EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 May 2016
EMA/HMPC/313623/2016
Committee on Herbal Medicinal Products (HMPC)

AESGP hearing at MLWP meeting, April 2016

Report

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

Hubertus Cranz, Christelle Anquez-Traxler, Werner Busse, Yvan Dierckxsens, Eva Hirt, Bruno Mabboux, Sandrine Maglione, Mónica Mennet-von Eiff, Christian Nauert, Bernd Roether, Silvia Sanner and Barbara Steinhoff

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.

Pyrrolizidine Alkaloids (PA)

AESGP presented the current research and testing activities of manufacturers, suppliers and growers in Germany to reduce and minimise the content of PA in herbal material/medicinal products as well as to propose options on how to achieve the implementation of the HMPC recommendation of 0.35 µg/day as maximum daily intake. As it has recently become apparent that PA can also be present in plant material due to contamination with PA-containing weeds, testing on PA within the quality assessment of medicinal products of herbal origin needs to be considered in general. Some health authorities have set a limit of 1.0 µg PA per day for the final product during a transitional phase. From the industry's point of view, a phased implementation approach is a feasible solution. Extensive questions and answers session and discussion followed, showing the high level of involvement of both health authorities and industry generated by this issue. The need for a common validated testing method was stressed and the HMPC will contact the EDQM with that purpose. MLWP and industry shared the view that a harmonised approach would be favourable. The HMPC will further discuss and reflect on the provision of further recommendation.

Public Statement on Products containing Pulegone / Menthofuran

As peppermint oil is not only used as an active substance but also as an excipient, the assessment of pulegone/menthofuran was coordinated within the Agency. The HMPC is close to reaching a final position, probably on a value higher than the initially proposed 3.5 mg. As to next steps, the HMPC will endeavour to finalise the reflection paper and then to continue the revision of pending monographs.

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Revision of the 'Guideline on the assessment of clinical safety and efficacy in the preparation of Community Herbal Monographs for well-established and of Community Herbal Monographs/Entries to the Community list for traditional herbal medicinal products/substances/preparations'

In relation to the above document, AESGP recommended the establishment of a procedure to check whether data to be used in a European Union herbal monograph are under protection. AESGP contended that published data do not mean that they can freely utilised.

It was underlined that the HMPC has clear procedures and clear legal mandate to follow when drafting an EU monograph. In addition, usually all data available in the public domain is considered to support the well-established use of a plant.

Reflection Paper on Polycyclic Aromatic Hydrocarbons (PAH)

The document has been on the work plan for a long time due to the absence of a Rapporteur. The document is now close to finalisation and will be published for consultation. The occurrence of PAH in food has been taken into consideration; data will be expected from companies in order to be able to come to a sound conclusion.

Call for data on *Piper methysticum* (Kava)

On 28 May 2015, a call for scientific data for *Piper methysticum* (Kava) was published. On 29 September 2015, the 'Public statement on prioritisation for assessment of herbal substances associated with safety concerns' was published, indicating that *Piper methysticum* had low priority. AESGP was wondering about this seeming contradiction. It was explained that following the German court case on Kava Kava, the HMPC decided to reach a harmonised opinion on the herbal substance which led to a call for scientific data. The first draft is expected this year.

Revision of monographs

AESGP asked for more clarity on the rationale for the revision of a monograph (i.e. whether it falls under the 5-year revision or if there is another cause). Indeed, the monograph on *Hedera helix* L., folium was revised for specific reasons (re-evaluation of the validity of the Bronchitis Severity Scale 'BSS') and more or less at the same time, a call for data for the systematic review of the monograph was published. This generated some confusion as to the grounds of the revision. The MLWP promised to consider this in the future and to possibly address it in the operating procedures.

Draft Questions & Answers on ethanol in the context of the revision of the 'Guideline on Excipients in the label and package leaflet of medicinal products for human use' – impact on herbal medicinal products

The last reference to the draft Q&A on ethanol, made in the report from the HMPC November 2015 meeting, indicated that: "With reference to the current state of discussion the Rapporteur considered neither the HMPC reflection paper 'ethanol/use in children' nor the HMPC monograph template affected. However, planned labelling requirements at lower thresholds are new and not toxicologically justified from existing EMA guidance documents. If HMPC maintains the standard reference to the (revised) excipients guideline, companies and NCAs will have to follow these new requirements." AESGP asked for the MLWP's understanding of the state of play of the Q&A and its impact on herbal medicinal products.

The HMPC does not lead but has shared its comments. When the document is final, the HMPC will analyse its impact on herbal medicines.

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- Assessors' trainings: it was explained that assessors' trainings initiated by the HMPC occur on a specific herbal issue and topics are identified by the HMPC. In order to extend the option of participation to more assessors of NCAs, the last training included participation via web-options. These assessor´s trainings are not directly linked to EMA/HMA training.
- International cooperation: it was confirmed that looking into products of other/non-European traditions was a priority of the HMPC in 2016 reflected on their work programme.
- AESGP gave the information, that it will present data on decentralised procedures with herbal medicinal products at the joint CMDh-industry meeting in November.