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Procedure Management and Business Support Division

Hearing AESGP during May 2014 MLWP meeting

Report

List of representatives from the Association of the European Self-Medication Industry (AESGP)

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The Chair of the Working Party on Community Monographs and Community List (MLWP) welcomed the AESGP delegation. Dr Cranz thanked the Chairs and the MLWP/HMPC for the opportunity to have a face-to-face meeting.

General functioning of the HMPC

AESGP expressed appreciation about the transparency level. The HMPC had always been working with quite high transparency standards and this has been even furthered with the publication of the HMPC agendas and minutes which allow a closer insight and more details on the issues discussed within the Committee. AESGP also thanked for the origin of the minority opinion to be made known in the published CM accompanying document; this is very valuable information for companies from a marketing point of view.

Given that the MLWP meeting occurs after the HMPC meeting, new information on the discussion of the working party (WP) on ongoing scientific assessment and Community monographs are only available 2 months later. AESGP would find useful to have a quick summary of the plants which have been discussed in the WP after the MLWP meetings and not waiting for the HMPC highlights. It was emphasized that key facts of MLWP´s work are already included into the HMPC meeting report. A more detailed information was not seen as feasible from a resource point of view of the HMPC secretariat. The status and provisional timeline for the CM on Melaleuca and Serenoa repens were given.

With regard to preparation of draft Community monographs, the MLWP explained that during the scientific evaluation process, the rapporteur sends a template to all Committee members with a request for completion with national data on MA and registration. Interested parties (IP) can always send missing info during consultation.

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EFSA positive opinion on laxatives

The European Food Safety Authority (EFSA) Panel on Dietetic Products, Nutrition and Allergies (NDA) recently published a positive Scientific Opinion on the substantiation of a health claim related to hydroxyanthracene derivatives and improvement of bowel function. The Panel also considered a number of HMPC Community Herbal Monographs and WHO Monographs. The HMPC had expressed their concern to the European Commission regarding the use of products containing hydroxyanthracene derivatives in a nutritional setting.

Use of herbal products in pregnancy and the use of herbal products in children in Member States

The January meeting minutes mentions survey activity on the above referred topics. The MLWP informed that a survey from authorised / registered products (product information) is ongoing in Italy on the food supplement market. Data were collected from 2500 pregnancies before pregnancy until the first trimester of life.

It was noted that the Kooperation Phytopharmaka is carrying out a similar initiative in Germany – the pilot is still ongoing.

Genotoxicity

Discussion on how to improve the genotoxicity data situation is continuing in the MLWP/HMPC. AESGP informed that the Kooperation Phytopharmaka in Germany plans to publish results of the AMES test for Valerian. This is the starting point of further publications but industry underlined that prior approval from companies is a condition.

Consequences on national markets of empty content of section 5 of the Community monograph

Due to Article 16c(1)(a)(iii), data on sub-sections 5.1 and 5.2 are not required and those sections are left blank. In virtue of the plausible efficacy, the pharmacological action of the plant and its constituents is assessed by the rapporteur and is cross-referred with the long-term use of the plant for a given symptom or pathology. If the pharmacological properties support the long-term therapeutic use, and if the 15/30 years of use criterion is fulfilled, then the traditional indication is reflected in the Community monograph.

Having no data in sections 5.1 and 5.2 makes it seem that there is no plausible pharmacological basis at all. Given that the pharmacological studies are reviewed and evaluated by the rapporteur, AESGP was wondering whether such information could be included in the Community monograph.

The MLWP stated that the evaluation of pharmacological data is always made in the context of the assessment report and it would consider adding data under sections 5.1 and 5.2 of the Community Herbal monograph on a case-by-case basis. When the PK-PD data are very clear, then this would argue in favour of having well-established indications rather than traditional use indication. Sometimes, the delimitation between what is well-established or traditional is very subtle. Related information in the assessment report can be used in regulatory submission. In the assessment report, distinction is now being made between primary and secondary pharmacology.

Revision procedures of Community monographs

As a rule, when a new herbal preparation is added into a CM, the revised CM is published as final but when a preparation or indication is removed, then the revision is published for comments as there could be an impact on products on the market. A lot of work is entailed by the rewriting and the formatting to fit the new format and standard. It was made clear that data submitted by interested parties will not necessarily lead to public consultation if everyone is in agreement.

MRP-DCPs on herbals

The publication of the Uptake of the traditional use registration scheme and implementation of the provisions of Directive 2004/24/EC in EU Member States showcases the use and impact of Directive 2004/24/EC. As Community monographs also enable the use of Community procedures, it would be of value to have information on herbal containing products which have been approved via MRP or DCPs. The MRI-Index on the CMDh website enables searches for THMPs in MRP-DCPs by entering the ATC code level 3 or 4. Information may however not always be complete.

EMA literature screening – list of plants

In accordance with article 27 of Regulation 726/2004 as amended, the EMA shall monitor selected medical literature for reports of suspected adverse reactions to medicinal products containing certain active substances. In line with this, the Agency has now published a tender for this service, together with specifications and a list of 300 chemical substances and 100 plants. The MLWP clarified that the working party was aware of the different initiatives relevant to herbal medicinal products, as more coordination between Committees is developing, but, due limited resources, cannot be active on every topic. It hence relies on the other committees to contact the working party in case of any issue. The HMPC is kept informed about Article 57(2) database related activities with a main focus on herbal substances.

Microbiology

AESGP commented that the detailed reflection paper is more demanding than the Ph.Eur. chapter 5.1.8. The rapporteur argued that, as far as the section on “Testing of the herbal substance, herbal preparation, and herbal medicinal product” is concerned, the reflection paper is a short compilation of microbiological statements from quality guidance documents and from the Ph.Eur. Hence it does not contain additional requirements in respect to the already existing ones.

AESGP cordially invited the MLWP to its conference in October and thanked again for the opportunity of these annual encounters which are very beneficial. The MLWP reciprocated and it was agreed that the next hearing would normally take place in May 2015.