ECHAMP

European Coalition on
Homeopathic & Anthroposophic
Medicinal Products

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, *Directive 92/73/EEC* 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.

Legislative Acts for Homeopathic Medicinal Products

Regulatory Provisions

Regulatory Milestones

Institutional Reports

1992

Directive 92/73/EEC: defines HMPs and introduces optional rules for simplified registration (*Article 14*) and marketing authorisation (*Article 16*)

1995

EDQM: First monograph on homoeopathic preparations (European Pharmacopoeia)

1997

EDQM: First Homoeopathic Working Party

European Commission: Report on application of Directive 92/73 EEC (*Com (97) 362*)

European Parliament: Resolution on the status of non-conventional medicine (A4-0075/97)

1998

European Parliament: Report (PE 227.183) on the Commission report on the application of Directive 92/73/EEC

2001

Directive 2001/83/EC: integrates content of Directive 92/73/EEC

2002

European Pharmacopoeia: Separate chapter 'Homoeopathic Preparations' (*4th edition*)

EU Pharmaceutical Regulation 1992-2020
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Legislative Acts for Homeopathic Medicinal Products

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2003

Directive 2003/63/EC: Annex I includes chapter on quality and safety requirements for HMPs

2004

Directive 2004/27/EC: Simplified registration for HMPs mandatory in all Member States; Mutual Recognition Procedure / Decentralised Procedure for simplified registered HMPs

Homeopathic Medicinal Products Working Group (HMPWG) set up by Heads of Medicines Agencies

2006

EDQM: Homoeopathic Working Party split into Homoeopathic Manufacturing Methods (WP HMM) and Homoeopathic Raw Materials and Stocks (WP HOM) (monographs)

2009

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'

2020

HMPWG : Questions and answers document on regulatory and legal issues concerning homeopathic medicinal products in the European framework

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