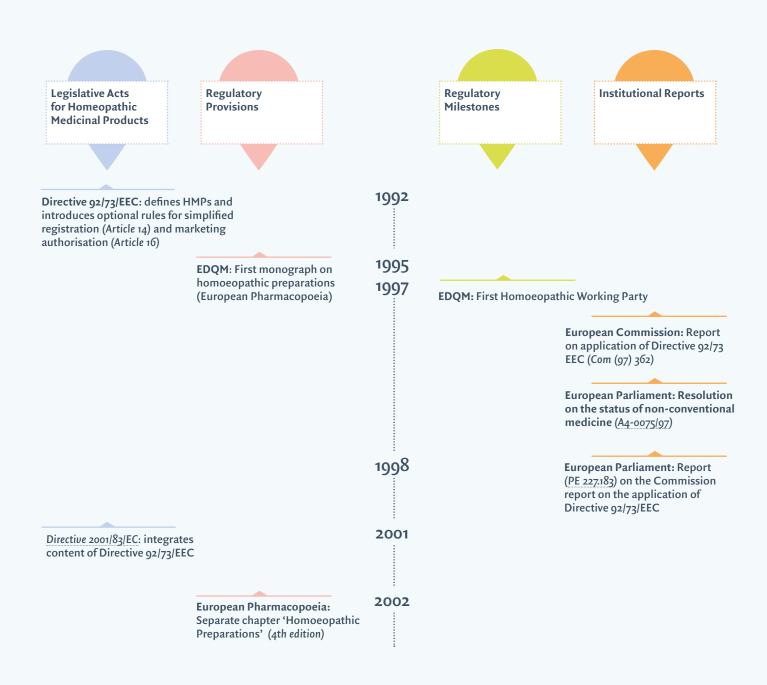


EU Pharmaceutical Regulation 1992-2020 The milestones for homeopathic medicinal products (HMPs)

Specific legislation for homeopathic medicinal products has deep roots in their broad use in the Member States. Even before the introduction of the first EU legislation in 1992, homeopathic medicinal products were prescribed and used in all Member States. Regulation of these products dates back to 1967 in France and 1976 in Germany.

In 1992, <u>Directive 92/73/EEC</u> created specific provisions for homeopathic medicinal products with the intention of creating a legal frame that would allow patients access to the medicinal products of their choice, while at the same time making sure that all precautions would be taken to ensure their quality and safety. The basic values for the legislation were free trade within the Community and freedom of choice for patients and the main motivation behind the legislation was the intention to safeguard quality and safety.



EU Pharmaceutical Regulation 1992-2020 The milestones for homeopathic medicinal products (HMPS)

Legislative Acts Regulatory Regulatory **Institutional Reports** for Homeopathic **Provisions** Milestones **Medicinal Products** Directive 2003/63/EC: Annex I includes 2003 chapter on quality and safety requirements for HMPs 2004 Directive 2004/27/EC: Simplified **Homeopathic Medicinal Products** registration for HMPs mandatory in all Working Group (HMPWG) set up by Member States; Mutual Recognition **Heads of Medicines Agencies** Procedure / Decentralised Procedure for simplified registered HMPs 2006 EDQM: Homoeopathic Working Party split into Homoeopathic Manufacturing Methods (WP HMM) and Homoeopathic Raw Materials and Stocks (WP HOM) (monographs) 2000 **Mutual Recognition Procedure: First** procedure finalised in one Reference and two Concerned Member States 2010 Directive 2010/84/EU (pharmacovigilance): includes specific provisions for registered HMPs (Article 14) 2011 **Decentralised Procedure: First procedure** finalised in one Reference and four **Concerned Member States** 2015 **European Commission:** releases Matrix Insight Report on Availability of Medicines, including chapter on HMPs and anthroposophic medicinal products 2017 **HMPWG:** Report on the Regulatory Status of Homeopathic **Medicinal Products for Human** Use in EU And EFTA Countries **European Parliament:** Resolution on EU options for improving access to medicines (2016/2057(INI)) calls for patient access to complementary and alternative therapies and medicines. **European Parliament: ENVI** Committee study (PE 614.180) 'Complementary and alternative therapies for patients today and tomorrow' **HMPWG:** Questions and answers 2020

document on regulatory and legal issues concerning homeopathic medicinal products in the

European framework