21 January 2026
EMA/HMPC/378565/2025
Committee on Herbal Medicinal Products (HMPC)

AESGP hearing[1] at HMPC meeting, 19 November 2025

Report

List of representatives from the Association of the European Self-Medication Industry (AESGP): A Müller, B Röther, C Anquez-Traxler, N Symma

1. Pharma legislation review

The AESGP delegation highlighted the importance of the legal basis WEU for HMPs in the frame of the upcoming new pharmaceutical legislation (NPL). Secondly, and linked to the content of Annex II, which describes the application dossier content, is the revision of the quality part of the dossier described in the ICH M4Q. Finally, as NPL will also entail a change in the structure of the EMA's Committees, AESGP also asked the HMPC for their opinion on the future.

WEU: AESGP presented a summary of points concerning the new article 13, as bibliographic legal basis is fully relevant to HMPs. The AESGP informed the HMPC of their request for the new article 13 to include an exemption for HMPs, considering the existing legal framework that refers to bibliographic applications for HMPs.

Annex II & ICH M4Q (R2): AESGP pointed out the relevance to maintain legal predictability and the *status quo* for HMPs, as changes to Annex II, which describes the content of the MAA, are foreseen in the near future. Furthermore, it was highlighted that, in parallel, the quality content of the dossier described in ICH M4Q is being revised by ICH (consultation ended in October 2025). On this regard, the AESGP foresees a few challenges for the selfcare sector, and thus for products already authorised under M4Q(R1), a progressive 10-year transition period following the SPQS (Structured Product Quality Standards (ICH M16)) implementation in the respective authorities may be necessary where applicants may convert the affected sections when submitting data-driven major post-approval changes. During a transitional period, dossiers may contain a mix of M4Q(R1) and M4Q(R2) sections. To minimise burden and support harmonisation, ICH members were also encouraged to converge implementation timelines wherever feasible.

The HMPC highlighted that the NPL is at an advanced stage and with that in mind the Committee will not comment on specific aspects of the NPL or the possible future interpretation of this legislation. Looking ahead to the future, one of the priorities for 2026 at HMPC is the continuous training of the experts/assessors to ensure the sharing of experience and knowledge to the next generation of HMPC

[1] The meeting was held in person.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

members. In addition, the HMPC is embracing digital initiates by EMA, including artificial intelligence, which could play a role in the committee's activities. Furthermore, some relevant reflection papers (e.g. use of information in EU herbal monographs and assessment reports for borderline issues, data requirements for (T)HMPs used in children) will be finalised considering the contributions from interested parties, including those from AESGP.

2. Update on RWD/RWE activities in Science/Industry.

AESGP presented a summary of real-world data (RWD) discussions on the use of HMPs with a special focus on two study reports presented at a workshop on RWD to document the use of HMPs in children during the annual congress of the Society for Medicinal Plants and Natural Products Research held in Naples. As conducting RCTs in children is often ethically and practically challenging or even impossible, RWD derived from sources such as electronic health records (EHRs), patient registries, pharmacy data, and observational studies, offer a valuable alternative to complement RCTs. For paediatric HMPs, the AESGP pointed out that RWD can provide insights into dosing, safety, and treatment patterns in routine practice. Due to the specific nature of non-prescription medicines (NPMs), which are usually not prescribed or reimbursed, RWD is not routinely collected, hence there is no or limited integration of HMPs data into registries/EHRs. In addition, herbal preparations in databases are inconsistently documented; there are difficulties in validating RWD for regulatory purposes and concerns about RWD quality, heterogeneity, and regulatory acceptance. From a regulatory perspective, it was emphasised that the pilot DARWIN EU® studies carried out by the EMA/HMPC to investigate the herbal use in children (e.g., Pelargonii radix), recognizes the role of RWD in paediatric HMPs.

A first study case of the Scientific Institute of Private Health Insurance, Germany (WIP) with thyme herbal preparations/HMPs used in children, based on a specific ATC code (R05CP01 Thyme herb) was presented. It demonstrated an increasing utilisation/demand for children/adolescents in specific indications (cough, cold, etc.). The use of antibiotics (J01) was also recorded. As main conclusion, it was highlighted the high use of preparations in age groups under 4 years, which contradicts the HMPC recommendations and which potentially could be an indication of off-label use. It was noted by HMPC that the risk seems uncertain due to a lack of clinical data and outcomes and private health insurance claims data are not capable of measuring outcomes or safety profiles (e.g. efficacy, effectiveness) and missing diagnosis is a crucial insufficiency but could be collected within a following study. A second prospective study was presented for the evaluation of the feasibility of virtual recruitment of patients with symptoms suggestive of acute rhinosinusitis (ARS), a questionnaire-based study on an existing as well as overcome disease, use of NPMs and symptom burden in ARS, and aiming to complement the evidence generated in RCTs. As main conclusions, it was pointed out the virtual recruitment of adults and adolescents ≥16 years with symptoms suggestive of ARS is possible; patient-reported outcomes (PROM) results (symptom severity, QoL) are in line with baseline PROM scores from a RCT and a meta-analysis on ARS. This feasibility provides a basis for a larger virtual prospective RWD study in Germany (N≥5000) with participants ≥12 years and a daily assessment of PROMs.

Two alternative proposals have been presented by AESGP to generate data: 1) explorative study on existing data in health insurance data bases; 2) generating prospective study data via social media sources. HMPC was asked to reflect on this kind of RWD surveys: could these RWD play a relevant role in the approval process of (T)HMPs and in the preparation of EU herbal monographs; does the HMPC have any recommendation to science and industry, which additional approaches are welcomed? As next steps/what could/needs to be done, the AESGP pointed out: ensure integration of (T)HMPs into the European Health Data Space (EHDS), national registries and EHRs, using identifiers like pharmaceutical registration numbers or pharmacy product numbers (nationally available); conduct and use pharmacy-based studies to complement existing data, while considering uniqueness of the active ingredient declaration; consider multiple data sources (registries, insurance databases, DARWIN EU);

design product/herbal drug-specific RWD studies; align research (academia/industry) with regulatory expectations by fostering interdisciplinary collaboration to design regulatory-acceptable RWD study protocols.

The HMPC acknowledged the relevance of topics presented by AESGP regarding the generation of real-world evidence (RWE) based on RWD related to the use of (T)HMPs. Furthermore, it was pointed out that the Committee plans to continue collaboration within the DARWIN EU network in 2026 exploring possibilities to conduct further RWD studies with specific research questions to gather dedicated data to support HMPC decision-making.

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 (T)HMPs.