

# The Availability of Homeopathic and Anthroposophic Medicinal Products in the EU

## Report Summary

Launch of Report: November 2013

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## 1. Conclusions of the Report

A new report from ECHAMP,<sup>1</sup> including data from two independent surveys by PwC,<sup>2,3</sup> provides an up to date and objective analysis of the status and deficits concerning the availability of homeopathic and anthroposophic medicinal products in the EU. It concludes that:

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### Demand

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There is significant to high demand for homeopathic and anthroposophic medicinal products in at least two thirds of EU Member States, and this applies to countries both with and without a long-term tradition for these products.

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### Availability

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Availability of registered/authorised homeopathic and anthroposophic medicinal products in the EU is insufficient and the demand cannot always be met. The types of products most widely available in pharmacies are those requested for self-medication.

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### European legislation

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Implementation and enforcement of European medicines legislation for this sector has been slow and is very incomplete even twenty years after its adoption. Divergent implementation, interpretation and enforcement policy in the Member States make it extremely difficult for companies to operate across Europe.

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### Regulatory environment

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The regulatory environment, including assessment capacity and policy at national level, is not proportionate to the large range of stocks and multiple finished medicinal products produced from these stocks, which are used in homeopathic and anthroposophic therapy. In many Member States the number of registered products poorly reflects the high numbers of homeopathic prescribers.

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### Sustainability

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Availability is threatened in some Member States by the lack of a registration process, and in others by an incomplete process for the renewal of existing registrations. The regulatory burden is such that it is not sustainable to maintain registrations for the full range of medicinal products required for proper practice of these therapies.

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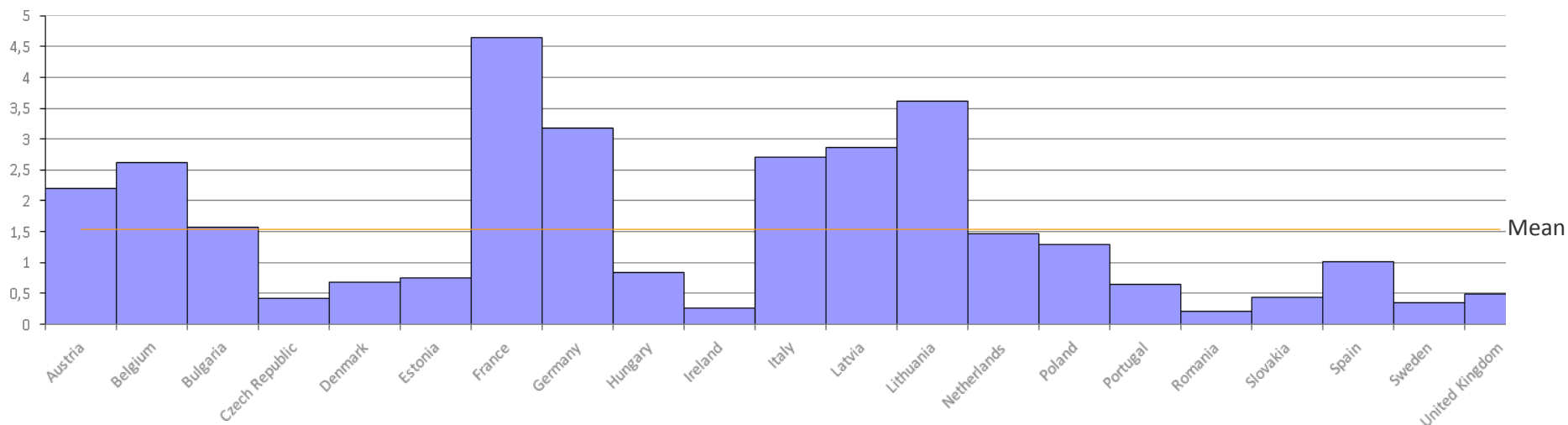
<sup>1</sup> The Availability of Homeopathic and Anthroposophic Medicinal Products in the EU, ECHAMP, May 2012

<sup>2</sup> Regulatory Status Survey Report – Survey on Homeopathic and Anthroposophic Medicinal Products, PwC, December 2010

<sup>3</sup> Survey on the Availability of Homeopathic and Anthroposophic Medicinal Products in five Member States, PwC, April 2012

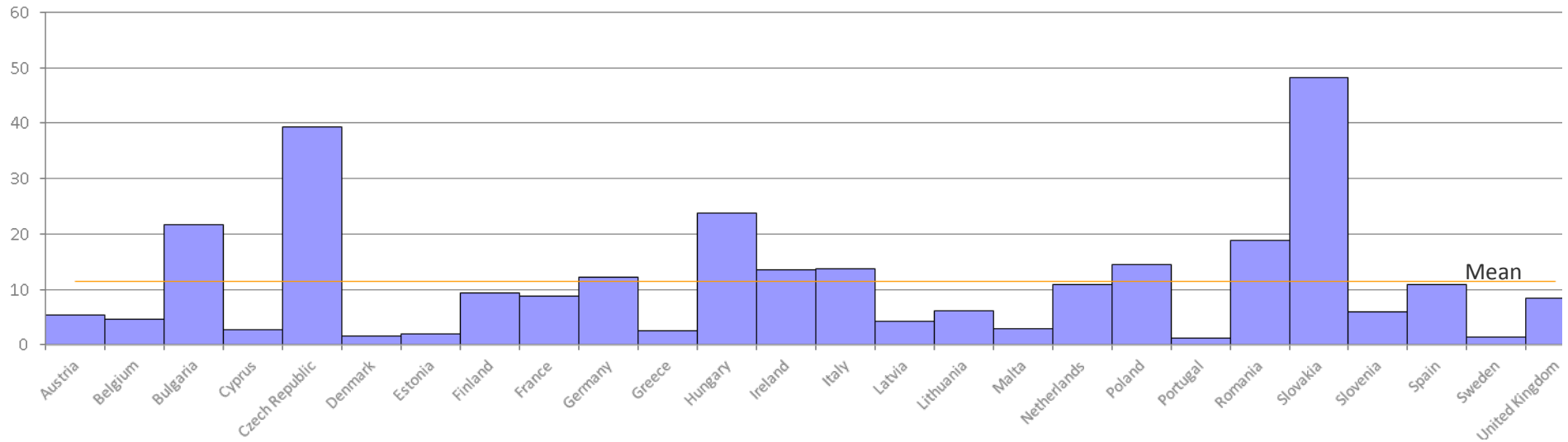
## 2. Socio-economic, Demand and Sales Data – Summary Charts

a. Sales of homeopathic and anthroposophic medicinal products per inhabitant in relation to GDP per capita expressed in PPS (€)



Source: The Availability of Homeopathic and Anthroposophic Medicinal Products in the EU, ECHAMP, May 2012

b. Number of homeopathic prescribers per 100,000 inhabitants



Source: The Availability of Homeopathic and Anthroposophic Medicinal Products in the EU, ECHAMP, May 2012

### 3. The Regulatory Status of Homeopathic and Anthroposophic Medicinal Products - Summary Table

	(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 <sup>2</sup>	(b) Web Dec 2010 <sup>3</sup>	(c) Web Dec 2011 <sup>4</sup>		(a) PwC <sup>2</sup>	(b) Web Dec 2010 <sup>3</sup>	(c) Web Dec 2011 <sup>4</sup>
Source:	ECHAMP <sup>1</sup>	ECHAMP <sup>1</sup>	PwC <sup>2</sup>	PwC <sup>2</sup>	(a) PwC <sup>2</sup>	(b) Web Dec 2010 <sup>3</sup>	(c) Web Dec 2011 <sup>4</sup>	PwC <sup>2</sup>	(a) PwC <sup>2</sup>	(b) Web Dec 2010 <sup>3</sup>	(c) Web Dec 2011 <sup>4</sup>
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	√	√	n/r	n/r	n/r	6209	4138	n/r	n/r	n/a	797
Belgium	√	√	15000	18000	39/0	n/a	n/a	0/0	35/1	n/a	n/a
Bulgaria	√	√	n/r	n/r	n/r	n/a	n/a	n/r	n/r	65	74
Cyprus	√	o	0	0	0	n/a	n/a	0/0	0/0	n/a	n/a
Czech Republic	√	x	316	0	317/316	3414/258	3310	0/0	x	x	x
Denmark	√	o	5000	5000	3/0	3306	n/a	0/0	0/0	n/a	n/a
Estonia	√	o	n/r	n/r	n/r	n/a	n/a	n/r	n/r	22	21
Finland	√	√	505	unknown	37/12	181	n/a	0/0	3/Unknown	n/a	n/a
France	√	√	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	√	√	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	√	o	n/r	n/r	n/r	n/a	n/a	n/r	n/r	n/a	n/a
Hungary	√	o	n/r	n/r	n/r	3404/269	n/a	n/r	n/r	n/a	n/a
Ireland	√	√	unknown	confidential	confidential/43	57	65	0/0	confidential/0	n/a	n/a
Italy	√	o	31000	31000	unknown	n/a	n/a	0/1	Unknown	n/a	n/a
Latvia	√	√	111	unknown	unknown	n/a	n/a	Unknown	Unknown	n/a	n/a
Lithuania	√	√	n/r	n/r	n/r	n/a	n/a	n/r	n/r	n/a	n/a
Luxembourg	√	x	n/r	n/r	n/r	n/a	n/a	n/r	x	x	x
Malta	√	o	n/r	n/r	n/r	n/a	n/a	n/r	n/r	n/a	n/a
Netherlands	√	√	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	√	√	n/r	n/r	n/r	578/336	n/a	n/r	n/r	n/a	n/a
Portugal	√	√	846	3300	1230/830	51212/832	39500	0/1	0/0	n/a	n/a
Romania	√	x	n/r	n/r	n/r	48	60	n/r	x	x	x
Slovakia	√	o	n/r	n/r	n/r	1036/110	970	n/r	n/r	n/a	n/a
Slovenia	√	o	n/r	n/r	n/r	n/a	n/a	n/r	n/r	n/a	n/a
Spain	√	√	n/r	n/r	n/r	n/a	n/a	n/r	n/r	n/a	n/a
Sweden	√	x	1200	550	1200/650	1196/615	2263	0/0	x	x	x
United Kingdom	√	√	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)

Source : The Availability of Homeopathic and Anthroposophic Medicinal Products in the EU, ECHAMP 2012

## 4. Survey on the Availability of Homeopathic and Anthroposophic Medicinal Products

### Executive summary of findings by PwC

An independent survey on the availability of homeopathic and anthroposophic medicinal products (HAMPs) was commissioned from PwC.<sup>4</sup> This was executed for six products in five Member States between January and March 2012. PwC summarises the results as follows:

“Based on the countries surveyed and the homeopathic and anthroposophic medicinal products questioned, a **difference in the availability of HAMP** is noticeable:

- Some countries have a **better developed market of HAMP**, such as France, Spain and especially Germany showing highest availability of most products and short delivery times if a product order has been placed.
- **Specific brands** of medicinal products with **no therapeutic indication**, reflecting the classical single remedy homeopathy, are often **difficult to find immediately** (i.e. without ordering). However, these products can **mostly be delivered to customers after a product order** has been placed. Of the two products questioned in the survey within this segment, Formica (rufa) was the hardest one to find.
- However, requesting **homeopathic medicinal products for specific symptoms**, i.e. medicinal products **with a therapeutic indication** (instead of specific brands for these symptoms), results in much **better direct availabilities**. Self-medication seems to be well-developed for the indications surveyed.
- **Anthroposophic medicinal products** are **seldom directly available** in the countries surveyed. Only in countries with a more or less well-functioning HAMP regulatory system, the products surveyed can be ordered and delivered accordingly, with Germany as best-in-class.
- The products’ **availability** does **not show significant differences across the geographical regions** within the countries surveyed: the availability of the products questioned is more or less the same in **big cities, middle-sized cities, and countryside areas**.
- As regards **registration or authorisation numbers**, a validation of the products provided has been done by a qualified person and led to the following general statements:
  - In **Spain** none of the products provided carried an authorisation number.
  - In **France** most of the products did not show an authorisation number either.
  - In **Germany** and **Bulgaria** most of the products provided carried an authorisation number.
  - In **Romania** the situation could not be validated due to the loss of the pack with the samples in the post.”

<sup>4</sup> Survey on the Availability of Homeopathic and Anthroposophic Medicinal Products in five Member States of the EU, PwC, April 2012, from The Availability of Homeopathy and Anthroposophic Medicinal Products, ECHAMP 2012