitable for other pharmaceutical forms (e.g. administer, inject) should be included as options to choose to improve overall readability of the leaflet. In addition, medicines indicated for children should be considered too. Before including in the template these standard terms should be user tested and checked for understanding in all languages. **Proposed change (if any):** e.g. 2. What you need to know before you <take> <use> **<u><give> <inject> <your child> <takes> <uses> <is given></u>** {(Invented) name}	
1409-1412	**Comment:** Is this repetition really to be recommended? Referring to the HCP should be used more carefully. In addition, this will lead to even longer leaflet. **Proposed change (if any):** Delete the text: [~~in case of long bulleted lists ...the action to talk to your doctor or pharmacist is repeated after each warning or precaution) are recommended~~]	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted here using 'track changes')*	Outcome *(To be completed by the Agency)*
1414-1421:	**Comment:** Regarding the proposal to present warnings and precautions (WP) relating to side effects in section 4 of the PL instead of section 2, we request that cross reference statement be included to direct patients to PL section 4 (Possible side effects) for serious side effects that could occur with use of the medicinal product. This is very important to ensure that patients do not miss the important safety information that will now be located only in PL section 4. Also, we request that where WP information from SmPC section 4.4 is included in PL section 4, informative subheadings be included in PL section 4 to clearly differentiate between "*Serious side effects*" that warranted inclusion in SmPC section 4.4 and those that did not (*Other side effects*). **Proposed change (if any):** Please see section 4 (Possible side effects) for information on serious side effects that could occur while <taking><using> {Invented name}. **Proposed change for PL section 4:** <Serious side effects> <Other side effects>	
1435-1437	**Comment:** It should be further clarified that the section for warnings and precautions for children and adolescents is only required *if appropriate* for the specific case, and it will not be required to be included in every case. **Proposed change (if any):** If there is not any specific warning or precaution related to children in the SmPC, a statement can be included if felt appropriate, e.g. "**<**The warnings and precautions for <children><and><adolescents> are the same as those presented for adults.**>**".]	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted here using 'track changes')*	Outcome *(To be completed by the Agency)*
1457-1458	**Comment:** Other medicines which interact with {(Invented) name} should be referred by their INN(s) or invented names to assist with their correct identification. **Proposed change (if any):** ..."Do not take {(Invented) name} with {(Invented) name **or INN of interacting medicine**} (a medicine used for {indication})... **[Use the most known and appropriate name]**	
1460	**Comment:** If the text below is unchanged in this document. However, such an effect needs to be given much more prominence as it could have real life-changing consequences for the patient (unexpected and unwanted pregnancy). It should be a requirement to at least also include the information under the "Contraception" section below. *"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).]"* **Proposed change (if any):** Inclusion of the information in the "Contraception" section below.	
1468	**Comment:** With the addition of "<and contraception>, <and fertility> needs to be changed to <,> <and> <fertility> **Proposed change (if any):** Pregnancy <and> <,> breastfeeding **<,>** <and**>** **<**fertility> <and contraception>	
Line 1469	**Comment:** In accordance with the heading "contraception" should be listed here as well. **Proposed change (if any):** [Where the information is significantly different, **information on** pregnancy, breast-feeding ~~and~~**,** fertility **and contraception** ~~information~~ can be presented under separate sub-headings.]	

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1481-1484	**Comment:** The use should not be limited to men, young children and neonates, as limitation is only for women who can become pregnant, who are pregnant or who are breast-feeding. The text should clearly reflect that (also be in line with SmPC 4.6). **Proposed change (if any):** *"[If there is not any relevant information to be included in this section (e.g. the medicine is not indicated in women), the section should still be kept and a relevant patient-friendly statement should be included, e.g ~~"The use of this medicine is limited to <men><young children><neonates>. It is not intended for use in people who can get pregnant or who are breastfeeding.".~~* "**This medicine is not intended for use by women who can become pregnant, who are pregnant or who are breast-feeding."]"**	
1487-1498	**Comment:** Consider revising the heading as shown below based to in line with the updated guidance related to impact on concentration. This would also require an update the guidance for SmPC 4.7. Text under this heading could include optional subheadings for adults and children/adolescents as needed. **Proposed change:** **<**Driving**><,> <**and**> <**using machines**> <and> <effect on concentration>**	
1491	**Comment:** Typo. Assume it should be "may be amended" **Proposed change (if any):** Applicants should bear in mind that medicines taken by children may need specific advice, and the subheading may be~~d~~ **amended** accordingly if that's the case.	

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1492-1496	**Comment:** We welcome this new inclusion, *"… or regarding alertness or concentration, the medicine may have an impact on children of school age, e.g. "This medicine may <<affect><have an effect on> your child's <ability to concentrate><vision>> <make your child sleepy>. Ask your child if they <have trouble seeing><feel drowsy>. If <you notice><they experience> problems with their <vision><attention>, they should not bike or walk unaccompanied until the effects have passed."* However, we have a few comments: 1: There should be consistent use of either "drowsy" or "sleepy" (both currently appear), 2: "bike" is not a verb therefore should be "ride a bike". **Proposed change (if any):** *"… or regarding alertness or concentration, the medicine may have an impact on children of school age, e.g. "This medicine may <<affect><have an effect on> your child's <ability to concentrate><vision>> <make your child sleepy>. Ask your child if they <have trouble seeing><feel ~~drowsy~~**sleepy**>. If <you notice><they experience> problems with their <vision><attention>, they should not **ride a** bike or walk ~~unaccompanied~~ **alone** until the effects have passed."*	
1512-1597	**Comment**: Section 7 " instructions for use" refers to section 3 but there is no information concerning instruction for use concerning MD (provided there are short) in section 3 nor cross-reference in section 3 to section 7 (where one is required). We propose to add after line 1557 a cross reference. **Proposed change (if any):** Add after line 1557: **[If instructions for use are too long to include in section 3, include a cross reference to section 7]** **<Detailed instructions for use are provided in section 7.>**	

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1519-1520	**Comment:** Sentences like "Always take the medicine as your doctor has told you" and "your doctor will tell you", are often perceived as patronizing by patients. In reality, it is not clear what the doctor really will tell the patient. Therefore, an active approach is recommended. See the proposed revisions below. Also, please note that similar advice is already given in section 2 ("Talk to your doctor <or> <pharmacist> <or nurse> before <taking> <using> {(Invented) name}") **Proposed change (if any):** ~~<Always> <t~~**T**ake> <use> this medicine ~~exactly~~ as described in this leaflet or ~~as~~ **in the way** your <doctor> <,> <or> <pharmacist> <or nurse>~~ <has> <have> told you~~ explained. Check with your <doctor> <or> <,> <pharmacist> <or nurse> if you if are ~~not sure~~**unsure.**>	""

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1614-1616	**Comment** The preferred term in SmPC section 4.8 is intentionally translated into a patient-friendly terms/descriptions to assist recognition. In the majority of cases the SmPC term is difficult to recognize and understand. The proposal to include this preferred term for each side effect in parentheses will increase the length of the leaflet, decrease readability while having limited added value for the patient. It would increase the complexity of this section which could be counter-productive to the overall goal of improving readability and overall value for the patient. Several preferred terms can map to a single patient friendly term in some circumstances, so the relationship between SmPC and PL is not 1:1. We propose to only include the preferred term in parentheses after the plain language terms in very limited circumstances as for example (as is already current practice): • after a list signs/symptoms that are related to a single condition to clarify that they all relate to that condition. • or in situations where there is clear value to the patient. **Proposed change (if any):** ~~The preferred term as presented in the table in section 4.8 of the SmPC should also be included in between parentheses for each side effect, where different from the plain language term/description. This can help patients find more information, if they desire to do so.~~	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted here using 'track changes')*	Outcome *(To be completed by the Agency)*
1618 - 1634	**Comment:** Frequency descriptions should be worded in the same standard way across all products so that patients are familiar with it and not confused if they are reading several different leaflets for several different medicines. As the following convention is frequently used in package leaflets, this should be included in the template as standardized black text in <> brackets. Currently frequency convention is only provided as green guidance text. If there are other suitable frequency descriptions commonly used and which are supported by user testing then these should be provided as alternative options in the template in <> brackets. For patients the convention for listing of adverse events should be harmonized as this would facilitate overall familiarity and understanding of leaflets. The possibility to use other structures when tested accordingly, is important. **Proposed change (if any):** **<**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**>**	
1645-1648	**Comment:** Please rephrase to more patient friendly wording. Please consider the revision shown below. **Proposed change (if any):** **Reporting of side effects** ~~If you get any side effects, talk to~~ **Tell** your <doctor> <or> <,> <pharmacist> <or nurse>~~. This includes any possible~~ **about** any **possible** side effects **you get, even if they are** not listed in this leaflet. You can also report side effects ~~directly via~~ **yourself using** the national reporting system listed in Appendix V.* By reporting side effects, you can help us collect more information on the safety of this medicine.	

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1685-1690	**Comment:** We endorse addition of the traceability statement. Standardization in the QRD template will aid adverse event report and quality complaint processes triggered by the patient or carer. As the location of this section might not be ideal due to large amount of information in Section 2, a subheading should be inserted to draw attention to the statement. The statement should also be re-worded to make it more clear *why* they should record the batch number for biological medicines. e.g. It is important to keep a record of the batch number of your medicine it will support the reporting of side effects. Also as it only applies for some products, the whole statement should be included in <> brackets. **Proposed change (if any):** **<Batch number** It is important **for reporting side effects** to keep a record of the batch number of your medicine. <Every time you get a new pack of ~~{(invented) name}~~**your medicine**,> ~~keep~~ **take** a note of the batch number (which is on the packaging after **Lot** ~~{abbreviation used for batch number}~~) and ~~keep~~ have this information **with you** ~~to hand~~ when talking to your doctor or pharmacist.**>**	
1700	**Comment:** Green guidance text should be added to clarify when the sentence can be omitted (i.e. for medicine stored in hospitals or administered by healthcare professionals only) **Proposed change (if any):** <Keep this medicine out of the sight and reach of children.> **[optional for products stored in hospitals or for products administered by health care professionals only]**	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted here using 'track changes')*	Outcome *(To be completed by the Agency)*
1704	**Comment:** Do not use this medicine after the expiry date which is stated on the <label> <carton> <bottle> <...> <after. It is not clear here whether the contents of the label and carton actually need to be stated individually, or whether, for example, the information on the carton is sufficient. For example, the PEI calls for this to be broken down as follows: "Do not use this medicine after the expiry date stated on the label after "verw. bis" or "EXP" or on the carton after "usable by" or "verw. bis" or "EXP"." This information unnecessarily complicates the content and does not contribute to good readability. We propose to remove the specification on where the expiry date is stated. **Proposed change (if any):** Do not use this medicine after the expiry date which is stated ~~on the <label> <carton> <bottle> <...>~~ after ~~{abbreviation used for expiry date}~~**EXP**.>	
1719-1726	**Comment:** We propose to create an Appendix VI, which includes list of official country specific websites as well as EU wide created information, like the Medsdisposal website (which also links directly to the official country websites). Alternatively, could use grey shading and refer to national sites linked in this site only. Linguistically, if this will always be a website then "at" instead of "in". **Proposed change (if any):** <Ask your pharmacist how to throw away medicines you no longer use <or read the information on how to throw away medicines ~~in~~**at** {name of website **as included in Appendix VI**}>*.	
1738	**Comment:** In cases where there is more than one excipient for which a cross-reference is required, including the full statement for each one leads to the text becoming very long and unwieldy. We therefore propose to include the cross-reference only once. **Proposed change (if any):** The other <(excipient(s))> is (are)... [A cross-reference to section 2 "{(Invented) name} contains {name the excipient**(**s**)**}" should be included **once** when applicable.]	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted here using 'track changes')*	Outcome *(To be completed by the Agency)*
1743-1746	**Comment:** Use of patient-friendly term is permitted on all packaging materials, not only small immediate packaging (e.g. for multilingual packs). **Proposed change (if any):** [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.	
1760-1778	**Comment:** Patients are not expected to know the different roles of the Marketing Authorisation Holder and Manufacturer or whether they are a suitable contact point for queries. The information of the batch release site is not relevant as a contact point. **Proposed change (if any):** [Name and address of the MAH ~~and of the manufacturer responsible for batch release, if different~~] Marketing Authorisation Holder ~~and Manufacturer~~	
1767-1768 1761-1767 and 1770-1771	**Comment:** In our experience 'Town/city' should be determined on a case-by-case basis. Often an official translation is available but is in fact not widely used and would therefore be inappropriate to include. In addition, there may be a space issue for multi-language packs. **Proposed change (if any):** Address: ~~town/city and~~ name of the country to be stated in the language of the text	
1780-1810	**Comment:** As mentioned in line 1782, as listing of local representatives is not a requirement, lines 1808-1810 should be in grey-shading.	

1810-1810	**Comment:** The addresses should be corrected to be consistent with the current translations of the QRD template. When preparing translations of the finalized QRD template version 11 it should be ensured that the list of local representatives is consistent in all translations. There are minor differences in template text in the language versions that cause differences during translation. **Proposed change (if any):** Lietuva {pavadinimas} <{adresas} LT {pašto indeksas} {miestas}> Tel÷**. +{**telefono numeris} <{e-mail}> Česká republika {Název} <{Adresa} CZ {město}> Tel**.**: **+{**telefonní číslo} <{e-mail}> Deutschland {Name} <{Anschrift} D-00000 {Stadt}> Tel**.**: **+{**Telefonnummer} <{e-mail}> Portugal {Nome} <{Morada} P-0000−000 {Cidade}> Tel**.**: + {Número de telefone} <{e-mail}> România {Nume} <{Adresă} {Oraş} {Cod poştal} – RO>	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted here using 'track changes')*	Outcome *(To be completed by the Agency)*
	Tel.: + {Număr de telefon} <{e-mail}> Slovenská republika {Názov} <{Adresa} SK-000 00 {Mesto}> Tel.: + {Telefónne číslo} <{e-mail}> Latvija {Nosaukums} <{Adrese} {Pilsēta}, LV{pasta indekss }> Tel.: + {telefona numurs} <{e-mail}>	
1833 (and 1337)	**Comment:** It should be optional to include the device type/strength within the heading "7. Instruction for Use" in order to specify the product in case it is known to be used with more than one device with different instructions for use (e.g. pre-filled syringe vs pre-filled pen) or if there are strength-specific details related to the medical device. **Proposed change (if any):** <7. Instruction for use **<of {(Invented) name} {type of device/strength}>**>	
Line 1834-1838	**Comment:** we suggest clarifying that section 7 is only to be added when needed. **Proposed change (if any):** If the medicine contains a medical device **and if necessary,** this section can include relevant information about the medical device that is necessary for the intended use of the medicine. This section should also be used in cases where the instructions for use are too long to be included in section 3.]	