

EN
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Answer given by Mr Andriukaitis
on behalf of the European Commission
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EU legislation on homeopathic medicines was introduced in 1992 with the aim of ensuring their quality and safety whilst at the same time providing a clear indication of their homeopathic nature. At the time of adoption of the legislation, it was considered that despite the differences in recognition between Member States, consumers across the EU should be adequately protected if they choose to use homeopathic medicines.

Under the current simplified registration procedure, homeopathic medicines must not mention specific therapeutic indications and must be diluted to a sufficient degree to ensure their safety. Furthermore, their labelling must clearly mention that they are 'homeopathic medicinal products without approved therapeutic indications' and shall bear a warning advising to consult a doctor if symptoms persist.

There are currently no plans to revise Directive 2001/83/EC¹ as regards homeopathic medicinal products or change their designation to "homeopathic substances".

¹ https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2001_83_consol_2012/dir_2001_83_cons_2012_en.pdf