

Safety, regulation and herbal medicines: a review of the evidence

A report prepared by the UK Herbal Medicines Advisory Committee (HMAC) for the Herbal Medicines and Practitioners Working Group (HMPWG)

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1. Executive Summary

1.1 Herbal medicines are widely used in the United Kingdom, including by individuals who are also taking conventional medicines for a range of conditions. They are available through health food stores, pharmacy outlets, internet sites or via herbal practitioners (*See Section 3: The use of herbal medicines, page 5*).

1.2 Such herbal medicinal products, like all other medicines, can have pharmacological effects on the body and so can give rise to adverse effects, or interactions with other conventional medications that the patient may be taking. Because of their pharmacological and toxicological effects, the risks of toxicity are significantly greater than is the case with many other complementary and alternative medicine *therapies* (*See Section 4: Risks associated with herbal medicine, page 6 and Appendix 1, page 42*).

1.3 Adverse events have also been linked to consumption of low grade products containing toxic ingredients because of misidentification or substitution. Unlicensed herbal medicines may be sourced from suppliers who provide no assurances as to standards. (*See Sub Section 4.3: Misidentification or substitution, page 12 and Appendix 1, page 42*)

1.4 Reports of adulteration of herbal medicines with potent conventional medicines or their analogues have increased in recent years, and have been associated with toxic effects. Many of these examples of adulteration are likely to be deliberate. There are also examples of adulteration with heavy metals such as arsenic, mercury or lead (*See Sub Section 4.4: Adulteration, page 13 and Appendix 1, page 42*).

1.5 Under current legislation as set out in Regulation 3 (paragraphs 2, 6, 9) of the *Human Medicines Regulations 2012* (formerly Section 12(1) of the *Medicines Act 1968*) an unqualified practitioner can prescribe an unlicensed herbal medicinal product to the public. (*See Section 5: Current Regulatory Framework, page 16*).

1.6 There is evidence that practitioners lacking expertise and with limited or no accountability are treating vulnerable groups in the population. There is also evidence that herbal medicines are being prescribed to groups at particular risk such as pregnant women, children, the elderly, in the perioperative period and in those with cardiovascular disease. (*See Sub Section 6.2: Risks arising from the use of herbal medicines without the involvement of a qualified practitioner, page 18*).

1.7 Members of the public can have significant difficulties in identifying a qualified, competent herbal practitioner who is also bound by a code of ethics and disciplinary procedures. There is currently no requirement for individual herbal practitioners to achieve the educational standards required to join an existing voluntary register of herbal practitioners, and a herbal medicine practitioner who is removed from a voluntary register or who chooses to resign can still continue in practice. (*See Section 7: Role of regulation in ensuring public safety, page 23*).

1.8 Risks associated with poor quality care include failure to refer the patient back to their general practitioner when required, failure to form a correct diagnosis and rationale for treatment, failure to consider the risks of herb-drug interactions, excessive claims to treat disease and failure to explain treatment and label prescriptions adequately. (*See Sub Section 7.4: Values and Communication skills, page 26*).

2. Glossary of Acronyms and Abbreviations

ADR: Adverse Drug Reaction

BHMA: British Herbal Medicines Association

CAM: Complementary and Alternative Medicine

DH: Department of Health

DILI: Drug-induced liver injury

EAG: Expert Advisory Group

EHTPA: European Herbal and Traditional Medicine Practitioners Association

EMA: European Medicines Agency

EPORWG: Extending Professional and Occupational Regulation Working Group

HCPC: Health and Care Professions Council

HMAC: Herbal Medicines Advisory Committee

HMPC: European Committee on Herbal Medicinal Products

HMPWG: Herbal Medicines and Practitioners Working Group

HMR: *Human Medicines Regulations 2012*

MHRA: Medicines and Healthcare products Regulatory Agency

NIMH: National Institute of Medical Herbalists

POM: Prescription Only Medicines

PSA: Professional Standards Authority for Health and Social Care

RCHM: Register of Chinese Herbal Medicine

Syn. (Synonym): A botanical name that is commonly used but is not botanically accepted as the correct term for a species

TCM: Traditional Chinese Medicine

THMPD: Traditional Herbal Medicinal Products Directive

THR: Traditional Herbal Registration

WHO: World Health Organisation

The UK Herbal Medicines Advisory Committee (HMAC)

HMAC was set up by the UK Government in 2005 under the provisions of Section 4 of the Medicines Act 1968 as an independent expert advisory body to advise Ministers and the Medicines and Healthcare products Regulatory Agency (MHRA). Its remit is to advise on the safety and quality of unlicensed herbal medicinal products and of herbal medicinal products regulated under the traditional herbal registration scheme. The Committee consists of representatives of the main strands of herbal practice, as well as lay members. It has since been designated as an Expert Advisory Group of the MHRA.

This review summarises evidence in the public domain related to the safety of herbal medicines and herbal medicines practice.

2. Use of herbal medicines

The use of herbal medicine is not restricted to the worried well or people with minor or transient conditions. Many patients take herbal medicines while also taking conventional medicines for serious medical conditions (*Posadzki et al. 2013C, Gratus et al. 2009*). A cross-sectional survey of oncology patients (n=1498) being followed up at a hospital in Coventry indicated a prevalence of herbal medicine use of around 20%. The use of herbal medicines increased with time since their diagnosis of cancer, and the most widely used agents used in that particular study were Evening primrose *Oenothera biennis*, Echinacea *Echinacea purpurea*, Garlic *Allium sativum*, Ginger *Zingiber officinale*, Ginkgo *Ginkgo biloba*, Milk thistle *Silybum marianum*, Ginseng *Panax ginseng*, Valerian *Valeriana officinalis*, Black cohosh *Cimicifuga racemosa* and St John's wort *Hypericum perforatum* (*Damery et al. 2011*). Problems can arise where the particular herb is inappropriate for that person. There is clear evidence, e.g. from clinic leaflets and websites, that many practitioners treat patients with serious medical conditions including heart disease, cancer, diabetes and asthma. Some practitioners treat particularly vulnerable groups, such as babies and children, patients with cardiovascular disease or the elderly. Another substantial area of usage of herbal medicines is to treat or relieve the symptoms of chronic, difficult-to-treat conditions, for example eczema. These situations will be discussed later in this report.

Survey evidence shows that many people do not tell the health professional looking after them that they are taking a herbal remedy (and many health professionals do not ask) and so the health professional might have no reason to suspect that an adverse event could be linked to consumption of an herbal remedy (*Thomson et al. 2012, Smith et al. 2004*). As a result, suspected adverse effects of herbal medicines may be overlooked and under-reported. When members of the public who had used herbal medicines were asked to comment on the statement "herbal medicines are safe

because they are natural” 40% either tended to agree or agreed strongly with that view (*MHRA/Ipsos Mori 2008*).

Prior to 2005, unlicensed herbal medicines on the UK market were not required to reach agreed standards of safety and purity. The UK Traditional Herbal Medicines Registration (THR) Scheme was introduced by the Medicines and Healthcare products Regulatory Agency (MHRA) in October 2005 to ensure that these products met specific standards of safety and quality. It was also introduced to ensure that they have indications based on traditional usage (i.e. not on evidence of effectiveness of the product) and are for use only in minor self-limiting conditions that do not require the supervision of a medical practitioner. The inclusion of patient information on the safe use of the product is also required and these products can generally be identified by a “certification mark.” After 30th April 2011 all herbal medicines placed on the UK market have required a THR (or product licence), although a sell-through period was allowed until 30 April 2014. There are now more than 320 products with a THR and unlicensed products can no longer be sold to consumers and must be removed from shelves. Although the regulation of herbal medicines continues to be an important safeguard, there is evidence that safety concerns still occur, as outlined below (*MHRA, 2014A*).

4. Risks associated with herbal medicines

Many plants contain significant amounts of pharmacologically active components, which may be potentially toxic. Adverse interactions may occur between herbal medicines and other medicines an individual may be taking. There is also evidence that such products may sometimes be adulterated, contaminated or contain the wrong herb, toxic herb, or other toxic substances such as heavy metals.

The volume of data on adverse effects of herbal medicines is expanding and Posadzki and colleagues (*Posadzki et al. 2013A*) identified 50 systematic reviews, mainly on the safety of single herbs. This issue is of increasing concern to regulatory agencies, and a study in Singapore (1998-2009) identified 627 adverse events associated with herbal products, including 10 deaths linked with hepatotoxicity (liver toxicity). In all, 46% of the adverse events were associated with products claimed to improve sexual performance (*Patel et al. 2012*).

Hung and co-workers (*Hung et al. 2011*) published a review of 137 case reports of suspected ADR's involving herbal medicines in the periods 1986-88, 1996-98 and 2006-08 and found that the quality of reports had improved such that 34% of the later reports were of high quality. However, the certain identification of the medicinal plants remains a major challenge and the likely herbal ingredient or herb responsible for the ADR's was not fully identified in 80% of these case reports.

4.1 Adverse effects of the herb

Many pharmaceutical medicines, ranging from aspirin for heart disease to taxanes for the treatment of certain cancers, have their origins in the isolation of active chemical constituents from particular plants. Therefore it not surprising that as with conventional pharmaceutical medicines, they may occasionally be associated with toxicity. Although any organ or system may be involved, toxicity involving the liver is of particular concern. This concern has been recognised for many years (*Shaw et al. 1997*). Over a ten-year period in the Spanish Registry, medicinal herbs were the 10th commonest medicines associated with drug-induced liver injury (DILI), a serious and sometimes fatal complication of exposure to medicines (*Andrade et al. 2005*).

Twenty seven selected herbs associated with hepatotoxicity according to a recent review are listed in Table 1, but the list is certainly not exhaustive (*Abdualmjid & Sergi 2013*). Navarro and colleagues have recently noted that in the USA, the proportion of liver injury cases attributed to herbal and dietary supplements reported to the Drug-Induced Liver Injury Network (DILIN) has increased significantly (*Navarro et al 2014*).

Black cohosh <i>Actaea racemosa</i> syn. <i>Cimicifuga racemosa</i>	Syo-saiko-to, Xiao-chai-hu-tang da- chai-hu-tang or TJ-9
Chaparral <i>Larrea tridentata</i>	Kombucha “mushroom” Tea
Serenoa <i>Serenoa repens</i>	Senna <i>Cassia angustifolia</i>
Comfrey <i>Symphytum</i> spp.	Pennyroyal oil <i>Hedeoma pulegoides</i> & <i>Mentha pulegium</i>
Wild Germander <i>Teucrium chamaedrys</i>	Margosa oil <i>Azadirachta indica</i>
<i>Teucrium polium</i>	St John’s wort <i>Hypericum perforatum</i>
Kava <i>Piper methysticum</i>	Valerian <i>Valeriana officinalis</i>
Greater Celandine <i>Chelidonium majus</i>	Mistletoe <i>Viscum album</i>
<i>Atractylis gummifera</i>	Skullcap <i>Scutellaria baicalensis</i>
Jin Bu Huan <i>Lycopodium serratum</i>	Noni juice <i>Morinda citrifolia</i>
Ma Huang <i>Ephedra</i> spp.	<i>Amanita phalloides</i>
Shou-Wu-Pian <i>Polygonum multiflorum</i>	Sassafras <i>Sassafras albidum</i>
<i>Dictamnus dasycarpus</i>	Echinacea <i>Echinacea angustifolia</i> , <i>E. pallida</i> , <i>E. purpurea</i>
Dai-Saiko-to or TJ-8	

Hepatic veno-occlusive disease, which can also affect the liver causing Budd Chiari syndrome, may be associated with certain herbs (e.g. *Senecio* species) containing pyrrolizidine alkaloids (see box).

Hepatic veno-occlusive disease may be associated with certain herbs e.g. *Senecio* species containing pyrrolizidine alkaloids. In 2006, the HMA advised that a consultation should be reissued on proposal to prohibit internal use of *Senecio* species. The Medicines for Human Use (Prohibition) (*Senecio* and Miscellaneous Amendments) Order 2008 came into force on 1 April 2008 prohibiting the sale, supply or importation of unlicensed medicinal products for internal use which contain *Senecio* species.

Black cohosh *Cimicifuga racemosa* is another example of a widely-used herb that may occasionally be associated with disturbances in liver function and more rarely with DILI. When the HMA and CHM reviewed the evidence for this association, it resulted in regulatory action (see box below).

Black cohosh is commonly used to treat menopausal symptoms and is widely available in herbal medicinal products in the UK. The Commission on Human Medicines and HMA reviewed all available data in 2006 and concluded that it underlined an association between Black cohosh and risk of liver disorders. Following advice from both committees, warnings were added to the labels of Black cohosh products and the MHRA worked with the herbal sector to ensure the public was fully informed about this potential risk (MHRA 2008A).

Black cohosh *Cimicifuga racemosa* is used traditionally for rheumatism and as an antispasmodic, but is now used worldwide for menopausal symptoms. Many case reports of hepatotoxicity associated with the use of Black cohosh have been published (*Borrelli & Ernst, 2008*), and these were reviewed by the European Medicines Agency (EMA) (*2006*). In six cases, a liver transplant was required including two instances in the UK (*Levitsky et al. 2005, Lim et al. 2013, Dunbar & Solga, 2007, Whiting et al. 2002*), and one patient died during surgery (*Lynch et al. 2006*). Differing views on the safety of Black cohosh have also been expressed (*Muqet Adnan et al. 2014, Teschke 2010*). Although substitution of different species has not been demonstrated to be the cause of these ADRs, the issue highlights the importance of quality assurance and provenance of medicinal plant materials. Much Black cohosh is sourced from the wild in forested areas of Eastern America, and difficulties in meeting the demand have led to usage of Chinese species and other North American species (*Jiang et al. 2011*).

There have also been several cases of hepatotoxicity associated with Traditional Chinese Medicine (TCM) herbal mixtures. In 1992 a case report was published of a 28 year-old woman who had been treated for eczema by a TCM practitioner, and developed liver failure and died after a liver transplant (*Perharic-Walton et al. 1992*). A second fatal case in the UK was reported in 1995 (*McRae et al. 2002*). These cases, alongside two further published cases of malaise and jaundice in the UK (*Kane et al. 1995*), were discussed in detail in a review alerting herbal practitioners to the situation (*Blackwell 1996*). The author, who is an experienced TCM practitioner, reviewed the prescriptions, and summarised the recommendations of the Register of Chinese Herbal Medicine which included the requirement for a detailed case history and for care with dosage. The warning to advise the patient to stop taking the medication in case of diarrhoea or any other adverse effect was added as in one fatal case, the patient had persisted despite suffering from diarrhoea.

The Chinese Medicine Advisory Service at Guy's & St Thomas' NHS Foundation Trust carried out a detailed review of case reports of liver injury following the use of TCM received between 1991-2006

(Shaw, 2010A). Of 40 cases, 3 patients died following failed liver transplantation, the remainder recovered with medical care. No known hepatotoxic herb was identified in these cases, and another review did not identify any one herb as responsible (Mcrae et al. 2002). A recent wide-ranging review of 58 cases from the UK, the USA and New Zealand adjudged the association with hepatotoxicity to be likely in 40 cases, but was still unable to identify any single herb or herb combination (Shaw, 2010B). Increasing attention has been given to safety in China, and a recent retrospective study of seven hospitals in China (2007-2012) identified 30 patients with acute liver failure who had taken TCM herbs, of whom 18 died in an environment where liver transplantation was not available (Zhao, et al, 2014).

4.2 Drug/ herb Interactions

Several clinically important drug/ herb interactions have been described which result in either reduction or loss in the wanted effects of a conventional medicine or in exaggerated effects/ toxicity of a conventional medicine (Gurley 2012, Gurley et al. 2012, Skalli et al. 2007, Williamson et al. 2013). They may occur because of *pharmacokinetic* interactions (when the herbal medicine alters the absorption, distribution, metabolism or elimination of the conventional medicine) or as a result of *pharmacodynamic* reaction (when the herbal medicine augments or antagonises the effect of any given concentration of the conventional medicine). Some clinically important Drug/ Herb interactions are shown in Table 2.

Herbal Product	Table 2: Some clinically important Drug/ Herb interactions (adapted from Williamson et al. 2013)
<i>Ginkgo biloba</i>	?antiplatelet agents, ?NSAIDs, ?warfarin ?efavirenz
<i>St John's wort</i>	Some anticonvulsants, antidepressants, benzodiazepines, calcium channel blockers, ciclosporin, digoxin, HIV-protease inhibitors, hormonal contraceptives, imatinib, irinotecan, ivadribine, NNRTIs, opioids, SSRIs, tacrolimus, voriconazole, warfarin
<i>Ephedra spp.</i>	caffeine
<i>Ginseng</i>	warfarin
<i>Schisandra</i>	midazolam, tacrolimus, ?ciclosporin
<i>Berberine</i>	ciclosporin

The main conclusion of an overview of 46 systematic reviews was that there were potential interactions between conventional medicines and 46 of the 85 herbs investigated. The quality of the reviews and the evidence was variable, but serious drug-herb interactions were noted in association with St John's wort *Hypericum perforatum* and Mistletoe leaf *Viscum album*, and moderately severe for *Ginkgo biloba*, Ginseng *Panax ginseng*, Kava *Piper methysticum*, Saw palmetto *Serenoa repens* and Green tea *Camellia sinensis* (Posadzki, et al 2013B).

In 2014, the MHRA reported two Yellow Card reports of unplanned pregnancies in 2013 where St John's wort was taken alongside implanted contraceptives. There have been 19 suspected interactions with contraceptives reported through the Yellow Card scheme since 2000, of which 15 resulted in unplanned pregnancies (MHRA 2014B). Although conventional medicines licensed in the UK, THR products and some food supplements carry warnings about the risk of interactions between St John's wort and drugs, some products are not labelled thus. A study in the UK analysed the labels on 15 St John's wort products purchased from health food stores, pharmacies or supermarkets, and found that only five listed interactions (Raynor et al.2011).

In the last quarter of 2013, MHRA received two Yellow Card reports of suspected interactions in women with implanted contraceptives containing etonogestrel (Nexplanon and Implanon). Both women started taking St John's wort and subsequently had unplanned pregnancies. On the basis of available data, the MHRA advised health professionals to "advise women taking hormonal contraceptives for pregnancy prevention not to take herbal products containing St John's wort and to encourage women to read the Patient Information Leaflet that comes with their hormonal contraceptive". (MHRA, 2014B)

The interactions with St John's wort are of particular concern, since the increase in metabolic elimination of the conventional medicine caused by the St John's Wort can result in reduced activity or loss of action of the conventional medicine (Borrelli & Izzo 2009). Several cases of rejection of transplanted organs have been described in patients receiving immunosuppressive medicines (e.g. ciclosporin or tacrolimus) as well as an association with unplanned pregnancies in women receiving hormonal contraceptives (see box above).

Herb-drug interactions are an evolving area of research where it is not always clear whether there is a pharmacokinetic or a pharmacodynamic interaction. An example would be *Ginkgo biloba* which should not be used alongside warfarin, but where the mechanism of possible interaction remains uncertain (Bent et al. 2005, Bone 2008). Tsai and co-workers (Tsai et al. 2013) conducted a

wide-ranging review of interactions between Chinese herbal medicines and two anticoagulant and four antiplatelet drugs, and validated their results using a focus group of 5 pharmacists in Taiwan trained in both western and Chinese medicine. They identified 306 interactions between one of these drugs and a Chinese herb, of which 80% were judged to have a pharmacodynamic mechanism, and the majority increased the risk of bleeding. Fifteen herbs were stated to increase the bleeding risk of all six medicines, and they highlighted the importance of four commonly used Chinese herbs: Danshen *Salvia miltiorrhiza*, Dong quai *Angelica sinensis*, Ginger *Zingiber officinale* and Licorice *Glycyrrhiza uralensis*. These four herbs are now also used by many Western herbal practitioners.

A further study evaluated the quality of the evidence for herb-drug interactions and concluded that a risk of interaction between warfarin and the herb is “highly probable” for Cranberry *Vaccinium macrocarpon*, St John’s wort *Hypericum perforatum*, Danshen *Salvia miltiorrhiza*, and “probable” for Dong quai *Angelica sinensis* and Ginger *Zingiber officinale* (Ge et al. 2014).

Patel and Gohil (2008) evaluated 63 published case reports involving possible interactions between warfarin and herbs, and classified 9 as probable and 54 as possible, with Cranberry most frequently implicated. There has been one fatal case in the UK attributed to the consumption of Cranberry juice alongside Warfarin, in a man in his eighth decade who consumed large quantities of cranberry juice in the aftermath of a chest infection (Suvarna et al. 2003).

There have been cases of internal bleeding associated with the use of Ginkgo *Ginkgo biloba*, and a recent review included 15 published case reports (Bent et al. 2005). Ginkgo has enormous sales worldwide, and the potential for interactions between Ginkgo and anticoagulant agents is therefore of concern. However Patel and Gohil (2008) identified only two case reports which they claimed suggested an interaction with Warfarin and other studies have proved inconclusive (Abad et al. 2010)

Because of the potential for drug/ herb interactions, it is of concern that when members of the public (who had used herbal medicines in the previous 5 years) were asked whether they agreed that it was “ok to use herbal medicines at the same time as conventional medicines,” 21% either tended to agree or agreed strongly with that statement. In addition, around 20% of respondents either tended to agree, or agreed strongly with the statement that when they visited their GP, there was no need to tell the GP if they were taking a herbal medicine (MHRA/ Ipsos Mori 2008).

4.3 Misidentification and substitution

Several cases of ill health are linked to consumption of low grade products containing undeclared ingredients. These problems may occur accidentally due to lack of expertise or intentionally due to substitution of one ingredient for another believed to have a similar action.

The challenge of nomenclature and identification of the source plant material has been highlighted by the World Health Organisation (WHO) Uppsala Monitoring Centre (*Farah et al. 2000, Farah et al. 2006*), but their recommendations can only be implemented through active involvement in quality assurance by all participants in the supply chain (*Booker et al. 2014*). Fortunately, there have been initiatives worldwide to improve reporting, to harmonise standards for the reporting of plant names, and to publish authoritative monographs on the quality of source materials (*Farah 2005, European Medicines Agency 2014, Upton et al. 2011*).

More than 100 women who had taken a slimming preparation at a medical clinic in Belgium developed kidney failure, and it was recognised that this was associated with a high risk of developing urothelial cancer (*Vanherveghem et al. 1993, Nortier & Vanherweghem 2002*). The preparation included *Aristolochia* species which had been mistakenly substituted for *Stephania* species. *Aristolochia* species were identified as the cause and there was an emergency ban in July 1999 after two reported cases in the UK (*Lord et al. 1999, MHRA 1999*). An EMA report published in 2005 notes that of 39 women who agreed to prophylactic surgery 18 were found to have urothelial carcinoma. The report also noted that in China, 12 of 17 patients who had taken *Aristolochia manshuriensis* supplied under the common name Mu Tong had died of renal failure (*EMA, 2005*). Population studies have subsequently confirmed that consumption of *Aristolochia* species is clearly associated with an increased risk of urinary tract cancer compared with other patients with end-stage renal disease (*Lai et al. 2010, Wang et al. 2014*).

Despite a ban on this ingredient in many countries, including the UK, problems still occur with the accidental supply of products containing *Aristolochia* which has a similar common name in Chinese and similar appearance to several other herbs. In 2010, the MHRA (2010) issued a press release to alert the public to presence of product containing *Aristolochia* spp. on the UK market. The warning stated that more than 900 packs of “Jingzhi Kesou Tan Chuan Wan” remained on the market after a recall by the distributor. The product had been found to contain *Aristolochia* spp. which had been banned in the UK in 2000. It was distributed to 20 TCM and herbal medicine outlets throughout the UK. A recall was initiated by the distributor but three quarters of the stock imported from China was

not been returned. It is notable that this warning was issued 17 years after the first alert to dangers associated with *Aristolochia* spp.

The quality of herbal medicinal products varies, and this presents important challenges in the pharmacovigilance (*Shaw et al. 2012*). Quality and safety are inseparable in herbal medicine, and this issue has recently attracted attention in the case of Black Cohosh *Cimicifuga racemosa* where poor quality of source materials has been an added problem in attempting to identify the association between hepatotoxicity and use of the medicine (*Jiang et al. 2006, Teschke et al. 2011*). The WHO Traditional Medicines Strategy aims to improve the regulatory framework for traditional medicine practice, and a central goal is to set standards for the quality of medicines which includes guidelines to monitor and reduce contamination of source materials (*WHO 2007, WHO 2013*). This is a global issue, and of continuing concern to medicines regulators (*Jordan et al. 2010, Zhang et al. 2012*).

4.4 Adulteration

Cases of adulteration of herbal medicines with pharmaceutical substances have increased in recent years (*Venhuis, et al. 2009*). Adulteration occurs frequently and has involved potent medicines such as anti-diabetics (e.g. glibenclamide), drugs for erectile dysfunction (e.g. sildenafil), appetite suppressants (e.g. sibutramine) and amphetamine-like drugs. A systematic review identified 19 case reports (*Ernst 2002a*), which included one death in the USA from agranulocytosis and septic shock associated with a preparation adulterated with two non-steroidal anti-inflammatory drugs (*Ries & Sahud 1975*). The cases of adulteration in the UK included two cases in 1992 and 1994 where a cream prescribed by a Chinese herbal practitioner contained corticosteroids, and one case of Cushing syndrome in a woman with rheumatoid arthritis who was under medical care but not taking oral steroids. The product had been purchased via the Netherlands, and was found to contain the potent corticosteroid dexamethasone as well as the non-steroidal anti-inflammatory medicine, indomethacin (*Forster et al. 1979*).

Another increasing problem is the addition of analogues of pharmaceutical substances, where a chemical derivative of a known pharmaceutical substance is included in a product e.g. fenfluramine analogues such as nitrosofenfluramine, or sildenafil (*Viagra*) analogues such as homosildenafil, and

In 2008, a man collapsed after consuming a product “Tian Li” which claimed to give sexual enhancement. He was also taking Viagra (sildenafil) on prescription. The MHRA analysed the product and discovered the hydroxyhomosildenafil and tadalafil. This product had been sold at 6 retail outlets and had been obtained for a salesman who had approached the wholesaler. MHRA enforcement officers subsequently seized a quantity of the product from the supplier. See more examples in Appendix 1

acetildenafil. The potential toxicity of the analogue is sometimes unknown, but can be greater than the “parent” molecule. For example, nitrosofenfluramine is associated with a high risk of liver toxicity. Irreversible liver failure was linked to a TCM slimming aid which contained nitrosofenfluramine (*Yuen et al. 2007*).

There is evidence of very high worldwide internet sales of counterfeit products for erectile dysfunction (*Jackson et al. 2010*). A recent study in the Netherlands examined 71 herbal food supplements intended to enhance sexual potency, and found that 23 products contained either sildenafil or one of eight analogous phosphodiesterase-5 inhibitors. They noted that 18 products contained concentrations which could exert significant pharmacological effects (*Reeuwijk et al. 2013*).

The most common adulterant of slimming products is sibutramine which was a POM Medicine but the marketing authorisation was withdrawn for safety reasons in January 2010 following a warning from the European Medicines Agency. Use of sibutramine can result in high blood pressure, seizures, heart attack or stroke. It may also interact with other prescription medicines. A study of 188 products, 2009-2012, in South Korea found that 62 were adulterated: 26% with sibutramine and 10% with analogues (*Kim et al., 2014*). A recent report from Hong Kong analysed 16 cases, 2004-2009, where patients admitted to hospital with psychotic symptoms had taken a slimming product. Of the 20 products, 19 were adulterated with sibutramine or analogues, and a further six other adulterants were identified (*Chen et al. 2010*).

In 2002, 24 samples of herbal creams which had been purchased by the parents of 19 children (median age 3.82 years) attending the Birmingham Children’s Hospital for treatment of atopic eczema were analysed. Twenty contained corticosteroids, and most were unlabelled or unnamed. Five samples, labelled “Wau Wa” cream contained the potent corticosteroid, clobetasol propionate which is only recommended for use in adults. In addition, the label on one of these preparations recommended that the cream be used all over the body, a practice which would be of concern in young children. The creams were obtained from “Indian/Pakistani herbalists/clinics” in three cities, by mail order, from a market stall in the UK, and from overseas. The one TCM sample was obtained from a city centre herbal practitioner (*Ramsay et al. 2003*).

Ayurvedic and TCM medicines may contain heavy metals and other toxic elements as ingredients including lead, mercury and salts of arsenic and mercury (*Ernst 2002B*).. These are added intentionally as part of the traditional formulations. This is a worldwide problem in that a recent

investigation of 193 Ayurvedic products purchased via the internet found that over 20% contained detectable levels of mercury, lead or arsenic (*Saper et al. 2008*).

Adulteration of ethnic medicines with heavy metals is a significant international problem. In 2013, the MHRA received several reports of the use of mercury, lead and arsenic in unlicensed Ayurvedic or traditional Chinese medicines. The inclusion of these metals, or salts containing them, poses a serious risk to public health. See Appendix 1 for more examples.

The Guy's and Thomas Poisons Unit (1987-1991) identified 5 cases of poisoning with heavy metals: five remedies contained lead, four contained arsenic and three contained mercury. In one case, nephrotic syndrome was ascribed to mercury. Two remedies were prescribed by practitioners (*Perharic et al. 1994*). A follow-up report (1991-1995) identified nine similar cases (*Shaw et al. 1997*). In a review of five cases of lead poisoning in the UK, Dargan et al. (2008) noted 50 reports worldwide since 1978. In one of the cases, the product had been purchased in India and the 60 year-old man with diabetes mellitus was admitted with confusion, then suffered convulsions, and was treated as an inpatient for 6 weeks for peripheral neuropathy. In a recent UK case report of lead poisoning, the product had also been purchased in India (*Mongolu & Sharp 2013*). It is notable that in this case and in six of the earlier cases, the person had diabetes, and this connection was indeed made in an earlier review (*Bateman et al. 1998*). People might be less tempted to bring products back from India if similar formulations, but guaranteed not to contain heavy metals, were manufactured here or imported via licensed wholesalers.

5. Current regulatory framework

Since 1994, representatives of herbal practitioners of all traditions have cooperated with the MHRA in seeking to update legislation concerning the supply of herbal medicinal products. This includes products whose only active ingredients are herbal substances (unprocessed plant parts) and/or herbal preparations (processed plant parts e.g. extracts, concentrates, powders, tinctures) (Regulation 8, *Human Medicines Regulations* 2012). Part of this process has been to seek a statutory definition of an herbal practitioner. Such a person is referred to in Regulation 3 (paragraphs 2, 6, 9) of the *Human Medicines Regulations* 2012 (formerly Section 12(1) of the *Medicines Act* 1968). This states that the requirement for a licence to manufacture a medicinal product does not apply where: “... a herbal medicinal product is manufactured or assembled by a person (“A”) if — (a) the manufacture or assembly takes place on premises occupied by A and from which A can exclude the public; (b) the product is for administration to a person (“B”) and A has been requested by or on behalf of B, and in B’s presence, to use A’s judgment as to the treatment required” (MHRA 2013A). However, “person (“A”)” is not defined.

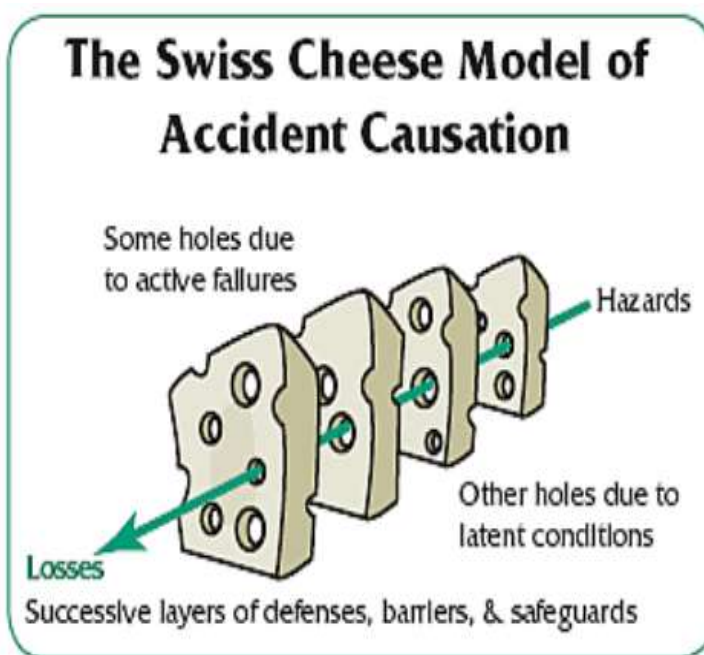
Most herbal practitioners compose an individual prescription for each patient that includes several herbs, and also dispense and supply the herbal preparation(s), which are mainly unlicensed and comprise mixtures of dried herbs, powders or tinctures. The term “prescribing” is used here to include the selection, dispensing and supply of herbal substances.

Issues have arisen over the supply of finished manufactured products. Until recently, many practitioners also dispensed and supplied such products, but this activity was undertaken under Section 12(2) of the *Medicines Act* 1968 which was repealed alongside the transposition of the Traditional Herbal Medicinal Product Directive (THMPD) in April 2011, industrially manufactured products cannot be placed on the market, since Regulation 3 of the *Human Medicines Regulations* 2012 states that the medicinal product must not be “manufactured or, as the case may be, assembled on a large scale or by an industrial process.” This problem is being considered by the HMPWG and is not discussed further here.

6. Risk of current regulatory framework

6.1 Risk-based Regulation in Herbal Medicine

Risk can be defined as the likelihood that a hazard (anything with the potential to cause harm) will actually cause harm. Government policy is to reduce regulatory burden and ensure that any proposed legislation is proportionate, consistent and targeted and based on a full risk assessment. The concept of Risk-based Regulation in healthcare is discussed further in Appendix 2, which recommends use of the “Swiss cheese” model of risk management to show how statutory regulation of herbal practitioners might reduce the risk of adverse events (*Reason, 2000*).



The risk of someone consuming a dangerous dose of a potent herb is a potential hazard or “latent condition.”

Professional knowledge, skills and values gained through education and clinical training act as barriers. These include careful dispensary management and labelling of herbs, following prescribing guidance, keeping a notice in the dispensary of maximum dosages of potent herbs, careful patient record-keeping, careful labelling and the communication skills necessary to explain the dosage instructions to the patient.

In 2010, two people were taken to Court in the UK accused of supplying *Aristolochia* species. At the Central Criminal Court, the charge of “administering a noxious substance so as to endanger life or inflict grievous bodily harm” was dismissed, but the defendant pleaded guilty to five lesser charges including selling a banned substance, and was given a two-year conditional discharge. The victim, aged 58, had taken large amounts of Long Dan Xie Gan Wan pills daily for 5 years between 1997 and 2002 for a skin complaint, but was diagnosed with renal failure in early 2003 and later developed urothelial carcinoma. See Appendix 1.

The focus of this section is on risk associated with the consumption of herbal medicines, but the risks arising from poor professional practice do not merely arise from prescribing. Wardle and Adams (2014) recently published a review of 442 publications concerning indirect and non-health risks associated with complementary and alternative medicine (CAM). They drew together the following

themes: variability in products, practitioners and information; assumptions that CAM therapies are safe, that both products and professionals are more regulated than in reality, that therapists and retail staff are more qualified than in reality; the risks of misdiagnosis or delayed conventional treatment or non-disclosure of CAM usage; and the risk of financial exploitation.

6.2 Risks arising from use of herbal medicines without the involvement of a qualified practitioner

Apart from the risk of being adulterated, products purchased online are associated with poor information on safety, even in the case of St John's wort where many reliable sources of information on indications and herb-drug interactions are available via Medline (*Thakor et al. 2011, Owens et al. 2014*). It is important that regulators are able to respond quickly to changing risk (*Black & Baldwin, 2010*). Risk from online purchases has increased recently as manufactured products which are not available via UK practitioners can be obtained over the internet. Long Dan Xie Gan Wan, the product implicated in poisoning by *Aristolochia*, is freely available on the internet and while it is claimed that the products contain no *Aristolochia*, a recent study found that some products did contain aristolochic acids (*Vaclavik et al. 2014*). While removal of counterfeit products, poor quality products and products unsuitable for public sale is the responsibility of the MHRA Enforcement and Intelligence Group (2014), identifying person ("A") must form part of the solution to the problem of the supply of industrially manufactured herbal medicinal products.

6.3 Groups at particular risk of toxicity

6.3.1 Pregnancy and breast feeding

No medicine (including herbal medicines) should be taken by pregnant women unless the benefit to the mother outweighs any possible risk to the foetus. Despite this, herbal medicines (and food supplements containing herbal ingredients) are widely consumed during pregnancy (*Moussally, et al. 2009, Nordeng et al. 2011*). A recent study from North-East Scotland indicated that a wide variety of CAM therapies (including herbal medicines) were actually recommended to pregnant women by approximately a third of healthcare professionals (*Stewart et al. 2014*). However in one multinational study, most women (80%) used herbal medicine in pregnancy on their own initiative, rather than as the result of a recommendation by a health professional (*Kennedy et al. 2013*).

Very little information exists concerning the amounts of herbal medicines entering breast milk, and, it is generally advised that breastfeeding mothers avoid herbal medicines due to the lack of

information on whether or not various herbal medicines pass into breast milk, and of scientific safety data. Another reason to support this recommendation is because contamination of herbal products with conventional medicines, pesticides or heavy metals cannot be ruled out (UKMi 2014). The same source notes that the risk of adverse events in a breastfed infant is higher for premature or very young infants and in those with a concurrent illness (UKMi 2014).

In a large study conducted in Taiwan, jaundice was much more common in breast-fed infants whose mothers did not consume the traditional Chinese herbal medicines than in breast-fed infants whose mothers did consume such medicines (Weng *et al.* 2012).

6.3.2 Children

Ross and co-workers (Ross *et al.* 2006) found that 8% (26) of general practices in their survey in North East Scotland prescribed oral herbal remedies to children less than 16 years old. Despite the fact that herbal medicines can interact with conventional medicines, Crawford and co-workers (2006) noted that 3% of 500 children and adolescents in a South Wales survey were using herbs and prescription medicines concurrently. Particular issues around herbal medicines use and examples of toxicity occurring in children have been summarised and commented upon by Choonara (2003). As the European Medicines Agency's *Guideline on pharmaceutical development of medicines for paediatric use* makes clear, "... the physical, metabolic and psychological processes inherent to growth from birth into adulthood reveal that children cannot be regarded as small adults nor they can be regarded as a homogeneous group in themselves" (European Medicines Agency 2013).

The Australian Paediatric Surveillance Unit received 39 reports of adverse events associated with CAM use, including four reported deaths during a three-year period (2001 -2003). The reported deaths were associated with a failure to use conventional medicine in favour of a CAM therapy (Lim *et al.* 2011).

A published literature case of fulminant hepatic failure following ingested clove oil in a child was presented to the HMA in 2008, who agreed that there was now sufficient evidence that overdose of clove oil is associated with serious adverse effects. Therefore variations to amend the Summary of Product Characteristics (SPCs) for all products containing 10% w/w clove oil, to ensure that they contain appropriate wording, were requested. The issue was communicated to healthcare professionals via an article in the April 2008 issue of *Drug Safety Update* (*Drug Safety Update. Volume 7, issue 8, March 2014*)

6.3.3 Elderly

The use of herbal medicines by the elderly is a worldwide phenomenon, and it is also this group of individuals who may be taking other (and often several) conventional medicines at the same time (*de Souza Silva et al. 2014*). This is likely to increase the risk of potential drug/ herb interactions, which might result in toxicity, or occasionally in loss of the beneficial effect of a concomitantly taken conventional medicine (*Elmer et al. 2007*).

6.3.4 Cardiovascular disease

Some herbal medicines have been advocated for the treatment of a range of cardiovascular conditions, including hypertension and heart failure. Given the potential for adverse effects and significant drug-herb interactions (*Mashour et al. 1998*), such an approach may be associated with significant risks.

Liquorice is widely consumed as confectionery, and excessive consumption can be a cause of unexplained hypertension which is resistant to treatment (*Ruiz-Granados et al. 2012, Sontia et al. 2008*). It is also commonly included in prescriptions by herbal medicines practitioners. Two very similar species are used: *Glycyrrhiza glabra* in Western herbal medicine and *Glycyrrhiza uralensis* in TCM. As well as causing sodium and water retention and reducing the effects of antihypertensive medicines, it may cause additive hypokalaemia (low potassium concentration in the blood) in patients receiving loop or thiazide diuretics. Finally pseudoaldosteronism, sometimes with serious sequelae, has been reported when liquorice is taken (*Williamson et al. 2013, Yoshino et al. 2014*).

6.3.5 Perioperative period

The use of herbal medicines in the perioperative period can be associated with adverse events, including electrolyte disturbances (e.g. hypokalaemia, prolonged bleeding, and excessive sedation (*Gallo et al. 2014, Werner et al. 2014*)). It is important that a full history of medicines (including herbal medicines) use is recorded. Yet In 2006, the majority (98.3%) of the 233 UK anaesthetic departments which responded to a questionnaire did not have a specific section for documenting herbal medicine use on their anaesthetic records and only 17 (7.3%) departments had a perioperative herbal medicine policy (*Hogg & Foo 2010*).

6.4 Public sale of potent herbal medicinal products to the public which should only be available when prescribed by a herbal practitioner after a consultation

In 2011, the MHRA received a report of a female patient suffering respiratory arrest after taking “Grenade Fat Burner” after taking only three tablets. This slimming aid which contains Ma Huang (*Ephedra* spp. or Ephedrine), *Coleus forskohlii* and *Citrus aurantium* (synephrine) was purchased from the internet. For more examples, see Appendix 1.

Paragraph 6 of Regulation 3 refers to a list of potent herbs which can only be prescribed by herbal practitioners, and these are referred to in Regulation 241 and listed in Part 2 of Schedule 20 of the *Human Medicines Regulations 2012*. These were formerly referred to as Schedule III herbs and the list was drawn up with the cooperation of the herbal profession in 1974 (Denham, 1999). Part 1 of Schedule 20 lists 24 prohibited dangerous medicinal plants; and Part 2 lists 12 medicinal plants with a restricted dosage, and four restricted to external usage (MHRA 2011). This Regulation transposed the text of The Medicines (Retail Sale and Supply of Herbal Remedies) Order 1977 (SI2130). Part 2 includes potent herbs such as *Ephedra* spp. noted in the box above. The MHRA has indicated that it would wish to update and extend Schedule 20 in the light of the modern knowledge and the increased use of medicinal plants from different traditions in the UK. In particular, there has been substantial research on the safety of herbal medicines used in TCM, and efforts to determine which herbs should be restricted to qualified herbal practitioners (Kim et al. 2012).

6.5 Risks associated with poor care from unregulated irresponsible practitioners.

In addition to the risks associated with some herbal medicines, risk can also arise from the obstacles for the public in identifying a qualified, competent herbal practitioner who is bound by a code of ethics and fitness to practice procedures. There is currently no requirement for individual herbal practitioners to achieve the educational standards required to join a voluntary register, and a wide variety of titles are used by herbal practitioners of each traditions.

Risks include failure to refer the patient back to their general practitioner when required, failure to form a diagnosis and rationale for treatment, failure to consider the risks of herb-drug interactions, excessive claims to treat disease and failure to explain treatment and label prescriptions adequately (MHRA 2008B). Many practitioners who belong to voluntary registers already endeavour to uphold such standards, but the current situation is that it is easy for irresponsible practitioners to practise outside any voluntary register. For example, the RCHM (2014) established an approved suppliers’ scheme in 2004 in response to the concerns about the quality of source materials. However, this is a voluntary register so only covers RCHM registrants.

In 2014, a woman visited her GP with concerns of weight gain and mild excess facial and body hair growth. The patient's only medication was than salbutamol for mild asthma. On further questioning however, she admitted to using an Indian herbal remedy for relief of asthmatic symptoms. Samples of the product, Shwasa Sanjeevani were tested and found to contain the potent corticosteroid, dexamethasone which is a prescription only medicine (POM). *For further details, see Appendix 1.*

This report has identified cases of public sale of herbal medicinal products to the public which make unsubstantiated claims, are adulterated, contain prohibited ingredients, are unsuitable for self-prescription, or all four. These include products of poor quality, and cases where there is deliberate adulteration of "herbal" products with conventional pharmaceuticals and products containing ingredients which should not be available for retail sale

7. Role of regulation in ensuring public safety

The weaknesses of the current voluntary registers are that practitioners are free to choose whether or not to apply to join a voluntary register, and practitioners who are removed from a voluntary register or choose to resign can still continue in practice. As there is no legally enforceable definition of a qualified herbal practitioner, there is no requirement for the individual to acquire the required knowledge, skills or values. Professional regulation is a form of risk management (*Hutter 2008*), and here the HCPC Standards are used to illustrate the role of statutory regulation in risk management through the promotion of safe practice.

7.1 Fitness to practice

Firstly, while the threat of removal from a register must be considered a last resort, robust fitness to practice processes for significant breaches of conduct including ethical misconduct must underpin standards (*Lloyd-Bostock & Hutter, 2008*). Cases where professional competence is in doubt are considered in the light of the HCPC *Standards of Proficiency*. Removal from the HCPC register is a serious matter because the practitioner is no longer able to use the protected title. Use of a protected title by someone who is not registered with the HCPC can lead to prosecution and a fine of up to £5,000. While many voluntary registers have updated their Codes of Conduct and fitness to practise processes, this has required considerable expertise and expense. To undertake fitness to practice processes in cases such as described in Appendix 1 would stretch the resources of any voluntary register, and the outcome would still be that the individual could continue in practice and remain a risk to the public. This concern was emphasized by the HCPC in arguing against the establishment of a voluntary register for social care workers (See Appendix 3).

7.2 Knowledge and skills

Safe practice depends on knowledge, skills and values, and these are set out in the HCPC *Standards of Proficiency* which encompass generic statements and profession-specific competencies. The DH Steering Group (2008) report considered the requirements for the statutory regulation of herbal practitioners and drafted profession-specific competencies. Education leading to standards of competence reduces risk arising from latent conditions. As the MHRA (2008B) stated, “Many risks arising from practitioner activity will be considerably reduced where the practitioner is well

qualified, responsible, and acts within the limits of their competence.” The WHO *Traditional Medicine Strategy 2014-23 (2013)* made a direct connection between the knowledge and qualifications of practitioners and patient safety.

The HCPC Standards require practitioners to “practise safely and effectively within their scope of practice; ...exercising their own professional judgement; understand the key concepts of the knowledge base relevant to their professions and draw on appropriate knowledge and skills to inform practice.” In 2008, the Steering Group included statements such as “know the concepts underpinning the herbal and traditional-medicine system in which the registrant practices” , “understand the toxicology of medicinal plants in the *materia medica*, possible adverse effects, cautions and contraindications” and “be aware of the potential for herb-drug interactions and formulate treatment accordingly.” The reference to underpinning concepts is important as one of the significant risks is that herbs from any tradition are used without regard to their traditional usage and dosage. A reference textbook for safe prescribing is Mills and Bone (2005) which gives an overview of adverse effects including hepatotoxicity, allergic reaction to herbs, drug/ herb interactions, safety in pregnancy and lactation, quality and pharmacovigilance. 123 of the more commonly prescribed herbs in western herbal medicine are then reviewed in detail.

Voluntary registers can now seek accreditation or kite-marking by the Professional Standards Authority for Health and Social Care (PSA) who evaluate the quality of the organisation and processes and their standards require that the voluntary professional register “only approves or accepts those education and training courses that equip students to meet its educational standards.” At present, degree level standards of education are voluntarily achieved by students of herbal medicine who undertake courses approved by the European Herbal and Traditional Practitioners Association (EHTPA) Accreditation Board (*EHTPA, 2014*). The *EHTPA Core Curriculum* is designed to provide the knowledge and skills required to hold a consultation, take a clinical history, make a physical examination, diagnose and plan a course of treatment. This includes clinical training at recognized training clinics, communication skills, safe prescribing, ethical behaviour and recognition of limits of competence. Graduates are educated to evaluate the evidence base and thus practice competently without making excessive claims.

However, the inability to enforce training standards across the sector is a major weakness of voluntary regulation. A survey in 2004 of 43 education providers in Australia analysed 65 courses in naturopathy or western herbal medicine and found wide variability in academic content and length of courses and in clinical training (*McCabe, 2008*). Wardle and co-workers (*2012*) associated this variability with the multiplicity of professional registers and accrediting bodies, and argued that

standards of education in Australia have deteriorated in recent years. The same outcome could occur in the UK without statutory regulation as current training courses may have no motivation to improve standards. The minutes of the National Institute of Medical Herbalists (NIMH) Council and of the EHTPA Council show that upholding standards of education has always been challenging. NIMH set up their first training school in 1868, and entry to the register remains only possible after completion of one of the courses approved by the EHTPA Accreditation Board. In contrast, the prospective student of herbal medicine in the UK is faced with an array of courses, including short online home study courses, which have an inadequate knowledge base in particular in the clinical skills required to form a diagnosis and plan a course of treatment, in safety of herbal medicines and in communications skills. It is of particular concern that training courses can claim to offer training in herbal medicine but offer no clinical training.

A requirement to refresh both knowledge and values through Continuing Professional Development is now considered essential in ensuring safe practice in healthcare and reduces risk arising from both latent conditions such as ignorance of current safety concerns, and active failures through carelessness. The HCPC requires registrants to confirm that they have met the HCPC criteria, and a random sample of registrants is audited. This is similar to the requirements of the six voluntary registers which belong to the EHTPA. However, this only covers practitioners who choose to join one of these voluntary registers. Safety in herbal medicine is an evolving area, and practitioners need to ensure that their knowledge is current. Practitioners who have inadequate qualifying education or who do not update their knowledge may remain unaware of important new safety issues.

7.3 Prescribing

Safe prescribing in herbal medicine requires a high standard of record-keeping. HCPC Standards require the practitioner to: "...maintain records appropriately; ... establish and maintain a safe practice environment. The Steering Group (2008) included the statement "be able to work in conformity with standard operating procedures and conditions relevant to herbal medicine preparation and dispensing according to the herbal and traditional-medicine system" (p. 73). The intention was to require herbal practitioners to maintain their dispensaries according to professional guidelines, keep full dispensary records to ensure traceability of all the ingredients of any prescription, and ensure that herbal medicines bought in by practitioners would be sourced from suppliers operating quality assurance systems to ensure the correct identification of botanical medicines free from contamination or adulteration. The HCPC would use their *Standards for*

Prescribing to inform the process of setting out expectations for prescribing by herbal practitioners. These *Standards* are used in the approval of courses for professions who undertake post-registration training to act as supplementary or independent prescribers. These require the prescriber to: “understand pharmacodynamics, pharmacokinetics, pharmacology and therapeutics relevant to prescribing practice; ... be able to undertake medicine calculations accurately; be able to identify adverse drug reactions (ADR’s), interactions with other medicines and diseases and take appropriate action; be able to recognise different types of medication error and respond appropriately.” Adherence to the HCPC standards would give substantially greater public assurance that registrants could safely prescribe potent herbal medicines and thus enable future extensions of Regulation 241 of the *Human Medicines Regulations 2012* to include herbs which were not considered when the first Schedule was drawn up in 1974.

7.4 Values and communication skills

Professional regulation in the UK has moved towards promoting the values which underpin safe practice. For example, HCPC Standards state that is necessary that practitioners “... practise within the legal and ethical boundaries of their profession; ... maintain fitness to practise; ...be aware of the impact of culture, equality and diversity on practice; ... practise in a non-discriminatory manner; ... reflect on and review practice; ...assure the quality of their practice.”

HCPC *Standards of conduct, performance and ethics* No. 14 states that: “You must make sure that any advertising you do is accurate” and warns against making recommendations influenced by financial reward, and practitioners are warned against making false and misleading claims in the Codes of Ethics of voluntary registers. To enforce this may require threat of penalties but for real change, there needs to be a change in culture and acceptance of standards of professional conduct.

There have been recurring complaints concerning claims on websites. An example reported to the MHRA in 2008 stated- *“No win no fee. We will refund what we charged if we cannot replace your coronary artery bypass and coronary angioplasty operation within six weeks of herbal treatment.”* This is an example of a site where the reference to TCM medical qualifications gained in China gives false hope to the potential patient. (see Appendix 1 for further examples)

Communication skills are fundamental to safe and ethical practice. Qualified practitioners are more likely to have the communication skills and values required to communicate risk to patients, and are more likely to know the limits of their competence and when to advise patients to seek the care of

their general practitioner. This can be a recommendation that the patient resists, and effective referral requires compassion and communication skills to ensure that the patient understands why the herbal practitioner is giving that advice. The greatest contribution to public safety arising from statutory regulation could be the improved communication which might then develop between patients, herbal practitioners and other healthcare practitioners and lead to more shared decision making (*Jansons et al. 2012*). A recent investigation into the regulation of naturopathy and western herbal medicine in Australia surveyed 2000 GPs and found they were uncertain about how to identify qualified practitioners, and 77% believed that herbal practitioners should be regulated. The conclusions of this report were that consumer protection would improve through better communication between providers of healthcare and through better public education in communicating risk to consumers (*Lin et al., 2009*).

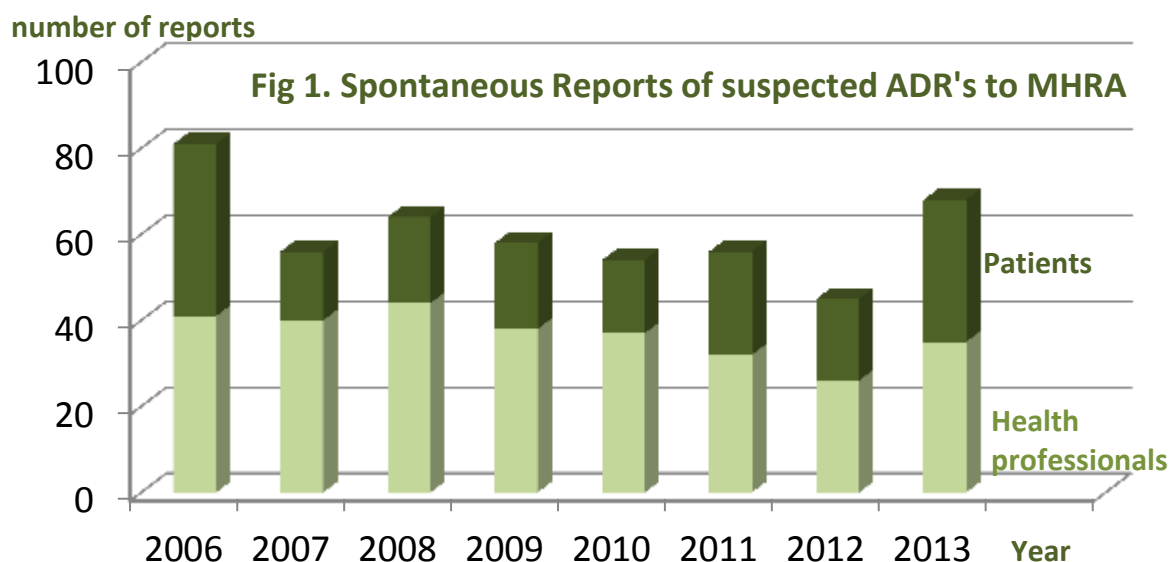
As discussed above, the public may not perceive that a food supplement could include active herbal ingredients, and so may consume herbal medicines without informing other healthcare providers (*Thomson et al. 2012, Chang et a., 2013*). At present, users of herbal medicines appear reluctant to admit that they have purchased over-the-counter medications, or sought the care of an herbal practitioner (*MHRA/ Ipsos Mori 2008*). This lack of communication may be a factor leading people to purchase products over the internet.

In 2008, the MHRA received two suspected ADR reports concerning an Ayurvedic remedy which claimed it could allow patients to stop taking medicines prescribed for diabetes. One patient experienced loss of diabetic control and the other patient experienced liver problems, increased blood glucose and increased blood pressure. See Appendix 1.

Pharmacovigilance of herbal medicines

For over-the-counter and herbal medicines, the MHRA recommends that health professionals should report all suspected adverse reactions that they consider to be serious (even if the effect is well recognised) via the Yellow Card scheme (MHRA, 2013B). Such reports do not necessarily indicate causation, but may identify possible associations which can be further examined, sometimes using other approaches. Over the last 8 years, an average of only around 60 Yellow Card reports involving herbal medicines have been reported to MHRA each year and 40% of these were submitted by the general public (e.g. patients or carers) rather than by health professionals (see Figure 1 below). It is well known that under-reporting, even of serious possible ADR's associated with conventional medicines, occurs, so this low reporting rate may reflect a degree of under-reporting of suspected ADR's to herbal medicines.

Among a total of 64,493 reports of suspected ADRs spontaneously submitted to the Swedish Medical Products Agency, 778 reports described 967 suspected ADR's associated with 175 different CAM products. The commonest reports concerned urticaria (8.3%), exanthema [skin rashes] (7.4%) and contact dermatitis (5.7%). In 221 reports, at least one ADR was categorised as serious, the most frequent of which were pulmonary embolism (1.7%), mixed liver reaction (2.8%), and anaphylactic reaction (2.0%). Eleven of the serious suspected ADR's was associated with a fatal outcome (Jacobsson et al. 2009).



The authors concluded that better populated the national, European or international (WHO) pharmacovigilance databases are with suspected ADRs, the more likely important safety issues will

be identified and addressed in a timely manner (*Jacobsson et al. 2009*). Reporting is also more likely where the product is licensed, and thus known to be on the market in any given country, or where it is supplied by a registered herbal practitioner (*Jordan et al. 2010, Shaw et al. 2012*).

NIMH established a Yellow Card system in 1994, and there have been 60 reports up to 2010 which are evaluated by the scheme coordinator, and discussed with the practitioner to attempt to identify the suspect herb in the mixture (*Broughton 2001; Broughton 2011*). In all cases the situation resolved on removal of the suspect herb. There have been 12 reports where St John's wort *Hypericum perforatum* was suspected: three cases of nausea, four of headaches, but no cases of drug/ herb interactions. This scheme has been extended to include voluntary registers who belong to the EHTPA, and the RCHM has a similar scheme. It is possible for voluntary registers to monitor risk, but for pharmacovigilance to be effective, all practitioners need to engage in reporting adverse event. Without statutory regulation, practitioners who do not belong to a voluntary register or practitioners who belong to a register which is too small to seek accreditation by the PSA would remain isolated outside formal pharmacovigilance procedures (*Barnes 2003, White et al. 2014*).

A recent review by experts in CAM proposed that while increased reporting of adverse events in CAM is important, there also needs to be more research into the beliefs and attitudes of practitioners and professional organisations to understand more about perceptions of safe practice (*White et al. 2014*). Adverse drug reactions (ADRs) to herbal medicines are underreported (*Jordan et al. 2010*) but for there to be an increase in reporting of adverse drug reactions by herbal practitioners, there would also have to be a change in attitudes and a desire to contribute to greater understanding of herbal medicine safety.

Macrae (*2008*) has argued that participation is the key to improving reporting and management of risk so that incidents are evaluated openly and as much as possible can be learned from "near-misses." The relevance to safe practice in herbal medicine is the emphasis on change in culture, and a more inclusive attitude to herbal practitioners would gradually allow practitioners to feel more comfortable about reporting adverse events and discussing adverse events with peers. NHS England (*2014*) is actively undertaking a campaign to promote a participative culture, and the same principles apply equally in herbal medicine. Indeed, a recent review concluded that all providers of herbal medicines need to engage in monitoring the safety of herbal medicines, but "for this to be effective, it would be essential to create an atmosphere of trust to facilitate adequate sharing of knowledge" (*Ekor, 2014*).

9. Concluding remarks

Herbal medicines are widely used in the United Kingdom, including by individuals who are also taking conventional medicines for a range of conditions. They may be available through health-food stores, internet sites or practitioners. Such herbal medicinal products, like all other medicines, can have pharmacological effects on the body and so can give rise to significant adverse effects, or interactions with other conventional medications that the patient may be taking. Because of their pharmacological and toxicological effects, the risks of toxicity are often greater than with many other complementary and alternative medicine therapies. Toxicity has also been associated with consumption of low grade products containing toxic ingredients because of misidentification or substitution. In addition, incidents of adulteration of herbal medicines with potent conventional medicines or their analogues are common, and have been associated with serious adverse effects. Many of these examples of adulteration are likely to be deliberate. There are also examples of products containing heavy metals such as mercury or lead and toxic elements such as arsenic which give rise to serious public health concerns.

Members of the public can have significant difficulties in identifying a qualified, competent herbal practitioner who is also bound by a code of ethics and disciplinary procedures. There is currently no requirement for individual herbal practitioners to achieve the educational standards required to join an existing voluntary professional association of herbal practitioners. There is evidence that practitioners lacking expertise and limited or no accountability are treating vulnerable groups, and that less responsible practitioners may purchase unlicensed herbal medicines from dubious sources that provide no assurances as to quality standards.

Risks associated with poor quality care include failure to refer the patient back to their general practitioner when required, failure to form a correct diagnosis and rationale for treatment, failure to consider the risks of herb-drug interactions, excessive claims to treat disease and failure to explain treatment and label prescriptions adequately.

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Appendix 1: Adverse events and MHRA safety warnings

Aristolochia spp.

2010: In a case taken to the UK Central Criminal Court in the UK, the defendant was accused of supplying *Aristolochia* spp. The charge of “administering a noxious substance so as to endanger life or inflict grievous bodily harm” was dismissed, but the defendant pleaded guilty to five lesser charges including selling a banned substance, and was given a two-year conditional discharge. The victim, aged 58, had taken large amounts of Long Dan Xie Gan Wan pills daily for 5 years between 1997 and 2002 for a skin complaint, but was diagnosed with renal failure in early 2003 and later developed urothelial carcinoma. According to the press report, the judge ruled that, as the sale of traditional Chinese medicines was totally unregulated, there was no evidence that the defendant knew of the potential harm. “Everybody accepts that you didn't know you were breaking the law,” he told the defendant. He highlighted the lack of regulation of herbalists and “that there may be a gap in our law that the government might wish to address.”¹

Note: practitioners belonging to the RCHM and NIMH and suppliers belonging to the BHMA were alerted immediately to the emergency ban on 28 July 1999. The defendant did not belong to a voluntary register. We understand that the defendant had made an application earlier to a voluntary register, but was not able to supply the requisite certificates.

2003: The patient had taken herbal preparations for almost three years for a skin complaint, and became ill in late 2001, and was diagnosed with advanced renal failure in early 2002. The preparations were shown to contain *Aristolochia* spp. The defendant denied four charges brought by the Department of Health of selling a medicinal product containing a prohibited substance between October 1999 and February 2001, but was cleared of the charges. According to the press report, the victim stated “I was introduced to an elderly lady who took my blood pressure and pulse and checked my tongue... She didn't speak any English but a young lady was translating. She prescribed medication and the young lady wrote it down on a piece of paper. There was cream, shiny pills, 15 in the morning, 15 in the evening, some brown rough ones, one-and-a-half lidfuls in the morning and evening, white glossy pills, one in the morning and one in the evening.”²

Adulteration of products which claim to treat erectile dysfunction

2014: The defendant was sentenced to 8 weeks in prison by the Crown Court for possession with intent to supply of 5,000 tablets of “Jia Yi Jian,” a fake “herbal” product which contained up to four times the dose of tadalafil, a POM for erectile dysfunction, and more than four times the former dose of the banned slimming drug sibutramine. The defendant had already been cautioned in 2009 on the same charge, and was sentenced to an added 8 weeks for breach of the suspended sentence

¹ See <http://news.bbc.co.uk/1/hi/uk/8520171.stm>; <http://www.telegraph.co.uk/health/healthnews/7257991/Chinese-herbalist-escapes-jail-for-supplying-banned-medicine.html> (accessed 19/10/2014).

² See <http://www.dailymail.co.uk/health/article-185217/Chinese-medicine-gave-kidney-failure.html#ixzz3CuyT7vh1>; http://news.bbc.co.uk/1/hi/england/southern_counties/3218973.stm (accessed 19/10/2014).

given after the defendant was stopped at Heathrow Airport in 2010 arriving from China with 51,600 tablets of “Herbal Viagra” which contained tadalafil.³

2008: A man collapsed after consuming “Tian Li” which claimed to give sexual enhancement. He was also taking Viagra (sildenafil) on prescription. The MHRA analysed the product and discovered the POM medicines hydroxyhomosildenafil and tadalafil. This product was found to have been sold at six retail outlets and had been obtained from a salesman who had approached the wholesaler. MHRA enforcement officers subsequently seized more of the product from the supplier.⁴

MHRA notices: warnings have been issued by the authorities in Israel (2012), Canada (2011, 2012), United States (2011) and Switzerland (2011) about the risks of herbal products containing POM medicines including tadalafil, sildenafil and related compounds.⁵

Adulteration of products claimed to help weight loss

2005: The defendant, a Chinese herbal practitioner, was convicted for offering patients a series of life-threatening slimming drugs. One patient was rushed to hospital hallucinating and suffering from the early signs of poisoning. According to the newspaper report, a patient called the practitioner who “went to her home where she saw the situation and forced her to be sick, showing that she was clearly aware of the potential dangers of these drugs.” Other patients were referred to hospital by their GPs after suffering breathing difficulties and heart palpitations. “The court heard one patient was charged £1,651, for a course of yellow pills containing the banned drug, fenfluramine hydrochloride.” The MHRA found products containing several restricted medicines, and the defendant was sentenced to 80 hours' community service, fined £30,000 and ordered to pay £20,000 costs after pleading guilty to 10 offences under the Medicines Control Act 1968.⁶

Note: We understand that the same practitioner had been removed from a voluntary register in 2002 for a similar offence.

2002: One person developed insomnia, anuria, palpitations, and constipation within two weeks of starting treatment with a Chinese herbal practitioner, and was admitted to hospital for IV fluids, and supportive measures. Other cases were discovered when enquiries were made with local GPs. “Herbal Flos Lonicerae (Herbal Xenicol) Natural Weight Loss Formula” was found to contain over twice the former prescribed dose of the sibutramine.⁷

³ See <http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON446011> (accessed 19/10/2014).

⁴ See

<http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Herbalmedicines/Herbalsafetyupdates/Allherbalsafetyupdates/CON014359> (accessed 19/10/2014).

⁵ See 28 November 2012 | [Advice to consumers not to use Shark Essence, a herbal medicine used to treat erectile dysfunction](#); 24 Feb 2012 | [Advice to consumers not to use unlicensed herbal medicines used for erectile dysfunction](#); 01 Jul 2011 | [Manufacturer recall issued after Canadian authorities issue warning about Durazest for Men and Once More](#); 01 Jul 2011 | [Manufacturer recall issued after Best Sexual Enhancer 150mg capsules found to contain an analogue of Prescription Only Medicine sildenafil](#); 01 Jul 2011 | [Swiss authorities issue warning after Goji More 10g sachets were found to contain an analogue of Prescription Only Medicine sildenafil](#) (accessed 19/10/2014).

⁶ See <http://www.telegraph.co.uk/news/uknews/1485984/Chinese-herbalist-fined-for-giving-banned-medicine.html>

⁷ See <http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON108745> (accessed 19/10/2014).

2008: A woman took “Li Da Dai” for slimming over three days and felt a bit weak and vomited. She contacted the MHRA after finding an item on the MHRA website about Li Da Dai Hua reported by the Dutch authorities to contain sibutramine. The product was tested and contained sibutramine.⁸

2011: MHRA received a report of a female patient suffering respiratory arrest after taking “Grenade Fat Burner” after taking only three tablets. This is an imported slimming aid which contains Ma Huang (*Ephedra* spp.), *Coleus forskohlii* and *Citrus aurantium* (synephrine). The product was purchased from the internet.⁹

MHRA notices: repeated warnings concerning adulteration of weight loss preparations with sibutramine and other banned or POM. For example, in 2010, an MHRA alert was issued after sibutramine was identified in “Payouji tea” on sale in the West Midlands. The MHRA had been alerted by a GP.¹⁰

Adulteration of other unlicensed “herbal medicinal products” with banned or prescription only drugs

2014: A woman visited her GP with concerns of weight gain and mild excess facial and body hair growth. The patient’s only medication was salbutamol for mild asthma. On further questioning however, she admitted to using an Indian herbal remedy for relief of asthmatic symptoms. Samples of the product, Shwasa Sanjeevani, were found to contain dexamethasone which is a POM.¹¹

Adulteration of products sold to treat eczema has been summarised by the MHRA.¹² Since 2005, the MHRA has investigated over 140 suspected cases of illegal inclusion of corticosteroids in topical creams, many of which claim to be natural or herbal. Of these 30 were found to contain steroids. For example, a parent became concerned when the cream, which he was assured only contained natural ingredients from India, cleared his son’s eczema within 3 days. The unlicensed product, supplied in an unlabelled plastic tub, was found to contain betamethasone dipropionate which is a POM.

⁸ See

<http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Herbalmedicines/Herbalsafetyupdates/Allherbalsafetyupdates/CON014359> (accessed 19/10/2014).

⁹ See

<http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Herbalmedicines/Herbalsafetyupdates/Allherbalsafetyupdates/CON013902> (accessed 19/10/2014).

¹⁰ See 06 Oct 2010 | [Herbal product alert: Payouji \(or Paiyouji\) tea and Pai You Guo \(Slim Capsules\)](#) ;

28 Nov 2012 | [Advice to consumers not to use Ultra Slim, a herbal slimming product](#) ;

24 Feb 2012 | [Herbal slimming products found to contain potentially dangerous undeclared pharmaceuticals](#) ;

11 Aug 2011 | [Herbal slimming products found to contain potentially dangerous undeclared pharmaceuticals](#) ;

01 Jul 2011 | [Canadian authorities issue warning over unauthorised Chinese weight loss medicine Fat Burner No. 1](#) ;

05 Nov 2010 | [Warning about 'herbal slimming pills' containing banned prescription only medicine sibutramine.](#) (accessed 19/10/2014).

¹¹ See

<http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Herbalmedicines/Herbalsafetyupdates/Allherbalsafetyupdates/CON413538> (accessed 19/10/2014).

¹² See

<http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Herbalmedicines/Herbalsafetyupdates/Herbalskincreamswarningsandalerts/index.htm> (accessed 19/10/2014).

2005: Report by a Nurse Consultant: samples of the products were analysed by the MHRA and found to contain the POM antihistamine, cetirizine, and creams containing the POM clobetasol. A large number of items were seized from the premises.¹³

2008: Report by a dermatologist: OSAS (intensive body lotion with aloe vera) has been supplied over the internet and from Asian and African beauty shops for the treatment of eczema and psoriasis. The MHRA found that samples contained variable amounts of the POM betamethasone.¹⁴

Adulteration with heavy metals

These reports were summarised by the MHRA in 2013.¹⁵ In 2004, the product Fufang Lu Hui Jiaonang was recalled from 35 outlets as it was found to contain high levels of mercury (between 11% and 13%). The same product was discovered again in 2005 after an unannounced inspection of a TCM wholesaler in London. In 2006, a TCM wholesaler and a TCM shop were being fined a combined total of over £5,000 for illegally supplying Fufang Lu Hui Jiaonang. One sample contained 117,000 times more mercury than is permitted in food substances in the UK.¹⁶

Irresponsible practice

2008: Two suspected adverse drug reactions reports have been received about an Ayurvedic remedy, DBCare which contains *Trigonella foenum-graecum*, *Tinospora cordifolia*, *Syzygium aromaticum*, and *Phyllanthus emblica* and was claimed to allow patients to stop taking medicines prescribed for diabetes. One patient experienced loss of diabetic control and the other patient experienced liver problems, increased blood glucose and increased blood pressure. The MHRA removed the product from the market and closed down the website.¹⁷

2008: A report was received via the Department of Health from a psychiatrist who expressed concerns about a clinic patient. The patient had been recommended to discontinue medication for schizophrenia and instead travel to India to try other therapies and the psychiatrist was concerned that without their medication the patient could be a danger to themselves and to others.¹⁸

¹³ See

<http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Herbalmedicines/Herbalsafetyupdates/Allherbalsafetyupdates/CON041331> (accessed 19/10/2014).

¹⁴ . See <http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON084741> (accessed 19/10/2014).

¹⁵ See

<http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Herbalmedicines/Herbalsafetyupdates/Allherbalsafetyupdates/CON307402> (accessed 19/10/2014).

¹⁶ See

<http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Herbalmedicines/Herbalsafetyupdates/Allherbalsafetyupdates/CON202360> (accessed 19/10/2014).

¹⁷ See

<http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Herbalmedicines/Herbalsafetyupdates/Allherbalsafetyupdates/CON014359> (accessed 19/10/2014).

¹⁸ See

<http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Herbalmedicines/Herbalsafetyupdates/Allherbalsafetyupdates/CON014359>

<http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Herbalmedicines/Herbalsafetyupdates/Allherbalsafetyupdates/CON014359>

2008: A 16 year old was admitted to hospital with recurrent abdominal pain and headaches after being prescribed several TCM preparations for the treatment of acne and sleep difficulties. He had been taking up to 114 tablets per day for 3-4 months.¹⁹

<http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Herbalmedicines/Herbalsafetyupdates/Allherbalsafetyupdates/CON018174>

¹⁹ See

<http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Herbalmedicines/Herbalsafetyupdates/Allherbalsafetyupdates/CON018174>

Appendix 2: Risk-based Regulation

Risk can be defined as the likelihood that a hazard (anything with the potential to cause harm) will actually cause harm. The degree of harm depends on the severity of the hazard, and the number of people affected (*Better Regulation Delivery Office, 2014*). The “Better Regulation” principles, devised in 1997, state that any policy intervention should be transparent, accountable, proportionate, consistent and targeted (*Better Regulation Task Force, 2003*). These five principles, with the addition of “agility” the ability to anticipate change, were used to conceptualise “right-touch regulation” in healthcare which remains the policy of the Professional Standards Authority for Health and Social Care (PSA) which oversees the statutory healthcare regulators (*Council for Regulatory Health Excellence, 2010*). In 2005, the Hampton Report recommended that regulators should use comprehensive risk assessment to implement these five principles (*Department for Business, Innovation and Skills, 2011*). Risk-based regulation is based on the premise that a certain level of risk is acceptable, and that regulators must identify, assess and target risks rather than merely enforce rules (*Black & Baldwin, 2010*).

Reducing regulatory burden requires regulators to base their activities on risk assessment (*Better Regulation Delivery Office, 2014*). Regulators are encouraged to consider whether policy objectives could be achieved without implementing new legislation. It may be that the potential costs, administrative and financial, or the potential restrictions placed on the activities of the public outweigh the benefit of the reduction in risk. Perceptions of risk can be subjective, or reflect the interests of specific groups in society and must inevitably have a political dimension (*Risk and Regulation Advisory Council, 2009*), and it is within this climate that the current debate over the statutory regulation of herbal practitioners is being conducted.

In 2009, the DH *Extending Professional and Occupational Regulation Working Group* (EPORWG) (2009) reviewed the status of professional groups in the UK and noted that the government had agreed to extend regulation to practitioners of acupuncture, herbal medicine, and traditional Chinese medicine. They recommended “that safety of patients and the public, as well as enhancing effective, high quality and respectful care, are the legitimate benefits to be considered in assessing whether to extend professional and occupations regulation” (Rec. 6, p. 28). In considering the nature of risk in healthcare, they used the “Ontario model” proposed by the provincial government of Ontario, Canada. This identifies risks as arising from “controlled acts” which have the potential for harm and include, *inter alia*, “Communicating to the individual or his or her personal representative a diagnosis identifying a disease or disorder as the cause of symptoms of the individual in circumstances in which it is reasonably foreseeable that the individual or his or her personal representative will rely on the diagnosis” and “Prescribing, dispensing, selling or compounding a drug as defined in the Drug and, Pharmacies Regulation Act, (pp. 19-20).

EPORWG considered additional factors which would increase the risk arising from the actions of any one practitioner including their clinical experience, the quality of their education and training and whether the practitioner undertook to remain up-to-date with current practice. They highlighted additional risk where the practitioner works alone. Finally, they drew attention to the risks arising from caring for vulnerable groups of patients. EPORWG highlighted rare but serious risks, rather than more common but less serious risks. The former are relevant in herbal medicine, where practice is generally acceptably safe but there have been some very important exceptions.

EPORWG concluded that they were not able to identify a robust risk assessment model as defining “controlled acts” identifies risks but does not explore methods to reduce risk. However, this paper uses the “Swiss cheese” model of risk management (*Reason, 2000*). This model has been variously

interpreted, but briefly suggests that the likelihood of a potential adverse event occurring can be minimised by putting barriers in place to minimize “latent conditions,” thus reducing the frequency of “active failures” (Perneger, 2005).

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Appendix 3: HCPC Standards

Health and Care Professions Council *Standards of Proficiency* require practitioners to:

1. be able to practise safely and effectively within their scope of practice;
2. be able to practise within the legal and ethical boundaries of their profession;
3. be able to maintain fitness to practise;
4. be able to practice as an autonomous professional, exercising their own professional judgement;
5. be aware of the impact of culture, equality and diversity on practice;
6. be able to practise in a non-discriminatory manner;
7. understand the importance of and be able to maintain confidentiality;
8. be able to communicate effectively;
9. be able to work appropriately with others;
10. be able to maintain records appropriately;
11. be able to reflect on and review practice;
12. be able to assure the quality of their practice.
13. Understand the key concepts of the knowledge base relevant to their professions;
14. be able to draw on appropriate knowledge and skills to inform practice
15. understand the need to establish and maintain a safe practice environment.

See <http://www.hcpc-uk.org.uk/publications/standards>

HCPC *Standards of conduct, performance and ethics* state that the *Standards of Proficiency* are considered when responding to complaints through the fitness to practise processes. This means that practice is considered against explicit standards of professional competence.

HCPC *Standards for Prescribing*, published in 2013, see

<http://www.hcpc-uk.org.uk/publications/standards>

The HCPC fitness to practise processes include lay and profession-specific representatives, and their resources and expertise could not be matched by any voluntary register. The HCPC also has the legal powers to enforce due process, including being able to compel disclosure of information and the attendance of witnesses at hearings. In 2012–13, 1,653 cases were received of which 38% were received from the public. Of these 1,653 cases, 563 were considered by an Investigating Committee Panel. The experience thus gained is shared in the Annual Report.

Protection of title, see <http://www.hcpc-uk.org/complaints/fitnesstopractise/furtherinfo/>

<http://www.hcpc-uk.org/aboutregistration/protectedtitles/>

Annual Report, see [http://www.hcpc-](http://www.hcpc-uk.org/assets/documents/100042D7Fitnesstopractiseannualreport2013.pdf)

[uk.org/assets/documents/100042D7Fitnesstopractiseannualreport2013.pdf](http://www.hcpc-uk.org/assets/documents/100042D7Fitnesstopractiseannualreport2013.pdf)

Prosecution Policy, see <http://www.hcpc-uk.org/aboutregistration/protectedtitles/>

Statement of policy on voluntary registers, see

<http://www.hcpc-uk.org/aboutregistration/aspirantgroups/adultsocialcareworkersinengland/>