Homeopathy: the need for robust evidence to inform consumer choice

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EASAC project on homeopathy: conclusions, recommendations and follow-up in the European Union

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What is homeopathy?

- Concept for manufacture and use of various highly diluted products to treat disease
- “Like cures Like” and “law of infinitesimals” – prepared by serial dilution and succussion
- Many scientists and medical doctors are highly critical of health claims made for homeopathic practices and consider explanations scientifically implausible
- EU market > €1 billion

EASAC project on homeopathy

- EASAC is formed by the national science academies of the EU Member States to enable them to collaborate in giving advice to European policy-makers. A means for the collective voice of European sciences to be heard
- EASAC views are independent of commercial or political bias and it is open and transparent in its processes
- Secretariat based in German National Academy of Sciences Leopoldina and policy networking office in Brussels
- Project proposed by Royal Swedish Academy of Sciences (KVA) and approved by Council of EASAC

EASAC project Working Group

- Expertise across disciplines in clinical medicine, public health, biology and physics; experts nominated by Academies: ter Meulen (chair, Germany); Bach (France); Denk (Austria); Ertl (Germany); Griffin (UK); Gundersen (Norway); Jungwirth (Czech Republic); Larhammar (Sweden); Laszlo (Hungary); Mantovani (Italy); van der Meer (the Netherlands); Fears (secretariat, UK)
- Working Group met in January 2017 and consensus outputs were independently peer reviewed. Report was endorsed by Council of EASAC and published late 2017

EASAC objectives for this work

- Purpose of EASAC project – to encourage and support:
  - Policy makers in the EU to take more explicitly evidence-based approach to assessing claims for homeopathy
  - All those interested in stimulating better public engagement on these contentious issues and improving consumers' rights to correct information
- Purpose of this discussion session at ESOF:
  - To review EASAC main messages
  - To explore how EASAC Statement has been received
  - To seek further feedback on the issues and consider next steps

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EASAC review of the evidence: our starting points

- Our agreed task was not to reanalyse all of the primary evidence for or against homeopathic products but instead to critically evaluate the science-based assessments performed by other authoritative and impartial bodies
- Sources of evidence included:
  - Our academies
  - Published meta-analysis of clinical trials and other comprehensive literature analysis
  - Cochrane Reviews
  - Evidence submitted to parliamentary inquiries, e.g. in UK
  - Other international assessment by public bodies

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Key issues and EASAC conclusions 1: scientific mechanisms of action

- Mechanisms claimed for homeopathy contradict very large body of evidence on dose-response relationships in medicine and drug-receptor interactions in pharmacology
- None of the mechanisms advanced are scientifically plausible
- In particular, detailed scientific analysis of influence of dissolved species on structure and dynamics of water refutes the homeopathic claim that water has long-term memory

Key issues and EASAC conclusions 2: clinical efficacy and placebo effect

- Our assessment supports the conclusion that the therapeutic effect as perceived by the patient is a placebo effect: we conclude that there are no known diseases for which there is robust, reproducible evidence that homeopathy is effective beyond the placebo effect
- Other factors, such as natural course of the illness and regression to the mean, may contribute to any perception of benefit
- Associated concern for patient-informed consent

Key issues and EASAC conclusions 3: labelling and promotion

- May pose significant harm if patient incurs delay in seeking more appropriate, evidence-based medical care
- More general risk of confusion and undermining public confidence in the nature and value of scientific evidence
- EU labelling regulations on listing of ingredients and quantities – makes exception for homeopathic products in allowing labelling with scientific name of stock material and degree of dilution: it is unlikely that the user understands that there is usually no active ingredient present

Key issues and EASAC conclusions 4: veterinary practice

- No rigorous evidence to substantiate the use of homeopathy in veterinary medicine
- Particularly worrying when such products are used in preference to evidence-based medicinal products to treat livestock infection
- Implementation of EU rules on organic farming, encouraging homeopathy, risks undermining science-based farming practices

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EASAC Recommendations 1

- *Regulatory frameworks* Should be consistent regulatory requirements to demonstrate efficacy, safety and quality for all products for human and veterinary medicine
- *Designation* In absence of objective and verifiable evidence, a product should not be approved or registered by national agencies as “medicinal product”
- *Reimbursement* Evidence-based health systems should not reimburse homeopathic products and practices unless demonstrated to be efficacious and safe by rigorous testing

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EASAC Recommendations 2

- *Labelling* Composition should be labelled in a similar way to other health products in pharmacy or elsewhere: accurate, clear and simple description of ingredients and amounts
- *Promotion* Advertising and marketing must conform to established standards of accuracy and clarity, based on demonstrable and reproducible evidence
- *Communication* More to be done to inform public engagement and patient education: academies of science have a responsibility to help lead the discussion

What has happened since publication of the EASAC Statement?

- Commentary published in Journal of Internal Medicine to raise awareness in wider medical community
- Significant media impact in many EU Member States – follow-up work by Academies to be discussed in this session
- Change in some Member States, e.g. in UK consultation by NHS England and decision to restrict prescribing of homeopathy in primary care
- Other international developments, e.g. in USA FDA proposed new risk-based enforcement approach to regulate homeopathic products
- Communicating our conclusions and recommendations to DG Sante and Heads of EU Medicines Agencies

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