"Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter-Century"

Homeopathy Research Institute Submission to FDA Public Consultation

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HRI is an innovative international charity created to address the need for high quality scientific research in homeopathy.

1. Introduction

HRI welcomes the opportunity to contribute to the current FDA public consultation on the safety aspects of homeopathic medicines.

Our submission is in response to the FDA's question "*What data sources can be identified or shared with FDA so that the Agency can better assess the risks and benefits of drug and biological products labelled as homeopathic?*"

In this submission we will share data which demonstrates the following key points:

- Reviews of the evidence currently available for the safety of homeopathic medicines are in support of its comparative safety.

- Direct adverse effects (a.k.a. adverse drug reactions) are most commonly associated with 'low potency' homeopathic medicines manufactured from allergens or toxic source materials (1x/D to 6x/D). Such reactions could be avoided by manufacturing to a higher level of potentisation.
- Adverse drug reactions following use of 'complex' products labelled 'homeopathic' (i.e. containing multiple constituents) can be due to the presence of non-homeopathic constituents such as potentially toxic adjuvants.
- There is under-reporting of adverse effects in homeopathy and more quality research is needed, especially for full assessment of the safety of over-the-counter and self-prescribed homeopathic products.
- There is a need to improve awareness of the potential for AEs within the homeopathic community as well as a need to increase pharmacovigilance of homeopathic medicines and standardise protocols.

2. Safety Concerns in Homeopathy

According to the Medicines and Healthcare products Regulatory Agency (MHRA: the UK's executive agency responsible for regulating and licensing medicines and medical devices[1]): "*For a medicine to be considered safe, the expected benefits of the medicine will be greater than the risk of suffering harm*"[2]. The scientific debate about the clinical benefits of homeopathic treatment and the specific efficacy of homeopathic medicines is on-going, with a body of clinical trial data both in support of, and against, homeopathy[3]. However, the currently available body of evidence assessing the safety of homeopathy is less equivocal with the majority of the evidence in favour of its safety.

Homeopathic medicines prescribed by homeopathic practitioners can be provided in a number of forms including tablets, pillules, liquids, gels, creams, powders, sprays and occasionally via injection. Over the counter (OTC) homeopathic medicines are more likely to be in tablet, pillule, gel or cream preparations. In the UK patients and consumers can access OTC homeopathic medicines in several ways:

- via a pharmacist (either in a general or specialist homeopathic pharmacy)

- directly online
- off-the-shelf in shops without consultation with any trained or qualified healthcare practitioner.

The risk of harm to patients/consumers accessing homeopathic medicines can be direct or indirect:

- **Direct harm (adverse drug reactions) –** causative factors include insufficiently diluted toxic substances, hypersensitivity to constituents/starting material, reactions to non-homeopathic ingredients including adjuvants, sub-standard manufacture or contamination of medicinal products, inappropriate usage/prescription, and "aggravations" within the homeopathic philosophy of treatment reaction.
- **Indirect harm** – includes delay in seeking essential conventional medical treatment or eschewing essential medical treatment in favour of homeopathy, clinical negligence on the part of qualified practitioners and treatment by an unqualified practitioner.

Steps are taken to mitigate these risks to the public as far as possible through regulation, monitoring, good manufacturing practice, code of ethics and practice and set standards for education. However, no health intervention is completely risk free.

3. Reviews of Safety in Homeopathy

Perception of the safety of homeopathic medicine differs between homeopathic practitioners, patients, pharmacists and detractors. Some homeopaths and patients assume that all homeopathic medicines are safe, with no risk of toxic side effects due to the high levels of dilution involved in remedy preparation and the assumption that remedies are made from natural materials. Detractors, however, focus on the potential for indirect harm to patients through the risks associated with a delay in seeking appropriate medical treatment or using "unproven" treatments instead of proven conventional treatments; detractors, at best, suggest that homeopaths are negligent, and at worst, that they kill patients. This begs the question, what is the evidence behind these varying positions?

Safety information for homeopathic medicine is located within published reports of clinical trials, case series, case reports, systematic reviews as well as Organisational and Government reports. Thus, to reach an informed position on the relative risk of harm from homeopathic treatment this body of evidence must be taken as a whole. To date, there have been nine main studies into the safety of homeopathic medicine, the findings of which are summarised in Table 1 below.

Systematic reviews represent the highest level of evidence available to inform medical opinion. When taken together, the systematic reviews support the conclusion that homeopathy is safe, or at least poses a low risk to patients. Three out of the four systematic reviews listed in Table 1 concluded in favour of the safety of homeopathic treatment, describing adverse effects (AEs) as mild to moderate and transient. Strikingly, the systematic review by Posadzki et al[14], reaches a conclusion that is significantly different to the other reviews – this finding is worthy of particular attention (see section 4).

Within the homeopathic profession, AEs are often considered to be a natural, or even desirable, part of homeopathic treatment, in which case they are referred to as "aggravations". Aggravations are believed to be followed by an improvement in a patient's general well-being whereas a true AE is not. However, this does have the potential to create indirect risk to the patient as worsening of the patient's symptoms is an anticipated or accepted aspect of practitioner-led homeopathic treatment rather than a reason for medical concern[13,15]. It is not, however, generally anticipated that OTC self-prescribed remedies will lead to homeopathic aggravations although no data is currently available on this.