ECHAMP
European Coalition on
Homeopathic & Anthroposophic
Medicinal Products

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Revision of the general pharmaceutical legislation
Combined Evaluation Roadmap/Inception Impact Assessment

ECHAMP, the European Coalition on Homeopathic & Anthroposophic Medicinal Products, represents the majority of the companies active in the production and distribution of those products in the EU. We endorse the rights of more than 110 million patients and consumers in the EU to have easy and comprehensive access to reliable homeopathic and anthroposophic medicinal products which meet the highest standards of quality, safety and effectiveness.

The EU is the global centre of expertise in manufacturing, quality standards and regulation of this industry, which has been serving the European market for decades. Homeopathic and anthroposophic products have a solid, long-standing legal framework in European pharmaceutical legislation.

ECHAMP understands and fully supports the need to develop a stronger EU health union in which the EU pharmaceuticals system can adapt to a changing competitive global environment. We also support the 'targeted approach' pursued by the Commission for the revision of the pharmaceutical legislation.
We welcome and appreciate the Commission's chosen consultation process of combining a mix of public and targeted consultations and ensuring a broad stakeholder input into the assessment of the impact of any changes.
The revision of the pharmaceutical legislation should result in a stable and flexible regulatory environment for both new and innovative medicines and for existing medicines. Existing medicines form the backbone of our medical systems and guarantee routine care for the daily needs of patients. A stable environment guarantees access to these products, thereby also contributing to the resilience of Members States' health systems.

While moving towards a stronger unification in the area of health, it is imperative that none of the 'established' products are lost. Access to these medicines should not be negatively or indirectly affected by the proposed changes. Regulatory improvements in the case, for example, of the application of digital technologies or the simplification of the system for variations, should, where relevant, be beneficial for all medicinal products, irrespective of their nature.

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We stress the need to ensure through this process that the strong fundament that has been created by the existing EU dual legislative framework of Directive and Regulation is retained. This will result in an inclusive system, which both facilitates innovation and fully exploits the potential of existing products, in a regulatory frame that continues to respect national competence and national traditions in order to deliver the best heath care for each EU citizen. The maintenance of the current structure fits best to the Commission's targeted approach.

The promise of a truly holistic, patient-centred, forward-looking EU pharmaceutical strategy must be fully reflected in the design of any future legislation so as to accommodate both the rich array of medicinal products – prescription and OTC – which are already available to the EU patient today, and new innovative medicines.