

Assessing and regulating homeopathic products

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Introduction

Homeopathy is a system of alternative medicine based on 'like cures like' whereby a substance that causes a symptom is used to treat the same symptom in illness. A process of serial dilution and shaking (succussion) is alleged to increase potency, and some practitioners claim that homeopathy works by causing the body to heal itself.

Many scientists and physicians are very critical of the health claims made for homeopathic products. Nonetheless, recent usage data from social surveys show that in some European countries (e.g. Austria, France and Germany), more than 10% of the population used homeopathy in the previous 12 months. Based on market analysis, it is anticipated that sales worldwide will grow substantially in the next decade.

The European Academies Science Advisory Council (EASAC) recently established a working group including the present authors and others (see Acknowledgements) to prepare a statement [1], building on work by many in the scientific and medical communities, to reinforce criticism of the health and scientific claims made for homeopathic products. EASAC is formed by the national science academies of the EU member states to enable them to collaborate as a collective voice of science in giving advice to European policymakers. EASAC initiated this project because of the increasing discussion in some EU member states and within their academies about issues associated with homeopathy, including its use and labelling, within a broader international context of growing interest in similar issues.

Here, we discuss some of the consensus conclusions and recommendations from this EASAC statement within the international context. Our purposes are to encourage policy makers to take a critical, evidence-based approach to assessing the claims for homeopathy and to support all those

who are interested in stimulating better public engagement and improving consumers' rights in this contentious area. In this Commentary, we focus on the medical claims for homeopathy and the issues associated with demonstrating, verifying and promoting such claims. The EASAC statement also considered scientific claims relating to potential mechanisms of action, for example effects ascribed to long-range, long-term imprinted memory of water, and concluded that all such claims are unfounded, implausible and contrary to the large, established evidence base regarding dose-response relationships and drug-receptor interactions.

Our starting point was the affirmation of the fundamental importance of basing both appropriately informed consumer choice and the prescription of medicinal products on accurate and clear information. This requires a standardized, knowledge-based regulatory framework to include the efficacy, safety and quality of all health products, underpinned by advertising practices that conform to established principles. We decided that our task was not to re-evaluate all the available evidence for and against the medical claims made for homeopathic products but rather to draw on the excellent science-based assessments already made by authoritative and objective bodies. Member academies of EASAC have individually advised on these matters, for example recently in detail in Sweden as well as in Hungary and the UK.

Clinical efficacy

The Australian government's National Health and Medical Research Council comprehensively reviewed the published evidence for 68 health conditions and concluded that there are no known diseases for which there is reliable evidence that homeopathy is effective [2]. An earlier UK parliamentary inquiry [3] concluded that all the evidence from systematic reviews and meta-analyses [4, 5] conclusively demonstrated that homeopathic

products performed no better than placebo. Cochrane reviews of homeopathic treatment of several indications, including asthma, dementia, irritable bowel syndrome and influenza, concluded that there was no or insufficient evidence to reliably assess a possible effect of homeopathy [6].

In reviewing the literature, the EASAC analysis emphasized that any therapeutic effect of the homeopathic preparations as perceived by the patient is due to its placebo effect. In addition, other factors, such as the natural course of the illness, regression to the mean, random variation, poor study design and publication bias, may variously contribute to an overall misperception that homeopathy is of value. The benefit of any placebo effect may be offset by significant harm in homeopathic practice. Patients using a homeopathic product may delay or be deterred from seeking more appropriate, evidence-based medical care [3], and this harm is exacerbated if homeopathic practitioners undermine mainstream medicine [5].

Some countries allow reimbursement of homeopathic products in public health systems, but EASAC concluded that, in the absence of robust evidence for efficacy, this reimbursement policy should be reconsidered. Provision in pharmacies is also becoming more controversial. Recent advice from an independent panel reviewing pharmacy regulations for the health department in Australia recommended in its interim report that homeopathic products should not be sold in pharmacies on the grounds that they do not work and place consumers at unacceptable risk [7].

The use of homeopathic products in veterinary medicine is also contentious. A systematic review of research to replace antibiotics led to the conclusion that there is insufficient evidence to support the use of homeopathic products in food-producing animals as a way to prevent or treat infectious diseases [8].

Quality control and safety

It has often been assumed that, because homeopathic preparations are diluted so many times that none of the original substance remains, there are no safety concerns. This may not be so. In recent investigations by the US FDA, severe adverse effects including infant deaths were found to have been reported for teething products using belladonna as the starting material [9]. There are important

implications for regulatory frameworks to ensure stringent quality control in production and continued monitoring to assess adverse events.

Labelling and marketing claims

In many countries, homeopathic products are exempt from regulations that require listing of ingredients and quantities. Labelling is allowed in terms of the scientific name of the stock material followed by degree of dilution, which may confer a spurious scientific legitimacy. This is not helpful for the consumer, who may not understand that there is little or no active ingredient present [10].

Reform of labelling should be accompanied by reform of marketing, to adopt advertising standards for evidence-based claims. Recent pronouncements, for example by the UK Advertising Standards Authority and the US Federal Trade Commission, which are discussed in detail in the EASAC statement, note the importance of basing medical claims on robust evidence, as part of the wider harmonization of regulatory procedures to apply a common standard of proof [11].

Public engagement

The growing popularity of homeopathy in some countries might seem to exemplify a more widespread problem: that scientific evidence is not always understood or accepted by policy makers or the public. Nonetheless, the significant decline in the use of homeopathy in public health services in some countries, for example the UK [12], could be taken as an indication of the progressive professional and public response to the accumulating evidence of lack of efficacy.

There is much more to be done to inform patients and the public in many countries about the nature and value of scientific evidence in healthcare choices. For example, lessons can be shared on how best to counter self-interested lobbying by those, including some homeopathic practitioners, who deny the value of immunization [13].

Summary

In conclusion, the EASAC statement concurs with the assessment that there are no clinical conditions for which there is robust and reproducible evidence that homeopathy is effective beyond the placebo effect. Our recommendations in support of

informed patient and consumer choice include the following.

First, there should be a consistent, coherent regulatory standard for claims of efficacy, safety and quality of all medicinal products. This must be based on excellent science, that is objective, verifiable and documented data. Adequate testing is essential in both human and veterinary medicine; in the absence of robust and reproducible evidence, products should not be approvable or registrable by medicines regulatory agencies.

Secondly, evidence-based public health systems should not reimburse for products and services unless they are demonstrated to be efficacious and safe.

Thirdly, the composition of homeopathic products should be labelled in a similar way to other health and consumer products. This labelling must include an accurate, clear and simple description of the ingredients and the quantities present.

Finally, advertising or other marketing claims made for efficacy and safety must conform to established standards and should not be permitted without sufficient verifiable evidence.

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Conflict of Interest

The authors declare no conflict of interest.

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