

- **Where and how are the finished products or ingredients sourced?**

From India or Sri Lanka, trade associations screen them. With the loss of products more people are sourcing products from abroad and increasingly people bringing in products from overseas and buying over the internet. Practitioners cannot guarantee the safety of these products, Unregulated source affects quality. Overseas companies (manufacturers) targeting these products at us – using the register to make contact

- **What procedures do you use for making up an individual treatment?**

These are not used in Ayurvedic medicine as a rule

- **Extent to which herbal dispensaries are currently used**

Not used commonly – this would be a good idea. However it will not be a sufficient replacement. The expertise is with the companies, it would be difficult for practitioners, and there would be the costs of running a dispensary. Companies have a long history in making up very complex products and the manufacturing processes themselves are complex and would be difficult to carry out even in a dispensary environment.

Other Ayurvedic products and treatments (e.g., oils) simply cannot be produced in UK – there just not the market. There are around 300,000 practitioners in India – they have dispensaries that they use to mix up manufactured products

- **How would you carry out the same treatments if the products were no longer available?**

Ayurveda only has 2 approved products. The application process and requirements are almost equal to Western medicines; the costs and requirements are difficult for overseas companies to meet. There is a regulation process in India – based on WHO GMP (food rather than pharma)

Increasingly patients are being referred to India for treatment. Risks of travel and no guarantees of safety; potentially a greater risk in sending them to other countries

Given the size of UK market and lack of incentive for companies to invest in the UK market, we should be looking at some sort of special scheme. Without this the market for Ayurveda in the UK could die out.

Products are deemed safe in the right hands, the key risks relate to the practitioners. There are 5 or 6 major companies worth negotiating with.

- **Are there products/ingredients that you have concerns about – what actions can or should be taken in this case**

It depends on dosage and patients – products are safe in right hands and if correctly imported. Mixing with mercury is a specialised practice – few people know how to use this – this could be fatal in wrong hands

- **Would you be able to produce a top hundred plants or combinations used?**

There are too many products to give a simple answer

- **Can any of the products used be considered as foods?**

A lot of our products are foods **and** medicines – the way it is practised, as a nutritional supplement, holistically. Dosage is the main criterion

- **What is the range of conditions?**

Practitioners will treat everything from colds to complications of cancer. Seen as a treatment of last resort quite often, so the complaints are often chronic. Success in skin disorders, holistic treatments in particular, quality of life issues

- **Qualifications/Training**

Middlesex is the only degree outside India/Sri Lanka Many practitioners will have a degree from overseas. Some practitioners in the UK are not properly qualified. The number of properly qualified practitioners overseas runs into the tens of thousands; they are well regulated in India and Sri Lanka. In India all practitioners are registered with Ayush (Indian Government). Courses held in parallel with Indian health departments.

- **Relationships with other providers of healthcare**

We routinely refer to NHS. Depending on the GP, this can be constructive with interested practitioners – some GPs are our are patients!.

Middlesex University course has some crossover with Western medicines, with some new doctors joining the course. Some doctors will refer to Ayurvedic practitioners independently but not within the NHS.

- **What are the key risks associated with current practice, how these will change once manufactured products are no longer permitted**

There are unqualified practitioners and we think it is a grave danger to public

- **What systems for adverse incident reporting are in place**

Practitioner associations run their own Yellow Card scheme; these are mostly about misconduct. Based on EHTPA model. Feedback from the client is reported to association – sent to the Members.

- **Is there any strong evidence of harm or risks?**

There is a reluctance to report. We know of isolated cases (of misconduct).

- **How well informed do you think the general public is about herbal medicines and associated risks.**

More awareness by public of THMPD, so they would be more likely to consider safety. People may go for cheaper. lower quality products. When not making use of practitioners people may take risks – self-medication with products bought over the internet.

- **Statutory v voluntary regulation of practitioners**

We want safety of public and practitioners and question how voluntary registration would stop non-legitimate practitioners? Acupuncture went through PSA route – suggest talking to them about the impacts of this.

Herbal Medicines and Practitioners Regulation Meeting with David Walker DCMO: Traditional Chinese Medicine (3 April)

Attendees:

Herbal Medicines and Practitioners Working Group

David Walker DCMO
David Tredinnick MP
Matthew Williams
Dr Kaicun Zhao ATCM UK
Professor Bo-Ying Ma FTCMP UK
Don Mei CMIR

TCM Sector representatives:

Dr Ming Hua Jia ACMP
Nick Pahl BAcC
Felicity Moir BAcC
Robert White ACMDS
Tony Booker HMAC

MHRA

Andrea Farmer
Julie Bishop

Summary of views expressed at the meeting

- **What is the current situation in respect of your products – types of product used, Tinctures, raw herbs, granules, tableted, % etc.**

A wide range of herbal base products are used; in their simplest forms these are loose raw herbs, powdered herbs, aqueous & ethanol extractions which can be freeze dried and granulated. A majority of practitioners now use concentrated extracts which are made into pill forms (using honey or starch) and tableted forms. These tend to be higher concentrations than raw herbs.

- **What % are made by practitioners and what % would be bought in.**

This varies across the practitioner groups and can depend on where the practitioner trained. UK trained practitioners and acupuncturists are more likely to buy-in rather than make up the remedies themselves. As a broad guide about 50% are manufactured and 50% made up either raw or combined, although in some cases there can be 100% buy-in.

TCM formulas tend to be very complex and can have as many as 18+ ingredients; there are concerns that practitioners will have problems in assembling these products and the possible impact on public health.

- **Where and how are the finished products or ingredients sourced?**

Primarily from China (GMP suppliers) and India – these are tested before import. RCHM operate an approved supplier scheme.

- **What procedures do you use for making up an individual treatment?**

It will depend on practice; some practices (depending on the size) will have their own dispensary on site, and remedies will be made up and dispensed following the consultation. Established TCM clinics would have a majority dispensed immediately. Smaller practices

(tend to be where practitioners trained in the UK) will not have a dispensary so will send a "prescription" to a dispensary which will make up the preparation and send back to the practitioner, who then supplies to the patient.

Different methods of preparation:

- Raw herbs/aqueous compounds – are taken home by the patient and decocted/reconstituted
- Raw herbs which have been dried & powdered (then encapsulated) are ingested by the patient
- Concentrated powders and granules and extracts (aqueous compounds that have been freeze dried etc.) are brought in from manufacture or obtained via a dispensary and these can be further mixed by the practitioner.
- Ethologic extracts (alcohol used in the extraction process) – are more pharmacologically active compounds; and consequently more risk of adverse effects.

However there are a lot of variations of how or extent to which these preparations are used within a practice. In any new regime the process should be defined as much as the product. While there is a tradition of use of raw herbs by practitioners to prepare remedies, this is less common with some of the newer formulations.

While a properly qualified Chinese practitioner should be able to make up prescriptions properly, risks of error increase where the preparation involves measuring small quantities of numerous different ingredients. There is potentially a greater risk where responsibility for making up the preparation is delegated.

There is no agreement between whether manufactured GMP complex products or made up on site products are safer. But individuals stocking herbs increases risk of quality assurance problems

However, the issue of risk is comparative – base risk is perceived to be low

There was a suggestion that we looked at how other countries regulate TCM. The Australian Government for example make an assessment of raw herbs *in situ* compared with our rules of importation .

TCM has modernised traditional practices and tested these. Factory production has improved and in the last 50 years there has been a vast increase in products use – and there is need to factor in patient choice; the western preference is for tableted forms of medication.

The TCM market is mainly domestic – very little appetite to work through EU requirements.

- **Extent to which herbal dispensaries are currently used**

Chinese practitioners have their own in their clinics, UK trained practitioners tend to use TCM companies make up preparations which (for legal reasons) are returned to the practitioner for dispensing to the patient; leading to a consequent delay in the patient obtaining medication. As a principle, legal well-regulated dispensaries would improve safety.

- **How would you carry out the same treatments if the products were no longer available?**

We think between 50-90% of usage falls into the manufactured category. It will cost much more to do individual patient treatments . Members are willing to do something but are finding the law too inflexible. Both sides need to work together to ensure that safety is assured.

Options might be to look at the foods angle, to have a light touch on enforcement, recognising associations for what they are.

One of the issues of reducing access is that we have less access to research. Also there is concern that the public are now using the internet without restrictions (this will increase when products no longer available from practitioners) increasing the risk to public safety.

- **Are there products/ingredients that you have concerns about – what actions can or should be taken in this case ?**

Products are generally very safe – however there are products which could be unsafe if a practitioner is not involved. The use of the internet is a real issue – pharmaceutical adulteration of herbals, herbal Viagra, heavy metals, this all goes on and is well-documented.

However, you could find dangers in any un-adulterated product. There are relatively few problems even in this unregulated environment. No law or banning would solve overdosing and other poor practice.

The mechanism if we wanted to make things even safer would seem to be controlling the practitioner. Possibly not legislation – it has to be commensurate with risk, proportionate and linked to individual products by that means. The associations already have good processes here.

In terms of medicines – the Chinese would be happy to go through EU GMP processes. The mechanism for this would need to be explored.

- **Would you be able to produce a top hundred plants or combinations used?**

There are too many in different combinations to provide a clear list

- **Can any of the products used be considered as foods?**

In China many of the herbs are used in cooking, and culturally there is less of a distinction. In the UK the food supplements regime would be problematic, and would probably restrict usage even further. It is not easy to apply to a different culture.

- **How many people do you treat annually? (How many people in UK)**

TCM has an estimated 1-2 million patients, each doctor has about 1500 appointments a year.

- **Qualifications/Training**

The level of qualifications between associations is consistent – education is regulated by professional bodies. There is a different teaching approach between UK and China, but the commitment equally high – equates to a degree level.

There would be little problem in finding a unified approach to TCM accreditation.

- **Relationships with other providers of healthcare**

At the moment this is purely a private practice, there is a desire to be properly accredited and work within the NHS.

There is overlap with acupuncture, with clinics in hospitals. Any NHS doctor can practise if they choose under cover of their professional liability. A routine approach is to cross-refer and work together with GPs.

- **How well informed do you think the general public is about herbal medicines and associated risks.**

This question was put back to MHRA. It was suggested that the public could be better informed about the risks, and the more accreditation/audit and assurance around the practitioners there was in place, the easier those messages would be.

- **Statutory v voluntary**

There was some division on this issue; but we should acknowledge public intelligence and the level of existing safety. Statutory regulation would protect title and provide a basis for good practice and facility to enforce appropriate sanctions.

How much would statutory regulation improve the safety of the public compared with voluntary ? It would seem less attractive to some without 5(1).

There was concern that it would be difficult to find consensus amongst the traditions if trying to establish a statutory registration scheme. (There was not complete agreement on the need of a single scheme and how this would work.)

- **Group representation (in numbers)**

CMIR has 350 Western medically trained practitioners

- **Final comments**

Members are worried about what is going to happen to the practice of TCM following the end of the sell-through period; if there is no solution on the use of herbal medicines then over time it will severely impact on the industry.

Safety to the public – herbals are not seen as 'safe' in the same way as biomedicines but it is important that we look at the benefits of herbals as well.

Herbal Medicines and Practitioners Regulation Meeting with David Walker DCMO: Trade (16 April 2014)

Attendees:

Herbal Medicines and Practitioners Working Group

David Walker	DCMO
Dick Middleton	Chairman, British Herbal Medicine Association
Helen Darracott	Director of Legal & Regulatory Affairs PAGB
Penny Viner	Chair Herbal Forum & HMFA
Emma Farrant	CEO, Register of Chinese Herbal Medicine

Herbal Trade Representatives:

David Whitely	Ayurvedic Trade Association
Gerard Sullivan	Mayway

MHRA
Andrea Farmer
Julie Bishop

Summary of views expressed at the meeting

- **Safety**

It is not always the case that herbals is a safe profession – we hear of cases of non-association practitioners and malpractice (this tends to be financial).

It was questioned whether GPs have evidence of herbalist malpractice and whether this could this be looked at. Collecting this kind of information has not been common practice.

A majority of issues in relation to herbals are about identification and avoidance of adulteration – the major safety and quality issue. There is a need to tidy up the supply chain.

Quality of the starting ingredients issues include:

- dried herbs – very few companies can analyse what they are getting (this could be done with training).
- Extracts (often from China) – it can be impossible to be certain what is being received

It was suggested that the regulatory authority should check suppliers; this already happens with some of the voluntary associations e.g., RCHM operates an approved supplier scheme. A competent authority doing that would to some extent solve many of the issues around quality.

- **TCM**

Many TCM practitioners have relied upon formulae. Patients are telling practitioners they will be getting products from the internet. It's becoming increasingly difficult for practitioners who can't access prepared medicines

TCM associations have their own Yellow Card complaints systems. They are unable to take action against non-members. There is no obvious route for identifying evidence of complaints. (Over the years evidence would have evidence may have been collected via MHRA, Trading Standards, MPs etc but this has not been collated to our knowledge)

- **Impacts**

Impact on businesses; disproportionate effects of regulation on SMES, but this cannot be avoided. Previous attempts to consider allowing supply by Government were welcomed. These appear to have gone by the board.

- **Herbal 'dispensary'**

Use of herbal dispensaries is common practice within the TCM sector. There was a query of whether this was ever allowed. MHRA confirmed that understanding of the legislation suggests this is not permissible.

It was queried whether the use of dispensaries could form part of an interim solution, with products being made up in this way (mainly TCM) because they are too complex for the practitioners to make up themselves. Many practitioners don't have the resources or competence to make up their own products. It would need clarity on when such products would be considered 'manufactured'.

Herbals is not set up for pharmacy practice in the same way as standard medicine with the regularisation of satellite dispensaries. Some form of audit independently of the associations would be needed; a suggestion that GPhC could do this as it is already set up to inspect pharmacies.

- **Voluntary & Statutory Regulation**

PSA could perhaps oversee a register of standards. However voluntary registration doesn't allow for strong enforcement of compliance. A bigger issue is what we do with people outside the system. Voluntary regulation doesn't allow for that.

Former retail sector issues of quality and safety are now faced by practitioners; this is the overarching issue. We don't see how anything other than statutory regulation would work for patient safety. There is an increasing public demand for herbs/herbalists, to fill gaps in NHS provision of support for chronic illnesses.

Self-regulation has been in place for some time – but there is a necessity of public awareness and some measure of consistency. Compliance – may be achieved by other means – eg CPD.

Most practitioners want to be regulated in some way. It's not just the risk it's beneficial as well. Standards may decline if voluntary is perceived to be replacing long-heralded statutory regulation.

Voluntary regulation would not encourage greater integration with other health care professionals, does not encourage referral or dialogue,

Other health care systems don't work that easily for herbals – we need to think creatively.

Herbal Medicines and Practitioners Regulation Meeting with David Walker DCMO: Western Herbalists (17 April 2014)

Attendees:

Herbal Medicines and Practitioners Working Group

David Walker	DCMO
Alison Denham	HMAC
Michael McIntyre	EHTPA
Mr Peter Jackson-Main	Association of Master Herbalists

Western Herbalist Representatives:

Robert Scott	IRCH
Helen Gardiner	Unified Register of Herbal Practitioners
Laura Stannard	National Institute of Medical Herbalists
Karin Mont	Alliance of Registered Homeopaths (ARH)

MHRA

Andrea Farmer
Julie Bishop

Summary of views expressed at the meeting

- **How herbalists work in this tradition.**

Working with individualised products made up from ingredients sourced both from British companies and outside of the UK; sometimes they will use herbs they grow themselves. (Growing your own herbs can also be problematic there are issues of space and climate in UK.) They will also use a range of finished products; a busy practice or lack of dispensary will lead to a need to buy in products and know they are of good quality.

- **What is the current situation in respect of your products – types of product used, Tinctures, raw herbs, granules, tableted, % etc.**

We buy from licensed and unlicensed manufacturers, small companies, and use fresh products. We could make the same prescription in different ways – but it's normally on an individual basis.

- **What % are made by the practitioner and what % would be brought in.**

There are a number of finished products – it is hard to say between practitioners – perhaps more buying in from newer practitioners, those working on a totally traditional basis do not buy finished products, they will build from scratch

- **Where and how are the finished products or ingredients sourced?**

There is a long standing issue of finished products falling away – we are able to obtain fewer products because of the regulatory situation. Some old products – PLR – have been registered as THRs by MHRA

There are some high quality finished products – there is much use of Australian products. The long-term regulation of products in Australia has led to greater use. 20% of Australian business – one company – has reduced because of the regulation position here.

There are complex therapeutic products – however the market drives the use of finished products.

- **What procedures do you use for making up an individual treatment?**

A consultation that looks at medical history, including diet and wellbeing. An example of a prescription was given – we would choose herbs based on symptoms, traditional as well as modern understanding of uses – with a very long tradition of use. Prescriptions will vary but include digestive systems, circulatory systems - overall we prescribe for the individual.

- **Extent to which herbal dispensaries are currently used**

There is limited use; practitioners had understood that the use of dispensaries was allowed under section 12(2) of the 1968 Medicines Act, with revocation of 12(2) this option removed. [MHRA clarified that this had not been the case in the first instance].

Would it be possible to set up a small group to agree the basic standards of herbals products, approved suppliers and so on? . A kind of intermediate tier before GMP– relating to starting material.

- **How would you carry out the same treatments if the products were no longer available?**

There are things that have to be put in place but it would be possible to support SMEs. There must always be some standards however small. Small suppliers are preferred as they are started and run by herbalists – a grass roots element to the profession.

- **Are there products/ingredients that you have concerns about – what actions can or should be taken in this case ?**

There was mention of Aristolochia but it was felt that the issue is usually one of poor practice. Neither a regulated nor unregulated herbalist can avoid the issues of falsification or adulteration.

- **Qualifications/Training**

NIMH involved in the development of degree courses, had set up a degree (now closed) – but courses already exist for all practitioners. There is a majority acceptance of a set of standards across all disciplines. Delay in progress in SR has resulted in a falling away of courses.

There is a long tradition of university level courses. There is now intellectual capital in the UK and this needs recognition; countries outside UK are looking at how we have developed courses.

- **Relationships with other providers of healthcare**

This depends on the individual relationships, but there are some good linkages. Not direct referrals in a formal sense. Statutory regulation would allow better integration.

Referrals for e.g., cholesterol, depression, anxiety, assisting with diabetic complications, digestive problems, auto-immune diseases where a simple conventional solution is not available. Supportive treatments

- **What are the key risks associated with current practice, how these will change once manufactured products are no longer permitted**

More access in the EU and wider means that average person outside the UK is more knowledgeable about herbals and how they work.

If products are restricted, irrespective of the regulation of the practitioner, that will eventually impact on the practice. There is a growing black market; already receiving emails from companies trying to sell products that will be illegal after April.

There are problems with codes of ethics and complaints as these only apply to members of organisations. If people are not registered the practitioner organisation does not have any power/jurisdiction over what they do. They do not as a rule log complaints about non-members. The key concern is with those outside of any voluntary organisation.

IRCH – have regulatory proceedings – members can be thrown out. In IRCH's view practitioner regulation is not the only solution.

The WHO position is that traditional medicines have a key role to play in the provision of healthcare – THMPD and the way regulations are set up do not have this as the main objective.

- **How well informed do you think the general public is about herbal medicines and associated risks.**

The public find the issues very complicated, but they want to continue to use herbal medicines.

- **Statutory v voluntary**

Ultimately SR is about public protection. We need the control of statutory regulation, it's about practice and activity (internal medicine). A question as to how you could deal with poor practitioners otherwise. If a group of people are on a statutory register you can insist they source their materials properly.

(There was not universal agreement to the need for statutory regulation, but agreement on minimum standards for compliance).

Concern that if VR was an interim stage it might be seen as an end in itself. However this must be balanced against risk that the market will go underground. There seems to be a suggestion of muddling through.