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The Case for the Statutory Regulation of Herbal Practitioners

“The two systems of traditional and Western medicine need not clash. Within the context of primary health care they can blend together in a beneficial harmony, using the best features of each system and compensating for certain weaknesses in each. This is not something that will happen all by itself. Deliberate policy decisions have to be made....The time has never been better, and the reasons never greater, for giving traditional medicine its proper place in addressing the many ills that face all our modern – and our traditional – societies.”¹ Dr Margaret Chan, Director-General WHO

The history of statutory regulation of herbalists in the UK

The statutory regulation (SR) of herbal practitioners has been under review for more than 15 years. It was recommended (sections 5.53 & 5.54) by the House of Lords’ Select Committee on Science and Technology in its Report on Complementary Medicine (1999-2000) which stated that *“the main criterion for determining the need for statutory regulation is whether the therapy poses a significant risk to the public from its practice”*.² The same conclusion was reached by two Department of Health sponsored Working Groups under the independent Chairmanship of Professor Michael Pittilo. The second of these Reports published in 2008 declared (section 6) that the statutory regulation of herbal medicine practitioners was *“in the public interest”* noting that statutory regulation differs from voluntary regulation because it could *“more effectively assure the standards of those regulated, protecting the public from poor or bad practice, because legal sanctions exist to remove individuals from a register.”*³

The reports from these two committees led to two public consultations that demonstrated overwhelming public support for the statutory regulation of herbal practitioners. It is noteworthy that voluntary regulation was rejected as a viable option by all three committees mentioned. They were of one mind; statutory regulation alone could ensure public safety.

Public choice and public safety

The new Working Group is discussing the provision of medicines supplied by third parties to practitioners under the main European Medicines Directive 2001/83/EC. However, whatever the outcome of deliberations on this matter, given the popularity of herbal medicine practice

¹ Speech given by WHO Director-General, Dr Margaret Chan, Beijing 2008.
<http://www.who.int/dg/speeches/2008/20081107/en/>. Accessed 16/02/2014.

² <http://www.publications.parliament.uk/pa/ld199900/ldselect/ldsctech/123/12301.htm> accessed 16/02/14.

³ A joint consultation on the Report to Ministers from the DH Steering Group on the Statutory Regulation of Practitioners of Acupuncture, Herbal Medicine, Traditional Chinese Medicine and Other Traditional Medicine Systems Practised in the UK. Available from the National Archive
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_086359?I dcService=GET_FILE&dID=169241&Rendition=Web as DH_086358.pdf, accessed 15/02/2014

(see data on page 2 below), the statutory regulation of herbal practitioners is manifestly in the public interest on grounds of ensuring public safety and public choice. Herbal medicine is internal medicine involving the prescription of pharmacologically active plant medicines. This differentiates herbal medicine practice from all other forms of complementary medicine in terms of risk. In this regard the Medicines and Healthcare products Regulatory Agency has publically commented (see also Appendix A below):

“given that in some cases practitioners, who may be inexperienced, are supplying potentially powerful unlicensed herbal medicinal products, the range of opportunities for things to go wrong is significantly greater than is the case with many other complementary and alternative medicine therapies.”

For this reason statutory regulation of this sector would seem an essential measure in the public interest.

SR of healthcare professionals - a matter for individual Member States

The original draft terms of reference circulated to members of the present Working Group state *“The Group will need to understand the constraints preventing statutory regulation which are posed by existing EU legislation and take a view on whether voluntary self regulation could instead assist with patient safety.”* However, there are no EU legal constraints on the Secretary of State for Health carrying through the Minister’s commitment to bring in the statutory regulation of herbalists made in February 2011 since the regulation of health professionals is entirely within the remit of each Member State. Accordingly, in the UK Section 60 of the Health Act 1999 says *“Her Majesty may by Order in Council make provision— (b) regulating any other profession which appears to Her to be concerned (wholly or partly) with the physical or mental health of individuals and to require regulation in pursuance of this section.”*⁴ To make such regulation binding throughout the United Kingdom, it would, of course, require the agreement of the Scottish Government and the Devolved Assemblies of Wales and Northern Ireland.

Herbal medicine widely available via practitioners throughout the UK

Herbal medicine practice is increasingly popular and millions of UK citizens regularly make use of herbal medicines. Research by Ipsos MORI (November 2008) for the Medicines and Healthcare products Regulatory Agency (MHRA) reported that:

- more than a quarter of the population had bought over the counter herbal medicines at least once in the previous two years
- around one in twelve had consulted a practitioner of Western herbal medicine⁵
- around one in twenty had consulted a practitioner of traditional Chinese Medicine

With regard to the extensive consultation by the public of practitioners, the Pittilo Report, using data published earlier than the Ipsos MORI report, commented:

“Survey data demonstrates high demand for complementary and alternative medicine. 10.6% of the adult population of England had visited at least one therapist providing any one of the six more established therapies (acupuncture, chiropractic, homoeopathy, hypnotherapy, medical herbalism, osteopathy) during 1998 with an estimated 22 million visits. It is important that those with whom they consult are properly trained, understand the limits of their competence and know when and to whom to refer.....Statutory regulation can more effectively assure the standards of those regulated,

⁴ <http://www.legislation.gov.uk/ukpga/1999/8/section/60> - accessed 15/02/2014

⁵ Available for download at <http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON036071> accessed 15/02/14.

*protecting the public from poor or bad practice, because legal sanctions exist to remove individuals from a register.*⁶

Ensuring high quality training and standards of practice - a public safeguard

The majority of herbal practitioners practise responsibly and safely. Those now training as herbal practitioners have the opportunity to be educated to degree level with a curriculum which includes appropriate training in biomedical sciences such as pharmacology and differential diagnosis. However, there is currently no enforceable UK regulation to ensure good standards of training and/or practice across the board. As things stand, anyone, whether trained or not, can call themselves a herbalist and thus prescribe potentially potent herbal medicines. In addition, training establishments are not required to undergo external accreditation. This state of affairs is clearly not in the public interest. Cases of serious harm and even fatalities are well documented by the MHRA (see appendix A below) and the Agency has warned:

“ . . . the public still remains vulnerable to some of the less responsible operators who peddle low grade, and sometimes, dangerous herbal products – portraying them as natural and safe whilst failing to meet any meaningful standards of safety, quality and consumer information.”⁷

There is evidence that well trained practitioners operate safely. The MHRA notes (Appendix A below) *“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.”* This safeguard is also highlighted in a key finding of *“Towards a Safer Choice: The Practice of traditional Chinese medicine in Australia”⁸* (1996). This notes:

“The practice of acupuncture and Chinese herbal medicine carries both inherent risks and risks associated with poor practitioner training... There is a link between the length of training in TCM and self-reported adverse incident rates.”

This consideration is similarly noted by the WHO Traditional Medicine Strategy 2014-23 which says *“The knowledge and qualification of practitioners have a direct bearing on patient safety.”⁹*

Report of the Working Group on Extending Professional and Occupational Regulation (REPOR)

The case for statutory regulation reducing risk was also well made by the 2009 DH Report of the Working Group on Extending Professional and Occupational Regulation (REPOR).¹⁰ REPOR utilised the Ontario Model¹¹ that identifies “controlled acts” as a means of

⁶ Section 6, page 9 of *A joint consultation on the Report to Ministers from the DH Steering Group on the Statutory Regulation of Practitioners of Acupuncture, Herbal Medicine, Traditional Chinese Medicine and Other Traditional Medicine Systems Practised in the UK*. Available from the National Archive http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_086359?1dcService=GET_FILE&dID=169241&Rendition=Web as DH_086358.pdf, accessed 15/02/2014.

⁷ MHRA press release on the Ipsos MORI report on herbal medicines accessed 12/01/2009. <http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON036071> accessed 15/02/2014.

⁸ Bensoussan A, Myers P. *Towards a Safer Choice: The Practice of traditional Chinese medicine in Australia*, 1996 Victorian Dept of Services NSW DoH & Queensland DoH, University of Western Sidney MacArthur.

⁹ http://www.who.int/medicines/publications/traditional/trm_strategy14_23/en/. Accessed 16/02/2014.

¹⁰ http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_102824. Accessed 17/02/14.

¹¹ *Definition of Controlled Act* – Government of Ontario, Canada, 1997 (quoted in REPOR pp.19-20).

identifying such risk which suggests taking legislative action to mitigate it. In particular, *inter alia*, the Ontario Model identified two controlled acts that specifically apply to herbal medicine practice.

- (a) *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. ...*
- (c) *Prescribing, dispensing, selling or compounding a drug as defined in the Drug and Pharmacies Regulation Act, or supervising the part of a pharmacy where such drugs are kept.*

Item (c) is particularly applicable in cases where herbal practitioners prescribe herbal medicines under Regulation 3, paragraph 2 and 6 of the Human Medicines Regulations 2012.¹²

In addition, the REPOR identifies (page 20 Section 2.5) a range of other “dimensions of risk” including:

- *Whether the act is carried out by a professional on their own, or as part of a supervised team who can support, guide and scrutinise practice;*
- *Whether the act is carried out by a professional who is part of a well managed organisation that has in place managerial assurance systems to protect patients and the public;*
- *Whether the act is carried out by a professional who has a stable employment pattern, where any problems might be identified over time, or whether it is carried out by a more mobile short tenure practitioner working in a variety of locations, whose practice is less likely to receive consistent oversight;*
- *The quality of education and training of the practitioner carrying out the act;*
- *Whether there are systems in place to ensure that the practitioner is regularly and effectively appraised and developed to ensure that they are up to date with current practice.*

In this context it should be taken into account that many practitioners using herbal medicine work on their own and are self-employed. They may also work in more than one location. Without statutory regulation there can be no reliable overall independent arbiter of the quality of education and training such as an autonomous accreditation process that statutory regulation might offer. In addition, without statutory regulation it is hard to see how secure systems can be put in place to ensure that practitioners (not already statutorily regulated) prescribing herbal medicine are regularly and effectively appraised. Taking stock of these criteria set out in the REPOR, the logical conclusion has to be that the only sensible way forward in regulating herbal medicine practice in the UK is to ensure that all practitioners prescribing herbal medicines are statutorily regulated.

Benefits of a statutory regulated herbal practitioner profession

In February 2013 the Director-General of WHO, Margaret Chan, said, “*The affordability of most traditional medicines makes them all the more attractive at a time of soaring health-*

¹²<http://www.mhra.gov.uk/Howweregulate/Medicines/Overviewofmedicineslegislationandguidance/TheHumanMedicinesRegulations2012/> accessed 16/2/2014.

care costs and nearly universal austerity. Traditional medicine also stands out as a way of coping with the relentless rise of chronic non-communicable diseases."¹³

In June the same year, in an address at the European Parliament, European Commissioner, Tonio Borg, reiterated the Director-General of WHO's view that CAM treatments could help solve the problem of spiralling healthcare costs saying,

*"Our health systems across Europe are under double pressure. From one side we face a tightening of public expenditure as a consequence of the economic crisis. On the other side, the cost of providing healthcare tends to constantly increase – this is partly due to the increasing demand of an ageing population, and partly to the mounting costs of healthcare products and services. Health systems are, in essence, being asked to provide more with fewer resources – a difficult problem to solve. The broad solution lies in increasing the overall efficiency of our health systems, and investing in cost-effective innovation. Alternative medicine can play an important role in this. Any treatment which demonstrates better outcomes at lower costs is a step forward on the path towards more sustainable health systems."*¹⁴

A relevant survey on the cost benefits of herbal medicine has been carried out by Mr Christopher Smallwood¹⁵. In its conclusions his report notes how CAM (Complementary and Alternative Medicine) therapy and in particular herbal medicine treatments benefit the public.

"Evidence ... indicates that many of the most effective CAM therapies correspond to recognised "effectiveness gaps" in NHS treatment. The main areas comprise chronic and complex conditions, anxiety, stress and depression and palliative care ... Despite the fragmentary nature of the evidence, there is good reason to believe that a number of CAM treatments offer the possibility of significant savings in direct health costs.... the benefits to the economy ... of a wider application of successful complementary therapies in the key areas could run to hundreds of millions of pounds..."

Regarding herbal medicine, Smallwood said:

"In many cases where the herbal remedy is sufficiently effective, cost savings would be generated by its wider use. For example, in 2004 the NHS spent £400 million on anti-depressant drugs at an average net ingredient cost of £13.82 per prescription. Compared with this a weekly course of St John's wort costs just 82p".

While under new Traditional Herbal Registration (THR) procedures, the cost of a weekly course of St John's wort is likely to exceed the Smallwood costing, the economic benefit of St John's wort has again been recently highlighted.¹⁶

*"St. John's wort was shown to be a cost-effective alternative to generic antidepressants. Patients are more likely to receive treatment for a duration consistent with professional guidelines for treatment of major depression due to reduced incidence of adverse effects, improving outcomes. This represents an important option in the treatment of Major Depressive Disorder."*¹⁷

¹³ From speech given by WHO Director-General, Dr Margaret Chan, at the International Conference on Traditional Medicine for South-East Asian Countries. New Delhi, India, 12-14 February 2013.

¹⁴ Speech accessible on EHTPA website <http://ehtpa.eu/>.

¹⁵ Smallwood C. *The Role of Complementary and Alternative Medicine in the NHS*, FreshMinds Ltd, Oct 2005.

¹⁶ Solomon D, Adams J, Graves N. Economic evaluation of St. John's wort (*Hypericum perforatum*) for the treatment of mild to moderate depression. *J Affect Disord.* 2013 Jun;148(2-3):228-34. 2013, Jan 3.

¹⁷ Ibid.

As Peters observes regarding effectiveness gaps:

“Such problems are complementary practitioners’ daily bread and surveys suggest high levels of satisfaction and useful outcomes. Their growing popularity with the public and acceptance by mainstream practitioners coincides with an increased interest in lifestyle change, health promotion and low technology treatments, approaches which if they could be integrated into primary care might provide inexpensive ways of augmenting conventional medicine... Integrated medicine marries the art and science of medicine.”¹⁸

Herbs to combat antimicrobial resistance

In light of growing concerns relating to microbial resistance to antibiotics, increasing attention is being given to the role that herbal medicines may play as autonomous anti-bacterial agents or as adjuvant treatments used to potentiate synthetic antimicrobial drugs. Written evidence selectively reviewing the evidence for herbal medicine as a valuable resource to combat bacterial resistance to antibiotics is currently available on the House of Commons Select Committee on Science and Technology’s website inquiring into antimicrobial resistance (AMR).¹⁹

More generally, there is a growing body of evidence that herbal medicine can answer the need to respond to effectiveness gaps in biomedical western medicine. A selective review scoping the evidence for the effectiveness of herbal medicines has been published in 2014 by the European Herbal and Traditional Medicine Practitioners Association (EHTPA).²⁰

Regulation of herbal practitioners would contribute to an improvement in public safety whilst maintain public choice.

A regulated profession:

- Will engender high standards of professional care and conduct. Currently, if a practitioner is expelled from a voluntary register, he/she can continue to practise outside the professional association and remain a risk to the public. Statutory regulation of herbalists would effectively protect the function as well as the title of herbal practitioner, since anyone in serious breach of professional standards, would be removed from the statutory register and thus lose the right to prescribe herbs under Regulation 3, paragraph 2 and 6 of the HMR 2012. After regulation, the right of prescribing herbs in this manner can be limited to those on the statutory register.
- Will reduce the reliance of the public on misleading internet information about herbal treatment and make it less likely that patients will be tempted to self medicate by buying herbal products from uncontrolled and often dubious websites.
- Will provide a pool of experts from whom other healthcare professionals can seek herbal advice; it will also make it easier for referrals to occur from other healthcare professionals to responsible herbal practitioners.

Via protection of title, the public will be able to identify a regulated herbal practitioner who:

¹⁸ Peters D. Integration, long-term disease and creating a sustainable NHS. *J. Holistic Healthcare*, Vol 6, issue 1, May 2009, 29-31.

¹⁹ <http://www.parliament.uk/business/committees/committees-a-z/commons-select/science-and-technology-committee/inquiries/parliament-2010/antimicrobial-resistance-amr/?type>. Accessed 16/02/2014.

²⁰ McClure L, Flower A, Price S. A Selective Review on behalf of the European Herbal and Traditional Medicines Practitioners Association (EHTPA), January 2014. Available as a download from the EHTPA website <http://ehtpa.eu/>.

- Has met the educational requirements of an accredited course that would lead to entry to a statutory register. This person would therefore have studied clinical sciences, the pharmacology, actions and indications of herbal medicines as well as relevant known drug-herb interactions.
- Is competent to take a detailed clinical history, examine the patient and form a diagnostic rationale for a herbal prescription or refer the patient to a doctor or other healthcare practitioner as appropriate.
- Will act upon safety notices issued by the professional association, regulator or the MHRA.
- Will source quality assured herbal supplies from authorised suppliers who are part of an approved supplier scheme and who will operate his/her dispensary according to professional guidelines.
- Will participate in a required continuing professional development programme
- Will be subject to Enhanced Disclosure and Barring Service (DBS) checks.
- Will enable future rational extensions of Regulation 241 of the Human Medicines Regulations (HMR) 2012. This Regulation transposes the text of The Medicines (Retail Sale and Supply of Herbal Remedies) Order 1977 (SI2130) into the HMR. Schedule 20 of the HMR lists the relevant medicinal plants determining that certain medicinal plants can only be supplied by a registered medical practitioner or pharmacist whilst others can only be prescribed at fixed dosages by a herbal practitioner on their own premises, after a request by the patient, in the patient's presence. Were there to be a legal definition of a herbal practitioner via statutory regulation, it would then be possible to expand the possible range of herbal medicines available to these health professionals.

Summary

In the interests of public safety and maintaining public choice, the Government should carry through its commitment made in February 2011²¹ to bring herbal medicine practitioners into statutory regulation. This is manifestly in the public interest; herbal medicine offers some real-world solutions to the growing funding crisis that faces the NHS. For example it can answer the need for affordable and effective treatments for many mild or self limiting conditions and 'effectiveness gaps' where western biomedicine is either inadvisable as a remedy of first recourse (as is sometimes the case in the prescription of antibiotics or sleeping pills) or relatively ineffective as, for example, in the case of irritable bowel syndrome or osteoarthritis. Here herbal medicine prescribed by a well trained professional herbal practitioner, who is also competent to offer advice on relevant lifestyle and dietary changes, plays a valuable role in the healthcare of UK citizens.²²

²¹ https://www.google.co.uk/search?q=Statutory+regulation+of+herbal+practitioners+Feb+2011&ie=utf-8&oe=utf-8&rls=org.mozilla:en-US:official&client=firefox-a&channel=sb&gws_rd=cr&ei=eLUBU9PUNYiLhQem44DwBw#channel=sb&q=Statutory+regulation+of+herbal+practitioners+Andrew+Lansley+Feb+2011&rls=org.mozilla:en-US:official. Accessed 17/02/14

²² McClure L, Flower A, Price S. *Scoping the Evidence for the Effectiveness of Herbal Medicines*. EHTPA, January 2014 available as download from <http://www.ehtpa.eu/>.

Appendix A From MHRA website²³

PUBLIC HEALTH RISK WITH HERBAL MEDICINES: AN OVERVIEW

Introduction

1. **There may be an erroneous perception in some quarters that the practice of herbal medicines poses few safety issues.** In fact, given that in some cases practitioners, who may be inexperienced, are supplying potentially powerful unlicensed herbal medicinal products, the range of opportunities for things to go wrong is significantly greater than is the case with many other complementary and alternative medicine therapies.
2. Many plants are **potent or toxic**. Indeed, many pharmaceutical medicines, ranging from aspirin to digoxin, have their origins in the isolation of active chemical constituents in particular plants. In considering issues of safety it is essential not to make the common mistake of confusing herbal medicine with homeopathy.
3. It is important to note that use of herbal medicine is not restricted to the worried well or to use by people with minor or transient conditions. Studies show that complementary and alternative medicine (CAM) use in patients with cancer is high and that this usage is increasing. It has been reported that over 40% of breast cancer patients and over 20% of patients with lung cancer in Europe use CAM. In all of these surveys herbal medicine was the most commonly used form of CAM. 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, or the terminally ill. A substantial area of usage of herbal medicines is to treat or relieve the symptoms of chronic, difficult-to-treat conditions, for example eczema. This will often occur in cases where patients have not been satisfied with the results of conventional medication (e.g. they don't like the side effects) and therefore in some cases there may be **long term usage** of herbal medicine.
4. Surveys show that the use of herbal medicines by older patients is increasing and that typically more than one herbal product is used at a time, often concomitantly with prescription medicines. Older patients are often reluctant to tell their doctor that they are taking herbal products and so are at risk of potential drug-herb interactions.
5. This overview focuses mainly on the risks arising with unlicensed herbal medicines and in particular poor practice in the sourcing and supply to patients of such products.
6. Where products are subject to systematic regulation (having a marketing authorisation or a traditional herbal registration) many risks are avoided, notably those arising from low manufacturing standards and a lack of systematic patient information. There however, remains some residual risk, for example the patient may not read the authorised patient information leaflet and could consume the product inappropriately, despite the inclusion of suitable warnings and contraindications. As with licensed conventional medicines that have an effect on the body, there is the possibility of adverse reactions or interactions with other medicines. Where these possibilities are known they are included in the patient information leaflet for regulated products.
7. By the same token, 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.
8. There are frequent references in this overview to problems associated with traditional Chinese medicine (TCM). In some cases it may be more accurate to regard some of the low grade products as "masquerading as TCM", for example where there is inclusion of potent undeclared pharmaceutical ingredients.

Examples of major public health risks due to herbal products: What can go really seriously wrong?

9. There was a wake up call to the herbal medicine sector and to regulators in the mid 1990s. Women attending a slimming clinic in Belgium were given a herbal medicine containing the **wrong, toxic, herb *Aristolochia*** species, (which has been used in TCM). **Over 100 women developed kidney failure and many subsequently went on to develop cancer.** An EMEA report of 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 out of 17 patients who had taken *Aristolochia manshuriensis* supplied under the common name Mu Tong 12 had died of renal failure. Despite a ban on this ingredient in many countries, including the UK, problems still recur with the accidental supply of products containing *Aristolochia* (it has a similar common name in Chinese and similar appearance to several other herbs).
10. **There is no reason to suppose that a major incident could not occur in the UK;** one difference is that it is less likely to be identified. Given the pattern of mostly small, dispersed herbal clinics across the UK it is

²³ <http://www.mhra.gov.uk/SearchHelp/GoogleSearch/index.htm?q=%20PUBLIC%20HEALTH%20RISK%20WITH%20HERBAL%20MEDICINES%3A%20AN%20OVERVIEW>. Accessed 16/02/14.

likely that in a comparable example the treatment of resultant cases of kidney failure would be spread over a number of different renal units and simply not be picked up.

11. Another comparison showing the possibilities for larger incidents is a case in the UK of irreversible liver failure that was linked to a TCM slimming aid (Shubao) containing nitrosfenfluramine, a drug closely related to prescription only medicine, fenfluramine which is now banned. Reports from Japan indicate that in 2001 – 2002 more than 800 cases of serious liver damage and at least 4 deaths resulted from the use of Chinese slimming products containing fenfluramine or nitrosfenfluramine.

Areas of public health risk from practice of herbal medicine

12. The main areas of risk with herbal medicines (taken from real examples) include:

- **Delay in effective treatment** for serious condition (e.g. *TCM practitioner advertising that herbal remedy will obviate need for coronary artery bypass graft*).
- **Interference with vital treatment** (e.g. *Ayurvedic clinic advising patient to discontinue antipsychotic medication and take alternative Ayurvedic remedies*)
- **Exploitation of vulnerable groups such as children and the seriously ill** (e.g. *parents wanting baby/child to have "natural" cream for eczema, unaware that the products supplied actually contain undeclared steroids; patients with cancer have been prescribed large quantities of TCM*)
- **Overloading patient with multiple medications** (e.g. *16 year boy with acne on over 100 TCM tablets a day for several months; patient hospitalised with serious unexplained abdominal pain*)
- **Unexpected rare but serious liver toxicity of plants** (e.g. *Kava, Black cohosh*) leading to liver transplants in some cases)
- **Toxic plants used** (e.g. *Senecio species used in TCM which may cause liver toxicity or liver cancer*)
- **Side effects** (as with any other medicine)
- **Interactions** with other medicines (e.g. *St John's Wort can interact with many prescribed medicines including contraceptive pill and immunosuppressant medicines. This has resulted in unwanted pregnancies and rejection of transplanted organs; ginkgo can interfere with the action of anaesthetics*)
- **Wrong, toxic, plant used** (either accidentally due to lack of expertise or intentionally due to practice in TCM of substituting one ingredient for another believed to have a similar action)
- **Adulteration with pharmaceutical substances.** (This is a frequent occurrence and has involved potent medicines such as anti-diabetics (glibenclamide), drugs for erectile dysfunction (sildenafil), appetite suppressants (sibutramine) etc)
- **Addition of analogues of pharmaceutical substances.** (This is a growing activity where a chemical derivative of a known pharmaceutical substance is included in a product e.g. nitrosfenfluramine, sildenafil (Viagra) analogues (homosildenafil, acetildenafil). The analogue is often more toxic than the parent molecule (e.g. nitrosfenfluramine) or is of unknown toxicity as in the case of many of the sildenafil derivatives)
- **Addition of heavy metals/toxic elements as ingredients** (e.g. *TCM product in clinic found with 117,000 times level of mercury permitted in foods, leading to a number of hospital admissions. TCM and Ayurveda traditionally use heavy metals and other toxic elements as ingredients. These include realgar (arsenic sulphide), cinnabaris (mercuric sulphide), calomelas (mercurous chloride), hydrargyri oxydum rubrum (red mercuric oxide). The current Chinese Pharmacopoeia includes 48 products containing at least one of these ingredients*)
- **Contamination** during manufacturing process (e.g. *poor control on use of pesticides, mycotoxins, microbiological loads*)
- **Confusion over standards** (e.g. *in TCM sector over whether traditional formulae have or have not had known toxic ingredients removed*)
- **Weak or missing information** (e.g. *about safe use of products or other poor practices such as over labelling list of ingredients on product with a different list*)
- **Communications** (Inability of practitioner to communicate in English – e.g. *to find out whether patient has a serious medical condition, such as diabetes, is on other medication, or is pregnant, breastfeeding*).

Scale of risk

13. Internationally, no one, whether regulator authority or academic, has been able to overcome the obstacles in the way of making reliable estimates of ill health caused by herbal medicines, including the likely significant distinction in levels of risk between herbal medicine practised (a) responsibly and (b) irresponsibly. Principal obstacles affecting the UK are that:

- A perception that **natural equates to safe** and therefore many herbal medicine users would not realise that a herbal remedy may be responsible for symptoms they have experienced

- Survey evidence shows that most people don't tell their doctor that they are taking a herbal remedy (and most doctors don't ask) and so the **doctor would have no reason to suspect that ill health was linked to consumption of a herbal remedy**; survey evidence also shows that patients are much less likely to report to their doctor the suspected side effect of a medicine if they believe it may be linked to a herbal medicine
 - It is a regular occurrence that cases of ill health are linked to consumption of low grade products containing **undeclared ingredients**. In this situation the chance of detection of any specific individual case is very low indeed
 - Many issues arise from low standards – e.g. sourcing from unreliable suppliers operating to low standards; in these circumstances the degrees of **adulteration/contamination/substitution of one species for another are random and erratic**
 - Herbal practitioners are largely supplying unlicensed products on a private basis; there may therefore be an **inbuilt disincentive for less responsible practitioners to report patient side effects** lest this affects adversely on them personally and at a wider level, undermines the business.
14. There are, however, pointers to what may lie beneath the surface:
- The MHRA currently receives about **70** suspected adverse drug reaction reports relating to herbal medicines each year. This is believed to represent only a small proportion of cases (e.g. in a year when there was considerable publicity about St John's Wort interacting with other medicines, reporting doubled). The expectation is that over time with better publicity and following the recent extension of the reporting scheme to patients, self reporting will increase
 - There have been a **handful of identified UK deaths** associated with use of herbal medicines; there is a **small but reasonably steady flow of cases entailing very serious illness** such as kidney or liver failure requiring transplant; and other cases (e.g. coma) involving prolonged hospitalisation. A high proportion of such cases have only come to light because of the actions of very alert clinicians who have taken the time to investigate causation of ill health and/or perhaps refer the case to a poisons unit
 - **There are a much higher number of cases where MHRA recover from the market dangerous unlicensed products (typically sold in, or destined for, clinics) which pose a clear risk to public health.** These include products with hazardous levels of heavy metals, highly potent or even banned pharmaceuticals, products which may be associated with infectivity e.g. containing human placenta or bat excrement. **In some cases the product seizures or recalls have been on substantial scale – e.g. products destined for distribution through nationwide chains of TCM clinics. The MHRA believes that it identifies and recovers only a small proportion of dangerous products; consequently many will have been used by the public.** A recent example was a **seizure in May 2008 by the MHRA and Police in a joint operation of nearly 500 boxes containing bottles of an unlicensed "herbal" lotion containing steroids**. The issue had been brought to our attention by a paediatric dermatologist concerned about the use of the product by parents on babies.
15. Worldwide, there is increasing study and scientific understanding of herbal medicines; also improved sharing of information between regulators. It is therefore predictable that over time new safety areas will be identified as well as further examples of known existing problems.

Variations in risk across the UK sector

16. Such has been the frequency of findings with low grade products in the **TCM** sector that on several occasions the MHRA has issued general alerts about patchy standards in the sector.
17. Issues of risk in the TCM sector can be complex and present difficult handling issues. For example, there are many traditional formulae in TCM. In some of these the old formulae includes a potentially dangerous ingredient such as a heavy metal or a toxic herb. Responsible operators in the sector would like to reach agreement with the MHRA that it is acceptable to use new versions of these formulae minus the potent ingredient. The issue in a largely unregulated environment then becomes whether it is possible to rely on a voluntary agreement to protect the public – and what to do about the likelihood that other players who are not part of such an agreement would continue to supply the former versions of the formulae.
18. With typical **western herbal medicines**, e.g. found in health food shops, supermarkets, etc the most frequent area of concern in the unlicensed sector is lack of systematic patient information. Some products fall short of what is desirable in terms of information about safe usage. With **Ayurvedic** medicines the most frequent problems are the illegal inclusion of heavy metals; also illegal product claims.

MHRA
Policy Division

July 2008

Appendix B

A selection of other MHRA warnings - outtakes from the agency website

MHRA warning August 2013 – heavy metals

Unlicensed Traditional Chinese and Ayurvedic Medicines found to contain heavy metals see

<http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Herbalmedicines/Herbalsafetyupdates/Allherbalsafetyupdates/CON307402> . Accessed 16/02/14.

Risks of buying herbal remedies on line

<http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Herbalmedicines/Staysafeusingnaturalremedies/Risksofbuyingherbalremediesonline/index.htm>. Accessed 16/02/14. Since 2005, the MHRA has tested 138 unlicensed 'herbal' remedies sold as treatments for erectile dysfunction. Of the products tested, 65% (89) were found to contain prescription only medicines, such as sildenafil, tadalafil, vardenafil or their analogues (chemically related compounds), or lignocaine. Quantities varied widely and in some cases amounted to what would be regarded as toxic overdose levels of prescription medicines. If you suffer from a heart condition, these ingredients could cause serious harm to your health.

Behind the high-tech websites featuring earnest doctors in white coats are garages, lock ups and appalling hygiene practices.

“In one place a man was replacing his clutch on one side of the garage and packing medicine on the other” said Mick Deats”, Head of Enforcement at MHRA.

At any one time the MHRA have under surveillance about 100 websites which sell into the UK from which a test purchase is made and then tested in the laboratory. From 100 test purchases:

- 15 never arrived
- 10 resulted in identity theft or credit card details being stolen
- 15 orders received but with a different product to the one ordered.

Of those tested many include unlicensed products that are not licensed and not authorised for sale such as herbs, or that include prescription only ingredients.

Do traditional Chinese medicines pose a serious threat to public health?

The public should be aware that there are some TCM products on the UK market that may be manufactured to low quality standards and may be deliberately adulterated or accidentally contaminated with toxic or illegal ingredients. These products do pose a direct risk to public health and it is not currently possible to distinguish between these products and TCMs that are made to acceptable safety and quality standards.

The shortfall in quality standards does not of course mean that every poor quality TCM is necessarily dangerous, but it does mean that there is an element of risk. The risks vary widely, depending on the ingredients and how they are used.

Why is advice being given now about the safety of traditional Chinese medicines?

The former Medicines Control Agency informed the public in 2001 via the general media of the advice given by the Committee on Safety of Medicines (CSM) that it was not possible to give the public assurances as to the safety and quality of TCMs on the UK market. Since then the Agency (now the MHRA) has continued to find examples of illegal and dangerous TCMs being supplied in the UK and consumers should be alerted to the continuing problem.

What evidence is there of unsafe traditional Chinese medicines on the UK market?

Recent samples of TCMs found on the UK which pose a risk to public health have contained:

- mercury
- toxic herbal ingredients (typically where a toxic herb has a similar name or similar appearance to the intended ingredient)

- potent prescription only medicines (POM), the safe use of which require supervision by a doctor

What potentially harmful effects can poor quality traditional Chinese medicines have?

The harmful effects of illegal toxic ingredients or inappropriately used potent ingredients can be serious and in some cases life threatening leading for instance to:

- liver damage associated with the use of slimming pills adulterated with the globally banned drug(s) fenfluramine and/ or nitrosfenfluramine. A UK patient has received a liver transplant after taking such a slimming aid called Shubao.
- irreversible kidney failure and cancer as in the case of Aristolochia
- dangerously low blood sugar levels, which can lead to coma and death, due to illegal inclusion of the Prescription Only Medicine Glibenclamide. Glibenclamide is an antihyperglycaemic drug used by doctors to control diabetes.
- thinning of the skin with irreversible changes to the skin structure can be caused by the illegal inclusion of steroids in skin creams. In the long term these creams can worsen eczema and dermatitis that they are used to treat. Since 2002, the MHRA has found steroids in 40% of the skin creams suspected of containing the substances.
- risk of transmitting viruses or bacteria via material such as human placenta.

Are the public at risk from western herbal remedies?

Herbal medicines are medicines. Western herbal medicines, as with any other herbal tradition, can have an effect on the human body and should be used with care. For example, some herbs used widely in western herbal remedies, such as St John's Wort, can interact with prescribed medication (those provided through your doctor or dentist) making them more or less effective. It is important that patients tell their doctor or pharmacist if they are taking a herbal remedy particularly if they are taking them with other medicines such as prescribed medicines or if they are due to have a surgical operation.

How can I tell which traditional Chinese medicine practitioners or clinics are reputable or reliable?

There is no entirely reliable way of doing so. However, various practitioner and trade associations operating in the sector follow codes of conduct. You may find it helpful to ask which body they belong to and what are the requirements for membership of that body. Questions which might be asked about products include: what arrangements are made to ensure that products are legal, safe and of acceptable quality? What steps are taken to ensure that labelling is accurate? What are the arrangements if you wish to make a complaint?

Ayurvedic medicines containing heavy metals

The MHRA have been made aware of at least six cases of heavy metal poisoning in the last 3-4 years associated with the use of Ayurvedic medicines. In most of these cases, the Ayurvedic medicines contained lead. There has also been a case of arsenic poisoning.

The Ayurvedic medicines in question were obtained from the Indian sub-continent and brought back to the UK for self use. Patients were treating diabetes, chronic fatigue syndrome and hypertension.

Previous concerns about the heavy metal content of some Ayurvedic Medicines were highlighted in a press release dated 17 August 2005 "[Ayurvedic Medicines may contain Heavy Metals](#)" from the Current Safety Issues on the MHRA website.

Appendix C

Outtake from *The WHO Traditional Medicine Strategy 2014-23*²⁴

Box 5: Described risks associated with T&CM (traditional and complementary medicine) products, practitioners and self-care:
• Use of poor quality, adulterated or counterfeit products;
• Unqualified practitioners;
• Misdiagnosis, delayed diagnosis, or failure to use effective conventional treatments;
• Exposure to misleading or unreliable information;
• Direct adverse events, side effects or unwanted treatment interactions

²⁴Op cit., page 31