The Safety of Homeopathy

An ECCH Report

January 2009




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ECCH has NGO Participative Status with the Council of Europe, is an Associate Member of the European Public Health Alliance (EPHA), is a Member of the European Federation for Complementary and Alternative Medicine (EFCAM) and is a Corresponding Member of the European Coalition for Homeopathic and Anthroposophic Medicinal Products (ECHAMP).

ECCH's vision is to bring the benefits of high quality homeopathic treatment to all members of the European public. In order to achieve this situation it is the Council's understanding that homeopathy should not only be accepted, but officially recognised in all countries.

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Summary

This document provides an overview of current evidence on the safety of homeopathy. Several authors point out that there is widespread belief that Complementary and Alternative Medicine (CAM) therapies such as homeopathy are safe, nonetheless, such claims need to be researched.

This report covers four main areas of concern:

- the safety of homeopathic medicinal products (HMPs) as a result of manufacturing methods;
- research evidence on reported adverse events and adverse drug reactions;
- the safety of treatment provided by practitioners; and
- the safety of patients self-administering HMPs.

In order to research these areas, we provide an overview of current regulation and production methods for HMPs, a literature review considering research evidence for the safety of HMPs, a survey on the safety of treatment provided by practitioners, an overview of regulation of the practice of homeopathy, and an overview of international measures taken by the profession to self-regulate.

Current evidence seems to support the claim that adverse drug reactions (ADR) resulting from HMPs are rare and where they occur they are only mild or moderate. We did not find any evidence to support a claim that HMPs may cause serious adverse events (AE) or ADR. HMPs seem to lack the potential for life-threatening side effects.

Current evidence appears to show a very low incidence of cases of unethical practice or malpractice by homeopaths. A number of precautionary measures have been put into effect, through national legislation for regulation and through self-regulation by the profession, to ensure the safety of patients.

We raise concern about patients self-administering HMPs, in particular as they may thereby arrive too late for treatment provided by a health professional and because it may be difficult for someone to consider how to proceed with self-treatment using HMPs without advice provided by a well-educated and trained homeopath.

In summary, current evidence seems to confirm the claim that HMPs are safe to use and homeopathic treatment provided by statutorily regulated or self-regulated homeopaths is safe.

Content list

Introduction

Safety is an area of major concern in medicine. In its Seventh Research Framework Programme the European Parliament and Council stress the importance of research into consumer protection and safety in medicine (European Parliament and Council of the European Union 2006). In its resolution the Parliament and Council specifically point out the need for addressing patient safety and the better use of medicines, including complementary and alternative medicines.

The public, regulatory agencies, practitioners and consumer protection agencies need reliable information about the safety of any therapy, whether conventional, complementary or alternative. This includes the safety of homeopathy.

There is widespread belief that Complementary and Alternative Medicine (CAM) therapies such as homeopathy are safe (Bornhöft et al. 2006, Chakraborti et al. 2003, Dantas and Rampes 2000, Ernst 2001, Katz et al. 2005, Kirby 2002, Monk 1986, Thompson et al. 2004). However, several authors have pointed out the need for such claims to be researched (Chakraborti et al. 2003, Dantas and Rampes 2000, Kirby 2002). Where Abbot et al. (1996) find it reassuring that little information about safety exists, others have pointed out that an absence of reports of adverse events does not mean that they do not happen (Kirby 2002).

The aim of this document is to provide an overview of current evidence on the safety of homeopathy. Considering the safety of homeopathy involves looking at several aspects of this therapy, but can generally be divided into four main categories:

- the safety of homeopathic medicinal products (HMPs) as a result of manufacturing methods;
- research evidence on reported adverse events and adverse drug reactions;
- the safety of treatment provided by practitioners; and
- the safety of patients self-administering HMPs.

For an overview of the main terminology used in this report, please refer to Appendix A.

Methodology

This report is based on the results of the following approaches:

- a description of regulation and production methods for HMPs;
- a literature review considering current research evidence for the safety of HMPs;
- a survey on the safety of treatment provided by practitioners;
- an overview of regulation of the practice of homeopathy; and
- an overview of international measures taken by the profession to self-regulate.

Description of production methods and regulation for HMPs

The description of production methods involves an explanation of measures taken through the manufacturing process in order to avoid toxicity as well as to ensure correct use of HMPs through appropriate labelling of end products. The overview of regulation for HMPs includes an introduction into European Union medicine directives.

Literature review considering research evidence for the safety of HMPs

The literature review includes an electronic search for articles through the AMED database[1], a search through Medline and a selection of major homeopathy and CAM research journals, including *Homeopathy*, *Complementary Therapies in Clinical Practice*, *Complementary Therapies in Medicine* and *Alternative Therapies in Health and Medicine*.

Our search includes publications in the period from 1995 to 2008. We have included experimental studies published in the period from 2003 to 2008, as another study reported on experimental studies prior to this period (Grabia and Ernst 2003). We include observational studies in the period from 1995 to 2008, as well as other researchers' reported results of both observational and experimental studies published in the period from 1970 to 1995 (Dantas and Rampes 2000).

The AMEDS and Pubmed searches included the following search words: 'homeopathy', 'homoeopathy', 'homeopathic' and 'homoeopathic'. The journal *Homeopathy* was searched for the words 'side effects' and 'safety'. The remaining journals were searched for the words 'homeopathy' and 'homoeopathy'. All relevant articles (incl. clinical trials, observational studies and case reports) have been included in this report.

Survey on the safety of treatment provided by practitioners

A survey was carried out in order to obtain reports on cases of malpractice and unethical practice in countries where the European Council for Classical Homeopathy (ECCH) has member associations. Any known cases of malpractice or unethical practice endangering the safety of patients were requested. This includes cases brought to court as well as cases brought to national homeopathic associations' ethics / professional conduct procedure committees.

Overview of regulation of the practice of homeopathy

An overview of national legislation regulating the practice of homeopathy and other CAM therapies has been presented.

Overview of international measures taken by the profession to self-regulate

An overview of measures taken by ECCH in order to self-regulate is presented. This includes an overview of a number of guidelines produced by ECCH in order to contribute to the safety of patients.

This report does not claim to provide a systematic review of the safety of homeopathy, but it aims to be sufficiently extensive to present main findings and to serve as a basis on which we will draw general conclusions and put forward proposals related to the safety of homeopathy.

[1] AMED is a database which uses references from the Medline database and covers a selection of journals in complementary medicine, palliative care, and several professions allied to medicine.

Results

A. The safety of homeopathic medicinal products – manufacturing

In order to consider the safety of HMPs, we will look at regulations for the manufacturing of HMPs. The next chapter will review the relevant literature to look at reported adverse events.

There are three ways in which any medicinal product could cause harm to users; as a result of contamination of the medicinal product, from toxicity due to its active principles and through incorrect use of the product.

Avoiding contamination

Contamination may involve the non-intended inclusion of substances such as toxins or infectious agents. The steps taken to ensure the quality of HMPs in the manufacturing process are similar to those applied to conventional drugs (Kirby 2002). All HMPs should be produced according to the well-established requirements for Good Manufacturing Practice (GMP) that are laid down in EU and national medicine regulations and the specific requirements outlined in established homeopathic pharmacopœias. According to the revised EU medicines directives the manufacturing process shall comply with the requirements of Commission Directive 91/356/EEC laying down the principles and guidelines of GMP for medicinal products for human use (OJ L 193, 17.7.1991) and with the principles and guidelines on GMP, published by the Commission in The Rules Governing Medicinal Products in the European Community, Volume 4 (European Parliament and Council of the European Union 2004). These regulations aim to help prevent the risk of contamination of all pharmaceuticals including HMPs.

Avoiding toxicity

The main difference between conventional drugs and HMPs is the process of potentisation that involves the progressive serial dilution and succussion of the original source substance (Kirby 2002). Kirby points out that from the point of view of safety, there is general agreement within the homeopathic profession and even among sceptics of homeopathy that high dilution of source substances greatly reduces the likelihood of adverse drug reactions (ADR) due to toxicity.

The revised EU directives state that: “Having regard to the particular characteristics of these homeopathic medicinal products, such as the very low level of active principles they contain and the difficulty of applying to them the conventional statistical methods relating to clinical trials, it is desirable to provide a special, simplified registration procedure for those homeopathic medicinal products which are placed on the market without therapeutic indications in a pharmaceutical form and dosage which do not present a risk for the patient.” (European Parliament and Council of the European Union 2004)

The following conditions must be met to comply with the above-mentioned special, simplified registration procedure:

- HMPs are administered orally or externally;
- no specific therapeutic indication appears on the labelling of the medicinal product or in any information relating thereto;
- there is a sufficient degree of dilution to guarantee the safety of the medicinal product; in particular, the medicinal product may not contain either more than one part per 10 000 of the mother tincture or more than 1/100th of the smallest dose used in allopathy

(conventional medicine) with regard to active substances whose presence in an allopathic medicinal product results in the obligation to submit a doctor's prescription.

A final point that needs to be mentioned is the identity of products. Some authors found that reported ADRs of HMPs were in fact cases of ‘mistaken identity’ (Fisher et al. 2002). This involves cases where the products are actually not homeopathic medicines, but contain herbal and other medicinal or toxic substances. Products that have not been subject to the process of potentisation cannot be accepted as HMPs (Laso and Galan 2007). These cases can therefore not be considered as ADRs of HMPs, but as ADRs from other products. This issue emphasises the importance of correct labelling of products, according to EU and national regulations.

Ensuring correct use of the product

Correct use of the product involves patients’ use of the product according to their practitioner’s prescription or, in case of self-administration, use of the product according to information either provided on labelling or in the enclosed documentation provided with the purchased HMP. Advice on use of the product provided by practitioners is related to their competence and will be discussed later in this document.

Conclusions regarding the safety of homeopathic medicinal products

The specific nature of HMPs that involves dilution through the potentisation process, the application of EU and national medicine directives, including requirements for GMP, to the production of HMPs and appropriate use of HMPs should contribute to ensuring the safety of these products. This is in line with the approach used in the USA where regulation classifies these medicines to be safe for over-the-counter use (Jonas et al. 2003). Risk assessment of HMPs should always be related to the end product placed on the market.

B. Reported adverse events and adverse drug reactions – research evidence

As previously stated in this paper, several authors have pointed out that homeopathy is considered a safe treatment modality. The safety of HMPs is regulated by European and national production regulations and the potentisation process arguably renders these products safe to use beyond the 1:10 000 dilution set out in the EU directives. Having said this, several authors point out that claims for the safety of HMPs should still be tested (Chakraborti et al. 2003, Dantas and Rampes 2000, Kirby 2002).

To this end, several randomised clinical trials[2] and observational studies[3] have been published. These either solely look at adverse events (AE) (and to some extent homeopathic aggravations (HA), which may be defined as a transient worsening of a patient's already existing symptoms and which is generally considered a favourable response indicating a curative action – see Appendix A) or also the effectiveness and/or cost-effectiveness of homeopathy. We will here only consider evidence related to AE and HA.

It may be difficult to draw conclusions based on single trials. Six publications provide systematic reviews evaluating existing reports on AE in homeopathy (Bornhöft et al. 2006, Dantas and Rampes 2000, Grabia and Ernst 2003, Pilkington et al. 2005, 2006, Woodward 2005).

A number of case reports[4] have also been published. These reports present claims of AE following homeopathic treatment. We will consider these at the end of this chapter.

Systematic reviews of adverse events in homeopathy

Dantas and Rampes – systematic review

Dantas and Rampes (2000) found 19 reports of clinical trials, 19 case reports and 15 homeopathic pathogenic trials (HPTs) from documents published in the period from 1970 to 1995 in the English speaking literature that contained information on adverse events (AE). They also carried out enquiries with manufacturers and regulatory agencies to obtain information on AE in homeopathy.

HPTs are trials where the intention is to produce symptoms in healthy volunteers who are testing a specific homeopathic medicine. These trials can therefore in our opinion not be considered AE as they are not testing the effects of HMPs prescribed for or self-administered by patients. Having said this, effects found in HPTs were not very different in nature from nocebo effects seen in phase I clinical trials in healthy volunteers.

The authors found that clinical trials showed a mean incidence of AE of 9.40 in homeopathy groups compared to 6.12 in placebo (ibid.). AE were mild and transient and included mostly headaches, tiredness, skin eruptions, dizziness, bowel dysfunction such as diarrhoea or loose stools, and, more frequently, aggravations of patients' pre-existing symptoms following administration of homeopathic medicines. Transient aggravations of pre-existing symptoms

[2] Aabel 2000, Aabel et al. 2000, Andrade et al. 1991, Attena et al. 1995, Balzarini et al. 2000, Bohmer and Ambrus 1992, Bourgeois 1984, Brinkhaus et al. 2006, Cialdella et al. 2001, Dorfman 1987, Dorfman 1992, Frass et al. 2005, Furuta et al. 2003, Hart et al. 1997, Jacobs et al. 2005a, 2005b, Katz et al. 2005, Kim et al. 2005, Lewith et al. 2002, Rahlfs and Mössinger 1978, Reilly et al. 1986, 1994, Shipley et al. 1983, Simpson et al. 1998, Smith et al. 2002, Smolle et al. 1998, Stevinson et al. 2003, Straumsheim 2000, Taylor 2000, Thompson et al. 2005, Weisenauer 1983, 1991, 1994, Whitmarsh 1997.

[3] Anelli et al. 2002, Endrizzi et al. 2005, Friese et al. 1997, Fisher et al. 2002, Güthlin et al. 2004, Jain 2003, Keil et al. 2006, Molassiotis et al. 2005a, 2005b, Pomposelli et al. 2003, Reilly 2005, Riley et al. 2001, Sevar 2005, Thompson and Reilly 2002, Thompson et al. 2004, Vickers and van Haselen 2001, White et al. 2003

[4] Aberer and Strohal 1991, Audicana et al. 2001, Cardinali et al. 2004, Chakraborti et al. 2003, Goodyear and Harper 1990, Ibsen et al. 1987, Kuenzli et al. 2004, Mevorah et al. 2003, Monk 1986, Mortelmans et al. 2004, Potier 1998, Stevens 1978, van Ulsen et al. 1988

are frequently encountered in homeopathic practice, and are often considered a necessary stage of the curative process (Cook 1989, Endrizzi et al. 2005, Pshyrembel 2000, Swayne 2002, Thompson et al. 2004).

A main conclusion based on the findings in this review is that the few AE that were seen in patients were mostly mild and transient. Of more concern was the relatively low number of trials found specifically referring to AE in homeopathic treatment. This suggests that there may be under-reporting of AE. It therefore seems relevant to consider reports of AE published after the year 2000 and to consider reports in the non-English speaking literature.

Grabia and Ernst – systematic review of clinical trials

A systematic review of randomised, placebo-controlled clinical trials was published by Grabia and Ernst (2003). The authors found 24 trials published in the period from 1966 to 2002 considering HA and AE. In total these trials included 3 437 patients. Results showed 33 cases of AE in placebo groups, compared to 97 in verum groups. Moreover, 50 cases of HA were seen in placebo groups, compared to 63 in verum groups. The articles provide no clear consensus as to precisely how HA were defined.

Collectively about three times more AE were reported in verum groups compared to placebo groups. The fact that all studies were double-blind implies that homeopathic remedies are not totally devoid of AE, and homeopathic remedies are not clinically identical with placebos. The review does not provide clear evidence of the existence of HA. The authors acknowledge that trials have not routinely collected data on AE and HA, which could reduce the validity of this review.

Bornhöft et al. – Health technology assessment

Bornhöft et al. (2006) in their health technology assessment report (HTA) considering the effectiveness, cost-effectiveness and appropriateness of homeopathy refer to both the above presented literature reviews and conclude that clinical studies show that homeopathy can be considered a safe treatment modality. An HTA can be seen as a multidisciplinary process summarising information in a transparent, unbiased and robust manner (EUnetHTA 2003/2006).

Pilkington et al. – systematic review of clinical trials in anxiety and depression

Two systematic reviews have been carried out on homeopathic treatment for psychological conditions, including one on depression (Pilkington et al. 2005) and one on anxiety and anxiety disorders (Pilkington et al. 2006). These reviews respectively identified two and eight randomised controlled studies. Both concluded that AE were limited to ‘remedy reactions’, which we previously have defined as HA.

Woodward – literature search

The author of a sixth report (Woodward 2005) states that interactions between homeopathic and conventional drugs “… are unlikely to arise from homeopathic medicines due to the enormous dilutions usually involved and the lack of classical pharmacological or toxicological effects except in circumstances where the homeopathic medicine has been prepared with inadequate dilution, either intentionally or otherwise.” This report claims to be based on a literature search for studies published up to January 2005, but does not provide further details of methods, including databases used for the search.

Conclusions based on reviews

Three of these five systematic reviews seem to indicate that homeopathic medicinal treatment may provoke AE, but that these are generally mild and transient. This is also the conclusion of Fisher et al. (2002) who pointed out that there seems to be under-reporting, that there are cases of 'mistaken identity' where herbal and other medicines were described as homeopathic (see end of this chapter), and that the main risks of homeopathy relate to the prescriber rather than the medicine (see later in this document).

Dantas and Rampes (2000) reviewed both observational and experimental studies published in the period from 1970 to 1995, whereas Grabia and Ernst (2003) only considered experimental ones, and Bornhöft et al. (2006) considered articles up to 2003. It is unclear how Woodward's (2005) literature search was carried out. We will therefore here consider observational studies published during or after 1995, as well as any experimental studies published during or after 2003 considering AE of homeopathy.

Observational studies published after 1995

We found 20 observational studies [5] (with a total of 7 275 patients) considering possible AE after homeopathic treatment. Results are presented in table 1. Reported AE varied from none (in nine studies) to 11 percent. No cases of serious adverse events (SAE) or serious adverse drug reactions (Serious ADR) were found, which means that no cases were found resulting in hospitalisation, life-threatening situations, persistent or significant disability/incapacity or congenital anomaly/birth defect. AE were primarily headaches, but also other localised pain, dryness of skin and eruption, eye irritation, digestive problems (upset stomach, vomiting), feelings of heat, agitation, and psychological symptoms such as increased irritability and feelings of depression.

HA were reported in six studies and varied from 7.4 (incl. AE) to 33.2 percent. As previously reported HA involve worsening of patients' already existing symptoms and are considered a favourable response to treatment which is often followed by improvement of patients' symptoms.

It must be kept in mind that there may be a whole range of possible explanations for reported AE in observational studies, including a nocebo effect, and results are in general less reliable than results found in randomised double-blind trials. Having said this, these studies seem to confirm previously published results showing that AE do exist, but that no SAE are found.

It is interesting to consider that some studies have compared AE or ADR from homeopathic and conventional treatment. An example of this was a study of 1 577 patients (857 on homeopathic treatment) where ADR occurred more frequently in adults receiving conventional treatment (7.6 %), compared to those in the homeopathic group (3.1 %) (Haidvogl et al. 2007).

Experimental studies published after 2003

We found 10 clinical trials[6] (with a total of 720 patients) considering possible AE after homeopathic treatment. Results are presented in table 2. Six trials reported no AE, four reported either no difference or results similar to placebo. One trial tested interference with conventional treatment, but was unable to find such an effect. Authors of one study pointed

[5] Anelli et al. 2002, Endrizzi et al. 2005, Everett et al. 2005, Güthlin et al. 2004, Haidvogl et al. 2007, Jain 2003, Keil et al. 2006, Lacroix et al. 2005, Li et al. 2003, Molassiotis et al. 2005a, 2005b, Pomposelli et al. 2003, Reilly 2005, Riley et al. 2001, Schmiedel and Klein 2006, Sevar 2005, Thompson and Reilly 2002, Thompson et al. 2004, Trichard et al. 2004, 2005.

[6] Brinkhaus et al. 2006, Frass et al. 2005, Furuta et al. 2003, Jacobs et al. 2005a, 2005b, Katz et al. 2005, Kim et al. 2005, Stevinson et al. 2003, Thompson et al. 2005, White et al. 2003.

out that effects were transitory. No SAE or Serious ADR were found. Results from these ten clinical trials indicate that AE resulting from HMPs are similar to effects seen from placebo and that effects are moderate or mild.

Case reports

Thirteen reports of 17 cases of possible AE[7] during or after homeopathic treatment have been found. They were all either cases of 'mistaken identity' or atypical for homeopathy practice. It seems clear that these thirteen reports do not support the hypothesis of side effects arising from HMPs.

At least five reports (Chakraborti et al. 2003, Montoya et al. 1991, Mortelmans et al. 2004, Potier 1998, Stevens 1978) seem to be cases of 'mistaken identity' as they appear to involve material doses of the original substance. These products are not below the maximum level of concentration allowed for HMPs set by the European Parliament and the Council of the European Union (2004), which is 1:10 000 or 1/100th of the smallest dose used in allopathy with regard to active substances whose presence in an allopathic medicinal product results in the obligation to submit a doctor's prescription. These products can therefore not be referred to as HMPs and can as a result arguably be disregarded here.

Nine articles[8] report on twelve cases of skin reactions allegedly occurring after homeopathic treatment. All reports are commented upon here.

Where the English summary of a Danish article reporting four cases of complications resulting from alternative treatment refers to the use of 'homeopathic advice and medication' (Ibsen et al. 1987), a closer study of the original text in Danish reveals that none of these patients were treated by homeopaths nor did they receive any homeopathic treatment. The English summary is simply an incorrect translation of the original text.

Another two articles refer to skin reactions developing after ingestion of high concentrations of the original substance (Cardinali et al. 2004, van Ulsen et al. 1988), and one case involved the parallel use of an ointment that is likely to have set off an eruption (Audicana et al. 2001). All three reports can be considered cases of 'mistaken identity'.

In a report of three cases, the authors (Aberer and Strohal 1991) claim patients experienced skin reactions and one patient anaphylactic shock resulting from 'homeopathic drugs', but the authors do not specify the concentration of the original substances in these medicines and thus these cases surely can not be considered here. Moreover, anaphylactic shock has not been reported in any previous publication on AE from homeopathic treatment. It is not unlikely that these cases are either unrelated to the ingestion of 'homeopathic drugs' or are cases of 'mistaken identity'.

Yet another report on skin reactions allegedly resulted from 'homeopathic medicines' (Goodyear and Harper 1990). The authors state that the patient had received nine different homeopathic medicines. With the exception of two substances, the authors again do not specify the concentration of the substances included in the product. It is therefore impossible to know whether this is another case of 'mistaken identity'.

Another case involved eczema after injection of a homeopathic medicine (Monk 1986), a mode of administration which is uncommon in homeopathy and may only be carried out by medical doctors. Having said this, a study specifically considering the safety of homeopathic

[7] Aberer and Strohal 1991, Audicana et al. 2001, Cardinali et al. 2004, Chakraborti et al. 2003, Goodyear and Harper 1990, Ibsen et al. 1987, Kuenzli et al. 2004, Mevorah et al. 2003, Monk 1986, Montoya et al. 1991, Mortelmans et al. 2004, Potier 1998, Stevens 1978, van Ulsen et al. 1988

[8] Aberer and Strohal 1991, Audicana et al. 2001, Cardinali et al. 2004, Goodyear and Harper 1990, Ibsen et al. 1987, Kuenzli et al. 2004, Mevorah et al. 2003, Monk 1986, van Ulsen et al. 1988

injectables for subcutaneous administration concluded that these products have a very low risk profile (Baars et al. 2005).

In a report on development of bullous pemphigoid in a child, the authors state that no conclusion about the role of homeopathy in triggering the complaints can be made (Kuenzli et al. 2004). They do however stress awareness of risk of withholding conventional treatment. This may therefore be an example of inappropriate case management, which will be discussed in a later chapter.

Based on these reports, claims of ADRs resulting from HMPs seem unsubstantiated.

Conclusions regarding adverse effects of homeopathic medicinal products

In spite of claims of homeopathy being considered a safe treatment modality, the safety of HMPs, as for all medicinal products, should be tested. Some authors claim that there may be underreporting of AE (Ernst 2001, Fisher et al. 2002).

Having said this, results found in 18 observational studies published after 1995 and 10 experimental studies published after 2003 seem to concur with conclusions published in six systematic reviews evaluating existing reports on AE and ADR in homeopathy. To the extent that AE in homeopathy have been documented, they seem only to be mild or moderate, and transient. We have been unable to find any SAE or Serious ADR resulting from HMPs. Moreover, as we have seen, claims of AE in case reports largely seem to be based on misunderstandings or misinterpretation of what homeopathy is or what constitutes an HMP.

Therefore, the specific nature of the medicines themselves and the research that we have considered seems at this stage to support the claim that homeopathic treatment has a very high level of safety, particularly in comparison with conventional medicinal products.

Table 1. Observational studies published after 1995 considering possible AE and HA

Author	Study design	Sample size	Indication	Homeopathic treatment	Adverse events	Homeopathic aggravation
Anelli et al. 2002	Prospective multi-centre observational	1 025 6 countries	All complaints	Individualised	2.7 %	33. 2 %
Endrizzi et al. 2005	Prospective observational	335	All complaints	Individualised	2.68 %	26. 3 %
Everett et al. 2005	Prospective observational	31	Postoperative complications	Unclear	None	Not specified
Güthlin et al. 2004	Prospective observational	900	All complaints	Unclear	7.4 %	(incl. in AE)
Haidvogl et al. 2007	Prospective parallel group comparative	857	Acute respiratory and ear complaints	Individualised	3.1 % 2.0 % [1]	Not specified
Jain 2003	Prospective observational	109	All complaints	Individualised	1 case	Not specified
Keil et al. 2006	Prospective parallel group comparative	118	Eczema	Individualised	None	Not specified
Laxroix et al. 2005	Prospective comparative	18	Effects on newborn children receiving breast milk	Unclear	None	Not specified
Li et al. 2003	Prospective observational	13	Asthma	Isopathy	None	
Pomposelli et al. 2003	Prospective	55	Arthritis/ rheumatism osteoporosis	Unclear	None	30.8 %
Molassiotis et al. 2005a	Descriptive cross-sectional survey on CAM therapies in general (incl. homeopathy)	956	Cancer	Unclear	None for homeopathy 4.4 % for other CAM	
Molassiotis et al. 2005b	Descriptive cross-sectional survey on CAM therapies in general (incl. homeopathy)	126	Colorectal cancer	Unclear	None for homeopathy 1 patient for other CAM	
Reilly 2005	Unclear	1 000	Acute complaints	Unclear	2 %	Not specified
Riley et al. 2001	Prospective parallel group comparative	281	RTI, allergies and ear complaints	Individualised	7.8 %	Not specified
Schmiedel and Klein 2006	Prospective parallel group comparative	397	Common cold	Complex HMP	None	Not specified
Sevar 2005	Prospective observational	455	All complaints	Individualised [2]	2 patients	Not specified
Thompson and Reilly 2002	Prospective observational	100	Cancer	Individualised	None	17 %
Thompson et al. 2004	Prospective observational	116	All complaints	Individualised	11 %	24 %
Trichard et al. 2004	Prospective parallel group comparative	268	Acute rhinopharyngitis	Individualised	4.9 %	Not specified
Trichard et al. 2005	Prospective parallel group comparative	241	Recurrent acute rhinopharyngitis	Individualised	4.6 %	Not specified

[1] Results were separated out for adults / children
[2] Presumed individualised based on description of results

Table 2. Experimental studies published after 2003 considering possible AE from homeopathic treatment

Author	Study design	Sample size	Indication	Homeopathic treatment	Adverse events
Brinkhaus et al. 2006	Randomised, double-blind placebo-controlled	227	Recovery after knee surgery	Single remedy	Low No difference to placebo
Frass et al. 2005	Randomised, double-blind placebo-controlled	70	Severe sepsis knee surgery	Individualised	None No interference with conventional treatment
Furuta et al. 2003	Randomised, double-blind placebo-controlled	40	Obstructive adenoid knee surgery	Three remedies	None
Jacobs et al. 2005a	Randomised, double-blind placebo-controlled	43	ADHD knee surgery	Individualised	None
Jacobs et al. 2005b	Randomised, double-blind placebo-controlled	83	Hot flashes after conventional cancer treatment	Individualised	None Transitory
Katz et al. 2005	Randomised, double-blind placebo-controlled (homeopathy, Fluoxetine, placebo)	6	Depression	Individualised (max. 30 remedies)	None
Kim et al. 2005	Randomised, double-blind placebo-controlled	40	Seasonal allergic rhinitis	Potentised pollen	None
Stevinson et al. 2003	Randomised, double-blind placebo-controlled	62	Prevention of pain and bruising in hand surgery	Single remedy	Similar to placebo[1]
Thompson et al. 2005	Randomised, double-blind placebo-controlled	53	Symptoms of oestrogen withdrawal in breast-cancer survivors	Individualised	No difference to placebo
White et al. 2003	Randomised, double-blind placebo-controlled	96	Childhood asthma oestrogen withdrawal in breast-cancer survivors	Individualised	Similar to placebo [2]

[1] Placebo (3): heartburn, sore throat, flu-like symptoms, faintness, headache. Arnica 30C (4): feeling unhappy/low, dry mouth, headache, feeling throbbing in head/neck. Arnica 6C (2): drowsiness, sore tongue
[2] Cases of AE: homeopathy 13, placebo 10.

Table 3. Case reports considering possible adverse events from homeopathic treatment

Author	Study design	Sample size	Reported adverse event	Possible explanation for reported adverse event
Aberer and Strohal 1991	Case report	3	Skin reaction, anaphylaxis	Material doses / mistaken identity
Audicana et al. 2001	Case report	1	Skin reaction	Simultaneous use of ointment
Cardinali et al. 2004	Case report	1	Skin reaction	Material doses / mistaken identity
Chakraborti et al. 2003	Case report	1	Arsenic intoxication	Material doses (dilution 1:10) / mistaken identity
Goodyear and Harper 1990	Case report	1	Erythema, limb oedema	Product containing 9 different substances, concentrations unspecified for 7 of them. Possibly material doses / mistaken identity
Ibsen et al. 1987	Case report	4	Skin reaction	Translation mistake, not homeopathic treatment
Kuenzli et al. 2004	Case report	1	Skin reaction	Exacerbation of skin condition from aborting ongoing conventional treatment
Monk 1986	Case report	1	Skin reaction	Reaction after injection of HMP
Montoya et al. 1991	Case report	1	Mercury poisoning	Material doses / mistaken identity
Mortelmans et al. 2004	Case report	1	Extreme agitation intoxication	Material doses probable / mistaken identity Patient also affected by speed and alcohol
Mevorah et al. 2003	Case report	1		
Potier 1998	Case report	1	Bromate intoxication	Material doses / mistaken identity
Stevens 1978 2004	Case report	1	Thallium intoxication	Material doses highly likely / mistaken identity
van Ulsen 1988	Case report	1	Skin reaction	Material doses / mistaken identity

C. The safety of treatment provided by practitioners

The safety of homeopathy is dependent on three factors: the safety of HMPs, the safety of patients self-administering HMPs and lastly the safety of treatment provided by homeopaths. The first of these areas has already been discussed in this paper. We will next consider treatment provided by homeopaths.

Some authors have suggested that where homeopathy itself may be considered free from direct risks, it might be associated with indirect risks (Ernst 2001, Fisher et al. 2002). Such risks include, for example, patients presenting too late for appropriate conventional examination and treatment as a result of a homeopath continuing to treat them with homeopathy when other options should be pursued. This may be referred to as 'error of omission', an error occurring as a result of an action not taken (JCAHO 2002, Aspden 2004). Another scenario could involve the situation where patients inappropriately discontinue the conventional treatment that they are taking either through their own initiative or following the direction of the practitioner (Schmidt and Ernst 2002). We would also like to add ethically inappropriate treatment or behaviour as another category. All these areas may be covered by the terms 'malpractice' and 'unethical treatment', involving some sort of inappropriate practice.

Several questions arise: First of all, do cases of malpractice occur and if so, to what extent, what kind of cases are they and who are the practitioners involved? Secondly, what are the steps put into place to prevent malpractice from taking place, and where there is a lack of such measures, what is needed? Thirdly, what has been done to deal with cases of malpractice if and when they occur?

Evidence of cases of unethical practice and malpractice

Unethical practice is here understood as practice that is in conflict with a homeopathic association's Codes of Ethics and Practice, whereas malpractice refers to a practice that is deficient in skill from what might ordinarily be expected of a professional and which is deemed illegal by a court.

Ernst (2001) states that there may be underreporting of cases of malpractice and little research appears to exist within this area. In order to obtain an overview of cases of unethical practice and malpractice, ECCH requested all its member associations to provide information on any known cases of unethical practice or malpractice in their countries, whether reported to the homeopathic associations or brought to the country's legal court. This 'survey' was carried out in the first half of 2008.

The results presented here therefore include cases that have been reported to national ECCH member associations as well as any publicly known cases reported to the authorities in each individual country over the past decades. For a complete overview please refer to table 4.

Out of a total of 24 countries where ECCH is represented, 18 cases of possible unethical practice or malpractice have been reported in eight countries. Out of these, ten cases involved practitioners who are members of ECCH member associations and the remaining eight cases involved other practitioners. In 15 countries no such cases are known.

The ten cases involving members of ECCH member associations include eight cases dealt with by the professional association/disciplinary committee. Out of these eight cases five practitioners were excluded from the association and its register, two received a warning and one was recommended to undertake supervision.

Cases brought to court

Seven reported cases were brought to court. Out of these, two practitioners were members of ECCH member associations, the remaining five were other practitioners.

The first court case involving a homeopath who was a member of an ECCH member association sentenced the practitioner for not having referred a patient suffering from a skin condition for treatment in a hospital. The medical doctor (general practitioner) who was responsible for the patient at the same time was not brought to court. The court stated that although the medical doctor should have referred the patient for specialist treatment at an earlier stage, this did not relieve the homeopath of his responsibility to advise the patient to seek such treatment. The homeopath was also criticised for poor record keeping, a fact which reduced the trustworthiness of the practitioner, who was sentenced to pay the patient a financial compensation.

The second court case involving a homeopath who was a member of an ECCH member association was acquitted by the court. The practitioner had been charged for providing preventive homeopathic treatment as an alternative to conventional anti-malaria treatment. The court found that the practitioner had acted within her bounds of competence, had informed the patient appropriately about the treatment including any available alternatives. The court also pointed out that conventional treatment would have involved considerable side effects, something the patient had previously experienced.

The five cases brought to court involving practitioners who were not members of ECCH member associations include a homeopath, a medical doctor, a physiotherapist and other practitioners.

The homeopath who was not a member of an ECCH member association had recommended a patient to discontinue conventional treatment. He was sentenced in court for malpractice. Such practice is also a violation of the ECCH Guidelines for the Bounds of Competence of Homeopaths (ECCH 2006b) which are presented later in this report.

A medical doctor was brought to court under charge of malpractice for having treated cancer patients. The outcome of this case is unknown to us. Moreover, a physiotherapist prescribing HMPs was sentenced in court for malpractice for having diagnosed patients and discarded a doctor's diagnosis. Two practitioners were sentenced for illegally using the title 'medical doctor'. And finally, a practitioner was sentenced for practising homeopathy and other CAM therapies, because treatment of patients by someone who is not a medical doctor was considered illegal at that point in time. Several other practitioners have since then been brought to court under the same charges, but they have all been acquitted and it is now not considered illegal to practise homeopathy for someone who is not a medical doctor in this country.

While underreporting of cases cannot be excluded, the evidence presented here indicates a very low incidence of cases of unethical practice and malpractice. We found only ten cases involving homeopaths who are members of ECCH member associations. In total, these associations represent over 5 000 practitioners. Out of these ten cases, only one was sentenced in court, whereas another one was acquitted.

Table 4. Reported cases of unethical practice and malpractice

Country	Number of cases	Type of practitioner	Type of reported case	Case outcome
Armenia	None known			
Bosnia and Herzegovina	None known			
Bulgaria	None known			
Czech Republic	1	Homeopath, member of national association	Inappropriate administration of HMPs	Excluded from association/register
Denmark	None known			
Estonia	None known			
Finland	None known			
Germany	None known			
Greece	None known			
Iceland	None known			
Ireland	1	Nurse, not a homeopath, but prescribing HMPs	Recommended a patient to discontinue conventional medication	No prosecution taken
Israel	2	Homeopath, not member of national association	Recommended a patient to discontinue conventional medication	Sentenced in court for for malpractice[1]
		Homeopath, member of national association	Unethical practice	Excluded from association/register
Italy	None known			
Macedonia	None known			
Malta	None known			
Netherlands	3	Two homeopaths, members of national association	Falsely accusing patient's parent of child abuse by disciplinary committee	Warning/reprimand
		Homeopath, member of national association	Breach of confidentiality	Warning by disciplinary committee
		Homeopath, member of national association	Provided preventive treatment as an alternative to conventional treatment	Acquitted by court
Norway	2	Physiotherapist, not member of national association	Diagnosing patients and discarding doctors' diagnosis	Sentenced in court for malpractice
		Homeopath, member of national association	Did not refer patient for medical treatment	Sentenced in court for malpractice
Poland	None known			
Portugal	None known			
Serbia	1	Medical doctor, not member of national association	Accused of malpractice for treating cancer patients	Unknown
Spain	4	Practitioner, not member of national association	Accused of practising CAM therapies including homeopathy[2]	Sentenced in court
		Two practitioners, not members of national association	Use of title 'medical doctor' in someone who is not an MD[3-4]	Sentenced in court
		Various practitioners[5], not members of national association	Illegal distribution and sale of a non-homeopathic product	Unknown
Sweden	None known			
Switzerland	None known			
United Kingdom[6]	4	3 homeopaths, members of national association	Unprofessional conduct / misconduct relating to professional boundaries	Removed from register
		Homeopath, member of national association	Practice management	Supervision recommended

[1] Israeli Supreme Court 2003.
[2] Mantero de Aspe M. (2000) El ejercicio medico de la homeopatia en España a finales de siglo XX. Sentence 217/90, 24 September 1990, Plama de Mallorca. Note: All cases brought to court charging practitioners for practising homeopathy without being a medical doctor after 1990 have been suspended/rejected.
[3] Mantero de Aspe M. (2000) El ejercicio medico de la homeopatia en España a finales de siglo XX. Sentence 132/99, 12 May 1999, Ibiza.
[4] Coruna, 2007. [5] Several medical doctors, pharmacists and three 'homeopaths', none members of national association. [6] Over the last 15 years.

Legislation for the practice of homeopathy and CAM

Homeopathy is practised throughout Europe and in countries all over the world (ECCH 2006a, WHO 2001, 2005). Legislation for regulation of the treatment of patients in general and for the practice of homeopathy in particular varies from country to country (ECCH 2006a, WHO 2001).

Homeopathy is currently practised by three categories of practitioners (ECCH 2001):

1. Homeopaths who have received a full training in homeopathy as a discipline in itself.
2. Medical doctors and other healthcare practitioners whose postgraduate training in homeopathy varies from short introductory courses to a full training in homeopathy.
3. Other practitioners who use a limited range of homeopathic remedies alongside other therapeutic options.

Statutorily recognised healthcare practitioners practising homeopathy are regulated through legislation established for each healthcare profession. This includes practitioners such as medical doctors, dentists, nurses, midwives, physiotherapists, and in some countries chiropractors (e.g. Denmark, France, Norway, United Kingdom), osteopaths (e.g. France, United Kingdom), naprapaths (Finland, Sweden), Heilpraktikers (Germany 1939/1974) and Naturheilpraktikers (Liechtenstein 2007).

Legislation and/or regulation of homeopaths and other CAM practitioners has been introduced in 10 European countries and has been planned for another two countries. For a complete overview please refer to table 5. The main aim of such legislation and regulation is to ensure patients' access to CAM while at the same time ensuring their safety. An example of this is the Portuguese law (2003) which "… enshrines the right of Portuguese citizens to freely choose the particular therapy they wish while also setting out the basis for the regulation of the practitioners who may practise these therapies as independent health care professionals."

Table 5. Legislation and regulation of homeopathy and CAM therapies in some European countries

Country	Legislation	Regulation	Introduced
Belgium	Legislation for homeopaths and three other categories of CAM practitioners		1999
Denmark		Public register for CAM practitioners	2004
Germany	Legislation for Heilpraktikers		1938/1974
Iceland	Legislation for CAM practitioners	Public register for CAM practitioners	2005
Ireland	Legislation for CAM practitioners		Planned (ref. 2002, 2005)
Liechtenstein	Legislation for CAM		2007
Netherlands	Legalisation of the practice of CAM		1993
Norway	Legislation for CAM practitioners	Public register for CAM practitioners www.brreg.no	2004
Portugal	Legislation for homeopaths and five other categories of CAM practitioners		2003
Sweden		Public register for CAM practitioners	Planned
Spain (Catalonia)	Legislation for CAM practitioners		2007
United Kingdom	Legislation for acupuncturists and herbal medicine practitioners, possibly for homeopaths in the future		Planned (ref. 2000)

Voluntary self-regulation of the profession

While national legislation is considered important in order to ensure patients' rights of access to homeopathy and other CAM therapies, as well as ensuring their safety, such legislation may be insufficient to deal with cases of unethical practice and complaints about the professional practice of homeopathy.

The profession has therefore taken on the responsibility of self-regulation, on both a national and an international level. This is partially due to practitioners wanting to ensure the quality of services in general and it has partially been motivated by lack of legislation in some countries. Voluntary self-regulation takes place through the actions of national associations representing homeopaths, as well as through guidance provided by ECCH which has taken on the role of representing homeopaths in Europe. ECCH comprises of 28 associations in 25 countries. Together with ECCH these associations have agreed common criteria for voluntary self-regulation to ensure the interests of patients (ECCH 2002). These are commonly agreed minimum criteria that are widely recognised as essential requirements for a responsible and mature profession. These criteria apply whether the profession is to be statutorily self-regulated or voluntarily self-regulated. In either case their implementation will ensure that patients have access to safe high quality homeopathic treatment. The Guidelines include recommendations for:

I. **A single national professional body, where appropriate, established according to common high standards of education, registration and practice agreed across Europe.** This ensures that patients have the confidence of knowing all practitioners are educated, registered and regulated by one professional body. It means the profession is united in each country, thereby strengthening its credibility. It also means that members of the public moving between countries can consult

homeopaths of other national registers in the confident expectation of equivalent standards to those in their own country.

II. **Patient/lay representation on all standard setting committees – particularly for complaints and professional conduct procedures.** There is a risk that if the profession is regulated only by its own members it can be perceived to be acting only in its own members' interests. Ensuring independent representation adds an element of objectivity, and that the profession is always aware of patients' interests.

III. **An accreditation process for institutions providing homeopathic education.** Accreditation ensures that there is an objective process designed to stimulate and encourage, as well as evaluate and assess, quality homeopathic education. It ensures that course providers are competent to produce graduates who are capable of practising homeopathy to the highest possible standard and who meet the requirements of the professional register for competent practice. The criteria for accreditation used to assess and evaluate each education programme are negotiated and agreed by representatives from within the professional community and the education sector.

IV. **Continuing Professional Development (CPD).** Established requirements for the undertaking of CPD ensure that each registered homeopath maintains a regular programme of study, which develops personal and professional growth from a variety of sources and experiences.

V. **Professional Indemnity Insurance.** This form of insurance offers the homeopath insurance cover for a variety of options. Most such packages would probably cover medical malpractice, libel and slander, public liability, and professional legal protection. Professional Indemnity Insurance is however likely to vary from country to country.

VI. **Code of Ethics and Practice.** This is a guide for practitioners and patients that sets out the guiding principles and expected standards for the ethical and competent practice of homeopathy. The Code is used as the contextual framework to assess any complaint made against a member of the register (complaints can be made by other practitioners, not just patients).

VII. **Complaints and Disciplinary Procedures.** A complaints and disciplinary process is necessary so that should issues arise between colleagues or between a patient and homeopath that they have been unable to resolve, there is an impartial system of inquiry available that gives all parties involved a fair and objective hearing before any decision is made.

Guidelines to ensure the safety of patients

In order to further contribute to the safety of patients, ECCH has established a number of guidelines agreed by national member associations as tools to assist them in their professional work. For an overview of these guidelines please refer to table 6.

Guidelines for education, accreditation, registration and CPD contribute to patients' safety by ensuring that practitioners registered with an association have achieved a standard of competency that enables them to take the independent responsibility for the homeopathic treatment of their patients.

Guidelines for codes of ethics, professional conduct procedures, bounds of competence and how to handle concerns and complaints, contribute to patients' safety by laying out the

requirements for the regulation of safe and ethically appropriate practice. These guidelines also lay out a system that enables patients to raise concerns, to be heard and to have a confirmed complaint acted on if appropriate.

Table 6. Guidelines introduced by ECCH in order to contribute to the safety of patients

Area	Published	Title of Document
Education	1993/2000	European Guidelines for Homeopathic Education
Education	2002	European Guidelines for Accreditation of Courses of Education in Homeopathy
Education	2004	ECCH Policy for Continuing Professional Development
Ethics/professional conduct	2002	European Guidelines for Code of Ethics
Ethics/professional conduct	2007	ECCH Guidelines for Professional Conduct Procedures
Ethics/professional conduct	2005	ECCH Guidelines for How to Handle Concerns and Complaints
Ethics/professional conduct	2006	ECCH Bounds of Competence
Regulation	2007	ECCH Guidelines on the Individual Route to Registration

Bounds of competence

The ECCH Guidelines for the Bounds of Competence of Homeopaths (ECCH 2006b) outline homeopaths' responsibility to act within their bounds of competence and to

- refer/recommend patients to other healthcare practitioners when deemed necessary for the patient's health and well-being
- not to change or discontinue medication/treatment prescribed by other healthcare practitioners
- consult with colleagues or other healthcare practitioners as appropriate and with the patient's consent

In order for homeopaths to act within their bounds of competence, they need to have achieved professional competence through education and training sufficient in order for them to e.g. recognise when to refer a patient to another healthcare practitioner (ECCH 2000). This involves possessing sufficient knowledge about general medical subjects such as anatomy, physiology, pathology and physical examination (within the boundaries of national legislation). Homeopaths who are not medical doctors should not make medical diagnosis (unless national legislation permits it). Homeopaths should however be able to recognise and understand signs of underlying disease or reasons why patients should be referred for further medical examination and/or for treatment.

Does self-regulation work?

The overview of agreed guidelines for self-regulation raises the question of whether such guidelines are effective. Guidelines and regulations need to be more than words on paper. Associations need to implement them and establish the required procedures to ensure the safety of patients.

The overview of cases of unethical practice and malpractice presented earlier in this chapter shows that only a very limited number of such cases are known to have occurred. Although there may be underreporting of such cases, it seems to indicate that cases of malpractice are rare. Moreover, cases brought to national associations showed that procedures provided for sanctions are indeed applied, such as the exclusion of members from the association and removal of their names from national registers. Patients who are consulting with or wishing to consult with a registered homeopath are likely to be reassured that their concerns, if any, will be heard and incidents of unethical practice or malpractice will be acted upon.

With regard to the possibility of HMPs interacting with other medicines (conventional and non-conventional), a key relevant consideration is highlighted by the study of Rossi et al. (2003) This study showed that many patients undergoing homeopathic treatment have used or are still using conventional drugs and in many cases a reduction in the use of these medicines can be demonstrated during homeopathic treatment. This might well contribute to the hypothesis that, in cases where ADRs have been found, some of the unwanted effects reported could result from the reduction or untimely suspension of conventional therapy. The study by Pomposelli et al. (2003) also tends to confirm this hypothesis.

Recommending patients to discontinue or change conventional treatment is in conflict with ECCH's Guidelines for the Bounds of Competence of Homeopaths (2006). The overview presented earlier in this chapter showed that identified cases of practitioners who recommended discontinuing conventional treatment were all practitioners who were not members of ECCH member associations.

D. The safety of patients self-administering HMPs

We did not find any reports or research evidence specifically referring to the safety of patients self-administering HMPs in our literature review (presented under the chapter entitled 'Reported adverse events and adverse drug reactions – research evidence'). However, information provided on the safety of HMPs resulting from manufacturing procedures and the results of our literature review considering research articles and reports on adverse events and adverse drug reactions, indicate that HMPs are relatively safe to use. The 2004 revised EU medicine directives (European Parliament and Council of the European Union 2004, § 21 introductory section) specifically state that: "*Having regard to the particular characteristics of these homeopathic medicinal products, such as the very low level of active principles they contain and the difficulty of applying to them the conventional statistical methods relating to clinical trials, it is desirable to provide a special, simplified registration procedure for those homeopathic medicinal products which are placed on the market without therapeutic indications in a pharmaceutical form and dosage which do not present a risk for the patient*."

We would however like to point out two areas of concern related to patients self-administering HMPs. First of all these patients may be suffering from undiagnosed disease and may arrive too late for homeopathic, conventional or other treatment as a result of postponing consultations with a health professional. According to the aforementioned EU medicine directives HMPs should be labelled with 'a warning advising the user to consult a doctor if the symptoms persist' (European Parliament and Council of the European Union 2004).

Secondly, the practice of homeopathy requires considerable education and training (ECCH 2000). It may be difficult for users self-prescribing HMPs to consider the potential effect of these products, in particular in treating any condition other than the most banal ones such as bruising resulting from falls and accidents or self-limiting conditions such as a common cold. ECCH would therefore strongly recommend users of HMPs to consult with a qualified homeopath for any conditions other than these. Such practitioners may be found through the ECCH website at www.homeopathy-ecch.eu

Conclusions

There is overall agreement between practitioners, national Governments and the European Union institutions that the safety of patients is of paramount importance. There is also a widespread and longstanding belief that CAM therapies such as homeopathy have a high safety profile when correctly administered. Some authors have however pointed out the need for such claims to be researched.

This document has considered the safety of HMPs, the safety of treatment provided by homeopaths, and the safety of patients self-administering HMPs. We have considered systematic reviews of AE in homeopathy, observational and experimental studies, as well as case reports and we have provided overviews of current legislation (as at the date of this report) and self-regulation of the profession of homeopaths.

Current evidence seems to support the claim that ADRs rarely arise in connection with HMPs and where they do they are only mild or moderate, and transient. We have been unable to find any evidence to support a claim that HMPs may cause serious AE or ADR. The results we have seen are in line with claims such as those put forward by Reilly (2005) who states that homeopathy lacks the potential for life-threatening side effects and it may be used in pregnancy and the treatment of infants and children without risk of harm.

We have also considered existing evidence of cases of unethical practice or malpractice. Although it is possible there may be underreporting of such cases, current evidence appears to show a very low incidence of such cases.

We have shown that a number of precautionary measures have been put into effect, both through national legislation for regulation, and through self-regulation by the profession, to ensure the safety of patients. These precautionary measures involve regulations governing the manufacture and sale of HMPs, the setting of standards for the competency and practice of homeopaths, as well as introducing systems that can effectively deal with any concerns or complaints raised by members of the public, patients or others.

We have raised concern about patients self-administering HMPs, in particular as they may thereby arrive too late for treatment provided by a professional and because it may be difficult for someone to consider how to proceed with self-treatment using HMPs without advice provided by a well-educated and trained homeopath.

In summary, current evidence seems to confirm the claim that HMPs are safe to use and homeopathic treatment provided by statutorily regulated or self-regulated homeopaths is safe.

Appendix A – Definitions

Definition of 'homeopathy' and 'homeopathic medicinal product'

Homeopathy can be understood as "that healing art and science of medicine which has been clinically developed from the principles discovered by Samuel Hahnemann and described in his treatise 'The Organon' (Hahnemann 2001). The practice of homeopathy involves the selection and prescription of a single remedy, which through prior testing on healthy people and from clinical experience, is known to produce a similar symptom picture to that of the patient. The remedy is prescribed in the minimum dosage required to bring about healing." (ECCH 1996/2007)

Where this definition describes the practice of homeopathy as defined by the European Council for Classical Homeopathy (ECCH), the issue of safety in homeopathy also needs to consider safety of HMPs when not prescribed according to these criteria. HMPs can be defined as "Any medicinal product prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in the Member States. A homeopathic medicinal product may contain a number of principles." (European Parliament and Council of the European Union 2004)

Definition of 'risk'

Safety of patients has been considered central in healthcare since the time of Hippocrates and the dictum 'first do no harm'. Its importance has been re-emphasized over the last fifty years with the introduction of 'The Nuremberg Code' (Weindling 2001) and the Helsinki declaration (1964/2004) in medical research. Non-maleficence, or the duty not to harm patients, is one of Beauchamp and Childress' (1994) widely accepted four major ethical principles.

Absolute safety is generally thought of as an unachievable goal, which is why the term 'acceptable risk' has been introduced (Krewski 2008). It describes the likelihood of an event whose probability of occurrence is small, whose consequences are so slight, or whose benefits are so great, that there is willingness to take or be subjected to the risk that the event might occur.

Terminology used to define reactions

Adverse Event (AE): The European Medicines Evaluation Agency (2002) defines an AE as any untoward medical occurrence in a patient (or clinical investigation subject) administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. This is in line with the Consolidated Standards of Reporting Trials (CONSORT) (EMEA 2002, Ioannidis et al. 2004). An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease whether or not related to the medicinal (investigational) product. It is recommended to use the term AE in order to describe harmful events occurring during a trial, as it is difficult to know whether it is related to the intervention or not.

Adverse Reaction (AR): According to the World Health Organization (WHO 1972) an AR is a response to a drug which is noxious and unintended, occurring at doses normally used for prophylaxis, diagnosis or therapy, or for modification of physiological function.

Adverse Drug Reaction (ADR): An ADR is an event where the causality link to the tested intervention is well established and strong or the relationship between a medicinal product and an adverse event is at least a reasonable possibility (EMEA 2002).

Serious Adverse Event (SAE) and Serious Adverse Drug Reaction (Serious ADR): This can be defined as any untoward medical occurrence that results in death, or is life-threatening, or requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability/incapacity or is a congenital anomaly/birth defect (EMEA 2002).

Homeopathic Aggravation (HA): A HA can be defined as a worsening of a patient's already existing symptoms occurring close to the time of taking a homeopathic medicinal product (Thompson et al. 2004). Such a reaction is temporary, and is generally considered a favourable response indicating a curative action (Cook 1989, Endrizzi et al. 2005, Pshyrembel 2000, Swayne 2002, Thompson et al. 2004). It is followed by symptoms settling again to their previous state or by an overall improvement of symptoms (Thompson et al. 2004). Most homeopaths claim to see such reactions in clinical practice (Popova 1991).

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