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Science Advisory Council

statement

European Academies' Science Advisory Council

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Homeopathic products and practices: assessing the evidence and ensuring consistency in regulating medical claims in the EU

Summary

EASAC, the European Academies' Science Advisory Council, is publishing this Statement to build on recent work by its member academies to reinforce criticism of the health and scientific claims made for homeopathic products. The analysis and conclusions are based on the excellent science-based assessments already published by authoritative and impartial bodies. The fundamental importance of allowing and supporting consumer choice requires that consumers and patients are supplied with evidence-based, accurate and clear information. It is, therefore, essential to implement a standardised, knowledge-based regulatory framework to cover product efficacy, safety and quality, and accurate advertising practices, across the European Union (EU).

Our Statement examines the following issues:

Scientific mechanisms of action—where we conclude that the claims for homeopathy are implausible and inconsistent with established scientific concepts.

Clinical efficacy—we acknowledge that a placebo effect may appear in individual patients but we agree with previous extensive evaluations concluding that there are no known diseases for which there is robust, reproducible evidence that homeopathy is effective beyond the placebo effect. There are related concerns for patient-informed consent and for safety, the latter associated with poor quality control in preparing homeopathic remedies.

Promotion of homeopathy—we note that this may pose significant harm to the patient if incurring delay in seeking evidence-based medical care and that there is a more general risk of undermining public confidence in the nature and value of scientific evidence.

Veterinary practice—we conclude similarly that there is no rigorous evidence to substantiate the use of homeopathy in veterinary medicine and it is particularly worrying when such products are used in preference to evidence-based medicinal products to treat livestock infections.

We make the following recommendations.

1. There should be consistent regulatory requirements to demonstrate efficacy, safety and quality of all products for human and veterinary medicine, to be based on verifiable and objective evidence, commensurate with the nature of the claims being made. In the absence of this evidence, a product should be neither approvable nor registrable by national regulatory agencies for the designation medicinal product.
2. Evidence-based public health systems should not reimburse homeopathic products and practices unless they are demonstrated to be efficacious and safe by rigorous testing.
3. The composition of homeopathic remedies should be labelled in a similar way to other health products available: that is, there should be an accurate, clear and simple description of the ingredients and their amounts present in the formulation.
4. Advertising and marketing of homeopathic products and services must conform to established standards of accuracy and clarity. Promotional claims for efficacy, safety and quality should not be made without demonstrable and reproducible evidence.

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EASAC

EASAC – the European Academies' Science Advisory Council – is formed by the national science academies of the EU Member States to enable them to collaborate with each other in giving advice to European policy-makers. It thus provides a means for the collective voice of European science to be heard. EASAC was founded in 2001 at the Royal Swedish Academy of Sciences.

Its mission reflects the view of academies that science is central to many aspects of modern life and that an appreciation of the scientific dimension is a pre-requisite to wise policy-making. This view already underpins the work of many academies at national level. With the growing importance of the European Union as an arena for policy, academies recognise that the scope of their advisory functions needs to extend beyond the national to cover also the European level. Here it is often the case that a trans-European grouping can be more effective than a body from a single country. The academies of Europe have therefore formed EASAC so that they can speak with a common voice with the goal of building science into policy at EU level.

Through EASAC, the academies work together to provide independent, expert, evidence-based advice about the scientific aspects of public policy to those who make or influence policy within the European institutions. Drawing on the memberships and networks of the academies, EASAC accesses the best of European science in carrying out its work. Its views are vigorously independent of commercial or political bias, and it is open and transparent in its processes. EASAC aims to deliver advice that is comprehensible, relevant and timely.

EASAC covers all scientific and technical disciplines, and its experts are drawn from all the countries of the European Union. It is funded by the member academies and by contracts with interested bodies. The expert members of EASAC's working groups give their time free of charge. EASAC has no commercial or business sponsors.

EASAC's activities include substantive studies of the scientific aspects of policy issues, reviews and advice about specific policy documents, workshops aimed at identifying current scientific thinking about major policy issues or at briefing policy-makers, and short, timely statements on topical subjects.

The EASAC Council has 29 individual members – highly experienced scientists nominated one each by the national science academies of EU Member States, by the Academia Europaea and by ALLEA. The national science academies of Norway and Switzerland are also represented. The Council is supported by a professional Secretariat based at the Leopoldina, the German National Academy of Sciences, in Halle (Saale) and by a Brussels Office at the Royal Academies for Science and the Arts of Belgium.

To find out more about EASAC, visit the website – www.easac.eu – or contact the EASAC Secretariat at secretariat@easac.eu

1 Introduction

Homeopathy is a concept for the manufacture and use of various highly diluted products to treat diseases, which was created in 1796 by Samuel Hahnemann. His doctrine was based on 'like cures like', whereby a substance that causes a symptom is used to treat the same symptom in illness. A second central principle is the 'law of infinitesimals', which involves a process of serial dilution and shaking (succussion) that is asserted to increase potency. Some practitioners claim that homeopathy works by stimulating the body to heal itself.

Many scientists and medical doctors are very critical of the health claims made for homeopathic products and practices and consider the explanations advanced for their efficacy scientifically implausible.

EASAC is publishing this Statement to reinforce and reiterate this extensive and well-founded critique, and to encourage and support (1) policy-makers in the EU in taking a more explicitly evidence-based approach to assessing the claims for homeopathy and (2) all those interested in stimulating better public engagement with these contentious issues and in improving consumers' rights to correct information. In preparing our Statement, EASAC is building on work already done by its member academies[1], in particular the Royal Swedish Academy of Sciences (KVA, 2015). Our Statement is prepared with the help of an expert Working Group (Appendix 1) whose members were nominated by the constituent academies of EASAC.

We decided that our task was not to reanalyse all of the evidence available for or against the claims for homeopathic products but to draw upon the excellent science-based assessments performed by other authoritative and impartial bodies. Our purpose is not to seek the prohibition of homeopathic products, and we recognise the fundamental importance of allowing and supporting consumer choice. Rather, we aim to explore the policy dimensions for ensuring informed patient choice with the emphasis on 'appropriately informed', and for achieving a standardised knowledge-based, robust regulatory framework and sound advertising practices across the EU, which can apply equitably to all medicinal products, whatever their origins and whatever their mechanisms. Regulatory procedures for health

Box 1 Wider strategic issues relating to complementary and alternative medicine (CAM) (including homeopathy)

In a statement published in 2015, the Standing Committee of European Doctors (CPME)[2] expressed grave concern at the widespread lack of legal safeguards for patients who choose CAM; these products being mostly unregulated in many EU Member States may pose significant risks to the health and safety of patients. The CPME advised that legal measures are required to prevent providers of alternative practices and therapies from making unfounded promises and using misleading advertising.

The European Commission-funded Framework Programme 7 project CAMbrella aimed to develop a roadmap for future European research in CAM[3]. The project concluded, '*In general, CAM should be considered along the same scientific lines that apply to medical research…*'. One of the work streams in CAMbrella was to assess citizens' needs in terms of access to CAM, access to information about CAM, and quality of care. This analysis showed that there are multiple dilemmas and tensions in the public health ethics of CAM but recommended that public health ethics should pertain to CAM as to other forms of healthcare (Nissen *et al.* 2013). CAM ethical issues are discussed in detail in a recent special issue of the journal *Bioethics* (Smith *et al.* 2016).

In its Traditional Medicines Strategy for the period 2014–2023[4], the World Health Organization (WHO) has objectives to develop more coherence and consistency among countries. WHO priorities include promoting efficacy, safety and quality of traditional medicines by expanding the knowledge base, providing guidance on regulatory and quality assurance standards, and by supporting therapeutically sound use of appropriate traditional medicines by practitioners and consumers. Although the WHO strategy mentions homeopathy and anthroposophic medicine, it gives them little attention (by comparison with herbal medicines, for example) and does not explain how its priorities would be met in these categories. A case can be made that the WHO should develop a more sceptical and differentiated perspective on the claims, and the evidence available to substantiate those claims, of different categories of traditional medicine.

[1] The topic is of interest also to academies worldwide. For example, the Russian Academy of Sciences recently published a Statement to conclude that homeopathy has no scientific grounds and is not safe, http://klnran.ru/2017/02/memorandum02-homeopathy.

[2] CPME position paper on complementary and alternative treatments, adopted by CPME Board 23 May 2015, CPME 2013/130 Final, on www.cpme.eu/cpme-position-paper-on-complementary-and-alternative-treatments/.

[3] Final Report on Cambrella, A Pan-European research network for complementary and alternative medicine, 1 July 2013 and individual Work Package documents on www.cambrella.eu.

[4] www.who.int/medicines/publications/traditional/trm_strategy14_23/en.

matters are of crucial importance and need to be based on excellent science.

Our recommendations are addressed to policy makers in EU institutions and in the Member States, to our academy members and others in the scientific and medical communities, and to all those who have a responsibility for outreach and informing public engagement. Our present focus is on homeopathy but in our preliminary EASAC deliberations we considered whether we should adopt a wider remit to cover other complementary and alternative medicine (CAM) products, for example to widen the scope to include herbal medicines and nutritional supplements. Other CAM products may be included in the concerns expressed by many in the scientific and medical communities about a lack of evidence base and inconsistencies in the operation of the EU product assessment system, which may emphasise product safety (harmlessness) but not efficacy (see Box 1 for further discussion). The Working Group advised that the claims for homeopathy were sufficiently distinctive to warrant a separate and focussed examination, although this Statement will also refer to issues that may be relevant more widely to consideration of CAM practices.

2 Current status of homeopathy: market, regulation and perspectives

2.1 Market statistics

According to data from the homeopathic producers group ECHAMP (the European Coalition of Homeopathic and Anthroposophic Medical Products, www.echamp.eu) in 2015 the market for homeopathic and anthroposophic medicinal products in the EU was greater than €1 billion. This market is growing by 6% annually and accounts for 7% of the total EU market for non-prescription medical products. The US market for homeopathic products is larger (greater than $3 billion in 2015) and according to one analysis the homeopathy market worldwide will exhibit substantial annual growth up to 2024 (Transparency Market Research, TMR 2016).

In the EU, again according to ECHAMP data, the homeopathy sector, from manufacturing to sales, employs about 10,000 people, mainly in Germany, France, Italy and Spain, where the larger companies are located. The five largest companies account for about 70% of the sector. Pharmacies are the main channel for sale of homeopathic products.

The extent of homeopathic practices varies across European countries, as does the extent to which homeopathy is included in public health systems and national health insurance coverage. Homeopathy is at least partly reimbursed by social security or insurance in France and Belgium for example. Usage data obtained from social surveys may depend on the methodology employed as well as on the respondent knowing what a homeopathic product is. Recent comparative European data from a social survey[5] show that the proportion of the population using homeopathy (in the previous 12 months) ranged from 1% (for example, the UK, Denmark, Ireland, Norway, Poland and Sweden) to 2–4% (for example, Czech Republic, Estonia, Spain, Finland, Hungary, Portugal, Slovenia and the Netherlands), to 7–10% (for example, Belgium, Lithuania and Switzerland) and up to 11–13% (Austria, France and Germany). The ECHAMP 2015 review also shows that demand for homeopathic products (in terms of GDP-adjusted sales per head of population) was greatest in France, and Germany, then Bulgaria, Italy, Lithuania, Austria and Belgium. Recent industry growth was highest (but in some cases from a low starting point) in Bulgaria, Czech Republic, Ireland, Romania and Slovakia. According to ECHAMP data, the relative number of homeopathic prescribers (compared with population) is highest in Slovakia, Romania, Bulgaria and the Czech Republic.

2.2 Regulatory positions

Extensive description of the legal and regulatory status, government supervision and reimbursement status in EU and other European countries for homeopathy is provided by the Norwegian National Research Center on Complementary and Alternative Medicine[6].

Homeopathy legislation for human applications derives from Directive 2001/83/EC as amended in Directive 2004/27. This Directive defines a homeopathic medical product[7] and requires Member States to ensure that such products can be registered without proof of therapeutic efficacy, provided there is a significant degree of dilution, from the original stock, to guarantee safety of the product (at least 1 in 10,000). Mutual Recognition and Decentralised Procedures manage the approval of homeopathic products, and these procedures are National Competent Authority-driven (with the European Medicines Agency, which provides the secretariat for a coordination group). The European Medicines Agency organised a workshop in 2006 to bring together the various homeopathic practitioners to hear their views

[5] Based on 2014 data from the European Social Survey (http://www.europeansocialsurvey.org) as discussed (February 2016) on http://www.natcen.ac.uk/blog/when-i-get-that-feeling-i-want-spiritual-healing-alternative-medicine-use-in-europe.

[6] http://nafkam-camregulation.uit.no/therapies/homeopathy/.

[7] Article 1 in 2004/27: Homeopathic medical product is defined as a medical product prepared from homeopathic stocks in accordance with a homeopathic manufacturing procedure.

on reforming the system[8]. The National Competent Authorities participate in a network of the Heads of the Medicines Agencies and this network has a Homeopathic Medicinal Products Working Group (HMPWG)[9] with a remit that includes exchange of regulatory and scientific expertise and production of guidance on assessment.

In response to the EU Directive, Member States have introduced various regulatory schemes. Broadly, there are two possible procedures for registering homeopathic products:

- simplified registration scheme—if diluted enough to guarantee safety, but does not allow specification of a particular clinical indication;
- national rules scheme—submitting data on quality and safety allows the claim, if used within the homeopathic tradition, for specific conditions (minor symptoms and conditions, which do not require the supervision of a doctor).

However, in many Member States, once a product is on the market there may be relatively little control on how it is promoted and used.

2.3 Previous work by academies and others

Royal Swedish Academy

In 2015, the Royal Swedish Academy of Sciences (KVA) made a critical statement in response to a report from the Swedish Medical Products Agency on how incorporation of anthroposophical homeopathic products into the Swedish directive on medicinal products could be constructed. KVA advised that this move would run counter to several of the fundamental principles about evidence-based medicine and medicinal products. In particular, KVA opposed the use of the term 'medicinal product' for substances lacking scientifically documented effects, noting that there is no scientific evidence for clinical effects of homeopathic preparations and that high dilution rules out effects by any known mechanisms. If any product might be considered to have effects justifying its use for treatment of disease, it should be evaluated by the same standards as other candidate drugs.

Recently the Swedish Ministry of Health has announced that the traditional exemption for anthroposophical homeopathic products (allowing specification of a clinical indication without substantial evidence of efficacy) will be renewed only for another 2 years. After a further 3-year transition phase, such anthroposophical products would have to follow the same route to registration as other homeopathic products.

Hungary

In a brief statement in 2015, the Hungarian Academy of Sciences Section of Medical Sciences expressed support for the KVA work and concluded that homeopathic products should follow the same strict scientific standards as 'normal' drugs[10].

UK

In 1999, the Royal Society submitted comments critical of CAM to the UK parliamentary House of Lords inquiry into CAM including homeopathy[11], noting the importance of careful evaluation of effectiveness and safety and supporting the values and methods of verifiable science: that is, requiring an evidence base from clinical research. When the UK medicines regulatory agency introduced the national rules scheme in 2006, criticism was expressed by the Royal Society together with the Academy of Medical Sciences on the grounds that efficacy claims should always be based on rigorous and objective evidence. A comprehensive assessment by a UK parliamentary inquiry (House of Commons, 2010) also concluded that the evidence for efficacy of homeopathy products was weak and scientifically implausible and that '*In our view, the systematic reviews and meta-analysis conclusively demonstrate that homeopathic products perform no better than placebo.*' This parliamentary committee also noted that the rigorous scrutiny on safety, quality and efficacy, applied by the UK medicines regulatory agency before medicines can be used by patients, was not applied to homeopathic products—but should be. The UK Government was urged to withdraw public funding and medicines licensing from homeopathy.

Australian National Health and Medical Research Council

A comprehensive assessment of evidence (NHMRC, 2015)[12] by the Australian Government's National Health and Medical Research Council analysed 57 systematic reviews on 68 health conditions. These conditions included rheumatoid arthritis, radiodermatitis, stomatitis due to chemotherapy,

[8] Report on EMEA workshop on homeopathic medicinal products, http://www.ema.europa.eu/docs/en_GB/document_library/Report/2009/11/WC500012237.pdf.
[9] www.hma.eu/380.html.
[10] http://goo.gl/WMnxjC.
[11] https://royalsociety.org/~/media/Royal_Society_content/policy/publications/1999/10080.pdf.
[12] Also discussed by P Glasziou, who chaired the Working Party, 16 February 2016, on www.blogs.bmj.com/bmj/2016/02/16/paul-glasziou-still-no-evidence-for-homeopathy.

HIV, asthma, anxiety, depression, attention-deficit–hyperactive disorder (ADHD) in children, malaria and stroke, although claims for these last indications and others were based on only a single study. The Australian review concluded that there are no known diseases for which there is reliable evidence that homeopathy is effective and advised that '*Homeopathy should not be used to treat health conditions that are chronic, serious or could become serious*'.

3 Key issues for evaluating and communicating evidence

In reviewing the outputs from the initiatives described in the preceding chapter, and considering the evidence available from other peer-reviewed sources, the Working Group identified a range of key issues to inform the EASAC recommendations.

3.1 Scientific implausibility of claims

Many homeopathic remedies are prepared from substances that have been diluted so many times that none of the original substance remains. Some homeopathic practitioners believe that, as a result of the succussion process, the original substance leaves an 'imprint' of itself on the water.

An explanation of a mechanism of action should be both scientifically plausible and demonstrable but the justifications of homeopathy have not fulfilled these criteria (House of Commons, 2010; Grimes, 2012). In general, the claims for homeopathy run counter to a very large body of evidence on the dose–response relationship in medicine and its long-established explanation in terms of drug–receptor interaction (see, for example, Tallarida and Jacob, 1979), a central principle in pharmacology that continues to be substantiated in more recent research (see, for example, Aronson, 2007). There is lack of scientific support for all the various mechanisms claimed in homeopathy, for example vitalism, electromagnetic signals and water memory (Grimes, 2012).

In particular, as discussed by the Working Group, detailed scientific analysis of the influence of dissolved species on the structure and dynamics of water has refuted the homeopathic claim that water retains a memory even long after the last molecule of homeopathic entity has been removed by serial dilution. The impact of dissolved species on water is short-range (of the order of nanometres, 10^{-9} metres), does not extend beyond their immediate hydration layer and does not demonstrate any long-term (nanoseconds, 10^{-9} seconds or even shorter) cooperative effect: the predictions from theoretical scientific studies are in agreement with the results of spectroscopic measurements and emphasise the untenability of ideas about long-range molecular order effects in space and time (Anick, 2004; Cowan, 2005; Texeira, 2007; Jungwirth, 2011; Stirnemann *et al.* 2013). Thus, the homeopathy proposition that efficacy can be explained by a long-term memory of water has been proved scientifically unfounded and implausible (Texeira, 2007; Jungwirth, 2011).

3.2 Clinical efficacy and placebo effects

The outputs from the authoritative bodies discussed in section 2 are substantiated by the conclusions from other major reviews. These include the following:

1. Comprehensive literature analysis of 110 homeopathy trials and 110 matched conventional medicine trials, exploring issues for random variation, publication bias and placebo effect (Shang *et al.* 2005). The finding from this assessment is compatible with the notion that the clinical effects of homeopathy are placebo effects.
2. An assessment of five large meta-analyses of homeopathy trials, including Shang *et al.* (2005), concluded that they all yielded the same conclusion (Goldacre, 2007). After excluding methodologically inadequate trials and accounting for publication bias and likely random statistical variation, this evaluation confirmed that homeopathy produced no statistically significant effect over placebo.
3. The continuing work of the Cochrane Reviews is also particularly important because their systematic assessments are characterised by rigorous peer-reviewed protocols, standardised evaluation procedures and transparent data analysis. Cochrane Reviews of homeopathy treatments include those for asthma, dementia, induction of labour, ADHD, irritable bowel syndrome and influenza. For each of these indications, the review concluded that there was no or insufficient evidence to reliably assess a possible effect of homeopathy[13].

Working Group discussion emphasised that the therapeutic effect of the homeopathic preparation as perceived by the patient will be due to its placebo effect. In addition to the placebo effect, other phenomena such as the natural course of the illness and regression to the mean, may contribute to the overall perception that homeopathy is of benefit. In any case, it raises issues of concern for patient-informed consent when the health practitioner recommends products that they know are biologically ineffective. Moreover, the Working

[13] http://www.cochrane.org/search/site/homeopathy.

Group emphasised that the benefit of any placebo effect may be offset by significant harms in homeopathy practice. The use of a homeopathic product by a patient may delay the seeking of more appropriate, evidence-based, medical care: examples of harm incurred are discussed in the sources cited previously (House of Commons 2010; CPME (see footnote 2)). This harm may be exacerbated by a routine feature of homeopathic marketing practice, which is to denigrate mainstream medicine (Goldacre, 2007). More general harm also accrues in consequence of public confusion about the nature and value of scientific evidence in decision making.

As noted in section 2, some Member States allow the use of homeopathic products in public health systems to be reimbursed. The Working Group advised that in the absence of robust evidence for efficacy, reimbursement listing should be reconsidered—a standard medicines policy instrument in times of austerity (Vogel *et al.* 2016) that should certainly be extended to homeopathic products.

Space does not now allow a full review of the literature discussing the efficacy of homeopathy, but contested claims were discussed further in a debate published in the *British Medical Journal* (Fisher and Ernst, 2015). We provide in Box 2 a list of disparate sectoral sources of some of those who support or promote the claims of homeopathy and can provide leads to their own research.

3.3 Quality control and safety

Although it has been customarily assumed that a homeopathic preparation is diluted to a degree where there should be no safety concerns, this may not necessarily happen in practice. For example, in a recent US Food and Drug Administration (FDA) investigation, severe adverse events, including infant deaths, were found to have been reported for homeopathic teething products (Abbasi, 2017). The toxicity was associated with varying levels of the starting material, belladonna, in the product. This, and other US evidence (Abbasi, 2017), raises important issues for regulatory oversight to ensure product quality control, assess safety and provide patient information on homeopathic products.

3.4 Veterinary applications

The use of homeopathic products in veterinary medicine is also controversial, and the recent implementation of EU rules risks undermining science-based farming practices. The European Commission Regulation EC No. 889/2008[14] lays down

Box 2 Sector sources of information on homeopathy claims

Among the interest groups of those who use, evaluate, manufacture, support or promote homeopathic products and services are the following:

AESGP: Association of the European Self-Medication Industry, **www.aesgp.eu**

ECHAMP: European Coalition of Homeopathic and Anthroposophic Medical Products, **www.echamp.eu**

CAMDOC: Alliance of ECH, ECPM and others, **www.camdoc.eu**

ECCH: European Central Council of Homeopaths, **www.homeopathy-ecch.eu**

ECH: European Committee for Homeopathy, **www.homeopathyeurope.org**

ECPM: European Council of doctors for Plurality in Medicine, **www.ecpm-europe.ch**

EFCAM: European Forum for Complementary and Alternative Medicine, **www.efcam.eu**

EFHPA: European Federation of Homeopathic Patients' Associations, **www.efhpa.com/cms**

EFPAM European Federation of Patients' Associations for Anthroposophic Medicine, **www.efpam.eu**

EUROCAM: Network of European organisations representing CAM patients, professionals and others, **www.cam-europe.eu**

HRI: Homeopathy Research Institute, **www.hri-research.org**

IAAP: International Association of Anthroposophic Pharmacists, **www.iaap.org.uk**

ISCMR: International Society for Complementary Medicine Research, **www.iscmr.org**

IVAA, International Federation of Anthroposophic Medical Associations, **www.ivaa.info**

WHAO: World Homeopathy Awareness Organization, **www.worldhomeopathy.org**

[14] https://ec.europa.eu/agriculture/organic/eu-policy/eu-legislation_eu.

detailed rules for production and labelling of organic products. Article 24 of this Regulation specifies that organic farmers should use homeopathic products in preference to antibiotics and other evidence-based veterinary treatments. Although an antibiotic can be used subsequently if the homeopathic remedy is found ineffective, this risks delay with potential harm for livestock and spread of the infection to other animals.

A recent comprehensive systematic review of the scientific literature on homeopathy in farming (Doehring and Sundrum, 2016) evaluated whether such remedies could replace the use of antibiotics for infectious disease or growth promotion (antibiotics are now banned for livestock growth promotion in the EU). This review noted that some studies were in favour of homeopathy, but that there was large heterogeneity in conditions, study conduct and the scientific quality of trials. The results from those studies supporting homeopathy lacked reproducibility and the systematic review concluded, '*Within the studies considered, the use of the same remedy administered to the same species with a comparable medical condition was never repeated*' and '*Replacing or reducing antibiotics with homeopathy currently cannot be recommended unless evidence of efficacy is reproduced by randomised clinical trials and proven in various farm practice conditions.*' [15]

Thus, while EASAC recognises the strategic importance of attempts to reduce antibiotic use in animals as part of broader efforts to control the problem of antibiotic resistance in patients (EASAC and FEAM, 2016), the use of non-scientific alternatives is not advisable. The proliferation of unfounded homeopathic practices should not be encouraged in either veterinary or human medicine.

3.5 Labelling and marketing claims

As emphasised by the UK House of Commons inquiry (2010), deficient labelling lends a spurious medical legitimacy to homeopathic products. The problem is exacerbated because, although EU labelling regulations usually require all pre-packaged products to contain a list of ingredients and quantities, an exception is made for homeopathic products, which are labelled with the scientific name of the stock material followed by degree of dilution. It is unlikely that the user understands that there is no active ingredient, or only a minuscule amount thereof, in the final preparation (Hansson, 2013).

EU legislation provides for consumer law protection, specifying advertising standards on evidence-based claims. The EU Directive 2005/29/EC on Unfair Commercial Practices prohibits misleading marketing but, with regard to health-related claims, the Directive notes that such claims may already be covered at the European Commission level by other specific legislation, for example on medicinal products. EU Member States interpret the EU intention to control misleading claims more or less stringently. For example, in 2016, the UK Advertising Standards Authority announced that it had seen no robust evidence that homeopathy works. The Advertising Standards Authority advised that '*Practitioners should therefore avoid making direct or implied claims that homeopathy can treat medical conditions.*'[16]

Also in late 2016, the US Federal Trade Commission (FTC) announced a new Enforcement Policy Statement on Marketing Claims for Over-the-Counter (OTC) Homeopathic Drugs[17]. This policy statement explains that the FTC will hold efficacy and safety claims for homeopathic drugs to the same standard as other products making similar claims. That is, companies must have competent and reliable scientific evidence for health-related claims. However, for the vast majority of homeopathic drugs, the policy statement observes '*the case for efficacy is based solely on traditional homeopathic theories and there are no valid studies using current scientific methods showing the product's efficacy. As such, the marketing claims for these products are likely misleading in violation of the FTC Act.*' This is an important international development although there is still scope for the US federal agencies – including the FDA – to improve harmonization of their approaches to regulating homeopathic products, and in particular to reconsider the OTC status of products that do not meet the same standards of proof applied to conventional medicines (Podolsky and Kesselheim, 2016)[18].

3.6 Public engagement

The continuing popularity of homeopathic products worldwide might be taken as demonstrating an unfortunate point – that scientific evidence is not always

[15] An accompanying press release summarises the conclusion '*There is insufficient evidence to support the use of homeopathy in food producing animals as a way to prevent or treat infectious diseases.*' See www.bmj.com/company/wp-content/uploads/2016/12/vet-record-homeopathy-livestock.pdf. The systematic review is also discussed in detail by a group of experts (December 2016) on www.sciencemediacentre.org/expert-reaction-to-literature-review-on-efficacy-of-homeopathy-in-livestock.

[16] 'Advertising standards for homeopathy', 29 September 2016, www.asa.org.uk/news/advertising-standards-for-homeopathy.html.

[17] FTC Press Release 15 November 2016 'FTC issues enforcement policy statement regarding marketing claims for over-the-counter homeopathic drugs. On www.ftc.gov/news-events/press-releases/2016/11/ftc-issues-enforcement-policy-statement-regarding-marketing. Text of the Federal Register notice is on www.ftc.gov/policy/federal-register-notices/federal-trade-commission-enforcement-policy-statement-marketing.

[18] For further information on how the FDA regulates homeopathic remedies, see the National Centre for Complementary and Integrative Health, https://nccih.nih.gov/health/homeopathy.

relevant to the policy maker nor understood by the public-at-large. In this eventuality, there might be only limited room for optimism that EASAC and others – in reiterating that homeopathic products and practices lack proof of efficacy– could influence the present situation.

However, the recent decline in the use of homeopathy in public health services in some Member States (for example, the UK National Health Service (Samarasekera, 2007)) might be interpreted as the gradual professional and public response to the accumulating advice on lack of evidence for efficacy. A recent case study (Crawford, 2016) of the UK Glasgow Homeopathic Hospital concluded that homeopathy advocates have been unsuccessful in maintaining and repairing moral legitimacy for homeopathy and suggests that there is an encouraging development towards open and transparent accountability for using limited public resources to maximise society's health and well-being.

The Working Group emphasised that there is much still to be done to inform public engagement. For example, it has been observed that public support for homeopathy might be partly because it is often confused with natural products such as herbal medicines; although many herbal medicines are unproven, some may have scientific plausibility, unlike homeopathy (Samarasekera, 2007).

Among key groups who shape public attitudes are journalists, and it has been shown that journalists' attitudes to homeopathy influence their reporting (Arendt, 2016). Therefore, engaging with journalists in their function as 'gatekeepers' of scientific knowledge is a critical task in facilitating the better dissemination of evidence-based scientific knowledge (Arendt, 2016). Academies of science have a responsibility to help lead the discussion.

4 Conclusions and recommendations

There must be parity of assessment in medicine. EASAC agrees that '*There cannot be two kinds of medicine – conventional and alternative. There is only medicine that has been adequately tested and medicine that has not …*' (Angell and Kassirer, 1998). As noted in section 1, the purpose of the present Statement is to explore the issues surrounding the objective to hold homeopathy to the same scientific standards of proof as any other form of medicine. The level of evidence furnished must always be commensurate with the claims being made. Academies worldwide have significant interest in examining the issues for a wide range of approaches in medicine and emphasise the common need to generate robust scientific evidence[19].

Based on the Working Group discussion of the points presented in the previous sections of this Statement, EASAC makes the following conclusions.

- Any claimed efficacy of homeopathic products in clinical use can be explained by the placebo effect or attributed to poor study design, random variation, regression towards the mean, or publication bias. Among these, the placebo effect can be of value to the patient but there are no known diseases for which there is robust, reproducible evidence that homeopathy is effective beyond the placebo effect.
- Homeopathy raises issues of concern for patient-informed consent if health practitioners recommend products that they know are biologically ineffective.
- There are also potential safety concerns for homeopathic preparations because of poorly monitored production methods, and these require greater attention to quality control and assessment of adverse effects.
- The scientific claims made for homeopathy are implausible and inconsistent with established concepts from chemistry and physics. In particular, the memory effects of water are too short-range and transient (occurring within the nanometre and nanosecond range) to account for any claimed efficacy.
- The promotion and use of homeopathic products risks significant harms. First, by incurring delay in the patient seeking appropriate, evidence-based, medical attention or, even worse, deterring the patient from ever doing so. Secondly, by generally undermining patient and public confidence in the nature and value of scientific evidence for decision making in health care and other societal priorities.
- In the absence of similarly robust evidence for homeopathic products in veterinary medicine, it is an error to require organic farmers to use these products in preference to prevention or treatment for which there is demonstrable efficacy and an established mode of action.

EASAC recommends the following.

- There should be a consistent regulatory requirement for claims for the efficacy, safety and quality of all medicinal products to be based on verifiable and objective evidence,

[19] For example, the The InterAcademy Medical Panel symposium in 2015 'Exploring traditional medicine', http://www.iamp-online.org/content/exploring-traditional-medicine.

commensurate with the claims being made. The necessity for robust data applies to products for both human and veterinary medicine. In the absence of such robust and verifiable evidence, a product should not be approvable by national regulatory agencies for the designation medicinal product.

- Public health-system budgets are under increasing pressure. Evidence-based public health systems should not offer reimbursement for homeopathic products and services unless they are demonstrated to be efficacious and safe by rigorous testing.
- The composition of homeopathic products should be labelled in a similar way to other health products available in the pharmacy (OTC) or elsewhere. That is, the current exceptional labelling permitted for homeopathic products should be replaced by a simple description of the ingredients and their amounts present in the formulation.
- Advertising and marketing of homeopathic products and services must be regulated to be accurate and clear: advertising claims made for efficacy and safety should not be allowed without demonstrable and reproducible evidence.

Our recommendations on testing, regulation, labelling and marketing have significant implications for the European Commission: in particular, for DG Sante (human and veterinary medicine), European Medicines Agency, and DG Justice and Consumers. There are also major implications for Member State health services and medicine regulatory agencies. In addition, there are significant challenges for patient education and dialogue, and public engagement. Our final recommendation is to our EASAC member academies: they should consider how they can now facilitate further discussion and action on the issues presented in this statement.

Appendix 1 EASAC Working Group

This Statement was prepared by consultation with a Working Group of experts acting in an individual capacity, nominated by member academies of EASAC:

Volker ter Meulen (Chair, Germany)
Jean-Francois Bach (France)
Helmut Denk (Austria)
Georg Ertl (Germany)
George Griffin (UK)
Kristian Gundersen (Norway)
Pavel Jungwirth (Czech Republic)
Dan Larhammar (Sweden)
Vecsei Laszlo (Hungary)
Alberto Mantovani (Italy)
Jos van der Meer (the Netherlands)
Robin Fears (secretariat, UK)

The scope for this project was discussed at a preliminary meeting between the EASAC Bureau and KVA in September 2015 (Stockholm, Sweden) with further discussions at Council meetings in Smolenice, Slovakia (November 2015) and Oslo, Norway (May 2016).

The Working Group was formed during the autumn of 2016 and met in January 2017 (Berlin, Germany). The output from the Working Group was peer reviewed by independent reviewers nominated by EASAC member academies.

EASAC thanks the Working Group members for their insight, commitment and support, and members of the EASAC Biosciences Steering Panel and the peer reviewers for their advice and guidance.

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