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Patient Health Protection

Minutes from the Joint Meeting Patients & Consumers Organisations (PCO) & Committee on Herbal Medicinal Products (HMPC) held on 13 March 2009 (10.00 – 13.00) on the content and publication of HMPC documents

Current situation & future perspectives

Welcome and introduction

The co-chairs welcomed the participants to the meeting and explained that the meeting had been convened to present the types of information produced by the European Medicines Agency on herbal medicines, how the information is presented on the Agency's website and the possible involvement of PCO in the generation and presentation of HMPC documents. PCO representatives were invited to raise any comments and suggestions on what can be improved during the presentations and subsequent discussion.

1. Role and tasks of the HMPC

An Agency representative gave a presentation overview of the role and tasks of the Committee on Herbal Medicinal Products. The HMPC was created in 2004, replacing the Working Party on Herbal Medicinal Products of the Committee for Proprietary Medicinal Products (CPMP). The HMPC was established in accordance with the new pharmaceutical legislation, which introduced a simplified registration procedure for traditional herbal medicinal products in the European Union (EU) Member States. The HMPC aims to assist the harmonisation of procedures and provisions concerning herbal medicinal products laid down in EU Member States, and further integrate herbal medicinal products in the European regulatory framework.

The HMPC primarily establishes Community herbal monographs whose purpose is to provide a scientific summary of data available on the safety and efficacy of an herbal substance and its preparations intended for medicinal use. For every herbal substance and derived preparations, the committee makes a scientific evaluation of available non-clinical and clinical data including documented long-standing use and experience in the Community. Depending on the level of evidence for safety and efficacy, the medicinal use of the herbal substance and that of each preparation are determined to be relevant to market access via a specific regulatory procedure:
- either the 'traditional use' simplified system;

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- or the 'well-established use' provisions (when the evidence is stronger).

The HMPC is also competent to establish a draft Community list of herbal substances and preparations for use in traditional herbal medicinal products, which is gradually being developed through the provision of information on a given herbal substance or preparation. Like for monographs, list entries contain in a structured manner the indication, strength, posology, route of administration and any other information necessary for the safe use of the herbal substance or preparation as an ingredient in a traditional herbal medicinal product. The list covers substances and preparations that have been in medicinal use for a sufficiently long time so that, together with available published data, they are considered not to be harmful under normal conditions of use. The legally-binding character of the list and current limitations to its establishment were explained.

The scientific assessment carried out by the HMPC is found in the Assessment Report that supports every monograph and/or list entry.

2. Current information on herbal medicines published by the Agency

The Agency gave a presentation overview of the existing documents on herbal medicines and their location on the Agency's website.

The Agency makes the following documents on herbal medicines available:

- HMPC opinions on Community herbal monographs;
- Community herbal monographs (and, if available, a Community list entry);
- HMPC assessment reports;
- Lists of references for assessment reports;
- Overviews of comments received on HMPC monographs.

Other documents such as procedural & regulatory guidance and scientific guidelines can also be found on the EMEA website. They either directly concern the preparation of the above-mentioned documents or are relevant for pharmaceutical companies and competent authorities in the national assessment procedures prior to the marketing of individual herbal medicinal products in the MS.

3. Website re-structuring

An Agency representative gave an overview of the 'Public Facing Online Interface' project which has been ongoing since last year and is aimed at restructuring and re-launching the Agency's website in order to better help its stakeholders find the information they need. It was hoped that the new website will be ready by December 2009.

A prototype of the proposed new website was presented, showing where and how information on herbal medicines is likely to be located and searched. The group welcomed this important step forward, and agreed that having information on herbal medicines presented in a more efficient way will be of clear benefit to patients and the general public.

4. Additional information needs

A Committee member presented a new proposed type of document to the group, a summary of assessment report for the public. This new document aims to summarise, in lay language, information on the data relied upon by the HMPC to issue its EU-wide recommendations and laid down in the HMPC assessment report. Two examples were presented: *Calendula* and *Valeriana*.

An Agency representative gave a brief highlight of the current process of preparation of these summaries and the intention to have them available in all official languages of the EU, in contrast to all other HMPC documents which are made available in English only. Participants were informed that the HMPC had expressed a great interest in the involvement of PCO representatives in the establishment of these summaries. The group noted that only a limited number of summaries could be prepared so far and resources limitations were acknowledged.

5. Discussion

The following comments and suggestions were raised in the discussion that took place during the joint meeting:

5.1. Concerning the role and tasks of the HMPC

- The group was asked whether they felt it to be important that patients know about the different procedures in which the HMPC is involved, in particular 'well-established use' versus 'traditional use' and 'Community list' versus 'Community monograph'. The group felt that it was important to show these differences and that they should be clearly labelled and described (the use of links and symbols will be explored).

- It was remarked that a clearer explanation of HMPC activities is desirable. For example, the definition of an herbal substance which covers not only plants but also algae, fungi and lichen is not always clear for the users.

- A member of the group asked how the Committee decides which monographs to work on. The Agency responded by saying that an inventory of European plants (a 'wish list') was established in 2005 with contributions from different interested parties. The Committee then decided on a priority list; such list is regularly updated when lead assessors ('Rapporteurs') are appointed for new plants, taking into account resources available to them. The Agency was then asked whether any interested parties can make a request to the HMPC, asking them to prepare a monograph on a specific plant. The Agency responded that suggestions can be made and that there is currently a specific procedure in place for this.

5.2. Concerning the currently published documents

- It was remarked that the monograph contains little information on the indications whilst the assessment report is rich in information on efficacy data. It was clarified that the monograph is intended for medical doctors, pharmaceutical companies and competent authorities: its structure and content are that of an SmPC. There is therefore limited opportunity to expand data on indications in the monograph itself.

- It was suggested that the format of published documents (html vs pdf) be harmonised.

- Access to information on herbal medicines via EudraPharm was questioned. It was clarified that EudraPharm is intended to be a source of information on all medicinal products for human or veterinary use that have been authorised in the EU and the European Economic Area. The documents produced by the HMPC are not product-specific and will therefore not be accessible in EudraPharm.

- The monograph could be more prominent, as it contains key information on the use of the herbal medicine.

5.3. Concerning the website functionalities

- Information on status of assessment is not of direct interest of patients and the general public and priority should be given on information on the use of herbal medicines.

- The search by therapeutic areas was welcome.

- It would be beneficial to have both the more technical documents and the 'patient-friendly' documents available and easily accessible for all audiences.

5.4. Concerning the intended assessment report summaries for the public

The group was asked whether they considered these documents to be suitable. They expressed satisfaction with the production of information on herbal medicines specifically adapted for patients and the general public. Specific comments were raised on the summaries:

- There is a great deal of information on contraindications in the monograph, while in comparison, not much is available on benefits. More clear information on benefits is desirable in the lay language document where information on 'interactions' could also be more prominent;

- One representative was of the opinion that, in some cases, the summary might not be necessary. In his view, the most useful information is already contained within the monograph, which could just be reproduced in lay language and translated;

- Some participants said that the information in the monograph is all at the same level. Some of it could be more prominent, such as the contraindications and warnings (e.g. not to drive after taking an herbal medicinal product). Another example is information on specific populations (e.g. pregnant and lactating women). The lay language document would allow prioritising information found most relevant by patients;

- Where recommendations deviate from current market situation, a justification for the decision should be provided (e.g. use of Calendula preparations in children under 6 years of age); in particular, it should be clear whether a recommendation comes from the absence of data or there is evidence for safety concerns;

- The differentiation between the various preparations should be made clearer; in particular the graduation in the risks associated with the various categories of preparations should be pointed out (herbal teas versus essential oils);

- Careful consideration should be given to information on the current knowledge of the herbal medicine's pharmacodynamic mode of action; it may be preferable not to refer to uncertainties;

- Information on non-clinical tests are usually of no interest for patients and the general public, unless their relevance was key for the decision-making;

- There is a need to make it clearer that the information provided refers to the medicinal use of herbal medicinal products. The format proposed is the same as is used for information on other types of medicinal product published on the Agency's website, so patients may expect the same level of information;

- The level of information available may vary from one herbal medicine to another. In this respect, the structure of the summaries of assessment report presented as examples could be too complex. Taking the existing experience in producing European Public Assessment Report (EPAR) summaries into account, and considering how EPAR summaries will be presented on the reconstructed website, it was suggested that other vehicles to provide information in lay language to patients and the general public should be explored, such as using of drop-down menus with the key information presented in lay language;

- The usefulness of information on comparability of herbal medicines vis-à-vis conventional medicines and food supplements was raised; it was however clarified that such information falls outside the remit of the HMPC. Details of comparative clinical trials conducted with a given herbal preparation will be found in the assessment report but no direct recommendation can be made that could appear as promoting the use of herbal medicines;

- It could be made clearer when the summary concerns herbal preparations for use in herbal medicinal products which can be used without the intervention of a medical doctor. Nevertheless each summary should contain a statement to the effect that patients are advised to inform their doctor of any co-medication.

- Participants recommended avoiding long summaries when targeting the patients as the audience to reach. These summaries should only contain the key information considered useful for the patients and the general public;

5.5. Concerning the process of preparation of assessment report summaries for the public

Some PCO representatives expressed interest in having information adapted to the public: one participant in particular enquired about the possibility of PCOs being involved in the preparation of the documents, as currently done with EPAR summaries. This will be further discussed by the Patients' and Consumers' Working Party (PCWP).

6. Conclusions and the way forward

The following points were agreed:

- Information on herbal medicines that the Agency produces is clearly of interest to patients and the general public. It will be beneficial to have more 'patient-friendly' documents beside the more technical documents.

- For the purposes of targeting patients and the general public, this information is perhaps not currently presented in the best format. Therefore, there is a need to explore how best to improve the current situation:

  - the ongoing reconstruction of the Agency's website is most welcome in this respect;
  - there is a need to improve the clarity of the information on herbal medicinal products appearing on the Agency's website (e.g. explain the differences between 'traditional use' and 'well-established use' of an herbal substance);
  - initiatives to provide information in lay language available in all EU languages are supported. The Agency should further explore and define the key information needed and the most appropriate vehicles for providing this information;
  - 'patient-friendly' information on herbal medicines needs to be easily understood and with accessible links to the more scientific documents for those who are interested.

- The process by which PCO representatives with a specific interest/expertise in herbal medicines could contribute to the preparation of the summaries should be investigated.

- Information on the benefits of herbal medicinal products should be more accessible to the users.

The Agency thanked the group for their very useful comments and contributions to this area of the Agency's activities. The contribution made by the group will be minuted and taken into account during the further progress of this area of work. Minutes from the joint meeting will be transmitted to the PCWP and HMPC for adoption prior to publication on the EMEA website. The participants, as well as members of the PCWP will be consulted on any specific proposals in the future.