25 September 2024
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Committee on Herbal Medicinal Products (HMPC)

AESGP hearing[1] at HMPC meeting, September 2024

Report

List of representatives from the Association of the European Self-Medication Industry (AESGP): A. Mueller; C. Anquez-Traxler; N. Symma

1. RWE / RWD for herbal medicinal products

The AESGP highlighted the increasing regulatory use-cases of real-world data/evidence (RWD/RWE) throughout the medicinal products' lifecycle with the quality of data being paramount to ensure meaningful and robust analysis. In this regard, the AESGP RWD/RWE working group has identified a number of requirements in the description of herbal medicines in scientific literature, databases or registries: name of the used herbal substance in Latin and, optionally, English; type of herbal preparation (e.g., dry extract, tincture); quantity of the (genuine) herbal preparation; and if feasible, the drug extract ratio (DER genuine) or equivalent quantity of the herbal substance (as a range); name and composition of extraction solvent(s). Also, and as a possible addition, the regulatory category as well as dosage form, posology and indication. This working group has also preliminary concluded that majority of RWD studies used primary healthcare in-house databases only, which brings to the question how to promote (T)HMPs to be incorporated in databases/registries. Moreover, and based on the research studies initiated by HMPC under the DARWIN framework, the AESGP pointed out that it there is an urgent need to find a way for having datasets on use of a specific herbal medicine in a particular population (e.g., paediatric population – use data in children/adolescents prescriptions are generally not totally captured since NP medicines are not yet part of available data routinely recorded in primary healthcare). In this regard, a possible study setting/workflow based on data collection via pharmacies was presented.

The HMPC acknowledged the relevance of RWD/RWE for establishing new and review EU herbal monographs. It was highlighted that NP medicines landscape is substantially different among EU countries, and in this regard sales databases/registries used by pharmacies are not necessarily harmonized. Concomitant use with other medicinal products, and information on safety use of herbal medicines (in addition to Pharmacovigilance data from Eudravigilance and PSURs databases) may also be relevant to be gathered. Finally, the HMPC informed the AESGP that the study report regarding the RWD study on pelargonium is foreseen to be adopted for publication in the upcoming months and also

[1] The meeting was held in person.

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that there is progress on the reflection paper regarding the data requirements for paediatric use of herbal medicines.

2. Revision of the Variations classification guideline

The AESGP highlighted that objective of the ongoing revision of the Variations framework, including the classification guideline, should be to make the system more efficient, reduce administrative burden and free-up resources. Additionally, there should be a more level playing field between classification for APIs of herbal origin and those of chemical origin. The draft revised Variations classification guideline partly delivers on that objective. For some variation classifications, higher classification, or extensive additional documentation (some examples: new/additional active substance or starting material manufacturer; extension of shelf-life of finished product; new or updates of CEPs; change to adhere to the Ph. Eur. for an active substance) were applied for APIs of herbal origin. In this regard, the AESGP emphasised that proposed changes are not in line with the revision of the EC pharmaceutical strategy for Europe to drastically reduce administrative burden; it is not clear why HMPs are subject to a higher requirements given the fact that there is no impact on the quality of the medicinal product; neither the authority approval nor the additional extensive documentation add to the quality for the product or the benefit to the patient (it just adds administrative burden to industry and authorities); the associated resources should be used in a better way to foster innovation, focus on substantial issues and promote Europe as attractive manufacturing site; it is key to ensure supply chain resilience.

The HMPC acknowledged that the Delegated Regulation - C(2024)1627 amending the Commission Regulation (EC) No 1234/2008 is still not covering traditional herbal medicinal products. It was also recognised that experience with Variations to the terms of marketing authorisation does not fall within the Committee's remit, but rather within the Member States' NCAs. In addition, HMPC emphasised that the Committee is not directly involved in the ongoing revision of the Variations framework, including Variations classification guideline.

3. Any other business

The AESGP and the HMPC highlighted the importance of these regular meetings, preferably in-person format, which represent an opportunity to renew dialogue on common interests in the field of HMPs.