



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 May 2022
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Committee on Herbal Medicinal Products (HMPC)

AESGP hearing at HMPC meeting, May 2022

Report

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

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*by virtual connection

1. Proposal for combinations of traditionally used herbal extracts

«Based on the "Species" monographs for tea combinations which permit the combination of certain corresponding herbal drugs used as teas, it is proposed to also create combinations for extracts in case they are covered by an HMPC monograph for the individual extract in the same therapeutic area»

Two different approaches for calculation of the posology are proposed: «Option A calculates the daily dose of an extract in an extract combination using the DER i.e. in case of herbal drug A instead of 800 mg herbal tea in a combination, 100 mg extract (DER 8:1) would be used in the combination (calculated with average of DER range)», and «Option B utilises the percentages of the extracts in the combination». These options were illustrated with examples. AESGP seeks a flexible framework for combinations of extracts considering it has already been implemented successfully in a pragmatic way in the published monographs on herbal teas combination (Species digestivae and stomachicae, Species amarae, Species sedativae, Species diureticae).

AESGP acknowledged that it is easier to apply the proposed model to aqueous extracts (as they are similar to herbal teas) than to ethanolic extracts; however, the extrapolation principle remains the same: the combination could be accepted as long as the different extracts fit within the range found in the respective mono-component monographs. The safety of the individual extracts is described in the monographs concerned and all recommendations for a safe use would be taken up for the combination.

Regarding the chemical correlation of individual components in the extract combination, AESGP pointed out that potential synergistic effects and interaction issues are related to individual components themselves, which are described in their respective monographs.

HMPC pointed to the lack of TU evidence for combination of ethanolic extracts. To the question of the need for such extract combinations, AESGP referred to the 'convenience' feature for patients that is applicable to any combination medicinal product, whether innovative or OTC. AESGP made a plea for a

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consumer-centric approach and a pragmatic and creative framework for companies. The HMPC also referred to the recommendations laid down in HMPC's guideline on fixed combinations.

2. Real-world data – real-world evidence (RWD-RWE) for non-prescription herbal medicines

AESGP presented a review article co-authored by members of AESGP's expert team on RWD/RWE:

["How can real-world evidence aid decision making during the life cycle of nonprescription medicines?"](#).

AESGP underlined that due to the specificities of non-prescription medicines – which are not prescribed nor reimbursed – the data sources are different than that of prescription medicines and data are rarely collected in electronic health records (EHRs) but they generally have to be generated. Hence the article makes the plea for a wide definition of RWD so that the selfcare sector can be covered.

In the subsequent discussion, HMPC agreed with the well-known difficulty of data quality in patient registries and that global convergence is needed to overcome obstacles linked to the diversity and variable quality of the data collected by patients/HCPs (physicians, pharmacists). A clear understanding of the specificities of herbal preparations (plant, plant part, solvent, DER, etc.) is critical for the usefulness of data collected on herbal medicines. HMPC pointed to ongoing work by a subgroup on real-world data concerning the use of herbal medicines in the paediatric population.

AESGP is looking forward to further dialogue and possible cooperation in this field.

3. Any other business

In the final exchange with the HMPC, AESGP indicated that HMPs represent around 15-20% of the OTC market in the EU (ranging from up to 40% in some Members States and down to less than 10% in others).

The decreasing number of herbal medicines' licensing applications in their countries was highlighted by some HMPC members.

AESGP emphasised the need for a pragmatic and risk-based approach to herbal medicines reflecting their specificities, also taking into account the fierce competition with products in other categories. It is hoped that the work of AESGP on RWD-RWE and herbals can also help sustain innovation in the area of herbal medicines.

AESGP thanked the Committee for the hearing and the opportunity to renew dialogue on shared interests.