EN
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Answer given by Mr Andriukaitis
on behalf of the European Commission
(23.11.2018)

1) The Commission is not aware of similar requests from other Member States calling for the amendment of the current legislation concerning homeopathic medicinal products.

2) The Commission considers that the current regulatory framework for homeopathic products takes into account their specific nature and strikes a balance between ensuring their quality and safety and informing consumers including health professionals, while at the same time giving citizens access to these products. In particular, producers shall not associate clinical claims with homeopathic products without demonstrable therapeutic efficacy. In addition, the label of these products shall include "homeopathic medicinal product without approved therapeutic indications" and a warning to "consult a doctor if the symptoms persist". There are no plans in the Commission at this time to evaluate or amend the legislation on homeopathic products.

3) Directive 2001/83/EC[1] requires that homeopathic and conventional medicinal products have the same scrutiny in terms of their manufacture, distribution and pharmacovigilance and lays down specific safety provisions for homeopathic products without therapeutic claims. It specifies what information may be used for the advertisement of these products and it does not allow the use of information on clinical efficacy.

   It is Member State competence to monitor that the advertisement of medical products is compliant with the legislation. Finally, Member States remain free to take actions at national level to raise awareness of the specific characteristics of homeopathic medicines.

[1] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:311:0067:0128:en:PDF