Questionnaire
http://ec.europa.eu/enterprise/policies/sme/public-consultation-new/index_en.htm

A ECHAMP contact details to be filled in

B1 Click on YES and then go below to final box 'here you can add "other" specific areas of EU legislation'.

Registration and Marketing Authorisation for Homeopathic Medicinal products

ECHAMP's concerns on four topics in brief:

1 ***Enforcement of the legislation in general:*** Enforcement and implementation of Directive 2001/83/EC is by no means complete for either Articles 14 or 16.2, twenty years after the adoption of Directive 92/73/EEC. This leads to practical difficulties to cater for growing demand and availability.

2 ***Administrative burden and resources (human and financial) issues:*** The administrative burden for establishing and maintenance of authorisations is too heavy for SMEs. This is largely due to the large portfolio of homeopathic stocks and finished products which is characteristic for our products sector.
The Mutual Recognition Procedures have failed, mainly because of duplication of efforts and increased burden (rather than the intended burden reduction and simplification of procedure). In fact, this procedure has only been implemented for two homeopathic stocks (out of a range of some thousand). The overall cost in terms of time and resources spent (both by industry as well as the competent authorities) was higher than the total sum of the turnover of these two products over two decades.
The regulatory environment, including the assessment capacity and policy at Member State level, is disproportionate and completely insufficient/ it does not help our sector, but actually hinders it. Moreover, it does not contribute to the quality nor to the safety of the finished products.

3 ***Practical difficulties with the implementation of article 16.2 (with indication*)**: Execution of this Article is problematic, mainly due to a lack of adequate rules and procedures.

4 **Non homoeopathically manufactured anthroposophic medicinal products** fall outside the scope of the current legislation, despite the fact that they are fully considered (and authorised) as medicinal products in some member states: This is not in line with the current increasing demand and growing emphasis on patient choice.

B2 Click on YES and then click under Consumer protection on Pharmaceuticals Directive 2001/83/EC

+ put in the box final box 'here you can add other pieces of EU legislation': **Commission Directive2003/63/EC, rules, procedures and formats for bringing the proof of quality, safety and effectiveness of medicinal products in the frame of the Registration and Marketing Authorisation of the European Union.**

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Directive 92/73/EEC on homeopathic medicinal products consolidated within Directive 2001/83/EC, registration procedures, including the Mutual Recognition. The basic rules for bringing the proof of quality, safety and effectiveness are laid down in Commission Directive 2003/63/EC (also known as Annex I to Directive 2001/83/EC).

The current regulatory framework obliges our members to apply (e.g. for market access authorisation) in each of the individual 27 Member States for the same products. As a result, the huge costs to put and keep products on the EU market as a whole render the EU market (the 'home market', the continent of origin and know-how on homeopathy and anthroposophic medicine) more difficult for our industry than the export markets.

This in turn leads to availability issues, and not being able to cater for the needs of patients and practitioners. Moreover, it leads to parallel trade and e-commerce of products which are not being submitted to the required quality and safety assessments. We therefore call on the Commission to take action to put in place a more proportionate, reasonable and actionable regulatory framework, which will actually support rather than stunt the growth and development of our industry.

B3 Click on 'no'

C Click on 'DO not Know' or 'No'

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