

HERBAL MEDICINES AND PRACTITIONERS WORKING GROUP

MINUTES OF FIRST MEETING, 30 JANUARY 2014

Attendees:

Professor David Walker (Chair)
David Tredinnick MP (Vice Chair)
Adam Smith
Alasdair Mearns (by phone)
Alison Denham
Don Mei
Dr Harald Gaier
Dr Indira Anand
Dr Huijun Shen
Dr Lezley-Anne Hanna
Dr Mike Dixon,
Dr Richard W Middleton
Emma Farrant
Jamie Hayes,
Kate Hoey MP
Marc Seale
Michael McIntyre
Penny Viner

Professor Phil Routledge
Professor Bo-Ying Ma
Professor Elizabeth Williamson
Matthew Speers
Simon Mills

Apologies:

Professor Derek Stewart
Professor Monique Simmonds

Officials:

Jonathan Mogford MHRA
Mark Wilson DH Legal Services
David Carter MHRA
Linda Anderson MHRA
Julie Bishop MHRA
Andrea Farmer MHRA
Scott McClelland MHRA

1. Introduction (Chair)

- a. The Chair welcomed everyone to the Working Group (WG) and acknowledged not only the considerable array of expertise around the table but also the frustration that this issue had not yet been resolved.
- b. The Chair reassured the members of the WG that no final government decision had been made on the statutory regulation of practitioners and emphasised that all options remained open.
- c. The Chair recognised the issues of the Members of the WG with regards to the Terms of Reference (ToR) and the timings associated with these. The Chair stated that the timescales for the review had already been condensed but it would take as long as it needed to take in order to find a solution to the problems. The Chair asked for all members to work together to achieve a consensus and highlighted his desire for this to be the final review conducted on this issue.
- d. The Chair expressed his thanks for the openness and clarity of views already expressed both in correspondence and at the opening of the meeting.

2. Presentation: Scene setting - background to date

- a. Julie Bishop (MHRA) gave a presentation to set out the historic background to the issue. The presentation is attached.

3. Presentation: Government position – with Q and A

- a. Mark Wilson (DH Legal Services) gave a presentation setting out relevant provisions of the Medicines Directive (Directive 2001/83/EC) and caselaw of the Court of Justice of the EU, to help understanding of the legal landscape.

- b. Mark highlighted two key concepts and emphasised that these concepts should be kept separate:
- EU law is relevant but it has very little to say about the regulation of Health Care Professionals (HCP);
 - EU law has a lot to say about placing manufactured medicines onto the market
- c. Mark explained that the aim of the Medicines Directive was to harmonise rules about the placing of medicines on the market to facilitate free movement resulting in better competition.
- d. Mark referred to the article 5(1) derogation and to relevant case law, including the case of EU Commission v. Poland. Although the Poland case does not concern herbal medicines, the judgment dealt with the derogation in general terms and placed strong emphasis on the derogation being available only in exceptional circumstances. Mark also explained that DH and MHRA officials had met with officials at the EU Commission to discuss the use of the 5(1) derogation as described in Andrew Lansley's announcement in Feb 2011. The Commission's clearly expressed view was that the use of the derogation under such circumstances would be a direct contravention of the Directive.
- e. The presentation is attached.
- f. The presentation was followed by a question and answer session; the main points discussed were:
- The Directive relates to industrially manufactured products – some Members called for a clear definition of what constitutes 'industrially manufactured' to help identify those products/practices that fall within the Directive and those that do not;
 - Only products that are intended to be 'placed on the market' require a Marketing Authorisation or Traditional Herbal Registration. Some Members again called for a clear definition of what is considered to be placing a product on the market is required;
 - The previous reviews and reports recommended the regulation of practitioners on a public safety ground, not for the purposes of the use of the article 5(1) derogation;
 - The policy has never been about preventing individuals who make their own products on a one-to-one basis, it is about preventing the placing of industrially manufactured and unlicensed products on the market;
 - There was a consensus to split the work-streams into two; the first being the statutory regulation of practitioners and the second understanding the issues raised in respect of the article 5(1) derogation;
 - Some members said that with the end of the sell-through period approaching quickly (30th April 2014) the first priority was to allow continued access to manufactured products thus possibly preventing the collapse of a number of small businesses that do not make up their own products;
 - There was an overwhelming consensus that allowing the provision of self-made products on a one-to-one basis by a practitioner without regulating that practitioner would undoubtedly lead to significant public health risks;
 - Marc Seale, CEO, Health and Care Professions Council, outlined the process for obtaining statutory regulation as follows: it requires legislation, in the form of a Section 60 (Health Act 1999) Order and this takes approximately 2-3 years; a title that is protected by criminal law; standards of ethics, conduct and proficiency; a register to transfer; and a grandparenting provision;

- Marc Seale stated that it was a well-tested process and had happened for similar other groups. However, this work does not begin without legislation and he also pointed out that the regulation of new professions was a devolved issue.

4. Group Discussions led by Chair and Vice-chair: Terms of Reference

Feedback from Practitioner Group:

- Make clear that there are no EU constraints concerning practitioner regulation as opposed to medicines;
- Consideration should be given to the recommendations and advice of previous reports;
- Disaggregate the issue of practitioner regulation from medicines regulation;
- Make clear to the government the public health issues about not regulating practitioners – these are not drawn out in the ToR;
- Make the distinctions clear between what would be provided under statutory versus voluntary regulation;
- Communications, especially to the public, need to be included in the ToR.

Products Group:

- Disagree with the terms of reference as they currently stand. Much of what is set out in the TOR is already in place and the responsibility of the MHRA.
- We should be looking at the scope of what practitioners can do. Setting out definitions about things such as specials and bulk products.
- The most urgent consideration is that companies are going out of business. We need to find a way to ensure that the widest ranges of products are available for practitioners

5. Actions arising, further meetings and organisation of proceedings (All actions by Secretariat unless stated)

- In summing up the Chair acknowledged that there was a lot of support for rapid statutory regulation of practitioners. There were significant concerns for public health from unqualified practitioners. There was anxiety from small businesses as the end of the transitional period for the Herbal Directive (sell through) approaches.
- The Chair recognised that both elements (practitioners and products) were urgent, consideration needs to be given to all of the issues and evidence is required that demonstrates the risk to public health.
- The Chair then outlined what would happen going forward:
 - **Action** Minutes and redrafted Terms of Reference, based on discussions today, to be sent to the WG;
 - **Action** Work to be prioritised and advice commissioned for the next meeting – likely to include safety aspects, products work, and clarity of the legal position from 1 May 2014;
- The Chair acknowledged the vast array of expertise within the WG and welcomed the submission of documents from WG members to the officials. He also asked authors to state whether they were happy to share documents with the entire WG or not.
 - **Action:** Documents should be submitted to Julie.Bishop@mhra.gsi.gov.uk

- e. The Chair stated that a Yammer group was being set up to allow the sharing of documents; with the presentations from the day being uploaded to this group. The Chair asked the WG members not to share official documents with the public unless the documents have been completed and permission granted by the officials. Members are reminded that this is a closed group and unless informed otherwise the content is solely for the eyes of the WG members.

- **Action:** An invitation to join the Yammer Group will be issued shortly;

- f. The next two meeting dates will be advised shortly with further information to be provided closer to the time.

6. AOB and Close.

- a. Several requests were received for a . Some Members made specific requests for dates of the next meeting. The Chair highlighted the difficulty of aligning such a large group of people's calendars and as such could not agree to hold meetings on a particular day.
- b. Some Members asked for for the WG to produce a discussion paper on the public safety aspects prior to the next meeting. (See item 6)
- c. It was asked whether the WG should consider how to handle the fall-out from the end of the sell through period. However, it was stated by the Chair that this did not fall within the remit of the group.
- d. Members again highlighted the common desire to amend the timetable and have the review concluded much sooner. The Chair reiterated that the review will take as long as it takes and that he was determined to make this the last review conducted on the subject.
- e. The Chair thanked everyone for their attendance and closed the meeting.

MHRA, 13 February 2014.

HERBAL MEDICINES AND PRACTITIONERS WORKING GROUP

MINUTES OF SECOND MEETING, 1 MAY 2014

Attendees:

Professor David Walker (Chair)
David Tredinnick MP (Vice Chair)
Adam Smith
Alison Denham
Don Mei
Dr Indira Anand
Dr Huijun Shen
Dr Lezley-Anne Hanna
Dr Mike Dixon,
Dr Richard W Middleton
Emma Farrant
Jamie Hayes,
Marc Seale
Michael McIntyre
Penny Viner
Professor Phil Routledge
Professor Bo-Ying Ma
Professor Derek Stewart
Professor Elizabeth Williamson
Simon Mills

Apologies:

Dr Harald Gaier

Officials:

Jonathan Mogford MHRA
Chris Jones MHRA
Linda Anderson MHRA
Julie Bishop MHRA
Andrea Farmer MHRA
Judith Thompson MHRA
Joseph Smith DH
Matthew Williams

1. Introduction (Chair)

- a. The Chair welcomed everyone to the Working Group (WG) and gave a brief update on progress made since the last meeting.
- b. The Chair explained that minor updates have been made to the terms of reference.
- c. The Chair said that he has had a number of meetings with small groups representing the different traditions in the sector, in order to understand their concerns and elicit ideas on a possible way forward. In addition there have been a number of communications from members of the WG regarding use of article 5(1). These were being progressed with MHRA. Any output from these discussions that may be important to the work of the WG would be made available.
- d. The Chair mentioned that he is happy to meet with members of the WG who have not attended the small group meetings, either individually or in small groups. In addition

the Chair said that he plans to make a visit to some practitioners to gain a greater understanding of the practitioner's role.

2. **Minutes of the last meeting and matters arising**

- a. The minutes of the meeting held on 30 January were agreed. It was suggested that references to the Directive and herbal products in the TOR are made clearer, spelling out the full title of the Traditional Herbal Medicines Directive (2004/24/EC) and definition of a herbal product. The Terms of reference were agreed subject to these minor textual amendments.

3. **Medicines Regulation – the current landscape**

- a. MHRA gave a presentation setting out the regulatory landscape, looking at how herbal products and food supplements are regulated. MHRA explained the criteria that apply to determine whether a product is deemed as a medicine or a food supplement. All manufactured herbal medicines require either a marketing authorisation or a traditional herbal registration (THR).
- b. The presentation was attached with the meeting papers.
- c. The presentation was followed by a question and answer session; the main points discussed were:
 - The main purpose of the regulations is to protect public health;
 - Clarification was provided on the definition of a food. It was explained that any food or food ingredient that does not have a history of food use is regulated as a novel food. A 'novel food' is defined as a food that does not have a significant history of consumption within the European Union (EU) prior to 15 May 1997. All novel foods must undergo a safety assessment and be authorised before they can be placed on the market in the EU. Evidence of significant food use would usually have to be demonstrated for an isolate, extract or concentrate of an existing (i.e. not novel) food. If evidence of use prior to 15 May 1997 can be demonstrated then it is the responsibility of the competent authority in the member state where the food was marketed to determine whether it was 'significant' use.'

4. **Feedback from small groups on medicines issues**

- a. MHRA gave a short overview of the aims of the meetings and main points raised.
 - It was clear that there is a wide range of manufactured products used and reliance on manufactured products varies across the sector; in the TCM sector it is estimated to be anything from between 50-100%. There was a request for clarity on what was considered to be an ingredient. The notes of the small group meetings are attached for further background. In addition to MHRA's summary, representatives from each Group made further points: There had been discussion about the options to make use of herbal dispensaries;
 - Statutory Regulation (SR) was seen as essential by some but not all participants in order to safeguard public health and ensure quality of practitioners

Feedback from TCM Group:

- It was thought that new practitioners are more reliant on manufactured medicines;
- Modernisation of Chinese medicine has led to a reliance on manufactured medicines;
- There had been consensus that practitioners need to demonstrate a certain level of education in order to practice;
- There had been a lot of discussion on whether SR is essential;

- Possible extension of the sell through period was raised;
- Some participants had identified key risks in the quality of practitioner and ingredients.

Trade Group:

- There has been a degree of consensus in the meeting that there would always be a difficulty with VR and its effectiveness in dealing with issues around low standards and quality;
- Work is required on authentication of starting materials and quality standards;
- There is a need to establish and build in checks on materials and ingredients into the supply chain

Western Medicines Group:

- In this Group, more practitioners reported that they continued to make up their own preparations;
- There was a similar discussion about the relative merits of SR and VR as in other Groups.

Ayurvedic practitioners Group

- At present there is no recognised form of herbal dispensary;
- Authorised suppliers and practitioners could have access to herbal dispensaries rather than imported products.

b. A copy of the presentation is attached.

c. The presentation was followed by a discussion; amongst the points discussed were:

- Whether only registered practitioners should be able to prepare and supply a herbal remedy;
- Whether registered practitioners should abide by a code of conduct
- Whether statutory registration would enable those not abiding by acceptable standards to be excluded from practice;
- If practitioners are not regulated could they be excluded from using certain potent ingredients;
- Whether registered herbal dispensaries, with independent controls and audit trail, would provide appropriate assurance to practitioners and the public;
- The opportunity of looking at the parallel with supply of unlicensed homoeopathic products i.e. manufacturers with registered pharmacists on the premises;
- Is there the capacity to provide a dispensary service and assure quality of products and sources of ingredients;
- Does the current regulatory framework permit the use of a dispensary service if the dispensary would not be placing anything on the market;
- Where assurance of starting materials could be obtained, these would require testing at manufacturing facility where the materials are coming from and introduce quality control throughout the supply chain;
- Whether practitioners should retain the ability to source and mix ingredients;
- The option to look at using the current specials legislation (article 5(1)) which would allow practitioners to hold stocks of some of the more popular remedies;
- Whether the services of dispensaries would only be open to those herbalists that are on the statutory register.

5. Medicines Regulation – Discussion by the wider group

a. The Chair mentioned that a scheme already exists for supplying manufactured products (THR) and questioned whether this should be the route through which

manufactured products are made available to practitioners. The consensus was that this scheme has a few limitations. The following points were raised:

- The cost of registering a product may be disproportionate if quantities are small;
 - THR products are only available for minor self-medicated conditions;
 - There is often difficulty in meeting the requirement that the product has been in traditional use in the EU for 15 years
 - The scheme is not viable for traditional herbal medications which have been traditionally used in combinations. This would exclude a lot of the Ayurvedic practice.
- b. The Chair raised the food supplement route .The number of herbal ingredients on the EU positive list is increasing and concerns were raised that certain herbal products were on the market in other member states (notably the Netherlands) as food supplements.. It was agreed that the regulation of foods in the EU and the option of classifying herbal products used by herbalists as food supplements should be further discussed at the next meeting.

6. **Practitioner Regulation – the current landscape**

- a. HCPC explained what SR would entail and outlined the steps needed to get a statutory scheme implemented. HCPC currently regulate 16 professions across the sector. Regulation covers England, Scotland, Wales and Northern Ireland. Mark stressed that if there is consensus across the profession it would take several years to get a scheme up and running. Mark said that Australia already registration scheme in place for herbal practitioners. It would be crucial for the sector to work together in order to achieve SR.
- b. A copy of the handout is attached.
- c. PSA was unavailable to attend the meeting to give an overview of voluntary accreditation. This will be carried forward to the next meeting.

7. **Chairman's summing up and actions**

- a. The Chair then outlined what would happen going forward:
- Action Minutes and redrafted Terms of Reference, based on discussions today, to be sent to the WG within 2 weeks of the meeting; (MHRA)
 - Action Chair to hold a number of small group meetings. Email requesting participation to be sent to Judith.m.thompson@mhra.gsi.gov.uk
 - Next meeting to focus on public health, practitioner regulations and VR of practitioners;
 - Work to be prioritised and advice commissioned for future meetings – likely to include the legal advice on use of herbal dispensaries, safety issues, food regulations and how food law is used in other European countries to regulate herbal (non medicinal) products.
- b. The Chair suggested that the WG make use of Yammer between meetings or or email Julie Bishop MHRA with any evidence or communications.
- Action: Documents should be submitted to Julie.Bishop@mhra.gsi.gov.uk
- d. The next meeting will be held on 10th July. Further information to be provided closer to the time.
- e. The Chair thanked everyone for their attendance and closed the meeting.

MHRA, October 2014

HERBAL MEDICINES AND PRACTITIONERS WORKING GROUP

MINUTES OF THIRD MEETING, 10 July 2014

Attendees:

Professor David Walker (Chair)
David Tredinnick MP (Vice Chair)
Adam Smith
Alison Denham
Don Mei
Dr Indira Anand
Dr Huijun Shen
Dr Lezley-Anne Hanna
Dr Mike Dixon
Dr Richard W Middleton
Emma Farrant
Marc Seale
Michael McIntyre
Penny Viner
Professor Bo-Ying Ma
Professor Elizabeth Williamson
Simon Mills
Helen Darracott
Peter Jackson-Main
Christine Braithwaite

Apologies:

Officials:

Chris Jones MHRA
Linda Anderson MHRA
Julie Bishop MHRA
Andrea Farmer MHRA
Judith Thompson MHRA
Matthew Williams
David Carter MHRA
Trudy Netherwood DH
David Gray FSA

1. **Introduction (Chair)**
 - a. The Chair welcomed everyone to the Working Group (WG) and highlighted the two key topics that would be covered in the meeting; food regulation and voluntary registration.

2. **Minutes of the last meeting and matters arising**
 - a. There were a number of suggested amendments to the minutes of the May meeting, which had been posted on Yammer. In addition it was suggested that para 6 should include HCPC's comment that voluntary regulation would not protect the public.
 - b. It was agreed that MHRA would issue the draft minutes to the WG for agreement in advance of the next meeting.
 - c. The minutes from the last meeting would be revisited in light of comments and circulated to the group for agreement.

3. **Chair's Update**

- a. Since the last meeting the Chair has met with the Chair of HMAc. HMAc has offered to provide an up to date review of safety issues associated with herbal medicine. The Chair also met with some members of the WG at their request to discuss future access to Schedule 20 herbs, education standards and quality assurance. A number of visits have also been planned to herbalists. The Chair reiterated that he is happy to meet with anyone from the WG should they have matters they wish to discuss with him.
- b. The Chair updated the WG on dispensary arrangements. Work with lawyers and officials is ongoing and it is expected that it will become clearer whether this is a workable option as a result.

4. **Food Law Presentation**

- a. MHRA, FSA and DH gave an overview of food legislation with particular reference to food supplements and the borderline with medicines legislation.
- b. MHRA gave a presentation on how a medicinal product is defined and explained the process the MHRA's Borderline Section follows to determine whether a product is classified as a medicine. MHRA also pointed to differences in the regulation of foods and medicines – highlighting that foods must not be injurious to health and, unlike medicines there is no measure of risk/benefit afforded to foods. Food law does not permit any food to make any claim to treat, prevent or cure an adverse medical condition and it would not be possible to restrict use of food supplements solely to practitioners
- c. A copy of the presentation is attached.
- d. DH gave a presentation on the regulation of food supplements. DH explained that food supplements are regulated under Food Supplements Regulations and Food Labelling Regulations. Food supplements also need to comply with other food legislation such as the Nutrition and Health Claims Regulations and Novel Food Regulations.
- e. The Food Supplements Directive lists vitamins and minerals, and forms which are permitted for use in food supplements. The legislation provides for the possibility that, in the future, certain other substances, such as 'botanicals', that have a physiological or nutritional effect on the body could be included on a list. The Commission has considered this and reported to the Council and European Parliament that other legislation is sufficient to regulate the area.
- f. The Nutrition and Health Claims Regulations looks at claims for individual ingredients or the product as a whole. More than 2000 health claims applications have been submitted for assessment. So far more than 500 have been given a negative opinion. Some EU member states and other interested parties have raised concerns about whether it was appropriate to subject botanicals to the same type of assessment as other substances in foods. They drew attention to the 'simplified traditional use registration' scheme introduced by Directive 2004/24/EC on Traditional Herbal Medicinal Products (THMPs) under which the normal requirement for medicines to have proven efficacy, as required under Directive 2001/83/EC, is replaced by a requirement to demonstrate 30 years traditional use for the required indication. The process for botanicals assessment has been put on hold pending further consideration. It is possible that legislation may be developed for a traditional use approach for health claims on botanicals in food supplements; however there is no indication that this will be taken forward in the short term..
- g. FSA gave a brief overview of food law. Food business operators that are supplying food on a regular basis are required to register with the local authority and comply

with all relevant aspects of food law, including hygiene legislation (e.g. use of a HACCP plan). Premises are inspected on a regular basis which is determined on the basis of risk. The underpinning principle of all food law is that products are safe for consumption (not injurious to health) and are not misleadingly labelled.

- h. A discussion on the presentations followed. Main points are summarised here:
- i. The Chair asked whether the DH' 5 a day' message was classed as prevention. DH explained that the 5 a day message is a Government healthy eating message and is not considered to be a health claim as Government messages are out of the scope of the health claims legislation. The health claims legislation is applicable to commercial communications.
- j. A question was asked about the level of risk acceptable for botanicals. DH explained that there is no central pre authorisation process for any food supplement, therefore a risk benefit is not carried out by authorities prior to placing the product on the market. Enforcement is carried out by Local Authorities that will inspect food business. If a risk is acknowledged enforcement action could apply. Risk is considered however as part of the authorisation process for novel foods and has been considered where higher doses of vitamins and minerals are being advocated or where there is emerging information of a risk. Health claims can only be made if a certain level of vitamins and minerals are contained in the supplement. DH would take into account how much someone would need to consume for any benefit but this must remain within the safe limits.
- k. A question was raised about allergenicity issues relating to food supplements and it was pointed out that a number of allergens are required to be clearly identified on the packaging of all foods, including food supplements. Allergenicity is a recognised issue in medicinal products and allergy warnings are included on the DH said that as botanicals develop this issue will be taken into account and known food allergies would require labelling. Certain components in Echinacea in particular are known to have allergenic properties.
- l. MHRA explained that there are a number of European Court of Justice Judgements that influence the borderline between food supplements and medicines and that dosage is one aspect that needs to be considered. MHRA also explained that they consider each borderline product on a case by case basis and as the legal position is that the onus is on the regulator to prove that the product is medicinal- it is not possible to say that a particular herb is always medicinal. The Borderline Section would also look at whether a particular dosage is considered medicinal.
- m. A number of EU Member States (MS) have lists of herbs that can be used in foods. DH said that there has been some discussion about an EU harmonised list but this has met with difficulty due to differences in the interpretation of the medicines borderline across the EU. Members States can have their own lists but these would not necessarily be acceptable to all EU MS. MHRA indicated that it was unlikely that the definition of a food supplement or herbal medicine would be modified as this would need to be done by amending the definitions which are set out in the relevant EU Directives which is in legislation. It was queried whether such a lack of harmonisation was not in the interest of consumers.
- n. comment was made that that whilst there is a place in the market for both herbal medicines and food supplements the quality of certain products needs to be addressed. DH confirmed that if European wide legislation for botanicals goes ahead quality may be taken into account.
- o. It was mentioned that France has recently adopted 60% of the 'Belfrit list' of 1000+ safe herbs and the Group was asked whether this could form the basis of a harmonised list. DH explained that there are a number of herbs on the Belfrit list

which the UK would consider to be medicinal. The MHRA pointed out that the Belfrit list has currently only been adopted by 3 member states and should not be regarded to be a harmonised list. DH confirmed that the UK has discussed the possibility of an EU harmonised process with Member States in the context of health claims legislation, but the nature of any legislation is not clear and this would need ministerial approval. The MHRA has produced a list of herbs which details their known medicinal, cosmetic or food uses for information purposes only. It was agreed that officials would look further into the background to these points.

Action MHRA/DH

- p. Unlike the herbal products which are administered by practitioners, products which are approved under the THR scheme are intended for self-medication and as such MHRA would not expect herbalists to prescribe them.

Aspects of Voluntary Accreditation

- a. PSA gave a presentation on the accredited voluntary registration scheme which was established by the 2011 Enabling Excellence White Paper. The presentation is attached. The scheme offers enhanced consumer protection. The Health and Social Care Act 2012 gave responsibility to the PSA to oversee practitioners and develop standards. The accredited voluntary registration scheme was launched over a year ago and currently has 13 organisations on the register covering a range of professions. Accreditation is reviewed annually.
- b. Practitioners in a voluntary accredited profession can practice without voluntary registration. Being struck off the register is not a bar to continuing to practice in itself. All registers set education standards, standards for practice, governance for organisations and complaints procedures. PSA requires annual accreditation of voluntary registers. However education standards are not uniform across the different registers. The general aim is to improve and raise standards
- c. This is now an established scheme which oversees 9 health organisations/bodies in the UK. It will take some time to build awareness. It is self-financing, operating on a not for profit basis. It is possible that there could be multiple voluntary registers for occupations. The scheme only covers those within it and the onus is on the public to choose those on the accredited list. It is however a requirement of the scheme for practitioners to have indemnity insurance.
- d. The HCPC made the following points in response to the PSA presentation outlining the differences between the two schemes:
 - i) Government will extend statutory regulation where there is a need to do so.
 - ii) Different approaches are being taken by the different devolved administrations.
 - iii) There is no protection of title under the voluntary system which it was said will result in confusion for the public.
 - iv) There are no powers to run tribunals or requirements to respond to complaints
 - v) A Law Commission Review over the last 3 years has recommended removal from regulators of powers to have voluntary registers
 - vi) Statutory regulated bodies have control over standards and delivery of courses at Universities
- e. The PSA concluded by suggesting that the WG think about the risk herbal medicines pose and the level of public protection needed. PSA are aware of the potential for confusion but pointed out that the public may believe that all health and social care professions are already regulated. A discussion followed. It was suggested that the public's needs for safe and convenient access to herbal medicines requires

practitioners to be suitably qualified and regulated in order to prescribe herbal medicines. Members raised the issue that voluntary professions cannot insist on their members undergoing CRB checks.

- f. It was suggested that as the voluntary accreditation process takes a minimum of 2 months it could possibly be an interim option. HCPC has estimated that it will take between 9 months and 2 years from the time that the legislation enabling SR comes into effect, and that it will not begin the process until that legislation is in place. A more realistic timeframe from the WG discussions is 18 months to 3 or more years.
- g. It was added that the accredited voluntary registration scheme has only been in operation for 2 years. There will be a review and report into its effectiveness shortly. Measuring effectiveness of outcome will be longer term.
- h. Some members added that evidence should be key to the discussions and whether there was evidence that the current system was putting people at risk. Given the diverse nature of the profession it would be difficult to set common standards. PSA said that the assured voluntary accreditation is mid-way between statutory regulation and voluntary registration and can accommodate the differences within the profession whilst meeting core standards. HCPC however said that statutory regulation creates standards that are owned by the profession. HCPC has set up registers for 16 different professions.

5. **Chairman's summing up and next steps**

- a. The Chair summed up the issues that the WG have considered:
 - Review of Government position and legal difficulties
 - Medicines regulation issues/classification of food supplements
 - Issues surrounding statutory and voluntary regulation
 - Meetings with small groups involved in herbal medicines
 - Series of visits to individual practitioners
 - Offer remains open from Chair to hold a number of small group meetings. Email requesting participation to be sent to Judith.m.thompson@mhra.gsi.gov.uk
- b. The Chair outlined the next steps:
 - Over the summer officials aim to pull together themes and consider legal advice
 - Put together evidence into a series of feasible proposals
 - Aim for this to be completed and circulated before the next meeting
 - Start to write the final report in the autumn with a view to agreement before Christmas
- c. The next meeting will be held in the Autumn. Further information to be provided nearer the time.
- d. The Chair thanked everyone for their attendance and closed the meeting.

MHRA, July 2014.

ANNEX:

1) Additional comments on points raised at the 10 July meeting

4f - It would be more informative for the WG members for the minutes to state that a total of 250 health claims have been authorised, relating to around 80 foods and food ingredients.

4f - The point is that, unless something is changed with how botanicals are assessed under the NHCR, they will be subject to more stringent assessment under the NHCR than under the THMPD. Because EFSA requires proof of a cause-and-effect relationship between the food or ingredient and the claimed health effect, the result of maintaining the status quo will be to end up with a tiny number of health claims for botanical ingredients – the most important component of the human diet. One option being considered by the Commission is to allow use of health claims based on traditional usage of botanical ingredients. This would better harmonise the NHCR with the THMPD.

4 j - These levels are defined in the conditions of authorisation for each individual health claim

4m - The point here is not whether there is likely to be an EU-harmonised list, but whether the UK authorities will consider adopting some or all of the existing lists. No satisfactory answer was provided by the DH to this question.

5 d- It should be noted in the minutes that the HCPC representative was unexpectedly invited to speak by a WG member – an opportunity that was not available to the PSA representative after the HCPC presentation at the previous meeting

APPENDIX TO HERBAL MEDICINES AND PRACTITIONERS WORKING GROUP

2) Letter from Professor Bo Ying Ma

Dear Colleagues,

Re: Minutes of Working Group Meetings (WG) on 31st Jan., 3rd April, 1st May, 10th July 2014

I really think the minutes should conscientiously record every comment voiced but the WG minutes do not and principally record opinions from MHRA, HCPC and PSA.

I have attended the above 4 meetings. The following key points regarding TCM in the UK had been voiced and should be included in WG's minutes:

- A. 31st Jan. 2014:
 - 1. I suggested recalling the decision of DoH in 2005 to have Statutory Regulation (SR) for TCM in the UK. Thereby a TCM doctor could prescribe patent medicines for patients after one to one individual consultations.
 - 2. DoH should continually protect the title of TCM Practitioner, which was promised in 2005, and the MHRA promised that qualified TCM practitioners can use patent medicines after one to one consultations.
 - 3. I also suggested that the MHRA suspend the prohibition of Chinese patent medicines until the end of this WG.

- B. 3rd April 2014 :
 - 1. I had prepared a PPT for this meeting but was not permitted to show it during the meeting. The main points should be put into the minutes.
 - 2. We reiterated the above 3 points.
 - 3. We suggested using the Australian method of checking the quality of patent medicines in China, then allowing their use in the UK.
 - 4. We also suggested to learn from Holland and import patent medicines as food.
 - 5. We pointed out that the quality and safety of Chinese patent medicines are much preferable to practitioners making them by themselves.
 - 6. To use Chinese patent medicines is beneficial for patients in the UK: easy to take and much cheaper.
 - 7. The EU directive 2004 runs counter to the principle of consumer protection.

- C. 1st May 2014
 - 1. The prohibition of patent medicines started. We voiced the TCM sector's complaint to the MHRA, which ignored our suggestion.
 - 2. I said: The EU laws are applicable to all states of the EU so that it should be legal if we buy Chinese medicines from Holland then use them in the UK.

- D. 10th July 2014
 - 1. We heard the introductions of the HCPC and the PSA, but what is the authority behind the PSA?
 - 2. If the PSA is an authority for voluntary registration, then the identity of "TCM Practitioner" should be acknowledged.

HERBAL MEDICINES AND PRACTITIONERS WORKING GROUP

MINUTES OF FOURTH MEETING, 6 November 2014

Attendees:

Professor David Walker (Chair)
David Tredinnick MP (Vice Chair)
Adam Smith
Alison Denham
Don Mei
Dr Lezley-Anne Hanna
Dr Mike Dixon
Dr Richard W Middleton
Emma Farrant
Michael McIntyre
Penny Viner
Professor Bo-Ying Ma
Simon Mills
Peter Jackson-Main
Christine Braithwaite
Dr Mike Dixon
Dr Rob Bracchi
Michael Guthrie
Dr Kaicun Zhao
Jamie Hayes

Apologies:

Dr Indira Anand
Dr Huijun Shen
Helen Darracott
Marc Seale
Professor Elizabeth Williamson
Professor Derek Stewart
Alisdair Mearns
Professor Phil Routledge
Dr Harald Gaier
Professor Monique Simmonds
Kate Hoey MP

Officials:

Chris Jones MHRA
Julie Bishop MHRA
Andrea Farmer MHRA
Judith Thompson MHRA
Matthew Williams
David Carter MHRA
Melissa Coutinho Lawyer MHRA/DH

1. **Introduction (Chair)**

- a. The Chair welcomed everyone to the Working Group (WG) and introduced the agenda items and paper.

2. **Minutes of the last meeting and matters arising**

- a. The Chair said that following discussion at the last meeting, the minutes from the 2nd meeting of the HPWG have been amended and circulated to the WG. In addition the minutes of the 3rd meeting have been amended and circulated. Comments on the minutes of the 3rd meeting have been appended as an annex.
- b. A few additional corrections were highlighted and made to the minutes of the 3rd meeting and these were agreed.

3. **Update on Medicines and legal issues**

- a. The MHRA circulated a paper which looked at some potential options for herbal medicines, specifically around:
 - i) Potent and toxic herbs
 - ii) Food supplement lists
 - iii) Herbal dispensaries
- b. It was suggested by the paper that there may be merit in banning or restricting the use of certain potent or toxic herbs. MHRA has mechanisms to deal with use of toxic and potent herbs such as updating existing regulation and working with the profession to introduce voluntary agreements.
- c. MHRA has looked at what the use and purpose of herbal food supplement lists across the EU, in particular the BELFRIT list which is an amalgamation of lists produced by Italy, Belgium and France.. On further investigation the MHRA notes that this list is not fully integrated and is still under development. The BELFRIT list is also markedly different to a more comprehensive German list (Stoff liste) which was published in September of this year. Whilst these lists are of interest, MHRA stressed that the approaches taken in the development of each list are different and it is clear that they have been developed from a food regulatory perspective in the four Member States. The MHRA is of the view that, while the lists are not without virtue in the context of food law, as Competent Authorities have to adopt a case-by-case approach for the classification of medicinal products containing medicinal herbs, their use in determining status under medicines legislation is relatively limited
- d. The term Herbal “dispensaries” in this instance relates to the idea that practitioners may have a product made up off site, following a face to face consultation. The MHRA confirmed that it is possible to amend UK legislation to remove reference to a medicine having to be made up on site without impacting on EU regulation. However, there would be a great deal of work needed in accompaniment to such a change in regulation, not least to assess the risk to public safety.
- e. Most of these options relate to non-manufactured non-industrially produced products and will not address the issues relating to access to unlicensed manufactured herbal products.
- f. The following points were raised by members of the WG:
 - i) Extending the Schedule 2130 Order has been anticipated for a long time.
 - ii) The paper incorrectly says ‘refer to’ when in fact the argument is whether the list should be ‘used’ to create a list of herbals which could be used as food supplements.
 - iii) Reference was made to a paper by Richard Woodfield from 2006 which explored a number of useful options.
 - iv) Dispensaries may be a way forward in allowing practitioners to get access to products, but there would need to be careful consideration of a number of supplementary issues. Some members considered the idea to be unworkable.
 - v) Some members felt that these options could only work alongside the regulation of herbal practitioners. It was also thought that the person doing the dispensing needs to be registered in order to provide controls and assurance of public safety
 - vi) Some members considered this could be a safer scenario than we have at present. There will be people whose expertise practitioners could draw on.
 - vii) It was suggested that if products are regarded as food supplements rather than defined as medicines this could increase public confusion.
- g. The Chair expressed his view that the EU Directive was meant to improve access to herbal products by means of a lighter touch registration scheme. Given the small

- number of registered products he asked whether the report should make more of this, and include a recommendation to revisit the EU regulations.
- h. In response, it was pointed out by some members that the UK has more THRs than anywhere else in Europe. It was also highlighted that the THR scheme has delivered what was expected and increased the safety of simple herbal medicines. The scheme was never meant for complex products and it has always been anticipated that there would be another route for these medicines. One WG member commented that the EU commissioned a review in 2008 which concluded that the Directive was not suited to holistic traditions but this has been overlooked.
 - i. The Chair suggested that the report sets out what is currently possible and asked for opinions as to whether:
 - i) The 2130 order needs to be revisited and reviewed at regular intervals
 - ii) Herbal dispensaries would be difficult to introduce but could increase the capacity for herbal practitioners to practise.
 - iii) Work could be progressed on whether lists of food supplements might further increase access to products.
 - j. The Chair said that an email would be circulated to the WG members putting forward these options and asking for comments. Actioned

4. **HMAC Report**

- a. The Chair introduced the HMAC report.. The report compiled evidence of risks to public health associated with the use of herbal medicinal products. It did not make recommendations about practitioner regulations. The report sets out the reasons why HMAC support statutory regulation. HMAC was represented at the meeting by Alison Denham and Dr Rob Bracchi. HMAC only considered information in the public domain and focused solely on UK cases. The report noted 5 prosecutions in the UK associated with adulteration of herbal medicines and supply of prohibited herbal medicines.
- b. Dr Rob Bracchi said that the report also drew on work carried out by HMAC lay members on the use of herbal medicines in oncology clinics. This showed that 20% of oncology patients use herbal medicines. He felt that these patients put all their faith in herbal products and as a result the profession should be regulated to improve this trust.
- c. A WG member asked whether there have been any proven cases where herbal medicine has caused a fatality in the UK. Alison Denham referred to cases discussed in the HMAC report where the use of herbal medicines, in particular TCMs, was linked with serious hepatotoxic reactions which included 3 deaths after failed liver transplants. Alison Denham confirmed in response to a question from the Chair that fatalities have resulted from use of both manufactured products and preparations of dried herbs prescribed and dispensed to individual patients.
- d. A WG member said that it is impossible to make a causal link due to the fact that a patient's history may make them predisposed to hepatotoxicity. Alison Denham referred to cases of adulteration of herbal medicines discussed in the HMAC report and in particular steroid containing cream at adult strength used on babies. The current situation also makes it hard for the public to identify a responsible source of information.
- e. Dr Rob Bracchi said that due to the fact that there is not the same requirement for clinical studies and formal pharmacovigilance procedures as there is for conventional medicines any problems can only be identified through the Yellow Card Scheme. Currently yellow card reporting is relatively low for herbal medicines. Regulation of practitioners would bring them into formal pharmacovigilance procedures. One member questioned whether there are any risks that can actually be attributed to unregulated practitioners. Another member responded citing a change in the insurance policy of acupuncturists following the introduction of the THR scheme. Insurers will no longer insure acupuncturists prescribing herbal medicines or unqualified practitioners. Whilst it is difficult to get data, Alison Denham acknowledged that there is evidence of unscrupulous practitioners and at present there is no facility to stop them practising.

- f. A WG member commented that it is difficult to collect data on herbal medicines but was aware of patient complaints about practitioners and potential risk to the public. He highlighted a case that was brought to court by the MHRA against an unqualified TCM practitioner after a patient suffered kidney damage. Alison Denham referred to two prosecutions in the UK for the supply of herbal products containing *Aristolochia* species whose use was prohibited in the UK in 1999 because of an association with renal failure and subsequent urothelial carcinoma. In both cases the practitioner was not a member of a voluntary register. And in both cases the patients developed renal failure.
- g. The MHRA lawyer pointed out that the purpose of the Directive, to create a simplified authorisation of herbal medicines, has been achieved. However this has only solved part of the problem as there are still a large number of products which are no longer legally available. MHRA has made successful prosecutions where practitioners or products have caused harm. She added that there is nothing to suggest that if practitioners are regulated there will not continue to be problems but it will be another way to handle it.
- h. A WG member commented that with an aging population there may be more reliance on herbal products and self-medication. It was therefore important that the group consider what the position will be in 10 to 15 years' time.
- i. The Chair said that he had found the HMA report very useful. He was concerned about the apparent lack of quantitative data in general showing the size of the risk. He stressed that the Working Group report will need to be based on evidence and rational arguments. The focus of the report must be primarily public safety and its recommendations must be proportionate to the risk posed to the public. An email would be sent to the HPWG members setting out the three options highlighted and asking for any comments. These would be subject to a full option appraisal. Actioned

Group discussion on issue of practitioner regulation

- a. The Chair asked for views of the HPWG for and against statutory/voluntary regulation/neither. He asked members to make points based on public safety not what they would like to see happen.
- b. A note of the points raised in the subsequent discussion is attached.

5. Chairman's summing up and next steps

- a. The Chair outlined the next steps:
 - MHRA would pull together an email to go to HPWG members setting out options for herbal regulation and the arguments for/against statutory/voluntary regulation.
 - WG members to provide any evidence to support the arguments made.
 - The evidence collected will be pulled together and collated.
 - The options will be subject to a full appraisal which will be fed back to the WG members.
 - Email requesting clarification about any of the above be sent to Judith.m.thompson@mhra.gsi.gov.uk
- b. The Chair said that this would most likely be the last meeting of the WG and thanked everyone for their contributions. He stressed that his view was that the final report should be based on solid evidence and be proportionate to the risk.

MHRA, December 2014.

**HMPWG:
NOTE OF DISCUSSION ON APPROACHES TO PRACTITIONER REGULATION,
6 NOVEMBER**

Do Nothing/ Other - Against¹	Do Nothing/ Other- For
<ul style="list-style-type: none"> • Unable to assess risks (no recognised group that could manage these, engage etc. No qualified advisor • Theoretical public health risk (can prescribe potent herbs without knowledge qualification • Reduced access to herbal products • Failure to refer to GPs (training gap) • GP – patients have no idea who to go to see • Not filling in yellow cards, driving practice underground • GP can't assess herbalists qualifications • Continued potential adulteration • Dependence on manufacturers (no professional guidelines) • Push down quality (practitioners and products) • Not clear what standard courses offer • Risk to ongoing academic training • No possibility of integration with other primary care practitioners • Government will have neglected its responsibility to provide safe healthcare to the public 	<ul style="list-style-type: none"> • Would enable other CAMs to continue to use herbs • Would make practitioners ' lives easier (no one looking over shoulder) • Low cost • Improvements in standards should continue
For Voluntary Schemes²	Against Voluntary Schemes
<ul style="list-style-type: none"> • Would mean that prescribing rights remain rights • Practitioners remain outside the establishment (people will want to continue using practitioners) • Provides external independent scrutiny of voluntary registers • In some cases have improved education; this would continue • Mutual recognition for groups on accredited register (when removed from lists you can avoid that person) • Time to implement; quicker • More responsive to the needs of the various traditions 	<ul style="list-style-type: none"> • Ability to use Article 5(1) (prescribe safely and competently) • Leaving a group outside the establishment leads to fragmentation • More likelihood of banning herbs • Lack of compulsion <ul style="list-style-type: none"> i. Not all registers will apply ii. Doesn't prevent the risk of continued practice • Can't improve educational standards (risk of going backwards if no legal framework) • Resource implication for small traditions (however can cluster - FOR) • No requirement for CPD – adds to cost [although PSA standards for accreditation require registers to require CPD of their members May improve knowledge but not

¹ no change to the status quo. No statutory regulation. And the professional bodies that current maintain registers and discipline their members continue as they do now.

² 2. Accreditation of voluntary registers through the PSA – the PSA accredit the existing voluntary registers for herbalists against their standards, providing independent oversight of their operations

	<p>compliance</p> <ul style="list-style-type: none"> • Creates inequality • Not simple for patients to understand • Lack of independent governance (but PSA use a firewall) • How to promote public safety? • Annual registration PSA (2 exceptions prescribing and removal) • VR confers no additional status than a member of public would hold (e.g. re use of potent herbs)
For Statutory Regulation	Against Statutory Regulation
<ul style="list-style-type: none"> • Enables NHS etc. to help in partnership (enabling better solutions for long term conditions) • Robust process, set standards, public confidence • Enable more research into herbal medicine • Better public information (through a single register replacing the multiple registers maintained by professional bodies that currently exist) • Assurance for public and practitioners (and perception) • Provide a means of quality control • Will help to ensure best practice • Giving public an informed choice • Compulsion – everyone has to register, removing someone from the register means they can't practice (using a protected title and/or exercising a protected function if linked to medicines legislation). 	<ul style="list-style-type: none"> • Most difficult of the options to achieve • Issues of a “one size fits all” approach • Limits to protection of title (can be got round) • Back-up plan for the excluded (osteopaths) • SR scheme will not remove all risks • Difficult for non-herbalists to continue to practice? • Reflecting that the ‘how’ matters and that there was a danger that statutory regulation might fail to appropriately recognise the identities of and differences between different herbal traditions