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Answer given by Mr Andriukaitis
on behalf of the Commission
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EU legislation on homeopathic medicines[1] 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 be diluted to a sufficient degree to ensure their safety[2]. Furthermore, their labelling must clearly mention that they are 'homeopathic medicinal products'.

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

[1] Council Directive 92/73/EEC of 22 September 1992 widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to medicinal products and laying down additional provisions on homeopathic medicinal products (OJ L 297, 13.10.1992, p. 8)

[2] Article 14(1) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67)