ECHAMP
European Coalition on
Homeopathic & Anthroposophic
Medicinal Products

Rue Washington 38–40
B-1050 Brussels
T +32 2 649 94 40
E office@echamp.eu
www.echamp.eu

Revision of the EU general pharmaceuticals legislation

Draft Directive

ECHAMP, the European Coalition on Homeopathic and Anthroposophic Medicinal Products, represents an EU-based industry that has been serving the European market for decades. EU legislation for homeopathic medicinal products has deep roots in their broad use in the Member States; the EU being the global centre of expertise in manufacturing, quality standards and regulation of this industry. Homeopathic products are used in 100 countries around the world, the third most popular specific complementary medicine.

ECHAMP supports the Commission proposal with its focus on provisions relevant to achieving the specific objectives of the review.

We welcome the Commission's proposal to maintain the dual legal format of Regulation and Directive, in line with the current legislation that is built on a system of both national and European marketing authorisations.

This dual framework will continue to facilitate the needs of patients using homeopathic medicinal products, balancing the quality and safety of these products while ensuring citizens have access to the medicines they require.
Awareness of homeopathy is high and the use of homeopathic medicines is widespread in the EU – 79% of French, 60% of Germans, 57% of Italians and 47% of Spanish have used homeopathic medicines in their lifetime. Research confirms significant added value to society, including clinical effectiveness, low incidence of side effects and cost-effectiveness. In addition, these long-established therapies and their medicinal products have a role to play in fields of specific relevance to EU health policy. These products offer valuable integrative healthcare treatment options in areas such as polypharmacy, non-communicable diseases, healthy ageing and for children and young adults.

ECHAMP also welcomes the Commission's proposal to preserve the existing provisions for homeopathic medicinal products without changing their substance, as stated in preamble 4 of the draft Directive. This remains in line with previous efforts on harmonization as expressed in the relevant preambles of Directive 2001/83/EC and applicable standards as set down in the European and national pharmacopoeias.

To ensure that the scope of the provisions referred to in preamble 4 is comprehensive, we ask the Commission to confirm that the medicinal product category referred to in preamble 22 of Directive 2001/83/EC (namely, anthroposophic medicinal products described in an official pharmacopeia and prepared by a homeopathic method) is also covered by preamble 4 so that the intent of these provisions is unambiguously carried forward, acknowledging their long-standing European tradition.
As data driven healthcare opens up immense potential for improved health situations, we recommend the use of broad definitions of data sources concerning real world data and real world evidence to inform decisions on medicines so as to ensure maximum inclusion of patient experience.

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We fully agree that environmental risks are associated with pharmaceuticals and environmental risk assessment and mitigation are important. We highly recommend close collaboration with the industry in order to leverage all available data to assist with prioritization avoiding duplication of work and ensuring proportionality.

Online reference: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12963-Revision-of-the-EU-general-pharmaceuticals-legislation/F3440592_en

Draft Regulation

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With regard to the proposed provisions for the monitoring and management of shortages and critical shortages, we recommend a proportionate and pragmatic approach: The provisions should be aimed at medicinal products on the lists of critical medicines, so as to avoid generating an unintended and purposeless administrative burden for both marketing authorization holders and competent authorities.

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