17 August 2015
EMA/HMPC/399737/2015
Committee on Herbal Medicinal Products (HMPC)

Hearing AESGP during May 2015 MLWP meeting

Report

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

Hubertus Cranz, Werner Busse, Esmeralda Buendía, Glenn Carpenter, Helen Darracott, Laurence Leonetti, Bruno Mabboux, Sandrine Maglione, Mónica Mennet-von Eiff, Christian Nauert, Bernd Roether, Silvia Sanner, Eva Schnabl, Raquel Solís 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.

Recent AESGP survey on the authorisation and registration procedures for herbal medicines

The results of an AESGP survey on authorisation and registration of herbal medicines in the EU, based on data from several companies were presented. The presentation was appreciated by the members. Although, it is not the primary role of the EMA HMPC to look at deficits in National Procedures, there was general agreement that it was beneficial background information how the system is working and monographs are used.

Revision of monograph in light of the validation data of Bronchitis Severity Scale (BSS)

The review of the assessments of *Thymus/Primula* and *Hedera* had been performed leading to revised monographs published as draft for consultation in February. Some delays were acknowledged with the review of the *Pelargonium* assessment, which has been started by the Rapporteur but not yet discussed at MLWP.

Draft Q&A 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'

The HMPC recognised the problems presented by AESGP but did not consider a specific solution only for herbal medicines as feasible. The HMPC will be involved in the discussion before finalisation of the document.

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Establishing standards for herbal combinations including herbal teas

AESGP had asked for some details with regard to the HMPC's intention to develop standards for herbal combinations including herbal teas. It was explained that currently the MLWP is working on a draft reflection paper on the assessment of combination products, considering how monographs on single substances could be used, in case combination monographs do not exist. In this context, existing national schemes for the assessment of combinations are also taken into consideration.

Publication of the mock-up as Annex to the Guideline on the use of the CTD format

AESGP asked for the regulatory relevance of the document currently being under public consultation, as companies fear that the content of this mock-up could go beyond the requirements laid down in pharmacopoeias or guidelines. It was replied that the mock-up is regarded as an example including minimum requirements. The intention is to give support to less experienced applicants and to demonstrate by the practical example of a Valerian extract how a real dossier is compiled. In any case the requirements depend on the individual case as well as on the existing guidelines.

Monographs on *Serenoa repens* and *Silybum marianum*

It was noted that these monographs are under discussion after public consultation and under discussion before public consultation, respectively.

Finalisation of the list entry Valerianae radix

AESGP mentioned that for Valerianae radix results of genotoxicity testing have recently been published, which could be useful for the finalisation of the respective list entry. The HMPC/MLWP representatives explained that this publication was taken into consideration and as the Valerianae radix package is under revision, a draft list entry is now also under development.

Calls for Data also in case of Public Statements?

General calls for data, in analogy to the procedure for monograph establishment, are not foreseen for specific public statements. Comments on the draft documents will – as always – be taken into account.

Microbiological Quality

AESGP asked about the status and the regulatory implications of the draft reflection paper on microbiological aspects. From an AESGP point of view, such a paper should not serve as a basis to develop more rigid requirements for microbiological quality of herbal medicinal products which go beyond the European Pharmacopoeia. The QDG chair explained that the document had been finalised and just adopted, so the final documents will be published soon. With regard to the concerns raised by AESGP, it will be clarified in the scope that the document does not aim to establish additional guidance, but to provide an overview of issues to be taken into consideration. As there seems to be a need for more clarification for National Health Authorities, specific Q&A are planned to be developed.

AESGP 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 2016.