

The implementation status of Article 16(2) of Directive 2001/83/EC

EU 28 Member States	16(2) not implemented	16(2) Implemented including specific rules for proof of efficacy for homeopathic medicinal products	16(2) provided by national law but specific rules for proof of efficacy of homeopathic medicinal products are either not published or not in practice
AUSTRIA		•	
BELGIUM		•	
BULGARIA		•	
CROATIA	•		
CYPRUS	•		
CZECH REPUBLIC		•	
DENMARK			•
ESTONIA			•★
FINLAND		•	
FRANCE		•	
GERMANY		•	
GREECE			•
HUNGARY			•
IRELAND		•	
ITALY			•
LATVIA		•	
LITHUANIA		•	
LUXEMBOURG	•		
MALTA			•
NETHERLANDS			•
POLAND			•
PORTUGAL		•	
ROMANIA	•		
SLOVAK REPUBLIC			•
SLOVENIA	•		
SPAIN			•

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SWEDEN	•		
UNITED KINGDOM		•	
Total number of Member States	6	12	10

* Submission of lower dilutions (<D4) is possible including Module 4