European Medicines Agency

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OVERVIEW OF COMMENTS RECEIVED ON REFLECTION PAPER - EPAR SUMMARY FOR THE PUBLIC

EMEA/126757/2005, RELEASED FOR CONSULTATION 15 DECEMBER 2005 – 12 JANUARY 2006

Table 1: Organisations that commented on the reflection paper as released for consultation

	Name of Organisation or individual	Country
1	MSD	Switzerland
2	AESGP	EU
3	EFPIA	EU
4	Hoffman-La Roche	Switzerland

As the full text of all the received comments are included in this overview, the comments will not be published separately.

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Table 2:Discussion of comments

GENERAL COMMENTS - OVERVIEW
[MSD] · We welcome the EPAR summaries for the public as a useful tool to convey information about new medicines to the patients. · We would like to emphasize that it is of outmost importance that the benefits and risks are described in a balanced way in the EPAR summaries, so that patients will understand that for new medicines approved by the CHMP the benefits outweigh the potential risks. The template in annex to the guideline seems to be appropriate in this respect and should be complied with when these reports are authored.
[AESGP] We think it is a useful initiative to provide information easily understandable to the public. However, it is not quite clear why the information given in the PIL (which will have been the result of patients' consultation) could not be simply used for the EPAR summary.
[EFPIA] EFPIA welcomes the reflection paper from EMEA and fully supports the concept of providing an EPAR summary for the Public, which is readily understandable by the patient. EFPIA agrees that it is vital that the public has access to information about their medicines, which is provided in a language that is neither technical nor complex. The EPAR summary, as proposed, is expected to be more informative to patients than the current EPAR and will help to meet the patient's information needs. The proposals in the reflection paper are well thought out and are a good basis on which to start publishing EPAR summaries. EFPIA recommends that the expertise of member companies be fully used during the development of the EPAR through effective processes allowing joint input between Companies and Agency in the provision of good information to patients. In general, the process for drafting the EPAR Summary for the Public, together with the proposed content and target audience appear appropriate although there may be opportunities to further simplify the language used in the template. Given the importance of ensuring that patients fully understand the EPARs, EMEA may wish to consider submitting model EPAR summaries to user testing before any procedures are finalised. It is recommended that patients other than members of the EMEA/CHMP Working Group with Patients' and Consumers' Organisations are involved. This is so that lay people, who have not had repeated exposure to medical terminology, can assess the readability of the proposed EPAR summaries. As a further refinement of the template it may be helpful to include an "Overview" as an introduction to the EPAR summary. This could include information previously found in the EPAR abstract but that is not present in the EPAR summary. It would be helpful if the EMEA could develop and advise companies of a schedule for the publication of EPARs for the Public for existing products. A specific proposal on this issue is given in section 3. To speed up the process of producing these EPARs, EFPIA would like to suggest that in some cases, companies could be allowed to provide initial drafts to the EMEA, this may be especially useful in cases where the Company's specialised knowledge and experience of the product would add value. Ultimately, the usefulness of the new EPAR summaries for the public will depend on making the EPARs easily accessible to patients, in all EU languages, using terminology, which is easily understood. In considering the accessibility of the EPARS it must be recognized that although the internet is clearly the best method of

reaching a wide audience, not all citizens of Europe have access to the internet. This limitation is particularly relevant with respect to the comment in section 4 that "the summary should aim at patients and other members of the public with none or very limited knowledge of the disease and treatment in question". This group may be more than likely than others to contain a high percentage of non-internet users. Therefore, EFPIA recommends that the EMEA consider how EPAR summaries will be made available via the internet to these disadvantaged members of the population and how awareness of the availability of EPAR summaries can be increased e.g. through an advertising campaign at the launch of the new summaries.

[Roche]

There is a big potential for overlap with the patient information leaflet. We propose that the EPAR summary be as short and succinct as possible, with the minimum of overlap with the patient information leaflet, sticking to the key and basic points about the drug as is reflected in the spirit of this document. We strongly recommend that the current EPAR abstract is maintained in addition to the summary for the public .

SPECIFIC COMMENTS ON TEXT

2. Problem statement

paragraph no.+ Line no.	Comment and Rationale	Outcome
Paragraph 3 line 6	This draft reflection paper was released after the 20 November 2005 and will not be published before January 2006, thus this sentence needs to be modified. Change text to: "*The provision* **was planned** ~~*is*~~ *to be implemented no later than 20 November 2005*" Or: "*The provision is to be implemented* **as soon as possible after** ~~*no later than*~~ *20 November 2005*." **[EFPIA]**	Agreed – sentence changed to: *The provision is to be implemented as of 20 November 2005.*
Paragraph 5 line 10	Add" if applicable" to this paragraph as this may not necessarily always apply. *"…a section reflecting any comparisons with other therapeutic options considered during the evaluation process, if applicable".* **[Roche]**	Not agreed –however, see amendment below where clarification has been added.
Paragraph 5 line 10	EFPIA has some concerns regarding the proposal from the EMEA Patients Working Group on "*comparisons with other therapeutic options considered during the evaluation process*". The exact intent of this proposal is not clear, and it does not appear to be addressed in the proposed template in the Annex to the reflection paper. Comparisons with other therapeutic options would only be valuable if conducted during the clinical development of the product in the context of adequate and well-controlled comparative studies. Any other form of comparison e.g. studies specifically conducted with respect to health	Agreed – clarification added: *In this instance, this relates solely to comparisons that were carried out as part of the clinical development of the medicinal product, and were assessed by the CHMP.*

	technology assessment would not be appropriate for inclusion. EFPIA believe that it would not be appropriate to include information about other products in the same class, or other treatment options, if these were not comparators in the studies. It is felt that this type of information could be taken out of context by a layperson who may have little understanding of the risk-benefit assessment for pharmaceuticals. Such information could therefore be misleading and could result in patients believing they should be treated with an alternative product. Insert following paragraph below the statement: *"…"a section reflecting any comparisons with other therapeutic options considered during the evaluation process"* **Data included in this section should refer to any studies conducted during the clinical development programme that compared the product with other medicinal product(s). Data should be included into the EPAR summary if the comparative clinical studies were submitted with the marketing authorisation application and were assessed by CHMP as adequate and well-controlled**." **[EFPIA]**	

3. Objectives and structure		
paragraph no.+ Line no.	**Comment and Rationale**	**Outcome**
Paragraph 1 lines 1-4	The reflection paper indicates that, in the first phase, the EPAR summaries for the Public will be made available for new applications for new Marketing Authorisations, and that EPAR abstracts will no longer be prepared for these products. Clarification is required on the process and timing for drafting EPAR summaries on existing products and for updating EPARs. Since an EPAR is updated throughout the life cycle of a product EFPIA propose that a renewal, a variation application or extension application, when approved, will trigger the preparation of the EPAR summary for the	Agreed – sentence added to end of paragraph: *Summaries will also be prepared for medicinal products already authorised.* This reflects the process used by the Agency to prepare summaries for medicinal products already authorised (project running in 2006 to replace all existing EPAR abstracts with EPAR summaries). More information on the project will be made available via the EMEA website.

	public. A transition period should be defined so that those products with no immediate regulatory activities are updated within a reasonable period of time. This process will facilitate a smooth transition to the new format of the EPARs and to the introduction of EPAR summaries for all approved products. Add a sentence to end of paragraph 1: "**In the second phase, EPAR summaries for the Public will also be prepared when an application to renew a marketing authorisation or to vary or extend a MA is approved. At the same time the abstract will be deleted from the EPAR."** **[EFPIA]**	
Paragraph 2 lines 6-7	Clarification is required regarding the type of "*additional information*" to be included in the EPAR summary for the Public. The summary should not include information that is not part of the marketing authorisation application dossier since it will not have been assessed by CHMP. Modify 2nd sentence of paragraph 2 to read: "*but also to include additional information, taken from the MAA, that is considered useful for patients."* **[EFPIA]**	Agreed – sentence amended to: *…but also to include additional information, <u>taken from the assessment report</u>, that is considered useful for patients.* Note: suggestion amended to read 'assessment report' instead of MAA, as this better reflects the source of the information for the EPAR summary.
Paragraph 2 lines 7-8	As stated under general comments we propose to maintain the EPAR abstract as this is a very useful summary of the product and not comparable to the public EPAR. **[Roche]**	Not agreed – the EMEA will only maintain EPAR summaries for the public. While the language is simpler than the language used in the Abstract, the Summary still fulfills the role of the former Abstract by providing sufficient information for a more scientifically trained person to be able to decide if they want to consult the Scientific Discussion to find more information.
Paragraph 4 line 13	The reflection paper states that "*The EPAR summaries for the public will be translated into all official EU languages*", but does not identify who will carry out the translations. EFPIA recommend that this is clarified and that readers are also reminded that the EPAR is available only in English. Modify paragraph 4 to read:	Agreed – paragraph modified to read: *<u>The EPAR scientific discussion is only available in English</u>. The EPAR summaries for the public will be translated into all official EU languages. <u>The translations will be organised by the EMEA.</u>* Note: suggestion amended to include 'scientific discussion', as the EPAR

	"**The EPAR is only available in English.** *The EPAR summaries for the Public will be translated into all languages* **by the EMEA. Companies will not be expected to provide translations.**" **[EFPIA]**	is modular, and some modules are available in translation.
4. Target groups		
paragraph no.+ Line no.	**Comment and Rationale**	**Outcome**
Paragraph 1 lines 1-3	It appears from the first paragraph that the degree and level of information to be included in the EPAR summaries have not yet been decided and are still open for discussion. EFPIA recommend that all concerned parties (including Industry) are involved in this discussion, to build on existing experience of communication to the general public. Modify paragraph 1 to read: "*The degree and level of information included in the EPAR summaries for the Public* **will be reviewed by interested parties including EMEA, patients' representatives and the Industry**. *Some people…"* **[EFPIA]**	Not agreed – the sentence in the Reflection paper is a general, introductory statement.
Paragraph 4 lines 12-14	Paragraph 2 and paragraph 4 of this section refers to readability without any specific information on how readability will be assessed. In paragraph 4 there is reference to the guideline on the readability of the package leaflet, which must be carried out on all PLs. This paragraph appears to indicate that testing to assess readability of the EPAR summary will also be required. The intent with respect to testing is considered too vague. Rather than just using the PL guideline as a "source of ideas" for readability criteria, it should be stated that a clear process for readability testing will be developed although it should not be necessary to submit all EPAR summaries for testing. This section does not indicate who will be responsible for evaluating the readability of the EPAR summaries. There is some suggestion in section 6 of the reflection paper that the EMEA will be responsible for performing this consultation with target patients groups. Responsibility	The reflection paper reflects the current position of the EMEA with regards to readability testing of EPAR summaries. The approach is currently under discussion. No further details need to be provided in the Reflection Paper. All detail of procedure, including responsibility regarding readability checking, to be included in internal SOP.

	should be confirmed. Replace 2nd sentence in paragraph 4 with: "**The Commission's current guideline on readability of package leaflets should act as the basis for developing a Guideline which** *outlines the process for carrying out a readability test on the* **summaries for the Public. The EMEA Product Team Leader should ensure that where necessary appropriate testing is carried out prior to the publication of the summary for the Public**." **[EFPIA]** It would be useful to get clarification on who will be responsible for evaluating the readability of the public EPARs? **[MSD]**	

5. Contents		
paragraph no.+ Line no.	**Comment and Rationale**	**Outcome**
Paragraph 1 lines 1-5	EFPIA agree that a Questions and Answers format for the summary for the Public is appropriate and that, as mentioned in the reflection paper, care must be taken that the summary is not a duplication of the Package Leaflet (PL). The information given in the attached template may not support this aim since the first four questions are also covered in the PL. EFPIA recommends that the PTL has responsibility for ensuring the consistency of the summary for the Public with the Package Leaflet. Insert at the end of paragraph 1: "**The EMEA PTL will be responsible for ensuring that a) information is not duplicated in the EPAR summary for the Public and the PL b) that the documents are consistent**." **[EFPIA]**	All detail of procedure, including responsibility regarding contents checking, to be included in internal SOP
Paragraph 2	This paragraph is not very clear. The 'conditions of use' listed summarise everything that is included in the PL. It is stated that the	Elements of paragraph 2 now included in paragraph 1, with a suggested

lines 6-11	EPAR summary should focus on and summarise the evaluation of the CHMP but if this has to be done for all items mentioned, the summary may become very long. In order to avoid duplication, it may be necessary to provide more details regarding what each document should contain. In order to avoid a very detailed review of the data supporting the conditions of use, an optimal length of the EPAR summary for the public should be recommended. Replace paragraph 2 by: "**The EPAR summary for the Public should not be a duplicate of the Package Leaflet. It should summarise the evaluation made by the CHMP regarding the conditions of use and reflect the assessment report. A clear definition of "conditions of use" is not provided in the legislation, but typically includes the information provided in the Package Leaflet on indications, contraindications, precautions, dosage, method of administration, handling, storage of the product, when to take it and what to do if the drug has been administered incorrectly (etc)."** **[EFPIA]**	length for the summary: Extra in paragraph 1: *The EPAR summary should remain a short document (2 pages), and should not be a duplicate of the Package Leaflet. It should summarise the evaluation made by the CHMP and reflect the assessment report.* Removed from paragraph 2: ~~However the summary should not be a duplicate of the Package Leaflet. It should summarise the evaluation made by the CHMP and reflect the assessment report.~~
Paragraph 3 lines 12-13	The EPAR summary should only contain information on approved indications and the summaries of studies leading to the recommendations on conditions of use **[EFPIA]**	Agreed – sentence amended to: *The summaries should provide an overview of the more relevant studies <u>on approved indications</u> and state how the evaluation performed by the CHMP led to the recommendations on conditions of use.*

6. Implementation - procedure		
paragraph no.+ Line no.	**Comment and Rationale**	**Outcome**
Paragraph 1 lines 1-4	A more detailed description of the process for the preparation and review of the EPAR summaries for the Public will need to be developed before the first summaries are produced. This section should recognise the need for a more detailed process since, as currently written, it leaves	All detail of procedure, including timing of writing and updating of EPAR summaries, to be included in internal SOP

	room for interpretation. EFPIA recommends that the preparation of the summary for the public be described in an amended version of the EMEA SOP Preparation of an EPAR (EMEA/SOP/H/3003). Proposals regarding a process for updating existing EPARs is provided in the comments on Section 3 (see above) Amend paragraph 1 to read: "**EMEA will first focus on the preparation of EPAR summaries for new applications and will amend the SOP "Preparation of an EPAR" (EMEA/SOP/H/3003) to reflect the new procedure for drafting and publishing the summaries. Procedures for updating summaries during the life of a product and for drafting summaries for already approved products will be further defined. Summaries for already approved products will be required when a MA is renewed, varied or extended**" **[EFPIA]**	
Paragraph 2 lines 5-6	The text should be expanded to clarify who is responsible for drafting the EPAR summaries (including the translations) (e.g. the Rapporteurs) and who will forward the summaries to the CHMP and the companies (probably the PTL). **[EFPIA]** It should be clarified who will be responsible for the translations? What will determine the number of languages the document will be translated to? **[MSD]**	All detail of procedure, including timing of transmission to rapporteur/co-rapporteur, companies, etc., to be included in internal SOP. Note: change to section 3 now identifies the EMEA as being responsible for translations..
Paragraph 3 lines 7-9	The EMEA proposes that companies receive the summaries "for a brief consultation". During this review the manufacturer will need to review the scientific content of the summary, check that no "commercially confidential" information is included and establish that no statements in the summary conflicts with information in the package leaflet. EFPIA believe that the EPAR summary should be based solely on the EPAR and recommend that the draft summary for the public be received with the draft I of the EPAR (step 3.1 of the EMEA SOP). It would be important that any consultation with target patient groups be done	All detail of procedure, including timing and length of consultation to be included in internal SOP. However, sentence amended to clarify the fact that the consultation will happen: ~~*It is suggested that*~~ *The relevant pharmaceutical companies <u>will</u> receive the summaries concerning their own products for a brief consultation. The EMEA will critically assess any comments from the industry as to keep the summaries free of commercial interests.* Note: the consultation procedure for EPAR summaries will be based on

	before the draft summary for the public is sent to the company. The term "brief" used for the consultation process should be replaced by a clear definition of timelines (working days) allowed for the applicant to review and comment on the draft EPAR summary. This review period could be similar to the one allowed to review the current EPAR, i.e. 10 working days, this will be within the consultation period allowed to the CHMP members and before the finalisation of draft II of the EPAR. Amend paragraph 3 to read: *"It is suggested that the relevant pharmaceutical companies receive the summaries concerning their own products for a ~~brief~~ consultation* **to be conducted within 10 working days following receipt of the summary by the company. The draft summary should be sent to the company with draft I of the EPAR and the company review should occur after any consultation with patient groups.** *The EMEA will critically assess any comments from the industry as to keep the summaries free of commercial interests."* **[EFPIA]** - Third paragraph: The sentences reading "*It is suggested that the relevant pharmaceutical companies receive the summaries concerning their own products for a brief consultation. The EMEA will critically assess any comments from the industry as to keep the summaries free of commercial interests*". We think that, <u>in any case</u>, pharmaceutical companies should be consulted on the summary of their own product. Companies should be given enough time to verify that the information provided is appropriate i.e. that the summary is informative and contains the right information while not putting at risk the interest and rights of the company. Therefore, we propose to rephrase these sentences as follows: ***"Pharmaceutical companies will receive the summaries concerning their own medicinal product for a ten-day consultation. The EMEA will assess comments so as to ensure that information contained in the summaries is appropriate, accurate and impartial."*** **[AESGP]**	that already existing for other modules of the EPAR.

	It is suggested that the relevant pharmaceutical companies receive the summaries concerning their own products for a brief consultation. The EMEA will critically assess any comments from the industry as to keep the summaries free of commercial interests. *Concerning the brief consultation it should be received at the same time as the EPAR itself and there should be sufficient time given to the company to review and comment on both documents.* **[Roche]** The length of the consultation period is not mentioned. Please define the length. **[MSD]**	
Paragraph 4 lines 10-13	It should be made clear to consumer and patient groups that the EPAR and the summary can only include discussion of the information provided in the MAA and considered by the CHMP in reaching its authorization decision. Consumer groups should focus on the readability and understanding conveyed by the text rather than the interpretation of the data. EFPIA propose that a broad forum of interested parties (rather than just the Patients Working Group) is involved in any evaluation, to ensure that a wide cross section of views is obtained. The evaluation should occur once the first few summaries have been produced, possibly after 6 or 12 months of operation of the scheme. Industry should be consulted since Companies want to ensure patients receive high quality information to facilitate appropriate use of products and are also an important repository of experience and information relating to the use and properties of any given product. Amend paragraph 4 to read: "*The involvement of patients,* **health professionals and the Industry** *in the preparation of the EPAR summaries for the public will need further discussion. One approach could be to invite* **all interested parties** *to comment on the summaries after 5 or 6 of these have been published* **or after the scheme has been in operation for 6-12 months.**" **[EFPIA]**	The approach is currently under discussion. No further details needs to be provided in the Reflection Paper.

Paragraph 5 lines 15-16	To allow accessibility by the greatest number of the other language versions of the EPAR summaries should be available as early as possible, e.g. within 14 days or one month from the date of the Commission decision. **[EFPIA]**	All detail of procedure, including timing of publication, to be included in internal SOP
Paragraph 5 lines 16-17	Last paragraph, last sentence reading: "*However, it is likely that only the English version of the Summary will be available at this point of time*". In order to really serve its initial purpose, the summary should be made available in <u>all the other EU languages as early as possible</u>, for example, within 2 weeks or one month from the date of the Commission decision. **[AESGP]**	Agreed – last sentence amended to: *All language versions of the EPAR summary will be published at the same time.*
ANNEX (TEMPLATE)		
paragraph	**Comment and Rationale**	**Outcome**
Date & version	It would be helpful if the date and version number of the summary are provided on the front page of the EPAR summary. **[EFPIA]**	Date of last revision included in EPAR Summary for the time being.
Boxed statement	The language used in this statement is complex. Simplification of this language is proposed. In addition to the statement that further information can be found in the PL, reference should also be made to the EPAR Scientific Discussion section. Amend statement to read: "*This document is a summary of the European Public Assessment Report (EPAR). It~~s purpose is to~~ explain***s** *how the ~~assessment done by the~~ Committee for Medicinal products for Human Use (CHMP) ~~on the basis of~~* **used** *the studies performed~~, led~~ to* **make** *the recommendations on ~~the conditions of~~* **how to** *use* **the medicine.** *If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR),* **refer to**	Agreed. Statement suggested slightly amended, and final version reads: *This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal products for Human Use (CHMP) assessed the studies performed to reach their recommendations on how to use the medicine.* *If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).*

	the EPAR Scientific discussion *or contact your doctor or pharmacist."* **[EFPIA]**	
What is <X>?	It is potentially confusing to include other approved indications but not the new indication in this first paragraph. It is proposed that this statement about other approved indication is moved to "What is <X> used for?", after the main indication. It should be clarified that the statement regarding previous authorisation applies to the EU. Amend statement to read: Indicate and briefly describe if the product is already authorised/used for any other indication/purpose in the EU Move above statement to "What is <X> used for?" **[EFPIA]**	As this guidance mainly relates to products which may have been available e.g. as food supplement prior to MAA, the guidance provided in the template has been amended and moved to How has <X> been studied? *Indicate and briefly describe if the product is/has been already used in the EU for any other indication/purpose.*
What is <X>?	The first three questions (what is X? what is X used for? How is X used?) should employ the text of the Patient Information Leaflet so as to avoid confusion. Issues relating to describing, for example, the Indications, Contra-indications and Warnings in terms understandable by the public will already been addressed by the Company through readability testing and during the assessment Use text from PL for basic information on Indication, Contraindications etc.of the MAA. **[EFPIA]** It can be confusing to the pts if the indication is written in different ways in the SPC, the leaflet and the public EPAR. We suggest it to be written in the same way as in the leaflet. **[MSD]**	Agreed – template guidance amended for this paragraph: *Use the terminology in the Package Leaflet, if possible.* The 'if possible' has been added, as the PL may not contain a complete description of the indication(s) as stated in the SPC, e.g. with regards to previous therapies, populations, etc
What is <X> used for?	It would be useful to add the legal status in lay terms. This could be added to either What is <X> for? or to What is <X> used for ?. e.g. <X> can only be prescribed by a doctor (or specialist or given in the hospital only)	Agreed – template guidance amended to suggest use of standard sentences: *Give the legal status of the product e.g. <The medicine can only be obtained with a prescription> <The medicine can be obtained without a*

	<X> can be bought from a Pharmacy without a prescription <X> can be bought from Pharmacies and other shops without a prescription. **[EFPIA]** We would suggest that the legal status (prescription/ non-prescription) of the medicinal product be mentioned. **[AESGP]**	*prescription>*.
How is <X> used?	The reflection paper states that handling, storage of the product and what to do if the drug has been administered incorrectly should be described. These items do not appear in the template. These items could be added to "How is <X> used?" **[EFPIA]**	Agreed – template guidance amended *Specify when there are special handling or storage instructions e.g. administration by a specialist, dilution, etc.*
What is the risk associated with X?	All "contraindications" should be listed since a contraindication is generally understood to describe a situation in which the product should NOT be used. For Warnings, the text should say "major warnings" instead of "relevant." Presumably all warnings are relevant to someone but it is reasonable to only include the major ones in the summary Contra-indications need to be specified as to whether medicines are contra-indicated based on safety findings or whether they are contra-indicated based on no data being available to assess the product. Some medicines will be used "off-label" and this might cause confusion in patients' minds if they find that the use of the medicine is contra-indicated if that has not been made clear that this is not for safety reasons but for lack of data. **[EFPIA]** The definition for a major contraindication is not clear. Please provide a definition. **[MSD]**	Agreed – template guidance amended: *List all contra-indications in the PL and the relevant warnings. If the contra-indications are extensive, consider using general statements(e.g.'<X> should not to be used in patients with bleeding disorders' or 'with kidney problems') and adding a sentence 'For the full list of restrictions, see the Package Leaflet'.* Note: 'relevant' left in for warnings, as warnings listed may be major, but also relevant to e.g. a risk management plan.
Why has <X> been approved?	With respect to the statement *Indicate if the authorisation has be re-assessed or renewed.* *We don't expect the layperson to understand difference between*	Agreed – mention of renewal now inserted as a standard statement in the paragraph 'Other information about <X>: *<The marketing authorisation was renewed on <date of renewal of the*

	procedural terminology such as re-assessment or renewal. *We propose not to include this statement or if it remains to distinguish reassessment and renewal by including the frequency i.e. re-assessed annually or renewed annually or after 5 years.* **[Roche]**	*Marketing Authorisation>.*
Why has <X> been approved?	It would be helpful to provide an electronic link to the scientific EPAR. Insert electronic link or web address. **[EFPIA]** Will an electronic link be provided to the scientific EPAR? Otherwise, how will pts know where to find the scientific EPAR? Please provide details where to find the "scientific EPAR"? **[MSD]**	Link to <u>full</u> EPAR inserted in paragraph 'Other information about <X>: (as this allows the reader to also find other modules such as Scientific Discussion and Product Information)
Which information is still awaited for <X>?	*We would propose not to include any of the specific obligations & follow-up measures here but to cross refer to the standard statement in the SPC/PL and annex II.* **[Roche]**	Not agreed. Feed back from Patients Organisations has shown that information on specific obligations is of interest to the public, especially for clinical obligations. While this section will normally only contain information from Annex II, cross referencing to Annex II is not felt appropriate as the information is not in lay language.
Other information about <X>	Define the term SMOP. **[EFPIA]**	Agreed. Term defined in guidance: *[Link all the product X related documents e.g. full EPAR, <u>Summary of Opinion</u> giving the weblink]*