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Committee on Herbal Medicinal Products (HMPC)

AESGP hearing at MLWP meeting, March 2017

Report

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

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Monographs on herbal combinations

AESGP expressed its appreciation concerning the development of a monograph on a herbal tea combination “Species diureticae” which it considered a pragmatic and flexible approach to cover a large number of combinations in one monograph. To the question as to whether further combination monographs (also apart from herbal teas) would be developed, the MLWP Chair said that proposals from industry are always welcome and would be considered for the next work programme.

Monographs on Horse-Chestnut seed and extract

The Ph.Eur. monographs on Horse-Chestnut have recently been published. They state a minimum content of 1.5% triterpene glycosides for the seed and a range of 6.5 to 10.0% for the extract, both expressed as protoaescigenin. AESGP pointed out that this not in line with the existing HMPC monograph which describe a dry extract (4.5-5.5:1, 50% aqueous ethanol) quantified to contain 16-20% triterpene glycosides, calculated as aescin, with a dosage of 240-290 mg of extract (quantified to a content of 50 mg aescin) 2 times daily under well-established medicinal use. The MLWP rapporteur clarified that new information was collected which will shortly be taken into account in the 5-year revision. This will be done in close connection with the Ph.Eur.

Draft Monograph on Silybi marianae fructus

The new draft describes a traditional use for the relief of dyspepsia and digestive complaints of hepatic origin, after serious conditions have been excluded by a medical doctor. As compared to a previous draft, the well-established use indication has been deleted, which AESGP found most regrettable given the existence of an extract standardised to silymarin, expressed as silibinin subject to a Ph.Eur. monograph. Due to the definition of a standardised extract, these compounds are regarded as those

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which contribute to the therapeutic efficacy. Reiterating its comments sent earlier in writing, AESGP made the plea for the inclusion of a well-established use indication. The MLWP indicated that the current draft is a compromise resulting from a long discussion and there was no majority in favour of the well-established use indication. The risk otherwise would be that no monograph be established. The monograph is on the agenda of the current MLWP meeting (March 2017).

Revision of the Monograph on Pelargonii radix

The adoption of the revised EU monograph on Pelargonii radix by the HMPC was postponed and the monograph and supporting documents sent back to the MLWP (cf. minutes of the HMPC November 2016 meeting). The MLWP explained that this was due to the fact that no *modus vivendi* could be found on the BSS score. However, finalisation is expected very soon.

'Reflection paper on Polycyclic Aromatic Hydrocarbons in herbal medicinal products/traditional herbal medicinal products' (EMA/HMPC/300551/2015).

Polycyclic Aromatic Hydrocarbons (PAH) arise from processing, roasting, pollution, etc. Based on the discussions in the food area and the inclusion of limits for PAH in Regulation 1881/2006, the HMPC has issued a Reflection Paper with a recommendation to the herbal industry to collect data on PAH. The MLWP explained that the substances will also be included in the revised guidelines on quality and on specifications. Good processing practices are considered helpful to avoid contamination of herbal products with PAH. AESGP recommended in its comments on the Public Statement that a risk assessment should be carried out as a first step. This should take into account the major potential sources for PAH as well as transition rates (herbal teas) and dilution factors in order to gain information about necessity and frequency of testing. As a second step data can be collected in order to establish a representative and conclusive collection. Submission of data would be useful once knowledge about a potential correlation between origin/production process and findings is available. The MLWP is generally in favour of collecting data within a time frame comparable to that of the EFSA/EC one. The acceptable limit needs to be carefully assessed with a broader view that takes into account a general exposition scenario as well as an environmental approach.

Experience concerning Mutual Recognition and Decentralised Procedures for herbal medicines

AESGP presented the results of its 2016 survey on MRP-DCP for herbal medicinal products. The MLWP was pleased to know that the EU monographs they develop have a positive impact on the market.

The importance of getting a transparent overview on how different DCP/MRP with (traditional) herbal medicinal products are finalised within the regulatory system, was commonly shared, as well as how to prevent unnecessary referral procedures. From the side of MLWP it was expressed that the presented overview does not cover by far all the DCP/MRP of recent dates, which was acknowledged by AESGP.

Proposal for simplification of some variations specific to herbal medicines / ROG

Changes during the life cycle of (herbal) medicinal products require appropriate variations in the marketing authorisation dossier. Due to their particularities, the risk assessment and change management of herbal medicinal products often differs from chemically defined drug products, in particular with regard to the different steps of the supply and production chain (starting material, manufacturing process and quality control). AESGP believes that a number of variations specific to

herbal medicinal products could be downgraded e.g. change of the origin of the herbal substance, change of extraction solvents or change of extraction process provided the quality is kept unchanged.

AESGP is considering addressing it to the Regulatory Optimisation Group (ROG) co-created by the HMA and IT Directors Group in May 2016. It is co-chaired by HMA and EMA and is looking at regulatory areas which could be simplified and made more efficient. The main focus of its 2017 work programme is on variation type IA and to maximise the use of existing database (XEVMPD and later on SPOR) for the (administrative) update of the marketing authorisations. The MLWP took note of these considerations.

Consultation on the evaluation of Regulation (EC) No 1924/2006 on nutrition and health claims

AESGP shared its views in the context of the so-called REFIT on nutrition and health claims made on food, in particular with regard to claims made on plants and their preparations.