

Briefing Paper from Michael McIntyre, Chair of the European Herbal and Traditional Medicine Practitioners Association (ehpa@globalnet.co.uk) on the Statutory Regulation of Practitioners of Acupuncture, Herbal Medicine, Traditional Chinese Medicine and Other Traditional Medicine Systems practised in the UK

Statutory Regulation of Practitioners of Acupuncture, Herbal Medicine, Traditional Chinese Medicine and Other Traditional Medicine Systems practised in the UK has been a long time coming and is urgently needed to protect the public from poor practice and substandard medicines whilst maintaining public access to these popular therapies. Below I include a copy of a letter I wrote to the Health Minister, Ben Bradshaw before meeting him in June this year. The letter clearly outlines the prolonged process of statutory regulation (SR) for this sector that has had the Government backing since 2001, following the House of Lords Select Committee on Science and Technology's Report on Complementary and Alternative Medicine in 2000. In fact, as mentioned in the letter to the Minister, the Department of Health (DH) undertook a public consultation on this subject in 2004 that demonstrated a very high level of support for statutory regulation of this sector (98.5% in favour) and this resulted in the setting out by the DH in 2005 of a timetable to achieve SR. The timetable has not been adhered to and the significant threat to public health from an unregulated sector identified by the DH Working Group report (see Document 2) and the MHRA (see Document 3) still remains. Now (November 2008) the Health Professions Council (the designated regulator) has weighed in with a letter to the Health Minister (Document 4) calling for the statutory regulation of this sector.

Herbal medicine and acupuncture are superb resources which in trained and skilful hands can do great good. But the current situation where anyone can set up in practice without any verifiable standards of training or practice is clearly untenable. The Government clearly recognised this after the House of Lord's Select Committee called for herbal medicine and acupuncture practice to be statutorily regulated. Given a constant change of Ministers at the helm of the DH, the Government now appears to have lost sight of its original understanding and intention and the public are consequently at risk of harm from poor practice and/or at risk of losing out from being able to access treatment from well trained, caring and competent practitioners. The Minister now plans yet another public consultation on this matter (next year) but further delay is unacceptable given the extraordinary time and effort that has already been given to consultation and the urgent need for regulatory action.

Michael McIntyre
Chair European Herbal and Traditional Medicine Practitioners Association 7/11/2008

"The current incoherent state of affairs is simply not sustainable. In the final analysis, without statutory regulation I believe that vulnerable members of the public will be at continuing risk and the efforts of responsible and well-trained practitioners to follow high standards will be undermined." Professor Michael Pittilo Chair of 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 May 2008

Document 1 Letter from Michael McIntyre to Health Minister Bradshaw May 08.

Ben Bradshaw MP
Minister of State for Health Services
Department of Health
79 Richmond House
Whitehall,
London SW1A 2NS
7/5/2008

Dear Mr Bradshaw,

I write to you as Chair of the European Herbal and Traditional Medicine Practitioners Association (EHTPA) which represents some 1,500 practitioners of herbal/traditional medicine across the United Kingdom. The EHTPA has been a major stakeholder in the process of moving towards statutory regulation of herbal/traditional medicine, acupuncture and traditional Chinese medicine over the past fifteen years. In particular, together with the DH and the Prince's Foundation for Integrated Health (PFIH), it was one of the three stakeholders in producing the Report of the Herbal Medicine Regulatory Working Group in 2003. The EHTPA is also a major stakeholder in the formulation of the Report by the Department of Health Steering Group, which I understand is due to be published in the next few weeks.

I am writing to you now because I have become aware that there may be some question about the need for statutory regulation of acupuncture, herbal/traditional medicine and traditional Chinese medicine (TCM) and that there is a possibility that this will not go ahead after all. Were this to be the case, this would have serious implications for public safety and would significantly adversely limit consumer choice. It also would represent an abrupt reversal of Government policy which, as I outline below, has since 2001 consistently sponsored, supported and encouraged statutory regulation of this sector.

As you know, the matter of public safety has been a driving factor in the move towards statutory regulation of acupuncture, herbal/traditional medicine and TCM since the House of Lords' Select Committee on Science and Technology called for immediate statutory regulation of herbal medicine and acupuncture in 2000 (Section 5.53 of the Report). Their Lordships made this recommendation because, as they explained, "these therapies carry inherent risk, beyond the intrinsic risk that all CAMs (Complementary and Alternative Medicine Systems) pose, which is the omission of conventional medical treatment." (Section 5.54). The Select Committee report recognised that acupuncture and herbal medicine had a coherent voluntary regulation system and a credible, if incomplete, evidence base. Significantly, the Select Committee Report acknowledged (Section 5.52) that "the Government have now identified acupuncture and herbal medicine as specific therapies they would like to see achieve statutory regulation."

The Government response to the House of Lords' Select Committee on Science and Technology's report was published by the DH in 2001. It proposed that professions using either acupuncture or herbal medicine (thereby also including Chinese herbal medicine, TCM and Ayurveda) should, in the interests of public safety, be statutorily regulated and that "it would be desirable to bring both acupuncture and herbal medicine within a statutory framework as soon as practicable."

Following this the DH undertook a "Scoping Study" which assessed the feasibility of the statutory regulation of herbal medicine and acupuncture (our organisation was particularly concerned with examining the case for regulation of herbal medicine). It is noteworthy that this DH Scoping Study (March 2001) set out a prospective timetable for this process that anticipated that a draft Section 60 Order would be published in March 2004, with the Order signed by Her Majesty the Queen in Council in March 2005. This DH Scoping Study noted that following signature of the Order, "the profession will achieve statutory recognition and must immediately start preparing draft rules to govern its functions."

As a result of a positive outcome from the DH “Scoping Study”, the DH in partnership with PFIH established two Working Groups for the regulation of acupuncture and herbal medicine. The Acupuncture and the Herbal Medicine Regulatory Working Groups both reported in 2003 and, in March 2004, the Department of Health consulted on a set of proposals for the statutory regulation of herbal medicine and acupuncture. In February 2005, the Department of Health reported on this consultation in a document entitled “The Statutory Regulation of Herbal Medicine and Acupuncture”. The DH website records that over 1000 copies of the consultation were distributed to interested individuals and organisations and a total 698 responses were received to the consultation, the majority of the responses indicating strong support for the introduction of statutory regulation in order to ensure patient and public safety. The Report noted that 98.5% of respondents expressed support for a UK-wide system of regulation of this sector and concluded with an update on the timetable for this process, affirming that it expected to publish a draft Section 60 Order for consultation later that year.

I have detailed this process over several years because it clearly demonstrates that the Government gave full backing to the move towards statutory regulation. Indeed, I attended meetings with DH officials who stressed that statutory regulation of herbal medicine and acupuncture was definitely going to happen in the interest of public safety and that I should make this clear to my colleagues.

In the event, following the Shipman tragedy, the process of statutory regulation of herbal/traditional medicine, acupuncture and TCM was delayed by the need to await the outcome of two reviews of professional regulation which were not published until July 2006 after which there was a further period of consultation. In June 2006, the then Minister for State in the DH, Jane Kennedy, established a new Steering Group to consider in detail the process of statutory regulation of acupuncture, herbal/traditional medicine and TCM. The Steering Group Report, now about to be published, strongly advocates that statutory regulation of this sector should go ahead as soon as possible on public safety grounds. In the light of this, it is hard to understand how the Government could possibly consider backtracking on years of consistent work and support for statutory regulation of this particular sector of CAM.

I was present at the recent PFIH launch of the Complementary and Natural Healthcare Council to hear you deliver an excellent speech on the importance of regulation of CAM and noted that you emphasised the need for ensuring public safety through appropriate regulation at a time when as many as one in three people are making use of CAM. The reason why statutory rather than voluntary regulation is essential for herbal/traditional medicine, acupuncture and TCM is because, as the House of Lord’s Select Committee on Science and technology noted, these therapies have a capacity to cause significant harm if practised by poorly trained or negligent practitioners. The MHRA website, unfortunately, records several worrying instances of such malpractice. In addition, it should be borne in mind that herbal practitioners have access via Statutory Instrument 2130 (The Medicines Retail Sale or Supply of Herbal Remedies Order) of 1977 to several potent plant remedies such as belladonna and datura which in the wrong hands have the capacity to cause harm. We argue that in the 21st Century, it is unacceptable for such remedies to be generally available to anyone who holds themselves out as a herbalist regardless of whether or not appropriate training has been undertaken and/or their fitness to practise determined. The only rational way to solve this problem is to safeguard the public by introducing statutory regulation so that failing practitioners can be removed from the register and thus effectively banned from practising.

Failure to bring statutory regulation to our sector will significantly reduce patient choice. In April 2011 the Directive on Traditional Herbal Medicinal Products (DTHMP) will become fully implemented across the EU. If herbal practitioners are not statutorily regulated, they will not qualify to be considered “authorised health professionals” under Article 5 of the main European Medicines Directive (2001/83/EC.). As a consequence, many products made for individual patients by a third party will no longer be available and patients will find their choice restricted by loss of these medicines that up to now have been prescribed by practitioners. In addition, the economic consequences of loss of revenue for relatively small herbal businesses that currently make and supply such products is likely to result in a number going out of business. The regulatory impact assessment of this scenario looks bleak.

I have been delighted in recent days to hear that the Government is affirming that it is listening to the electorate. The fact that as many as one in three people in the UK regularly consult CAM practitioners

demonstrates the increasing popularity of this sector and it is surely right that the Government protects consumer choice whilst ensuring safe practice as far as possible. The DTHMP will assure the safety of traditional herbal products sold over-the-counter whilst the statutory regulation of acupuncture, herbal/traditional medicine and TCM will provide a corresponding system to ensure safe practice of these modalities and put the UK at the forefront of developing a scheme for safe and accountable delivery of these popular forms of CAM.

The regulation of CAM is a matter of considerable media interest and it is to be hoped that we can agree on the way forward based on the Report shortly to be published by the DH Steering Group before this becomes a matter of public debate.

I look forward to your response.

Yours sincerely,

Michael McIntyre
Chair EHTPA

Document 2: Key recommendations and summary of The Report to Ministers from the Department of Health Steering Group on the Statutory Regulation of Practitioners of Chinese Medicine and Other Traditional Medicine Systems Practised in the UK

The Report was published in May 2008 by the Steering Group established in summer 2006 by Jane Kennedy, then Minister of State at the Department of Health.¹

Purpose of the Report

The Department of Health Steering Group was invited to prepare the ground for the regulation of practitioners of acupuncture, herbal medicine, traditional Chinese medicine and other traditional medicine systems practised in the UK.

In particular, the Steering Group was asked to identify issues and propose options in relation to education and training, registration, fitness to practise and other essential aspects of regulation.

Steering Group composition and working schedule

The Steering Group, comprising practitioners and lay members appointed by the Department Health, is chaired by Professor Michael Pittilo, Principal and Vice-Chancellor, The Robert Gordon University, Aberdeen (for further information see biography below).

The Steering Group has also been advised by representatives from the Department of Health, the Medicines and Healthcare products Agency (MHRA) and the Health Professions Council (HPC). In addition, the Steering Group consulted representatives of the devolved Parliament and Assemblies. The Steering Group met several times during an eighteen-month period to consider the Report's recommendations..

Background to Report

The launch of the Steering Group by the Minister of State marked a significant further step in the move towards statutory regulation of acupuncture, herbal/traditional medicine and traditional Chinese medicine. This process has been consistently and fully supported by the Department of Health since it made, in 2001, a positive response to the report on CAM by the House of Lords' Select Committee on Science and

¹ *The Report to Ministers from the Department of Health Steering Group on the Statutory Regulation of Practitioners of Chinese Medicine and Other Traditional Medicine Systems Practised in the UK May 2008, ISBN 9781901085938*

Technology that called for the immediate regulation of acupuncture and herbal medicine practitioners.² Since that time the Department of Health has undertaken a scoping study and published timetables for statutory regulation of this sector. The process has also been ably supported by the Prince's Foundation for Integrated Health.

In February 2005 the Department of Health consulted on the statutory regulation of herbal medicine and acupuncture.³ Over 1000 copies of the consultation were distributed to interested individuals and organisations and a total 698 responses were received to the consultation. 98.5% of respondents expressed support for a UK-wide system of regulation of this sector.⁴

Thus throughout this process, the Government has led the way towards the statutory regulation of this sector, asking the Steering Group under the Chairmanship of Professor Michael Pittilo to consider this process in detail.

It should be noted that since the Government first accepted the public health case for statutory regulation of these therapies, the evidence relating to the risk to vulnerable members of the public from poorly trained, less responsible practitioners has continued to grow. These therapies have a capacity to cause significant harm if practised by poorly trained or negligent practitioners. In particular, the MHRA website, records several instances of substandard and unacceptable practice.⁵

The move to statutory regulation of herbal/traditional medicine and traditional Chinese medicine will put the UK at the forefront of developing a scheme for safe and accountable delivery of these popular forms of CAM.

Professor Pittilo is on record as saying *“The current incoherent state of affairs, is simply not sustainable. In the final analysis, without statutory regulation I believe that vulnerable members of the public will be at continuing risk and the efforts of responsible and well-trained practitioners to follow high standards will be undermined.”*

Key Recommendations of Steering Group Report

- The Steering Group (SG) is of the view that there is an urgent need to proceed without delay with the statutory regulation of practitioners of acupuncture, herbal medicine, traditional Chinese medicine and other traditional medicine systems. The primary reasons for this recommendation are to safeguard the public by allowing removal of failing practitioners from the statutory register and to enable informed choice by those who wish to access these forms of treatment
- The SG also notes that statutory regulation of this sector will continue to permit the manufacture of herbal medicines by a third party for the use of individual patients. After the Traditional Herbal Medicinal Products Directive is fully implemented in 2011, this important facility will disappear unless these practitioners are statutorily regulated and thus able to have such products made up under Article 5 of Directive 2001/83/EC (the main EU Medicines Directive).
- The SG also recommends that statutory regulated practitioners from this sector should be able to demonstrate a reasonable standard of English language ability by being able to achieve an International English Language Testing System (IELTS) score of at least 6.5. The SG believes this to be important to safeguard patients and to ensure that practitioners from this sector can communicate effectively with both patients and other health professionals.

² House of Lords' Select Committee on Science and Technology 2000. *Complementary and Alternative Medicine*. HMSO, London Section 5.53 & 5.54.

³ Dept. of Health,, Regulation of herbal medicine and acupuncture, proposals for statutory regulation, March 2004. DH website: http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_4083508

⁴ Dept of Health, Statutory Regulation of Herbal Medicine and Acupuncture, Report on the consultation, Feb 2005, http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_4083508

⁵ <http://www.mhra.gov.uk/index.htm>

- The SG recommends that Section 12(1) of the 1968 Medicines Act, that permits the supply of herbal medicines to individual patients without the need for a marketing authorisation, should be limited to those on the statutory register. The report recommends that the grandparenting process, by which existing practitioners are adopted onto the statutory register, should be as inclusive as possible.
- The SG is strongly in support of the Government suggestion made in the recent White Paper (2007), *Trust, assurance and safety – the regulation of health professionals in the 21st century*, that this sector should be regulated by the Health Professionals Council (HPC). The SG has had ongoing and most constructive discussions with representatives of the HPC regarding the provision of statutory regulation of this sector by the HPC.
- The SG made specific recommendations about titles that could be protected by statutory regulation (Section 19 on page 15 of the report).
- The Report agrees standards of education and training submitted as Annexes (2-4) as well as agreeing standards of conduct, performance and ethics that are consistent with those operated by the HPC.
- The SG strongly recommends further research to underpin the practice of acupuncture, herbal medicine, traditional Chinese medicine and other traditional medicine systems practised in the UK. Research and resource issues are examined in some depth in Annex 1.
- The Report also names those professional bodies that have provided satisfactory criteria that would seem to permit their members to be transferred en bloc directly over to HPC regulation without risk to the public (Annex 7). The report also provides a list of existing taught provision within the UK (Annex 5). Annex 6 makes specific recommendations about the approval of accreditation boards.

Document 3: from Medicines and Healthcare products Regulatory Agency
July 2008

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 inexpert, 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 homoeopathy.
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 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 nitrosofenfluramine, 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 nitrosofenfluramine.

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; *gingko* 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

Document 4. Letter from the Health Professions Council 5 November 2008.

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President: Dr Anna van der Gaag
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The Rt Hon Alan Johnson MP
Secretary of State for Health
Department of Health
Richmond House
79 Whitehall
LONDON SW1A 2NS

5 November 2008

Dear Secretary of State

Re: Medical Herbalists, Acupuncturists and Traditional Chinese Medicine Practitioners

At a meeting of the Health Professions Council on Thursday 11 September 2008 it was decided that Medical Herbalists, Acupuncturists and Traditional Chinese Medicine Practitioners should be recommended for regulation.

Article 3 (17) of the Health Professions Order 2001 states:

(17) The Council may -

- (a) make recommendations to the Secretary of State concerning any profession which in its opinion should be regulated pursuant to section 60(1)(b) of the Health Act 1999

Yours sincerely

A handwritten signature in black ink that reads 'Marc Seale'. The signature is written in a cursive style with a long horizontal stroke at the end.

Marc Seale
Chief Executive and Registrar

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