European Medicines Agency
Post-authorisation Evaluation of Medicines for Human Use

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COMMITTEE ON HERBAL MEDICINAL PRODUCTS

Hearing with interested parties

MINUTES

7 Westferry Circus, Canary Wharf, London E14 4HB
EMEA, conference room 3A, 3rd floor
22 November 2005 17.30 to 19.30

Chairman: Dr K. Keller

SUMMARY
The first hearing with interested parties after the establishment of the Committee on Herbal Medicinal Products (HMPC) proved to be an appropriate forum to interact with external parties representing industry associations, healthcare professionals'/patients' organisations as well as scientific societies.

The purpose of the hearing was for HMPC to present the key achievements since its establishment in September 2004 and for the interested parties to express their views on the Committee's work and their expectations for the Committee's deliveries in 2006.

The hearing provided a good opportunity to exchange information and viewpoints on a range of issues concerning the Committee's work. A key outcome of the meeting was a further clarification of the issue regarding support by interested parties to the Committee in relation to its duty of establishing Community herbal monographs and a draft 'List of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products'[1]. Many organisations offered their support to the principle and a number of them have sent or will in the immediate future send their priority lists based on the criteria they consider most relevant for the prioritisation in the medium/long-term perspective. In addition, a number of organisations expressed their willingness to provide literature references and/or data associated to the level of access by their own members. The HMPC welcomed these contributions to its work and will take the received input into consideration in the ongoing work.

The Committee and all interested parties appreciated this opportunity of open dialogue and expressed hope for a close and successful collaboration in this area of medicine. Furthermore, the HMPC indicated that opportunities for dialogue with interested parties in other fora than annual hearings will be investigated.

INTRODUCTION
The Chairman welcomed the participants at the hearing representing 14 European associations with interest in (traditional) herbal medicinal products.
For purposes of successful cooperation in this area of medicine, the Committee published in November 2004 a call for interest to identify interested parties to the activities of the HMPC. As an outcome of this call for interest the Committee established a list of interested parties inviting them to this hearing.

ACHIEVEMENTS OF THE HMPC BETWEEN SEPTEMBER 2004-NOVEMBER 2005
The Chairman gave a brief introduction and overview of the working structure, composition and mandate of the new Committee, which was established in September 2004 replacing the former CPMP Working Party on Herbal Medicinal Products (HMPWP). He summarised the current activities and the progress being made over

[1]In the following referred to as 'the List'

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the past year on various tasks arising from the new pharmaceutical legislation including the traditional-use registration and the authorisation of herbal medicinal products.
As current priority, the HMPC focuses on the establishment of Community herbal monographs and on the preparation of a draft 'List of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products' with a view to facilitate European harmonisation for traditional herbal medicinal products, however, in view of limited available resources, the Chairman considered this as a major challenge for the Committee.

PRESENTATIONS BY INTERESTED PARTIES
Interested parties were invited to present their expectations and priorities for 2006-2007 as well as to share their views on the criteria that should be considered by the Committee in the medium/long term perspective when prioritising the establishment of Community herbal monographs and the preparation of the List. They were also requested to individually provide the Committee with a 'priority list' of plants, which in their respective view should be subject to a monograph or be entered in the List in the respective well-established and traditional use areas.
The Chairman gave the floor to each association to present their views and their possible input to the work of the Committee.

Industry associations

AESGP (European Self-Medication Industry)
The representative of the AESGP, Dr Petrini considered the continuous cooperation of the European Self-Medication Industry and the Committee (as well as previously the HMPWP) as a useful activity. He congratulated the HMPC for its transparency and found that the release of overview of comments on the EMEA website including the rational for having them taken on board or not, was very useful. In relation to the meeting reports, he expressed his wish for an earlier availability of the documents that allow interested parties to monitor and follow up on the activities of the Committee.
With regard to the priority tasks of the HMPC (Community herbal monographs), the AESGP welcomed the fact that in 2006 significant time would be devoted to this issue within the 6 plenary meetings. AESGP reaffirmed its support to the development of monographs and underlined that the HMPC should take the time necessary to develop them as quality is of greater importance than speed. The Committee was reminded that a prioritised list[2] (with high/medium/low priority) based mainly on market relevance had already been submitted by the AESGP for consideration by the Committee in relation to the establishment of monographs/List entries. The AESGP expressed its willingness for a continued collaboration with the Committee in this field.

AEFMUTA (European Association of Manufacturers of Medicines for Anthroposophic Therapy)
The representative, Mr De Herdt, gave an overall introduction on the association representing manufacturers of anthroposophic medicinal products in the European Union. He reflected that the products in this area of medicine have been on the market in some Member States for around 30-50 years. He handed over to all the committee members a written statement of AEFMUTA together with three publications, one on anthroposophic medicine in general, one on anthroposophic medicinal products and one on their pharmaceutical background.
The representative summarised the association's expectations for the years to come and was pleased to express their willingness to cooperate with the HMPC in its activities. Reference was made to the association's letter of 5 April 2005 with the lists of plants of high/medium/low priority they had drafted for the traditional use area to be considered by the Committee. They confirmed their willingness to complete their list by references and data to the extent that these are available to their members.
Questions were raised concerning combination products as well as the way of forwarding proposals in relation to List entries. In particular, clarification was sought whether Member States, interested parties or manufacturers themselves could initiate such introduction.

EFPIA (European Federation of Pharmaceutical Industries and Associations)
Mr Brückner, the representative of EFPIA (the EU research based industry) expressed his appreciation about the number one priority work of the Committee to develop monographs/List entries in the interest of harmonisation with the aim of providing patients with access to high quality herbal medicinal products across Europe. In order to facilitate this work, the representative confirmed that EFPIA would also send a priority list of 20 plants to the Committee by the end of 2005. Further to the question of the Chairman, they expressed their willingness to also provide the literature references for the plants included in their list, if necessary.

[2] Circulated under agenda point II.2.4 of November 2005 HMPC meeting

EGA (European Generic Medicines Association)
The representative gave a brief introduction on the generic medicines association, which also represents a number of manufacturers in the field of herbal medicinal products. As regards their views, Ms Tobolska informed the Committee that a reply to the points raised would be provided later on and expressed the intention of the association to support the activities of the Committee in the harmonisation process.

EHPM (European Federation of Associations of Health Product Manufacturers)
Ms Viner briefly introduced the association, which represents health product manufacturers in Europe. She explained that many of their member companies, most of which are small and medium-sized enterprises (SMEs), are manufacturers of herbal preparations, as well as of natural and traditional remedies, and are seeking pragmatic solutions in this area.
As far as their contribution to the work of the HMPC on the planning and establishment of monographs in the medium/long-term perspective, the representative announced that the EHPM would provide a priority list (containing mainly traditional/ayurvedic products) to the Committee for consideration.

EUROPAM (European Herb Growers Association)
The representative of the European Herb Growers Association, Dr Sessa, thanked the Committee that EUROPAM had been considered as an interested party to the HMPC. Dr Sessa took the opportunity to make reference to the Guidelines for Good Agricultural Practice (GAP) of Medicinal and Aromatic Plants prepared by the association and he drew attention to the forthcoming workshop[3] organised in this regard. The Chairman expressed his expectations that compromise could be found and the principles could soon be implemented.

Scientific societies

EFCAM (European Forum for Complementary and Alternative Medicine)
The EFCAM representative, Mr Schmidt, expressed his appreciation that EFCAM was considered as an interested party to the HMPC. Mr Schmidt outlined that this umbrella organisation represents various stakeholders, health practitioners with broad areas of interest. He raised the borderline issue between well-established and traditional use categories, and commented that a clear distinction of a plant by indication would not be possible. Furthermore he expressed his concern about the possible consequences of the establishment of the List, by noting that as a result, certain preparations might vanish from the market.
As part of their contribution to the Committee, Mr Schmidt offered that, if requested, the EFCAM could present the dossiers as submitted by a large number of their members on complementary and alternative medicines (especially on Traditional Chinese Medicine). He also added that their members have access to a significant amount of literature, which they would be willing to share with the Committee upon request.
The Chairman stressed that the availability of literature references is an important aspect for the Committee in prioritisation of its work.

ESCOP (European Scientific Cooperative on Phytotherapy)
Prof Kemper gave a brief introduction explaining that the ESCOP is an umbrella organisation representing national phytotherapy associations across Europe since 1989. To assist with the harmonisation of the regulatory status of herbal medicinal products at European level, they offered their principal support especially in the collection of scientific data as a basis for the preparation of monographs. Their input would also cover submission of unpublished data e.g. from findings and results from clinical trials. As a response to the question raised by the ESCOP, the Chairman confirmed, that based on the clarification of the European Commission, any kind of information, including unpublished studies that are not protected, can be used in support of the preparation of monographs and entries to the List.
Prof Kemper was pleased to announce that the ESCOP Research Committee was recently founded, which together with the ESCOP Scientific Committee would play an active role to contribute to the work of the HMPC when prioritising the establishment of monographs and the preparation of the List in the medium/long term perspective. A proposal for an initial list of traditional herbal substances had already been submitted to the Committee together with an explanation of the criteria for the literature research carried out for the preparation of the ESCOP monographs.

GA (Society for Medicinal Plant Research)
Prof Bauer reminded the Committee that the activities of the Society for Medicinal Plant Research aiming at the advancement of research and science in the field of medicinal plants have been ongoing for many years. For purposes of cooperation in this field, the GA already attended hearings with the former HMPWP. Prof Bauer shortly introduced the society, outlining that the GA currently has almost 1200 scientists from 77 countries that are actively involved in the following fields related to herbal medicinal products:

[3] See November 2005 HMPC meeting agenda point III.3.1

- Biological and pharmacological activities of the compounds
- Breeding and cultivation of the plants
- Manufacturing and Quality Control
- Regulatory Affairs

Prof Bauer welcomed the progress being made by the Committee so far in the development of Community herbal monographs and entries to the List, which he considered essential to facilitate the authorisation/registration of such products. However, beside the well- established and traditional use categories of herbal medicinal products, he proposed that attention should be paid also to specific extracts with own clinical data. He was of the view that the ESCOP monographs could serve as a good basis for the elaboration of the Community herbal monographs. As regards prioritisation in the medium/long-term perspective, he presented the suggestions of the GA on the criteria for both the well-established use area (evidence of therapeutic efficacy based on published literature and market value) and for the traditional use area (market value and safety aspects). Prof Bauer also confirmed that the GA's priority list of 20 plants established on the above-mentioned criteria would be forwarded to the Committee.
The Chairman welcomed the clear criteria given by the society.

PSE (The Phytochemical Society of Europe)
The Chairman was pleased to welcome the Phytochemical Society of Europe at the hearing as a 'new' scientific organisation with a strong academic and research focus showing interest in the activities of the Committee.
Dr Gibbons shortly introduced the PSE, a research based scientific society that has nearly 900 members with a wide range of expertise. He expressed the society's willingness to cooperate with the HMPC based on the broad basis of expertise covered by its individual members with access to a wide scope of scientific information and sources. He stated that the issue of cooperation would be raised within the society's meetings to be held 2 times a year. Dr Gibbons expressed his wish to get in contact with the Chairman on a regular basis.

Healthcare professionals & patients'/consumers' organisations

The Chairman expressed his regret that representatives from the European Consumers Organisation (BEUC) and from the Standing Committee of European Doctors (CPME) were not present at the hearing.

EHPA (European Herbal Practitioners Association)
Dr McIntyre presented the views of this umbrella organisation comprising professional herbal practitioners across Europe. He addressed some questions to the Committee seeking clarification for distinction of the categories for well-established use and traditional use herbal medicinal products. He also commented on the draft Community herbal monograph on Valerian root in this regard pointing out the differences between the well-established use and traditional use categories (traditional use indication excludes extracts/tinctures). As a response to these questions on the well-established use vs. traditional use criteria, the Chairman informed the participants that the Committee had recently received some clarifications from the European Commission confirming that all evidence could be used for marketing authorisation applications under the well-established use provisions. Therefore, the Committee now has to develop acceptance/borderline criteria between the well-established use and traditional use areas. In relation to the specific question to the monograph on Valerian root, the Chairman explained that if a traditional herbal medicinal product fulfils the criteria for a marketing authorisation, the legislation does not allow the possibility for traditional use registration.
Dr McIntyre expressed his appreciation of the Committee's approach to transparency and made a few suggestions in this regard. He proposed to create more opportunities for dialogue through informal meetings that would allow more interactions between the Committee and interested parties. He also insisted on the importance that overviews on comments received during public consultation periods are published on the EMEA website together with explanations whenever comments have not been taken on board.
Dr McIntyre took the opportunity to draw the Committee's attention to the quality control guideline and its impact on products with a multitude of active substances (technical difficulties and financial burden). He voiced his concern about the fact that due to the high costs associated to the quality control of multicomponent products, many small and medium sized companies would not be able to afford to licence such products.

IAPO (International Alliance of Patients' Organizations)
The representative of the IAPO, Ms Harkness gave a brief introduction on the association, which represents around 150 patients' organisations of all disease areas. She expressed her regret that she could not convey the IAPO's views on the agenda's points to the Committee at the hearing and would provide an answer at a later stage.
The Chairman commented that the Committee would particularly appreciate and welcome input from patients' organisations considering that this area of medicine is very much consumers' and patients' driven.

IVAA (International Federation of Anthroposophical Medical Associations)
Dr Mulder presented the views of the IVAA, an association with a strong focus on anthroposophic medicines consisting of a wide range of herbal and other medicinal products including a substantial number of combination products. He explained that the IVAA shows a high interest in the availability of this particular area of herbal medicinal products and highlighted their wish to keep such products on the market. He also outlined that the IVAA has specific interest in the quality aspects in the process of growing plants as well.
As regards criteria for the Committee to consider in prioritising the establishment of Community herbal monographs, it was suggested to focus firstly on substances with identifiable low risk in the normal context of use as this approach would enable a larger number of preparations to be processed both in the well-established use and traditional use categories. The IVAA also provided the Committee with a priority list of such low-risk plants, which they consider should be subject to a monograph or an entry to the List. The selected plants have been proved to be safe during long-term use and are considered important for patients and practitioners in this field.

PGEU (Pharmaceutical Group to the European Union)
On behalf of the PGEU, Mr Ferguson shortly introduced the association to the Committee indicating that the group represents around 400,000 community pharmacists from 29 European countries. Mr Ferguson informed the Committee that the PGEU would like to reiterate its interest in keeping a closer relation to the activities of the HMPC as a continuation to attendance to hearings with the former HMPWP. He explained that the PGEU Board started a consultation process on the points raised in the invitation letter and he would be able to report on the outcome of the consultation after the hearing.
The Chairman responded that the Committee looks forward to receive the contributions from the PGEU, which would be particularly welcome given that pharmacists are often the first contact points to patients/consumers.

CONCLUSIONS
The Chairman thanked all participants for attending the hearing and sharing the views of European associations with interest in the field of herbal medicinal products.

He was pleased about the positive feedback received from many organisations with regard to the Committee's general transparency and confirmed that every effort would be made also in the future to provide early information on the EMEA website on the progress and follow up of the Committee's work. He referred to a future initiative of creating the possibility of receiving automatic e-mail alerts when any new information would be published on the website (although this is foreseen not to be specific for herbal medicinal products).
To further enhance transparency, the Chairman announced that the list of references used for the establishment of monographs would also be published as part of the public version of the assessment reports. In addition to this, comments and outcome of the public consultations would also be made public.
The Chairman stressed that dialogues and interaction with interested parties are of high importance for the Committee, for which the annual meetings as well as the meeting reports from each plenary session could serve as a good starting point. Similarly to the recent meeting with ESCOP/AESGP, the Committee would investigate the possibility of organising special hearings to exchange information with interested parties.

With regard to the submission of literature references, the Chairman briefly addressed the copyright problem explaining that the Committee was currently exploring the situation within the EMEA and searching for possible solutions/alternatives. Reference was made to the call for scientific data published by EFSA in the Official Journal of the European Union, which could serve as an example in this regard.
The Chairman emphasised that the Committee would appreciate to receive information and input from interested parties. It was also announced that during its work the Committee would take into consideration the priority lists submitted by the associations, however, lack of relevant literature might affect the ongoing work of the HMPC and the establishment of priorities.

The Chairman raised the outstanding issue of the genotoxicity requirements, which was on the agenda of the Committee's November meeting, and asked the interested parties to express their views in this regard.
The ESCOP was against the idea of the necessity to submit a full set of genotoxicity tests in support of applications. From their point of view, performing the standard set of in vitro tests would be reliable and sufficient. The GA raised the idea of organising a workshop/meeting within the society to address the point and stimulate discussion. The Chairman agreed that such a scientific conference would be an appropriate forum to discuss the problem and arrive at a consensus.

The Chairman thanked all the representatives for taking the time to participate at the hearing. The participants expressed their satisfaction about this opportunity of interaction and looked forward to a fruitful cooperation.

List of participants

Industry associations

Mr Patrick Sirdey	AEFMUTA
Mr Nand De Herdt	AEFMUTA
Dr Orlando Petrini	AESGP
Dr Barbara Steinhoff	AESGP
Mrs Marie-Hélène Weber	AESGP
Dr Werner Busse	AESGP
Dr Christelle Anquez-Traxler	AESGP
Mr Thomas Brückner	EFPIA
Mrs Sylwia Salczyńska Tobolska	EGA
Mrs Penny Viner	EHPM
Dr Carlo Sessa	EHGA-EUROPAM

Scientific societies

Dr Mathias Schmidt	EFCAM
Mr You-Ping Zhu	EFCAM
Prof. Fritz H. Kemper	ESCOP
Dr Simon Mills	ESCOP
Prof. Rudolf Bauer	GA
Dr Simon Gibbons	PSE

Healthcare professionals & patients/consumers organisations

Dr Michael McIntyre	EHPA
Ms Amrit Ahluwalia	EHPA
Ms Jo Harkness	IAPO
Mr Frank Mulder	IVAA
Mr John Ferguson	PGEU