European Medicines Agency

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REFLECTION PAPER

EPAR SUMMARY FOR THE PUBLIC

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1. Introduction

The European Public Assessment Report (EPAR) shall be prepared at the end of every centralised evaluation process to provide a summary of the grounds for the opinion in favour of a marketing authorisation as taken by the Committee for Human Medicinal Products (CHMP).

The EPAR is derived from the assessment of the documentation submitted by the applicant and the scientific discussions undertaken by the CHMP during the evaluation process. The EMEA makes the EPARs available to the public after deletion of commercially confidential information. Furthermore, the EPARs are updated throughout the life cycle of the product to reflect changes to the original terms and conditions of the marketing authorisation.

Since their introduction, the EPARs have become increasingly technical and complex and therefore less understandable for laypersons in search of knowledge of a given medicine. The EPAR abstracts were originally intended to provide information understandable to the general public, but they are nevertheless often too technical as well. This is the main reason that EPAR summaries with the specific objective of being understandable to patients and other members of the public are explicitly mentioned in the revised EU-legislation as described in the next section.

2. Problem statement

Reference is made to the revised Community legislation, i.e. article 13 (3) of Council Regulation (EC) No. 726/2004. In the article it is stated that:

"The European Public Assessment Report (EPAR) shall include a summary written in a manner that is understandable to the public. The summary shall contain in particular a section relating to the conditions of use of the medicinal product."

The provision is to be implemented as of 20 November 2005.

Furthermore, the EMEA/CHMP Working Group with Patients' and Consumers' Organisations has published a set of recommendations[1] with implementation of EPAR summaries understandable to the public as a priority. The group suggests that such a summary should include:

"…a section reflecting any comparisons with other therapeutic options considered during the evaluation process".

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.

The Working Group has on the meeting of 28 February 2005 recommended that the title of these summaries should be *"EPAR summaries for the public"*. In the rest of this document they will therefore be referred to under this heading, or simply as "summaries".

This reflection paper addresses the objectives, target groups, processes and further actions in relation to the implementation of EPAR summaries for the public.

3. Objectives and structure

The legislation limits the preparation of EPAR summaries for the public to centrally authorised products. They are intended for medicinal products for human use and for veterinary medicinal

[1] The title of the document is *"Outcome of Discussions: Recommendations and Proposals for Action"*, and is available at www.emea.eu.int

products. In the first phase of implementation, the preparation of these summaries will be restricted to new applications. Summaries will also be prepared for medicinal products already authorised.

As mentioned, the current abstract is recognised to have become a rather technical document. The objective of the EPAR summary is not only to be a non-technical version of the abstracts, but also to include additional information, taken from the assessment report, that is considered useful for patients. The EPAR abstracts will be made redundant by the EPAR summaries for the public and the preparation of these will therefore be discontinued.

As for the question of accessibility (which will be internet based), this is to be part of the in-depth reflection on the restructuring of the EMEA website, and will also take into account the development of the database as referred to in Article 57(1)(l) of Regulation (EC) No 726/2004.[2]

The EPAR scientific discussion is only available in English. The EPAR summaries for the public will be translated into all official EU languages. The translations will be organised by the EMEA.

4. Target group(s)

The degree and level of information included in the EPAR summaries for the public can be discussed. Some people are very competent and well informed of their illness. Others are less so, maybe due to differences in age or just in how they wish to deal with their situation.

It is suggested to keep the scope of the EPAR summaries at a basic level. At the same time, the contents should include an appropriate amount of information, enabling patients and the general public to obtain adequate information of the given product. In other words, the summaries will target the 'average layperson', both in terms of readability and contents.

This is primarily based on the assumption that the very resourceful and well-informed patients would look for additional information in already available formats, e.g. the scientific assessment provided in the EPAR. The summaries should therefore aim at patients and other members of the public with none or very limited knowledge of the disease and treatment in question.

Criteria for readability are difficult to establish, and various approaches can be used for assessment of this. The Commission's current guideline for readability on package leaflets (PLs) may represent a source of ideas with regard to the readability of EPAR summaries for the public.

5. Contents

It is suggested that the text itself is laid out as questions and answers, i.e. formulated as the contents of the PLs, and that the summaries should include a general sentence explaining the objectives of the document and advising readers to seek further information from health care professionals. As some information found in the summaries will resemble information in the PLs, it is important to stress that the documents serve each their purpose. 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.

A clear definition of "conditions of use" is not provided in the legislation, but would from a general understanding typically include information on indication, contraindication, 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).

[2] SPCs and PLs are also included as part of the database.

The summaries should provide an overview of the more relevant studies on approved indications and state how the evaluation performed by the CHMP led to the recommendations on conditions of use.

6. Implementation - procedure

The preparation of these summaries will first focus on new applications.
Any update of EPARs where a summary is available will also include a review/update of the latter. The procedure for updating the summaries will be further defined.
In addition the summaries for already existing EPARs will be progressively prepared and published.

The CHMP will receive the relevant summary for information together with the EPAR. Due to the practicalities of translation, the summary will not be available in all languages at this stage.

The relevant pharmaceutical companies will 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.

The involvement of patients' and consumers' organisations in the preparation of the EPAR summaries for the public will need further discussion. One approach could be to invite the patients' organisations involved in the EMEA Working Group to comment on the summaries after 5 or 6 of these have been published.

Concerning the timing of publication in general, it is suggested to publish the EPAR summaries for the public at the same time as the EPAR itself, i.e. at the time of the Commission decision. All language versions of the EPAR summary will be published at the same time.

ANNEX

(template EMEA/324038/2005, version 3.0)

EMEA/H/C/product number

EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

INVENTED NAME OF PRODUCT

EPAR summary for the public

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).

What is <X>?
Indicate active substance, route of administration, strength and dosage form.

What is <X> used for?
Describe the claimed indication + other names of the condition if relevant. Describe target population. Use the terminology in the Package Leaflet, if possible.
Give the legal status of the product e.g. <The medicine can only be obtained with a doctor's prescription> <The medicine can be obtained without a prescription>.
For orphan drug, describe the orphan condition, and ensure that the cross reference to the designation in 'Other information about <X>' is completed.

How is <X> used?
Describe how to use the medicine, duration of treatment, dose adjustment, food interaction. Specify when there are special handling or storage instructions e.g. administration by a specialist, dilution, etc.

How does <X> work?
[pharmacological class]
Describe as simply as possible the principal mechanism of action, clinically relevant to the indication applied for – detailed information may be needed for medicinal products with new mechanism of action..
Clarify whether X is curative, preventive, preventive of worsening of the disease, palliative.
Highlight recommendations for use deriving from mechanism of action.

How has <X> been studied?
For the non-clinical part of the application, use the following standard sentences:
<The effects of < > were first tested in experimental models before being studied in humans. >
<The applicant presented data on experimental models from the scientific literature. >

Indicate and briefly describe if the product is/has been already used in the EU for any other indication/purpose.

For the clinical part of the application describe how X has been used in the studies concentrating on the pivotal studies. Describe briefly the population studied (number, age ranges, etc), comparison to other treatments or placebo, and the endpoint(s).
If relevant, describe other studies leading to the recommendations on how to use the medicine, duration of treatment, dose adjustment, food interaction

What benefit has <X> shown during the studies?
Describe the results from clinical trials, and the benefit derived from them, based on the CHMP evaluation.

What is the risk associated with <X>?
In this paragraph, use the terminology of the PL.
Describe the main findings about safety during the clinical trials and post-authorisation surveillance if relevant – list only adverse events which have been shown to be frequent (> 1 in 10) or serious/severe. Add a sentence 'For the full list of all side effects reported with X, see the Package Leaflet'.If appropriate, list specific risks which will need to be addressed in the risk management plan. List specific risks linked to the drug interaction profile.
Contra-indications:
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'.

Why has <X> been approved?
Describe the conclusions of the CHMP on the benefit/risk ratio – based on the wording in the CHMP Assessment Report. Crosslink to EPAR Scientific Discussion section for further information.

[the following two sections are optional]
What information is still awaited for <X>?
[include section only for medicinal products under conditional approval or approved under exceptional circumstances]
The information can be taken from the PL (cross-reference to annex II) – do not routinely include follow-up measures unless very significant, e.g. major interaction study.
Include relevant post-authorisation studies on for example long-term efficacy studies, children, elderly, renal /hepatic impairment and safety studies if not in the risk management plan.

Which measures are being taken to ensure the safe use of <X>?
[include section only for medicinal products for which a Risk Management Plan has been filed.]
Describe briefly the main elements of the plan.

Other information about <X>:
The European Commission granted a marketing authorisation valid throughout the European Union for <X> to < Name of the holder of the Marketing Authorisation> on < date of issue of the Marketing Authorisation>. <The marketing authorisation was renewed on <date of renewal of the Marketing Authorisation>.

[For orphan drugs: include reference to the EMEA website for the Orphan Designation Summary of Opinion, or EC website if the Summary of Opinion is not available]
[Link all the product X related documents e.g. full EPAR, Summary of Opinion giving the weblink]

This summary was last updated in {MM-YYYY}