

REPORT ON THE REGULATION OF HERBAL MEDICINES AND PRACTITIONERS

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Professor David Walker

1. Foreword

Herbal medicine has been practised in many countries for centuries. There are particularly strong and established traditions in some Asian countries, notably in China and India but also in Europe including the UK. The sector is diverse and many of the traditions have now been exported to other countries. In the UK, use of herbal medicines is common and it is estimated that up to 20% of the population use herbal products at some time in their lives.

Much has changed since the previous reviews of herbal medicine by the House of Lords Science and Technology Committee in 2000 and the Department of Health Review chaired by Professor Michael Pittilo (2008). The largest change has been the Introduction of the European Traditional Herbal Medicinal Products Directive in 2004 which took full effect in the UK in 2011. This legislation effectively banned the importation and sale of large-scale manufactured herbal medicine products. This step severely limited the scope of some herbal practitioners to continue practising, particularly those from the Traditional Chinese Medicine (TCM) and Ayurvedic traditions. The possibility of enabling continued access to unlicensed manufactured herbal medicine products by authorised practitioners was explored but was not feasible under European regulations.

The Herbal Medicines and Practitioners Working Group was established to support me in examining the options for regulation of herbal products and practitioners in the light of the new European legislation. The group comprised herbal practitioners from many traditions, academics and experts from the Herbal Medicines Advisory Committee (HMAC), supported by the Department of Health and the Medicines and Healthcare products Regulatory Agency (MHRA). The working group provided expertise and challenge in the discussion of the issues and although they could not achieve consensus on all areas, notably that of practitioner regulation, they were able to bring considerable rigour and focus to the discussion of the key issues.

The working group expressed concern that the European legislation had not achieved all of its objectives in that it had failed to encourage the licensing or accreditation of safe herbal products in order to make them available to the public following the implementation of the Directive. Although the UK has been at the forefront of the new licensing arrangements, with over 300 herbal products achieving Traditional Herbal Registration accreditation, this is only a small percentage of the number of products being used. To date one product of Tibetan tradition and one of TCM tradition have been registered.

At present under UK law it is permitted for a herbal practitioner to see individual patients, offer diagnoses and prepare herbal treatments on their own premises, as long as these preparations do not contain banned or restricted substances. This is unchanged by the Traditional Herbal Medicinal Products Directive. Many practitioners do not have the facilities or training to prepare their own herbal treatments on their own premises. Often they have relied on pre-formulated manufactured herbal products which are no longer available. The possibility of allowing off-site preparation of individualised herbal medicines should be considered

A large number of herbs and herbal products are in common use as food supplements. The categorisation of some herbal products as food supplements has been explored by a number of

European countries and this approach might offer greater clarity about the regulatory status of these products.

At present a number of herbal ingredients are banned or restricted in their use because of concerns that they may be harmful to health. The list of banned substances has not been reviewed in recent years. The introduction of a process for regular ongoing review would strengthen our safety arrangements.

The issue of whether and how to regulate practitioners of herbal medicine was undoubtedly the most contentious area addressed by this review. The majority of herbal practitioners on the working group were in favour of statutory regulation of practitioners on the grounds that it would protect public safety by ensuring that practitioners were properly trained and that their practice could be assured by a regulatory body. Detractors contended that statutory regulation would confer an inappropriate level of legitimacy on herbal practice which was poorly supported by scientific evidence. The question I considered was whether statutory regulation was a necessary and proportionate response to the threat to public safety from herbal medicine practice.

In considering this issue I encountered three areas of difficulty. The first relates to the evidence of effectiveness of herbal medicines. There are a small number of studies indicating benefit from herbal medicine in a limited range of conditions but the majority of herbal medicine practice is not supported by good quality evidence. A great deal of international, primary research is of poor quality. When this research is examined in high quality systematic reviews, most studies either have to be excluded on methodological grounds or offer weak evidence due to poor study design with the result that reviews usually produce equivocal results. Herbal medicine practice is therefore currently based upon traditional practice rather than science. It is difficult to differentiate good practice from poor practice on the basis of this evidence in a way that could establish standards for statutory regulation.

The second issue is that there is very limited understanding of the risks to patient safety from herbal medicines and herbal practice. A review of safety data was commissioned from HMA as part of this review. This review identified many anecdotal reports and case studies but little systematically collected data. Most herbal medicine products have not been through the rigorous licensing process that is required of conventional pharmaceutical products to establish their safety and efficacy. Indeed, only a small proportion have even been subject to the less rigorous Traditional Herbal Registration (THR) process. Some herbal sector representative bodies have attempted to collect data on adverse reactions to herbal medicines using the Yellow Card system used for conventional drugs but the number of reports is relatively small and it is not clear whether this is because there are few adverse reactions or whether the low numbers recorded are due to under-reporting.

The anecdotal evidence of risk to patients from herbal products in the safety review highlighted the prominence of manufactured herbal medicines in the high profile serious incidents which have been reported in recent years. Many of these reports relate to harm thought to be caused by industrially manufactured herbal products which contained either dangerous herbs, the wrong constituents, toxic contaminants or adulterants. All such industrially manufactured products are now only available under European regulations if their safety is assured through MHRA licensing or THR accreditation; and specific dangerous herbs have been banned under UK law. This has weakened the

case for introduction of statutory regulation as a further safety measure. The paucity of evidence about safety is concerning given the extensive use of herbal medicine in the UK and there is a need for prospective collection of safety data to quantify the true risk to patients.

The third issue is the identification of educational standards for training practitioners and the benchmarking of standards for accrediting practitioners. With no good data on efficacy or safety, it is difficult for practitioners and patients to understand or quantify the potential benefits and risks of a proposed therapeutic intervention. Training programmes could accredit knowledge and skills in some areas including pharmacology and physiology, professional ethics and infection control but without a credible evidence base relating to the safety and effectiveness of herbal medicine it is hard to see how they could form the basis of accreditation in this field of practice. There are a number of educational university programmes offering courses in herbal medicine although the number has declined in recent years. Some of these courses are accredited by practitioner organisations which is a potential governance risk as the accreditation may be based on benchmarks established by tradition and custom rather than science.

The herbal medicine sector is in a dilemma. Some practitioners would like to continue to practise as they do now, with no further regulation, and accept that their practice is based on tradition and personal experience rather than empirical science. The logical consequence of adopting this form of practice is that we should take a precautionary approach in order to ensure public safety. The public should be protected through consumer legislation to prevent false claims, restricting the use of herbal products which are known to be hazardous to health and through the use of environmental controls to ensure hygiene and infection control risks are minimised. In this scenario it would still be important to encourage good professional standards through voluntary accreditation or self-regulation schemes.

A second model, preferred by many practitioners is to establish herbal medicine as a scientific discipline analogous to conventional medicine, in which regulated practitioners practice evidence based herbal medicine in conjunction with other clinical services. Moving to this model would require considerable development of the sector. It will require the embracing of a research culture where treatments are properly tested for safety and effectiveness in high quality studies. It will require the discrimination between effective and ineffective treatments and the reflection of this in clinical practice. It will require collaboration within the sector to establish professional standards and norms and the establishment of an evidence base for both safety and effectiveness which is developed and refined over time. This will be challenging because of the diverse and fragmented nature of the sector and the lack of existing academic and professional infrastructure. There are opportunities for progress in this area, however. Herbal medicine researchers are eligible to compete for national sources of research funding such as the National Institute for Health Research and there are research design services available to support the development of research.

Professor David Walker, Chair

2. Introduction and scope

There have been ongoing discussions about the possibility of regulating practitioners of herbal and traditional Chinese medicine since the House of Lords Select Committee on Science and Technology reported in 2000 on complementary and alternative medicine and specifically recommended that practitioners of acupuncture and herbal medicine should be statutorily regulated because they met key criteria that included risk to the public through poor practice.

This report and the findings of subsequent working groups and reports led to an announcement by the government in 2011 that it proposed to introduce a form of practitioner regulation for herbal practitioners, by asking the Health and Care Professions Council (HCPC) to set up a statutory register for practitioners. It was further intended that, as any practitioner on the HCPC's register would have been classified as a 'healthcare professional' they would have been permitted to supply unlicensed manufactured herbal medicines to meet individual patient needs. (Since the European Directive 2004/24/EC took full effect in April 2011 it is no longer legal for herbal practitioners in the UK to source unlicensed manufactured herbal medicines for their patients.)

Subsequent issues were raised about the lawfulness of introducing such a scheme for access to unlicensed manufactured medicines, and Ministers also decided that there was a safety risk in proposals that would provide a route for unlicensed herbal products onto the UK market without any checks being made on the products' quality or safety. They therefore concluded that the whole area of professional and product regulation should be reconsidered before any further steps were taken.

In a debate in Parliament in July 2013, on the issue of herbal medicines and practitioners, and the government's proposals around regulation, Dr Dan Poulter MP, Parliamentary Under-Secretary of State for Health, announced that an independent group would be established to look at all options and to advise the government on what steps to take.

The group was chaired by Professor David Walker, Deputy Chief Medical Officer and the Vice Chair was David Tredinnick MP. A full list of members and the Terms of Reference of the group can be found at Annex A.

The group met during 2014 to discuss the issues and options around the regulation of herbal practitioners and medicines, with a particular emphasis on public safety. The work of the group has been supplemented by a series of smaller meetings and visits conducted by me, and I also commissioned specific evidence and welcomed additional supporting material and evidence from the working group and other interested parties. A full list of meetings, visits and materials consulted are at Annex B.

The review has focused primarily on the protection of public safety, and most of its recommendations are based on that premise.

It looks at what evidence of risk has been demonstrated by the current system, which has no regulation of practitioners, and where there are a number of unlicensed products in use.

It asks whether evidence is available to demonstrate that the introduction of either statutory assurance, or voluntary accreditation, of practitioners, would reduce that risk.

It looks at whether evidence is available to indicate a risk from products, and whether further safety measures need to be introduced, but also whether options could be considered to allow some additional access to unlicensed products where risk is deemed low.

It also sets out the current regulatory picture, and makes recommendations about regulation and about evidence for safety.

3. Evidence and information

How the Review was undertaken

Following an announcement in Parliament in 2013 by the Under-Secretary of State for Health, Dr Dan Poulter MP, an independent working group was set up, comprising representatives of the main herbal traditions and of manufacturers, Members of Parliament, health experts, professional standards representatives, and other interested groups. Membership of the group, and its terms of reference, was decided by the government. These can be found in Annexes A and B. Professor David Walker, the Deputy Chief Medical Officer at the time, was invited to chair the Group, and David Tredinnick MP, a Member of the Health Select Committee, who has spoken many times in Parliament on the issue of herbal and complementary medicines, acted as the Vice Chair.

In addition to representation from the group, a number of practitioners and campaign organisations asked to be included in the review work. Whilst it was not possible to accommodate everyone, Professor Walker accepted submissions from anyone who wished to write or speak to him about the review

Secretariat for the working group was provided by MHRA. Department of Health, Food Standards Agency, and the government's Herbal Medicines Advisory Committee also provided expert input and support.

Meetings of the working group

The working group met formally on four occasions in 2014: on 30 January, 1 May, 10 July, and 6 November. At the first meeting, on 30 January, the group considered the draft Terms of Reference, problems of current medicines regulation, especially in light of advice from the European Commission about the use of article (5)1 of EC 726/2004, and long-standing uncertainty about the government's intentions around the regulation of herbal practitioners¹. A number of representatives gave written submissions before and after the meeting, and this was the case for the duration of the Review. .

Before the second meeting, the Chair decided that he wanted to hear more detailed information from the main traditions involved in the practice of herbal medicines – traditional Western herbalism, traditional Chinese medicine and Ayurveda – about the impacts of regulation on their practice; and also views from the representatives of herbal manufacturing and trade. He held four meetings with relevant working group members, along with attendees who were either nominated by them, or had approached him separately with views. The proceedings are reported in Annex B

At the second working group meeting, the terms of reference were formally adopted. Outputs of the smaller group meetings were discussed, and there was detailed discussion about issues of medicines regulation. There was also a presentation about the process that would be necessary to implement statutory regulation of practitioners.

¹ More background information on this issue and the overall regulatory framework is given in Section 5

At the third meeting, presentations were made about the potential use of food supplements, and their regulatory background, and also about the process and options for schemes of voluntary accreditation of practitioners. The Chair reported that he had asked HMAc for a report on the safety issues of herbal medicines, as he wanted to review more evidence in this area.

At the fourth meeting, the working group discussed the HMAc report and undertook a detailed assessment of options around practitioner regulation, with the group invited by the Chair to submit any further evidence not presented during the course of the review.

Other evidence gathering

The secretariat of the working group set up a social network site on Yammer to support further participation by the group between meetings. The Yammer discussion forum enabled group members to debate issues related to all aspects of herbal medicines regulation, and to present further evidence, consider drafts of minutes, and receive copies of presentations.

The Chair held bilateral meetings with members of the group at their request throughout the process. He also undertook visits to some herbal premises in order to experience at first-hand what went on in herbal practice, and to hear direct from practitioners their views and concerns. The list of premises visited can be found in Annex B.

One point raised a few times by practitioners was that they felt they had an incomplete understanding of how their activity was being regulated, and what they needed to be aware of in practice. Chapter 4 sets out the landscape of current regulation, in part to address this point.

The Report

The findings and conclusions of the report are informed by the evidence, information and support given to the Chair from the above sources. The Chair is extremely grateful to the group and other associates for the amount of time they have given to this review, and acknowledges the depth of understanding and expertise in the area of herbals by participants. It is important to be clear, however, that the report is made by Professor Walker and not by the working group.

The Chair has sought the evidence and opinion from the diverse traditions represented by the group, in order to ensure all of the problems and many potential solutions were raised. It is inevitable that, given the wide range of representation on the group, there would not be consensus on a single approach to take. The fundamental concern in recommending further regulation is the safety and wellbeing of the public, which overrides any other reasons and arguments that may be advanced for regulation. This report is therefore the result of close working between the group and Professor Walker, but he is the overall author of its findings and recommendations.

4. Current Regulation

The existing practice of herbal medicine is governed by a number of UK and EU regulations. These relate in the main to the classification, use of and access to herbal products; although a few rules relate to practitioners.

In order to assess the options and proposals for herbal regulation, it is important to set out the detailed framework of existing regulation. There are also certain circumstances in which herbal medicine can be practised without regulation and which would therefore not fall within the scope of this review.

The MHRA reports that practitioners and the public often ask for clarification of what and what is not allowed under current regulation. It may therefore be of wider benefit to clarify the overall position.

Cases where no legal restrictions apply

Anyone can practise herbal medicine without the need for a licence or any qualifications. There are a number of voluntary registers which require that certain standards of practice and education are met, but these are not legally binding.

Anyone can, in the course of their business, make up, supply and administer herbal medicine, providing that they do so, on their own premises, that those premises can be secured, and a face to face consultation is carried out beforehand.²

In the circumstances described above, therefore, there is no impact on regulation, and such situations are outside the scope of this report

Other aspects of herbals where restrictions apply

There are rules for the classification of herbal medicines, and these affect how they may be used.

Products generally need to be licensed, except in limited cases, and the purpose of such regulation is first and foremost to protect public health. There are further rules governing the use of medicines in herbal practice.

² Regulation 3 of the Human Medicines Regulations (HMR) 2012 (formerly Section 12(1) of the Medicines Act 1968) provides that the licensing provisions of the HMR “do not apply to the sale, supply, manufacture or assembly of any herbal remedy in the course of a business where:

- (a) the remedy is manufactured or assembled on premises of which the person carrying on the business is the occupier and which he is able to close so as to exclude the public; and
- (b) the person carrying on the business sells or supplies the remedy for administration to a particular person after being requested by or on behalf of a particular person after and in that person’s presence to use his own judgement as to the treatment required.”

Determining whether a herbal product is a medicine

A 'medicinal product' is defined in two 'limbs', one relating to presentation, the other to function³. A product is medicinal if it falls within either of the limbs:

- 1) 'Any substance or combination of substances presented as having properties for treating or preventing disease in human beings'; [the first limb]
- 2) 'Any substance or combination of substances which may be used in, or administered to, human beings, either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis' [the second limb].

Medicinal products may well fall under both limbs of the definition but the European Court of Justice has confirmed that falling under either limb is sufficient to classify a product as a medicinal product.

This applies to all medicines, herbals included. A product is medicinal if it falls within either of those definitions. Case law has determined that definition must proceed on a case by case basis.⁴

Licensing a herbal medicine

If a product is determined as a medicine, it requires either a marketing authorisation (product licence) or since 2004, it can be licensed using a simplified THR.

Directive 2004/24/EC required each Member State to set up a THR scheme for manufactured traditional herbal medicines suitable for use without medical supervision. This is a simplified form of marketing authorisation.⁵

Under the Directive, herbal medicinal products can receive a certificate of registration instead of a marketing authorisation. The THR scheme is administered by MHRA. To achieve THR for their products, manufacturers or suppliers must demonstrate:

- a history of traditional use for at least 30 years (of which generally 15 years must have been in the EU); evidence of safety; adherence to appropriate manufacturing standards; and provision of appropriate product information to users.

The THR scheme is for minor self-limiting conditions including infections such as viral, bacterial and fungal diseases, colds and respiratory problems, and skin conditions.

³ Article 1 of Directive 2001/83/EC as amended

⁴ "... for the purposes of determining whether a product comes within the definition of a medicinal product 'by function' within the meaning of directive 2001/83, the national authorities . . . must proceed on a case by case basis, taking account of all the characteristics of the product, in particular its composition, its pharmacological properties, to the extent to which they can be established in the present state of scientific knowledge, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail." HLH Warenvertriebs, 2005 (C-211/03). See MHRA, Guidance Note No 8 (2012) for further advice.

⁵ The UK originally transposed the European Directive on traditional herbal medicinal products through the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005 - SI 2005/2705. This created the traditional herbal registration (THR) scheme. (These Statutory Instruments are now part of the HMR 2012.)

Unlicensed manufactured medicines and 'sell-through'

It has already been stated that unlicensed remedies can be made up and supplied by a practitioner to meet the needs of an individual patient following a one-to-one consultation, and these are not restricted. However, unlicensed manufactured medicines produced on a large scale are not permitted on the market under the Traditional Herbal Medicinal Products Directive.⁶

When it was introduced, Directive 2004/24/EC permitted a maximum transitional period of 7 years, giving companies a significant period of time during which to ensure that they were in a position to meet the new requirements. That period ended in April 2011. From that date all manufactured herbal medicines placed on the market require a full marketing authorisation (product licence) or a traditional herbal registration. The government chose to extend that period to April 30 2014, in order to allow companies further time to sell through stock. It is no longer lawful to sell a manufactured herbal medicine in the UK without a marketing authorisation or a Traditional Herbal Registration.

⁶ The European Court of Justice issued a ruling on 29 March 2012, where the Court stressed that no medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that State in accordance with the Directive or Regulation 726/2004. In other words, placement on the market is, as a rule, dependent on a marketing authorisation issued on the basis of the full records and data required by the law, allowing for the assessment of the safety, efficacy and quality of the product in question.

However, there are exceptions to this rule. Under Article 5(1) of the Directive, a Member State may exclude from the Directive's scope, in order to fulfil special needs, medicinal products supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of an authorised healthcare professional and for use by a named individual patient under his direct personal responsibility (commonly known as the "named patient specials exception").

The Court emphasised that the concept of "specials" applies only to individual situations justified by medical considerations and presupposes that the medicinal product is necessary to meet the needs of the patient. Where the doctor providing treatment wishes to prescribe a medicinal product but another product with the same active substance, the same dosage and the same form is already authorised and available on the national market, it would not be permissible to use the named patient specials exception.

5. Options for products

This chapter considers the position in relation to the regulation of herbal products supplied by herbal practitioners. In particular it looks at whether, in relation to the current regulations applying to herbal medicines, further changes or options may be explored in relation to (i) increasing public safety and (ii) improving access for practitioners to a wider range of products than is currently available.

Since the European Directive 2004/24/EC took effect in April 2011 it is no longer legal for herbal practitioners in the UK to source unlicensed manufactured herbal medicines for their patients.

In total around 315 products have been granted a THR.⁷ It has been established that individual preparations made up on site for a named patient are also available to practitioners. However, this represents a much smaller number of products than those that are in use. Unlicensed manufactured medicines are estimated to comprise about 50% of use, which varies between the different traditions of medicine.

In this climate and in view of the unresolved situation in relation to practitioner regulation, the following were considered:

- Whether certain herbal ingredients in use were potentially dangerous in themselves, and whether it would be reasonable to consider whether to ban or restrict a number of potent or toxic herbs for public safety reasons.
- Whether certain lists of food supplements (such as the BELFRIT list) could be adopted in the UK, and if this would provide a means of allowing greater access to herbal ingredients.
- The extent to which some form of off-site herbal 'dispensaries' could operate, extending the capacity for practitioners to supply medicines. However, public health and safety issues would need to be assessed alongside this.

Banning or restricting potent or toxic herbs

Information about the toxicity of certain herbs, pharmacological interactions with the body and cases of substitution and adulteration, has been documented for years.

A range of case studies, reports and other information were looked at in relation to this question. Professor Walker commissioned HMAc to produce a report reviewing key published literature into the safety issues, and other information about safety has been provided to the group, and also drawn on for the report (Annex C).

It has been difficult to draw firm conclusions from this wide range of evidence, without putting it into a more systematic review framework. However, as public safety is at the core of the work of

⁷ <https://www.gov.uk/government/publications/herbal-medicines-granted-a-traditional-herbal-registration-thr>

this review, it seems appropriate to propose that such a review framework should be set up, and it should go forward with the aim of banning or restricting substances if sufficient safety concerns are raised. This should draw on the existing processes and controls, which are a mixture of regulation and voluntary agreement.⁸

The full range of herbal ingredients now used in the UK is not known given that the traditional medicinal practice has become far more diverse. Little is known about the composition or physiological effects of some of these herbs, or of new plants introduced to existing practice.

It is therefore likely that a more systematic review of herbs would need to be carried out, drawing on professional expertise and with consultation; and a process for banning, restricting and or limiting, whether voluntary or through the use of current regulation, would need to be drawn up, based on current procedures and using the resources of MHRA and HMA, but with the overall aim of a minimal level of regulation and restriction.

Members of the working group reported anecdotally in meetings of safety issues with a number of ingredients. It would seem apposite to follow these up in a more formal and systematic review.

It has been noted by MHRA, HMA and members of the working group that the reporting of adverse drug incidents using, but not limited to, the Yellow Card Scheme appears lower than expected in the case of herbal medicines. Reasons for this may be attributed to a number of causes. There may be a reluctance to report the use of herbal products, or it may be the case that a patient may be using a combination of therapies, and it is difficult to ascertain whether a herbal product is solely responsible.

There is also a lack of safety data with regard to, for example, herb-herb, herb-food, herb-drug interactions, cautions, contra-indications and adverse effects. This limits the evidence available to practitioners to make prescribing decisions.

Most but not all members of the working group agreed that there could be more safety reporting and assessment of risks. Those who were not in agreement mainly considered that the existing controls were adequate – although there was general agreement on under reporting. One or two members felt that increased safety measures would inhibit the practice of herbal medicine.

⁸ See list and legislation at: <https://www.gov.uk/government/publications/list-of-banned-or-restricted-herbal-ingredients-for-medicinal-use/banned-and-restricted-herbal-ingredients>

Recommendation 1

The government should consider the feasibility of a systematic review of herbal ingredients drawing on existing legal frameworks with a view to amending current lists of known potent or toxic herbs, where sufficient safety concerns are raised. Such a scheme could initially be linked to a voluntary register of practitioners under an umbrella arrangement that could seek accreditation from the Professional Standards Authority for Health and Social Care, in due course.

Food supplements

The issue of food supplements and the relationship with herbal medicines was examined. In particular it was considered whether certain lists of food supplements in use in EU Member States could be adopted in the UK, and if this would support herbal practitioners, by clarifying which ingredients could be used as food supplements.

Another consideration was what scope there might be for reclassifying herbal products which are not subject to a THR or marketing authorisation (product licence) as foods. This is discussed later.

Two known lists ('BELFRIT' and 'Stoffliste')⁹ and the work that was behind them were looked at in further detail.

The lists have been produced to try to assist food regulatory authorities and enforcement bodies in the respective European Member States. They clarify novel food status. As all novel foods require a safety assessment and approval before they can be placed on the EU market this is particularly useful for industry in the area of herbal supplements. There are marked differences in the methods that were employed to compile the lists but they are regarded as being:

- helpful for industry and enforcement bodies;
- drawn up with particular emphasis on use in both foods and/or food supplements.

BELFRIT (Belgium, France, Italy)

This lists plants that are (a) not permitted for food, (b) edible mushrooms and (c) plants which can be used with some restriction. It has been compiled from three domestic plant lists and limited to food supplement use only. The Belgian list contains 645 plants; the French has 548 and the Italian has 1182 entries. The single or harmonised version of the list contains 1043 plants and fungi. A second list containing around 100 plants continues to be evaluated.

The BELFRIT list has a number of parameters – these include botanical names and synonyms, plant parts that are traditionally consumed and whether use as a food supplement is permitted in each of the countries. The list also includes a brief description of components which may be a cause for

⁹ Stoffliste -

http://www.bvl.bund.de/SharedDocs/Downloads/01_Lebensmittel/stoffliste/stoffliste_pflanzen_pflanzenteile_EN.pdf?__blob=publicationFile&v=4

BELFRIT is unpublished at present.

concern and where appropriate, stipulates labelling requirements prior to being placed on the market.

Although the list has been compiled to facilitate mutual recognition between the three Member States, it is important to note that companies would still have to follow the normal procedures for placing food supplements on the market in each of the Member States. Where herbal supplements are not on the market in all of the three domestic markets, this could include a full evaluation of the safety and regulatory status of the supplement.

A final BELFRIT list is not yet published and MHRA reports that at the time of publication, the list is currently undergoing an extensive consultation in the respective Member States and the final version will be published some time in 2015.

STOFFLISTE (Germany)

This was developed as a joint project of various food competent authorities in the German government with extensive input from competent bodies in a number of German States and the German food risk assessment agency. The German medicines agency also inputted during the drafting stages. The list took around 10 years to compile and was published on 9 September 2014.

The authors adopted a detailed, and relatively complicated, decision tree to categorise the plants. The approach tries to categorise plants in accordance with known medical uses, novel food status (use as a food ingredient and/or a food supplement) as well as classifying the plants into one of three categories (under scrutiny, restricted, and banned). The list also details the Latin name and plant part. The list includes a number of categories: it details which herbal products are typically regarded to be medicinal, which are novel foods and includes format of the three categories similar to those seen in an annex in the EU fortified food legislation, which is designed to control prevent or restrict the use of certain food ingredients in foods.

Findings

It was established that the food supplement lists were at different stages of development and that a harmonised list for the EU was not in the pipeline. Further, the basis of the work that had been undertaken was to establish the status of ingredients as potential food supplements and in relation to foods legislation and not primarily in relation to any medicines status

Members of the working group saw relatively little value in attempting to extend or appropriate lists of food supplements purely as a means of gaining access to a wider range of herbal ingredients, although evidence was supplied for the low risk of harm posed in general by the use of food supplements. It was observed that the EU lists had no basis in law.

There was however some interest expressed by the group in further research of the lists currently in development and an exercise to examine the lists currently in development with the option to develop and publicise a list of herbal ingredients accepted by the UK government for use in food supplements could be worthwhile. However, MHRA advised that such a list would not be straightforward to produce and would run counter to the UK's stated position, based on case law, which is to adopt a case-by-case assessment of individual products.

Recommendation 2

MHRA, Department of Health and/or other relevant government agencies should review the food lists currently in development and consider whether these could be used to assist the UK's assessment of the status of herbal products.

If appropriate, the feasibility of a UK list, which could assist herbal practitioners' understanding of the regulatory status of the herbal ingredients, could be investigated.

Moving forward a mechanism should be established to allow for regular review.

Reclassification

The group considered three questions in relation to reclassification of foods and medicines:

- whether a product that was already classified as a herbal medicine could be reclassified as a food;
- whether a product that was being used in herbal practice but was not classified as a medicine would benefit from being classified as a food; and
- whether it would be possible to reclassify products currently unavailable as medicines (unlicensed manufactured herbal medicines) as foods to make them available to practitioners.

If a product is classified as a medicine in the UK, it cannot be regarded as a food supplement.

Medicines and foods are regulated differently. There is no measure of risk benefit for foods. The underpinning principles of EU food law are that food products are safe for consumption (not injurious to health or unfit for human consumption¹⁰) and information provided about those products (for example labelling) is not misleading¹¹. EU food law specifically excludes medicinal products¹² from the definition of "food" meaning that foods that can treat, prevent or cure an adverse medical condition are likely to be viewed as misleading.

Other than restricting use for children of certain food supplements and alcohol, there is little restriction to the use of food although food businesses providing foods for certain categories of consumers must in those cases give regard to the health sensitivities of those consumers¹³. If a product can be legally placed on the market as a food, then it can be sold without restriction by food business operators as long as its safety can be demonstrated. Food business operators that are supplying food on a regular basis are required, in the UK, to register with the local authority, or be approved if they are manufacturing certain products of animal origin and comply with all relevant aspects of food law, including hygiene legislation.

If practitioners want to supply food supplements, they would need to register as a food business operator and comply with all relevant aspects of food law; they could also be sold by other food business operators, including high street health food stores. Food supplements are regulated under

¹⁰ Regulation (EC) 178/2002, Article 14, 2.

¹¹ Regulation (EC) 178/2002, Article 16.

¹² Regulation (EC) 178/2002, Article 2 (d).

¹³ Regulation (EC) 178/2002, Article 14,4 (c).

Food Supplement and Food Labelling Regulations, and need to comply with other applicable food legislation such as the Nutrition and Health Claims Regulations and Novel Food Regulations.

Medicines are defined more closely and the method of determination is tightly governed.

Case law has determined that classification of medicine . . . ‘must proceed on a case by case basis, taking account of all the characteristics of the product, in particular its composition, its pharmacological properties, to the extent to which they can be established in the present state of scientific knowledge, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail’.

Products may be presented direct to MHRA as the UK licensing authority, for an initial determination, but they may also come to MHRA’s attention, by reporting, or through enforcement activity. In such cases, if voluntary compliance is not achieved MHRA can formally determine the status of a product¹⁴

The very different approaches and procedures in food and medicines regulation militate against any wholesale repackaging or classifying of products from medicines to foods.

Members noted that the products which are currently unavailable to practitioners under the Traditional Herbal Medicinal Products Directive (such as unlicensed, manufactured herbal medicines) will be used for the treatment of underlying illness and, as such, will have features that will lead MHRA to regard them as medicines. Such products will therefore be automatically excluded from consideration as food supplements.

A few members thought that, while food supplements might on occasion be used by herbal practitioners, as indeed they may be recommended by GPs, their purpose is not as a medicine and, as such, not intended to treat, prevent or cure illness. Patients consult herbal practitioners to maintain general wellbeing or for the relief of a wide range of conditions, meaning that herbs used could be both used medicinally to treat, prevent and cure and illness but also as a food supplement.

However the rationale for attempting to overcome a number of legal and regulatory hurdles by facilitating the supply of ‘medicinal products’ as food supplements may, in practical terms, have little impact on herbal practitioners, as many of the products that they would routinely supply would clearly fall within the definition of a medicinal product.

Dispensary type approach

The extent to which it may or may not be possible to build a workable system that would allow small scale assembly of products off-site on a named patient basis using a ‘dispensary type approach’ was examined.

The law permits an individual in the course of their business, to make up, supply and administer herbal medicine, providing that they do so, on their own premises, that those premises can be

¹⁴ Human Medicines Regulations 2012, Part 9, Borderline Products, Provisional Determination

secured, and that a face to face consultation is carried out beforehand. It does not therefore allow for a third party or off-site preparation of such products.

The group is aware that such practices do occur – there are third party off-site premises at the moment, as well as anecdotal evidence of purchasing from the internet. It felt that further investigation into this area might be sensible in the interests of public safety.

It was found that it is technically possible to amend the provision in domestic legislation without affecting the EU Directive. If the requirement to dispense on the premises was removed, this would pave the way for a potential off-site ‘dispensary type approach’ in some cases.

However, questions are raised about the potential for increased risk to the public by the relaxation of the existing arrangement and the extent to which further controls might be required to compensate. This would need to be properly assessed.

There is also a question as to what relationship such ‘dispensaries’ might have with existing pharmacies regulated by the General Pharmaceutical Council, and whether this would entail that such arrangements would have to be brought under a statutory footing enabling inspection, assessment and fitness procedures. It is also recognised that any further discussions may need to involve the pharmaceutical industry and pharmacy owners.

There were a range of opinions expressed by the working group about the introduction of such an idea. Some members in favour of the idea considered that it should operate alongside a scheme of statutory regulation of practitioners to provide additional assurance. Others felt that it could operate without much additional regulation, in order to provide a simplified route of access to medicines that patients wished to use. A few members suggested standards that could be used in the ‘dispensary type approach’. The ongoing importance of the primary face to face consultation with a practitioner was however stressed.

The option for ‘dispensary type approach’ appeared to be contingent on a number of factors that would possibly benefit from further research and consultation.

Recommendation 3

The government should consider further the idea of a system that would allow small scale assembly of products off-site on a named patient basis using a ‘dispensary type approach’.

Access to unlicensed manufactured herbal medicines

The approaches discussed in this chapter, if adopted, might moderately increase the overall access of practitioners and patients to some herbal products. They may also benefit the public health by removing the most dangerous substances, and increase awareness by providing information about certain types of herbal products including those that are classed as food supplements. However, such medicine-based approaches would not make available any unlicensed large scale manufactured herbal medicines, as these are prohibited under the Traditional Herbal Medicinal Products Directive.

Some practitioners, particularly those practising TCM, many of whom make extensive use of unlicensed manufactured herbal products, consider that they have been significantly disadvantaged

by the limitations set by the Directive. There have been calls throughout the duration of the review for the Directive to be challenged.

It is important to recognise that it is now some 10 years since the Directive was introduced, giving the sector a long period of time to adapt to its requirements. We should not overlook the aim of the Directive and the UK THR scheme of helping ensure that the public have access to herbal medicines (including TCMs) that are safe and meet appropriate quality standards. The UK government has aimed to be as supportive as possible within its framework, through the design and facilitation of the THR scheme, and in allowing a further period of time for the sale of stock that had legally been purchased before the end of the transition period, allowing retailers to 'sell through' such products (until 30 April 2014).

It is recognised however, that compliance with the Directive has been inconsistent across the herbals sector.

Recommendation 4

In the longer term the UK government may wish to invite the European Commission to review the operation of the Herbal Directive, as many of the herbal medicinal products used by herbal practitioners, in the UK, fall outside its scope.

6. Options for practitioners

The Terms of Reference for the working group required it to:

“With the Department of Health and other relevant bodies consider the extent to which some form of regulation of herbal practitioners may support safe access to unlicensed manufactured herbal products. The group will need to understand the restriction on using statutory regulation as a means of employing the article 5(1) derogation. And clarify the differences between voluntary self-regulation and statutory regulation, in terms of what could be achieved, and what might be the impacts.”

In the context of wider government policy intent as set by the ‘Enabling Excellence’ Command Paper¹⁵ the specific phrase “some form of regulation of herbal practitioners” is very important, as it commits the working group to considering options, rather than just the option of the statutory professional regulation.

This subtlety is important and the reasons for it need to be understood so that the direction of travel makes sense within its wider context. The ‘Enabling Excellence’ Command Paper (at paragraph 4.13) committed the Department of Health to introducing statutory regulation, by the HCPC, for herbal practitioners including Chinese herbal medicine practitioners. This decision was as a result of a number of reports and consultations that identified possible risks to patient safety from herbal practitioners, but critically was also required to ensure that the public had continued access to herbal products manufactured by a third party in light of European legislation.

This work programme commenced with the HCPC working in partnerships with stakeholders to deliver the policy intent. The legal framework for doing this was provided through European Law. However, as this work was developing, the scope of the legal powers was brought into question by a judgement by the European Court on the case of the Commission v Poland¹⁶.

It is worth reflecting on the specific detail of this case as this is important to the understanding of how government policy has and will continue to evolve. The decision to regulate in 2011 was prompted by the government’s intention to allow regulated herbal practitioners lawfully to source third-party manufactured herbal medicines.

However, since April 2011 the European directive has made it illegal for herbal practitioners in the UK to source such products for their patients. Therefore, following on from the Commission v Poland case we have had to reassess the risks and as a result the policy intent, which is now to consider the most appropriate form of regulation, as opposed to just considering the option of statutory regulation. Whilst the Commission v Poland case concerned unlicensed manufactured medicines being used because they were cheaper - and clearly there is a distinction between those products and herbal medicines - we had to look at all the implications of this judgement. The scope of the

¹⁵ ‘Enabling Excellence. Autonomy and Accountability for Healthcare Workers, Social Workers and Social Care Workers’. TSO. February 2011.

¹⁶ See explanation in Ch. 4

case also considered the special regime and critically it emphasised how strictly the regime must be applied. This meant that the proposals for the use of herbal medicines manufactured by a third party without a licence left the UK exposed to the very high risk that it could be infringed by the Commission.

Therefore, in order to provide an informed response the working group has undertaken some consideration of the options for regulation. In simple terms these are: do nothing, introduce statutory regulation or accredited registers. Whilst some members of the working group have previously declared their views on what the response should be and their arguments for it, we would like to thank them for participating in this discussion in an open and frank way. The debate included a session on the benefits and risks from each option and allowed for supplementary written evidence to be provided to support arguments made on the day.

In considering the case for the statutory regulation of herbal practitioners there are a number of key issues to consider:

- How effective is herbal medicine?
- What evidence underpins an evaluation of the case for the statutory regulation of herbal practitioners i.e. what are the risks to patient safety?
- Are herbal practitioners and the infrastructures that support them sufficiently prepared for statutory regulation?

With regard to the first issue, a complete review of the evidence base for the effectiveness of herbal medicine practice was beyond the scope of this review. The working group through discussion and the submission of written information did provide, and reference, papers on the effectiveness of herbal medicine but was unable to identify a consistent, high quality evidence base which might support herbal medicine practice.

There are a small number of studies indicating benefit from herbal medicine in a limited range of conditions. However, the majority of herbal medicine practice is not supported by good quality evidence. A great deal of international, primary research is of poor quality. When this research is examined in high quality systematic reviews, most studies have to be excluded on methodological grounds, with the result that reviews usually produce equivocal results. We reviewed a random sample of over 100 reviews of herbal medicine interventions from the Cochrane Database of Systematic Reviews (Annex C) and in almost all cases the evidence from available research was found to be insufficient to confirm a benefit or was of poor quality. A number of previous studies have highlighted the lack of high quality evidence for the effectiveness of herbal medicine interventions. Herbal medicine practice is therefore currently based upon traditional practice rather than science¹⁷.

¹⁷ R Guo, P H Canter, E Ernst. A systematic review of randomised clinical trials of individualised herbal medicine in any indication. *Postgrad Med J* 2007, 83: 633-637

Ling Wang, Yulin Li, Jing Li, Mingming Zhang, Lin Xu, Wenming Yuan, Gang Wang and Sally Hopewell. Quality of reporting of trial abstracts needs to be improved: using the CONSORT for abstracts to assess the four leading Chinese medical journals of traditional Chinese medicine. *Trials* 2010, 11:75

This means that it is difficult to differentiate good practice from poor practice on the basis of this evidence in a way that could establish standards for statutory regulation.

The second issue is that there is very limited understanding of the risks to patient safety from herbal medicines and herbal practice. A review of safety data was commissioned from HMA as part of this review. This review identified many anecdotal reports and case studies but little systematically collected data. Most herbal medicine products have not been through the rigorous licensing process that is required of conventional pharmaceutical products to establish their safety and efficacy.

Indeed, only a small proportion have even been subject to the less rigorous THR process. Some herbal sector representative bodies have attempted to collect data on adverse reactions to herbal medicines using the Yellow Card system used for conventional drugs, but the number of reports is relatively small and it is not clear whether this is because there are few adverse reactions or whether the low numbers recorded are due to under-reporting.

The anecdotal evidence of risk to patients from herbal products in the HMA review highlighted the prominence of manufactured herbal medicines in the high profile serious incidents which have been reported in recent years. Many of these reports relate to harm thought to be caused by industrially manufactured herbal products which contained either dangerous herbs, the wrong constituents, toxic contaminants or adulterants. All such industrially manufactured products are now unavailable under European regulations, unless their safety is assured through MHRA licensing or THR accreditation and specific dangerous herbs have been banned under UK law.

The third issue is the need to be able to identify common and consistent educational standards for training practitioners and the benchmarking of standards for accrediting practitioners. Without these underpinning standards, statutory regulation will not work as there is no basis for evidence based decisions relevant to admission onto and removal from a statutory register. Therefore, the statutory register will fail in its primary aim of protecting the public.

With no good data on efficacy or safety, it is difficult for practitioners and patients to understand or quantify the potential benefits and risks of a proposed therapeutic intervention. Training programmes could accredit knowledge and skills in some areas including pharmacology and physiology, professional ethics and infection control but without a credible evidence base relating to the safety and effectiveness of herbal medicine it is hard to see how they could form the basis of accreditation in this field of practice.

There are a number of educational university programmes offering courses in herbal medicine, although the number has declined in recent years. Some of these courses are accredited by practitioner organisations which is a potential governance risk as the accreditation may be based on benchmarks established by tradition and custom rather than science.

For the public to be re-assured and for the profession to provide that assurance, independent accreditation of education and training standards is required. Whilst this can be given through

Jinnong Li, Zhenhua Liu, Ruiqi Chen, Dan Hu, Wenjuan Li, Xiajing Li, Xuzheng Chen, Baokang Huang and Lianming Liao. The quality of reports of randomized clinical trials on traditional Chinese medicine treatments: a systematic review of articles indexed in the China National Knowledge Infrastructure database from 2005 to 2012. *BMC Complementary and Alternative Medicine* 2014, 14:362.

statutory regulation, as explained above this has to be informed by a well-developed infrastructure relevant to education and training, which does not yet exist in the herbals sector. Without this there is no consistent basis upon which to regulate and therefore to assure the public that the practitioner and their practice is safe.

Therefore, at present, an evidence-based case for the introduction of statutory regulation for herbal practitioners to provide an appropriate and proportionate response to risks to public safety is not made.

That is not to say there are not risks. The HMAC report identifies examples of actual and potential risks to public safety relevant to the use of herbal products by vulnerable groups as a result of poor herbal practitioner practice such as:

- little sharing of information between herbal practitioners and GPs, for example, resulting in possible under-reporting of adverse incidents;
- some source products being potentially toxic;
- lack of control over actual contents of products;
- herb/medicine interactions; and
- adulteration of products.

However, it should also be recognised that while the HMAC Report identifies potential risks it does not offer a clear evidence-based conclusion on how the sector should be assured to mitigate these risks. The need for an evidence base that identifies a process for assurance is important because current government policy as given in the 'Enabling Excellence' Command Paper (paragraph 4.12) is that "the extension of statutory regulation to currently unregulated professional or occupational groups . . . will only be considered where there is a compelling case on the basis of a public safety risk and where assured voluntary registers are not considered sufficient to manage this risk."

From the discussions of the Working Group, the supplementary evidence submitted, and a general review of relevant literature it is clear that there is not an overall consensus view on the level of assurance that is required and how that is delivered most effectively. A short description of the diversity of views about the potential risk to the public from herbal medicine practice is provided as follows:

Don Mei, Chair of the Chinese Medical Institute and Register (CMIR) in his paper to the working group states that, "I cannot find in the (HMAC) report any mention of fatalities that have been definitely proven to be caused by herbal medicines" and "it is the CMIR's opinion that whilst any adverse event is regrettable, the number and severity of the adverse reactions in the HMAC report represent a very low risk to the public."

Michael McIntyre, chair of the European Herbal and Traditional Medicine Practitioners Association in his paper "The Case for Statutory Regulation of Herbal Practitioners" of 19 March 2014 states that "in the interests of public safety . . . the government should carry

through its commitment . . . to bring herbal medicine practitioners into statutory regulation”.

The final meeting of the working group on 6 November 2014 discussed and considered the options for assuring the public: statutory regulation, accreditation of voluntary registers, or maintenance of the current position. Reference to the reasons given for statutory regulation is enlightening in considering whether statutory regulation provides assurance to the public that is appropriate and proportionate to the risks presented. The group identified the following as reasons for statutory regulation:

- Enables the NHS and other relevant organisations to work in partnership
- Robust process to set standards and gain public confidence
- Enable more research into herbal medicine
- Better public information
- Assurance for public and practitioners
- Provides a means of quality control
- Will help to ensure best practice

Whilst all are valid aspirations for any professional or occupational group and all may be met to a great or lesser extent through statutory regulation, they do not mean that statutory regulation is the best or most appropriate mechanism to achieve these goals.

Since the debate on the regulation of herbal practitioners started, the options available to a profession to assure the public now includes accreditation of voluntary registers (AR) by the Professional Standards Authority for Health and Social Care (PSA). This option was also considered by the working group, which was concerned that as accredited registers were not compulsory they would be less effective than statutory regulation. This was echoed in the written submissions of evidence, such as those from Don Mei, Chair of the Chinese Medical Institute and Register who in his paper to the working group states “we have looked closely at the AR scheme and whilst it does offer some public assurance of the quality of an association and therefore its members, we believe that it will not significantly reduce the small risk posed by herbal medicine”.

This takes us to the heart of the issue for herbal practitioners in respect of statutory regulation. Whilst there is vocal support for regulation, this does not rest on a scientific evidence base which clearly links poor practice to patient risk to the extent that it demonstrates a compelling case for statutory regulation on the basis of a public safety risk and where accredited registers are not considered sufficient to manage this risk.

The PSA’s process for the accreditation of voluntary registers does not provide for the same level of assurance of statutory regulation; that is not its intention. What it does provide is a process where the organisation which holds the register meets the demanding standards set by the PSA including the following areas: governance; setting standards for registrants; education and training; managing

the register. This in turn supports the public, employers and commissioners to make an informed choice, as an individual practitioner on an accredited register will be committed to upholding standards relevant to their behaviour and training.

Other professions with similar characteristics to herbal practitioners such as acupuncturists through the voluntary register held by the British Acupuncture Council; complementary practitioners through the Complementary and Natural Healthcare Council; and homeopaths through the Society of Homeopaths; have submitted their voluntary registers for PSA accreditation. As the accreditation is reviewed annually, the process itself is a driver for rationalising, improving and maintaining higher standards of education, training and behaviour across a group.

Recommendation 5

As a first step it would be helpful for the sector organisations to develop an umbrella voluntary register that could support the development of standards and begin to collaborate on the collection of safety data and the establishment of an academic infrastructure to develop training and research. This voluntary register could in due course seek accreditation from the Professional Standards Authority for Health and Social Care (PSA)

Recommendation 6

In order for an evidence based decision to be made about the level of assurance required to ensure public protection the working group recommends that the government should support further research. This should consider evidence that:

- Clarifies the risks to public health associated with herbal medicine practice;
- Assesses how those risks are currently mitigated and whether further intervention is required;
- If intervention is required, it must provide an evidence base that informs the rationale for the decision on how risk to public protection will be mitigated;
- Looks at the case for assurance of herbal practitioners in the wider context of control of herbal medicines.

7. Overall approach and recommendations

Practitioners

Having taken into account the evidence available and the views of representatives of the sector, I consider that, despite strong calls by many for statutory regulation, there is not yet a credible scientific evidence base to demonstrate risk from both products and practitioners which would support this step. There is also very limited evidence of effectiveness of herbal medicines in improving health outcomes. This makes it difficult to establish the boundaries of good practice which would be required for both educational qualification and for the implementation of statutory regulation.

The herbals sector must recognise that its overall approach (including the rationale for use of products and methods of treatment, education and training, and interaction with the NHS) needs to be more science and evidence based if in order to be established as a profession on the same basis as other groups that are statutorily regulated.

Products

The Herbal Directive (2004/24/EC) has provided a simplified registration scheme for traditional herbal medicinal products suitable for self-medication. However, many of the large scale manufactured herbal medicinal products, used by herbal practitioners in the UK, fall outside the scope of the Herbal Directive. In response many herbal practitioners have called for the scope of the EU directive to be challenged. However, a more proportionate way forward is suggested by the recommendations below, and a reminder to the sector of what is allowed under current legislation (see chapter 4).

Recommendations:

Recommendation 1

The government should consider the feasibility of a systematic review of herbal ingredients, drawing on existing legal frameworks with a view to amending current lists of known potent or toxic herbs, where sufficient safety concerns are raised. Such a scheme could initially be linked to an accredited voluntary register of practitioners under an umbrella arrangement that could seek accreditation from the Professional Standards Authority for Health and Social Care in due course.

Recommendation 2

MHRA, Department of Health and/or other relevant government agencies should review the food lists currently in development and consider whether these could be used to assist the UK's assessment of the status of herbal products.

If appropriate, the feasibility of a UK list, which could assist herbal practitioners' understanding of the regulatory status of the herbal ingredients, could be investigated.

Moving forward a mechanism should be established to allow for regular review.

Recommendation 3

The government should consider further the idea of a system that would allow small scale assembly of products off-site on a named patient basis using a 'dispensary' type approach.

Recommendation 4

In the longer term the UK government may wish to invite the European Commission to review the operation of the Herbal Directive, as many of the herbal medicinal products used by herbal practitioners in the UK fall outside the its scope.

Recommendation 5

As a first step it would be helpful for the sector organisations to develop an umbrella voluntary register that could support the development of standards and begin to collaborate on the collection of safety data and the establishment of an academic infrastructure to develop training and research. This voluntary register could in due course seek accreditation from the Professional Standards Authority for Health and Social Care (PSA).

Recommendation 6

In order for an evidence based decision to be made about the level of assurance required to ensure public protection the government should support further research. This should consider evidence that:

- Clarifies the risks to public health associated with herbal medicine practice;
- Assesses how those risks are currently mitigated and whether further intervention is required;
- If intervention is required, it must provide an evidence base that informs the rationale for the decision on how risk to public protection will be mitigated;
- Looks at the case for assurance of herbal practitioners in the wider context of control of herbal medicines.

Annex A - Working group membership and Review Terms of Reference

1. Terms of Reference

HERBAL MEDICINES AND PRACTITIONERS WORKING GROUP

TERMS OF REFERENCE (FINAL)

In a debate in Parliament on the issue of herbal medicines and practitioners and the government's proposals around regulation, Dan Poulter MP, Parliamentary Under-Secretary of State for Health, announced that an independent Group will be established to look at all options and to advise the government on what steps to take.

The group will be chaired by the Deputy Chief Medical Officer, Professor David Walker. Vice-Chair of the Group will be David Tredinnick MP. A full list of members is annexed.

Secretariat for the group will be provided jointly by the Department of Health and the Medicines and Healthcare products Regulatory Agency.

Remit

The group's remit will include:

- Consideration of Herbal Medicines

Setting out the different categories of herbal products available and the legal and regulatory framework for their supply and use. (For example, herbal medicines with a marketing authorisation, licensed herbals (THR), unlicensed herbals and food supplements)

With MHRA and other relevant bodies, considering the range of products which are affected by the Traditional Herbal Medicine Products Directive, particularly those unlicensed manufactured herbal medicinal products which are not available for practitioners to use, and consider potential solutions.

- Consideration of Herbal Practitioners

With the Department of Health and other relevant bodies, considering the extent to which some form of regulation of herbal practitioners may support safe access to unlicensed manufactured herbal products. The group will need to understand the restriction on using statutory regulation as a means of employing the article 5(1) derogation and to clarify the differences between voluntary self-regulation and statutory regulation, in terms of what could be achieved, and what might be the impacts.

- Other considerations

The work of the Review will consider issues of proportionality, public health, and take into account the differences between the traditions of herbal medicines practice.

The group will refer to, but not duplicate, the work of previous reports and working groups in this area. The Group may from time to time call in additional expert advice as it sees fit.

The group will look at the public health, legal, and other risks in this area. Determine whether there needs to be communications on these issues and what form this should take.

Outputs and Milestones

The group will make recommendations to the government on the way forward. The first meeting will be held in January 2014.

Meetings will be quarterly unless decided otherwise by the Chair.

The group will report with recommendations in 2015 or sooner if it concludes its work before that date.

First meeting – introduction to the issues, discussion of terms of reference, outline of issues by stakeholders.

Other Outputs

- A completed review of the position regarding types of products affected
- A review of impacts on practitioner regulation
- Draft Report completed and shared informally
- Final report published

Reporting

- Dr Dan Poulter has asked to meet three times next year with DCMO and David Tredinnick with an update – these will be timed to follow on from meetings of the working group.

2. Working group members:

Professor David Walker DCMO	Chair
David Tredinnick MP	Vice Chair
Adam Smith	Association of Master Herbalists
Alasdair Mearns	ATCM UK - Scottish Representative
Alison Denham	Herbal Medicines Advisory Committee (HMAC)
Christine Braithwaite	Professional Standards Authority
Don Mei	Chinese Medicine Institute and Register
Dr Harald Gaier /Peter Jackson Main	General Naturopathic Council
Dr Indira Anand	British Association of Accredited Ayurvedic Practitioners.
Dr Huijun Shen	Association of Traditional Chinese Medicine
Dr Lezley-Anne Hanna	Queen's University Belfast
Dr Mike Dixon	NHS Alliance
Dr Richard W Middleton	British Herbal Medicine Association
Emma Farrant	Register of Chinese Herbal Medicine
Helen Darracott	Proprietary Association of Great Britain
Jamie Hayes	All Wales Therapeutics and Toxicology Centre
Kate Hoey MP	MP for Vauxhall
Marc Seale	Health and Care Professions Council
Michael McIntyre	European Herbal & Traditional Medicine Practitioners Association
Penny Viner	Herbal Forum
Prof Phil Routledge	Herbal Medicines Advisory Committee (HMAC)
Professor Bo-Ying Ma	Federation of Traditional Chinese Medicine Practitioners
Professor Derek Stewart	Robert Gordon University
Professor Elizabeth Williamson	Reading University
Professor Monique Simmonds	Kew Innovation Unit
Simon Mills	European Scientific Cooperative on Phytotherapy

Annex B - List of evidence used in the Review

1. Evidence commissioned for the Review

- 2014 - Herbal Medicines Advisory Committee. Safety, regulation and herbal medicines: a review of the evidence

2. Other sources of information referred to

- 2013 - Westminster Hall Debate – Herbal Medicine Regulation. Hansard, 9 July 2013: Column 1WH
- 2011 - Statement by the Secretary of State for Health – Consultation on Acupuncture, Herbal Medicine and Traditional Chinese Medicine, Hansard, 16 February 2011, Column 84WS
- 2008 - Report to Ministers from the Department of Health Steering Group on the Statutory Regulation of Practitioners of Acupuncture, Herbal Medicine, Traditional Chinese
- Medicine and Other Traditional Medicine Systems Practised in the UK (Pittilo Report).
- 2006 - Informal discussion papers on possible reforms of s12(1) of the Medicines Act 1968 and its associated provisions, MHRA,
- 2000 - House of Lords Select Committee on Science and Technology Sixth Report, Complementary and Alternative Medicine, 21 November 2000.

3. Proceedings of the working group

Minutes are attached of the four meetings:

- 30 January 2014;
- 1 May 2014;
- 10 July 2014; and
- 6 November 2014.

4. Proceedings of the 'small group' meetings

Minutes are attached of the four meetings held with practitioners representing:

Ayurvedic Medicine;

Traditional Chinese Medicine;

Trade associations; and
Western Herbalists.

5. Details of visits

Four visits were made to herbal practitioners.

21 November 2014:

- Hydes Clinic, Leicester;
- Ayurvedic Herbal Clinic, Leicester; and
- Ashby Acupuncture Traditional Chinese Medicine Centre, Ashby-de-la-Zouch.

7 August 2014:

- White Crane Healing Centre, London.

Annex C - A random sample of reviews from the Cochrane Database of Systematic Reviews.

Oral herbal therapies for treating osteoarthritis. Melainie Cameron and Sigrun Chrubasik. Online Publication Date: May 2014.

Herbal medicines for treatment of irritable bowel syndrome. Jian Ping Liu, Min Yang, Yunxia Liu, Mao Ling Wei and Sameline Grimsgaard. Online Publication Date: January 2006.

Chinese herbal medicines for treating osteoporosis. Yunxia Liu, Jian Ping Liu and Yun Xia. Online Publication Date: March 2014.

Padma 28 for intermittent claudication. Joanne R Morling, Heather Maxwell and Marlene Stewart. Online Publication Date: July 2013.

Herbal medicines for fatty liver diseases. Zhao Lan Liu, Liang Zhen Xie, Jiang Zhu, George Q Li, Suzanne J Grant and Jian Ping Liu. Online Publication Date: August 2013.

Herbal preparations for uterine fibroids. Jian Ping Liu, Hong Yang, Yun Xia and Francesco Cardini. Online Publication Date: April 2013

Chinese herbal medicines for type 2 diabetes mellitus. Jian Ping Liu, Mei Zhang, Weiya Wang and Sameline Grimsgaard. Online Publication Date: July 2002.

Ayurvedic medicine for schizophrenia. Vishesh Agarwal, Akhil Abhijnhan and Prakesh Raviraj. Online Publication Date: October 2007.

Chinese herbal medicine for chronic neck pain due to cervical degenerative disc disease. Xuejun Cui, Kien Trinh and Yong-Jun Wang. Online Publication Date: January 2010.

Chinese herbal medicines for treating skin and soft-tissue infections. Yun Fei Wang, Hua Fa Que, Yong-Jun Wang and Xue Jun Cui. Online Publication Date: July 2014.

Herbal medicines for viral myocarditis. Zhao Lan Liu , Zhi Jun Liu , Jian Ping Liu and Joey SW Kwong. Online Publication Date: August 2013

Chinese herbal medicine for primary dysmenorrhoea. Xiaoshu Zhu, Michelle Proctor, Alan Bensoussan, Emily Wu and Caroline A Smith. Online Publication Date: April 2008.

Chinese herbal medicines for hypertriglyceridaemia. Zhao Lan Liu, George Q Li, Alan Bensoussan, Hosen Kiat, Kelvin Chan and Jian Ping Liu. Online Publication Date: June 2013.

Chinese herbal medicine for diabetic peripheral neuropathy. Wei Chen, Yin Zhang, Xinxue Li, Guoyan Yang and Jian Ping Liu. Online Publication Date: October 2013.

Topical herbal therapies for treating osteoarthritis. Melainie Cameron and Sigrun Chrubasik. Online Publication Date: May 2013.

Chinese herbal medicines for hypercholesterolemia. Zhao Lan Liu , Jian Ping Liu, Anthony Lin Zhang, Qiong Wu, Yao Ruan, George Lewith and Denise Visconte. Online Publication Date: July 2011.

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