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Evaluation of Medicines for Human Use

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HMPC WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)

Hearing AESGP - 6 May 2008
Report

List of AESGP representatives
Dr Christelle Anquez-Traxler, Dr Hubertus Cranz, Dr Werner Busse, Mrs Irène Chetcuti, Dr Barbara Steinhoff, Mrs Marinella Trovato and Dr Frans van den Dungen.

The MLWP Chair welcomed the representatives from AESGP and Dr Cranz thanked the MLWP for the opportunity to meet and discuss a number of questions, notably in relation to the establishment of Community herbal monographs and Community list entries.

W. Busse gave a presentation on the outcome of an internal survey that AESGP carried out amongst its members on 'undiscovered opportunities' for herbal medicines. It was first remarked that companies are currently involved in the 2011 process i.e. compliance with the new requirements at a national level and the priority is therefore not on the European dimension of the new piece of legislation. This may explain why only a limited number of companies have investigated the new EU opportunities.

Scientific advice on herbal medicines is not sought from the EMEA because fees are too high as compared to the limited commercial value that may be obtained for herbal medicinal products and because of concerns on the relevance of the advice given (in the absence of a *a priori* acceptance of the advice given by the EMEA, there is not predictability on the outcome of national procedures in mutual recognition).
Concerning the provisions related to products with **less than 15 years of medicinal use in the Community**, most companies would not seek traditional use registration in the absence of data protection, because of limited commercial interests in plants unknown in European and as using such clause seems complicated and time consuming because national authorities have to be addressed first.
A high percentage of companies are interested in the submission of traditional use registration for combination products for which the number of ingredients has been reduced following sourcing limitations, analytical reasons or safety concerns. For those companies which already submitted an application for such type of product, registration was refused for grounds of safety and clinical profile i.e. plausibility of efficacy. The HMPC Chair pointed to the successful outcome of a referral to the HMPC that appears to be an efficient way forward to solve the problems.

Many companies are not considering using the **MRP/DCP** for a herbal medicinal product containing substance, preparation or combination thereof covered by a monograph/list entry. The reasons include insufficient commercial incentive of the indications approved so far and concerns with respect to the acceptance of the monographs by the competent authorities.

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AESGP reported about the **competitiveness** on the national markets for herbal medicinal products with other products under different regulatory frameworks. Competitiveness is a serious issue for Small and Medium Enterprises more than it is for the large pharmaceutical companies. A greater understanding of herbal medicines is needed in Europe from the regulators. The HMPC Chair reassured AESGP of the understanding of the situation by the members of the committee and the working party and their shared concerns with respect to the borderline between therapeutic indications and health claims for herbal ingredients.

Concerning the ongoing **revision of the Regulations on Variations**, Dr Cranz stated that the herbal medicines industry is of the view that it may be wise not to include traditional herbal medicinal products in the new draft regulation on variations so as to continue benefiting from simple variations systems where they exist in some Member States. Pragmatic and/or simplified variations systems are in place for examples in Germany, Austria and United Kingdom. AESGP will reflect on the comment from the HMPC Chair that according to the legislation, the publication of a Community herbal monograph should trigger variations for the concerned products. European harmonisation is slowed down by the fact that many companies prefer to keep their products on a national level rather than to try a harmonisation of the labelling at European level. The level of risks associated with **referral procedures** is still perceived as very high despite reassuring statements expressed during discussions between industry and regulators. The HMPC Chair reiterated his view that referral procedures at European level are important procedures leading to binding decisions with well-adhered timetables that can ensure harmonisation for herbal medicines across the Member States. The MLWP Chair was very optimistic with regard to the outcome of referral procedures involving coordination between the CHMP and the HMPC.

The lack of binding character of the **HMPC monographs** remains a challenge. It was highlighted that indeed national competent authorities may have divergent views on the content of adopted monographs with possible consequences on their position about the need to submit some or all of the references supporting a given monograph and its assessment report. The HMPC Chair however reassured participants that a broad acceptance of Community herbal monographs in traditional use registration should be the rule and that duplicate submission of literature used in monographs should not be necessary.

AESGP indicated that, in their comments on the draft 'Reflection paper on the criteria and timelines for revision of final Community herbal monographs and Community list entries' currently under public consultation, they will suggest accepting to initiate the **revision of an adopted monograph/list entry** upon submission of a detailed justification based for example on an analysis of the published assessment report or the identification of discrepancy between adopted texts. Dr Cranz announced AESGP's intention to submit such a request for revision of one of the adopted monographs.

AESGP presented a list of **priority combinations** for which the establishment of a Community herbal monograph would be desirable and pointed out that a vast majority of traditional products are combination products. The MLWP Chair indicated that the working party would like to receive a justification for the priority level in order to assist with the planning of assessment work by members of the MLWP. AESGP agreed to consider the issue and to deliver additional information.

During the presentation, difficulties for companies to obtain **support from national authorities** were raised, for example in relation to the registration of products with less than 15 years of use in the Community. The HMPC Chair indicated that the committee could consider the option for companies to submit to the HMPC via the secretariat requests for support with a view to identifying one or several members ready to assist with the registration application. The HMPC could act as a platform for liaison between companies and national competent authorities if such problems would occur. This would be further investigated.

The MLWP Chair thanked AESGP representatives for the fruitful discussion on current challenges and perspectives for solutions to improve the situation. The AESGP reiterated its support to the work done by the Committee and the HMPC Chair expressed its appreciation of this continued collaboration.