

The Availability of Homeopathic and Anthroposophic Medicinal Products in the EU

Annex II.1 Regulatory Status of Homeopathic and Anthroposophic Medicinal Products - Synthesis of Regulatory Data

Source:	(i) Implementation of Directive 2001/83/EC		(ii) Estimated number of finished HMPs on the market	(iii) No of notifications	(iv) No of Article 14 Registrations			(v) Participation in Mutual Recognition Procedure	(vi) No of Article 16.2 Authorisations		
	(a) Article 14 and provisions for mutual recognition procedure	(b) Article 16.2			(a) PwC ²	(b) Web Dec 2010 ³	(c) Web Dec 2011 ⁴		(a) PwC ²	(b) Web Dec 2010 ³	(c) Web Dec 2011 ⁴
Key:	v: implemented	o: optional implementation provided for x: not implemented	n/r: No response <i>Italics</i> : approx number	n/r: No response <i>Italics</i> : approx number	n/r: No response Applications/of which registered	Total registered products/number of stocks or singles n/a: not available	n/a: not available	n/r: No response as RMS/as CMS	Applications/of which granted a MA n/r: No response x: not implemented	n/a: not available x: not implemented	n/a: not available x: not implemented
Austria	v	v	n/r	n/r	n/r	6209	4138	n/r	n/r	n/a	797
Belgium	v	v	15000	18000	39/0	n/a	n/a	0/0	35/1	n/a	n/a
Bulgaria	v	v	n/r	n/r	n/r	n/a	n/a	n/r	n/r	65	74
Cyprus	v	o	0	0	0	n/a	n/a	0/0	0/0	n/a	n/a
Czech Republic	v	x	316	0	317/316	3414/258	3310	0/0	x	x	x
Denmark	v	o	5000	5000	3/0	3306	n/a	0/0	0/0	n/a	n/a
Estonia	v	o	n/r	n/r	n/r	n/a	n/a	n/r	n/r	22	21
Finland	v	v	505	unknown	37/12	181	n/a	0/0	3/Unknown	n/a	n/a
France	v	v	n/r	n/r	n/r	1163 Liste Jnl Off 350 Monographs Ph.Fr 173 Applications	1163 Liste Jnl Off 350 monographs Ph.Fr 308 applications	n/r	n/r	34	34
Germany	v	v	n/r	n/r	n/r	3692	3641 (1937 single; 1704 complex)	n/r; info members 2/0	n/r	1309	1270 (166 single; 1104 complex)
Greece	v	o	n/r	n/r	n/r	n/a	n/a	n/r	n/r	n/a	n/a
Hungary	v	o	n/r	n/r	n/r	3404/269	n/a	n/r	n/r	n/a	n/a
Ireland	v	v	unknown	confidential	confidential/43	57	65	0/0	confidential/0	n/a	n/a
Italy	v	o	31000	31000	unknown	n/a	n/a	0/1	Unknown	n/a	n/a
Latvia	v	v	111	unknown	unknown	n/a	n/a	Unknown	Unknown	n/a	n/a
Lithuania	v	v	n/r	n/r	n/r	n/a	n/a	n/r	n/r	n/a	n/a
Luxembourg	v	x	n/r	n/r	n/r	n/a	n/a	n/r	x	x	x
Malta	v	o	n/r	n/r	n/r	n/a	n/a	n/r	n/r	n/a	n/a
Netherlands	v	v	3800	No notification system	3283/3183	n/a	4464 (Art. 14 + Art. 16)	0/3	699/619	n/a	4464 (Art. 14 + Art. 16)
Poland	v	v	n/r	n/r	n/r	578/336	n/a	n/r	n/r	n/a	n/a
Portugal	v	v	846	3300	1230/830	51212/832	39500	0/1	0/0	n/a	n/a
Romania	v	x	n/r	n/r	n/r	48	60	n/r	x	x	x
Slovakia	v	o	n/r	n/r	n/r	1036/110	970	n/r	n/r	n/a	n/a
Slovenia	v	o	n/r	n/r	n/r	n/a	n/a	n/r	n/r	n/a	n/a
Spain	v	v	n/r	n/r	n/r	n/a	n/a	n/r	n/r	n/a	n/a
Sweden	v	x	1200	550	1200/650	1196/615	2263	0/0	x	x	x
United Kingdom	v	v	759	unknown	317/262	825/285	224	0/1	14/1	1	1

Sources:

1. Homeopathic and Anthroposophic Medicinal Products in Europe, Facts and Figures 3rd Edition, ECHAMP 2011
2. Survey on Homeopathic and Anthroposophic Medicinal Products - Regulatory Status Survey Report, PwC, October 2010 (Annex II.2)
3. Websites of the medicines agencies December 2010
4. Websites of the medicines agencies December 2011 (Annex II.3)