ECHAMP
European Coalition on
Homeopathic & Anthroposophic
Medicinal Products

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European Academies Science Advisory Council (EASAC) Statement on Homeopathic Products and Practices

Response from ECHAMP

EASAC's statement[1] seeks to provide a scientific basis for policy making for homeopathic medicinal products in the EU; yet its assessment is based on incomplete knowledge of the current EU regulatory system for these products. Its review of the evidence for homeopathy depends on unreliable reports and studies and contains only second hand scientific analysis.

ECHAMP shares EASAC's goal of allowing and supporting consumer choice and continuously works to ensure an appropriate regulatory environment for these products. However this should be based on accurate and up-to-date information, reflecting current European practice. We remain open to a meaningful dialogue to best support the choice of the millions and growing numbers of patients in Europe who benefit from and choose to use these medicines.

EU – a global centre of expertise

Homeopathic medicinal products cover a broad portfolio of safe, effective and high quality medicines generally derived from natural substances.

Europe is the global centre of expertise for the manufacture of these medicines. Manufacturers in Europe work to the highest quality standards; they have a long track record of safety and the use of the products is supported by long documented use and an emerging and evolving evidence base.

Quality control and safety

EASAC claims that there are potential safety concerns for homeopathic preparations because of poorly monitored production methods; this does not reflect the facts for licensed homeopathic medicines in the EU.

In the EU, licensed homeopathic medicinal products comply with the highest standards for manufacture and quality control, along with all pharmaceutical products.

The authorisation for a homeopathic medicinal product to be present on the market in the EU for human use is regulated by Directive 2001/83/EC, completed with specific provisions on the proof of quality, safety and efficacy in Directive 2003/63/EC.

In the EU, these products are further governed by quality standards of official pharmacopoeias and produced according to current Good Manufacturing Practice (GMP) as determined by EU

[1] http://www.easac.eu/fileadmin/PDF_s/reports_statements/EASAC_Homeopathy_Statement.jpg

and national pharmaceutical legislation for all pharmaceutical products. This guarantees that each product released onto the market can be traced back to the specific batch in which it was made and the date on which it was manufactured. Likewise, the raw material can also be traced back to its origin.

Homeopathic medicinal products subject to the regime for simplified registration are by definition very safe, given the conditions of this procedure. Products that do not meet these conditions are subject to standardised pharmacovigilance (surveillance of product safety) procedures according to the law.

Long-term experience, as confirmed by studies, demonstrates that these medicines have a high safety profile.[2] The frequency of adverse reactions to homeopathic medicinal products is very low and serious adverse reactions are very rarely reported.

Labelling and marketing

EASAC calls for accuracy in labelling and marketing of these products, demonstrating limited knowledge of the existing EU requirements.

In the EU, packaging and labelling of homeopathic medicinal products are regulated by Title V of Directive 2001/83/EC, meaning they are already required to include an accurate, clear and simple description of the ingredients and their amounts present in the formulation.

Medicines registered under Article 14 of the Directive are required to be sold with a disclaimer, without indications and with restricted information. Those authorised under Article 16.2 follow normal guidelines for the packaging and labelling of medicinal products based on the licensing process, following rigorous market authorisation procedures. In addition, national rules require transparency on the nature of the scientific evidence.

The promotion of homeopathic medicinal products follows overall European rules for the advertising of medicinal products as supplemented by the individual rules of the Member states.

Clinical evidence

EASAC's statement relies on a number of negative and unreliable studies and reports, failing to carry out any scientific analysis and excluding any quality evidence from the wider body of homeopathic research that supports the efficacy of homeopathy.

The statement bases its assessment of the evidence base for homeopathy on three unreliable studies - the discredited 2010 UK House of Commons Science and Technology Committee's report[3] on homeopathy; the Australian National Health and Medical Research Council's (NHMRC) 2015[4] review of homeopathy that is currently under investigation by the

[2] http://www.echamp.eu/our-sector/practice-and-evidence/clinical-data-and-research/fewer-side-effects
[3] House of Commons Science and Technology Committee Evidence Check 2: Homeopathy 2009–10 – see also https://www.hri-research.org/resources/homeopathy-the-debate/uk-select-committee-report/
[4] NHMRC Information Paper – Evidence on the effectiveness of homeopathy for treating health conditions, March 2015; see also https://www.hri-research.org/resources/homeopathy-the-debate/the-australian-report-on-homeopathy/

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Commonwealth Ombudsman for a number of irregularities in the way it was conducted; and the 2005 Shang[5] review, which has attracted widespread criticism and has now been superseded by a more positive later study.[6]

EASAC appears to have simply accepted and repeated the questionable findings of studies and reports that support a critical view on homeopathy rather than investigating in a scientific way the emerging and most up-to-date scientific debate around this topic.

Public engagement

EASAC suggests that the public use homeopathy in ignorance or because they confuse it with other therapeutic systems.

There is a significant to high demand for homeopathic medicinal products in two third of EU Member States and market data demonstrates growing use of homeopathy across the EU.[7] Patients say they choose these medicines for their safety and effectiveness, their very low side effects and because they are natural and non-toxic. Studies demonstrate a high level of patient satisfaction with homeopathic medicines.[8]

Further Notes

1. ECHAMP is the European Coalition on Homeopathic & Anthroposophic Medicinal Products. It works to develop the industry for these medicinal products so as to ensure availability of both medicines for self-medication and medicines recommended by prescribers. It advocates in favour of an appropriate regulatory environment for these products in the EU.

2. Homeopathic medicines cover a broad portfolio of products mostly derived from natural substances. They have a proven positive safety profile and are part of a long-standing European therapeutic tradition that continues to grow in popularity with patients, doctors and practitioners. Thousands of these products have been safely on the market in Europe for many decades.

[5] Shang A, Huwiler-Muntener K, Nartey L, et al. Are the clinical effects of homeopathy placebo effects? Comparative study of placebo-controlled trials of homeopathy and allopathy. *Lancet* 2005; **366**: 726–732 ; see also https://www.hri-research.org/resources/homeopathy-the-debate/the-lancet-paper-by-shang-et-al/

[6] Mathie RT et al. Randomised placebo-controlled trials of individualised homeopathic treatment: systematic review and meta-analysis. *Systematic Reviews*, 2014; **3**: 142

[7] Homeopathic and Anthroposophic Medicinal Products in the EU – Profile of an Industry, ECHAMP 2015

[8] http://www.echamp.eu/our-sector/practice-and-evidence/clinical-data-and-research/patient-satisfaction