Chinese Medical Council response to Herbal Medicines & Practitioners Working Group Report

27th March 2015

1. Introduction

On 26th March 2015 the Herbal Medicines and Practitioners Working Group (HMPWG) Chair Professor David Walker published his independent report and recommendations concerning herbal medicine regulation[i]. This much anticipated report is the culmination of over a year of meetings with a selected group of experts and academics in the field of herbal medicine and medicine law. The Chinese Medical Council (CMC) was represented in the Working Group by Mr Don Mei (Chairman of the Chinese Medical Institute & Register and vice-chair of the CICCM World Federation of Chinese Medicines Societies) and Professor Bo Ying Ma (Chairman of the Federation of Traditional Chinese Medical Practitioners).

This open paper is the CMC opinion of the report and its recommendations. The CMC understands that there are many passionate views surrounding the issues discussed at the Working Group and that it would have been impossible to find consensus on everything. This paper offers the CMC position on the various discussion points and is presented with a fundamental respect of differing views and a desire for collaboration and unity as we move forward.

The CMC would like to thank Professor David Walker and Vice Chair David Tredinnick MP for their hard work during this process.

2. About the CMC

The Chinese Medical Council (CMC) was set up in 2003 as an umbrella group for the Chinese Medicine sector to develop unified standards of practice and conduct in Chinese Medicine and to speak with one voice regarding the regulation of Chinese Medicine. It brings together the following professional member associations: Chinese Medical Institute & Register (CMIR),

Federation of Traditional Chinese Medical Practitioners (FTCMP), Association of Chinese Medicine Practitioners (ACMP) and Anglo Chinese Medical Doctors Society (ACMDS). The CMC is happy to involve all other Chinese Medicine associations who share our aspirations for a unified movement to promote, support and build assurance in Chinese Medicine in the EU.

3. Product Regulation - The failure of THMPD

One of the Traditional Herbal Medicinal Products Directive's (THMPD) stated aims was to help ensure that the public have access to herbal medicines including TCM. Clearly after 10 years since its introduction it has failed to meet this stated aim. We are pleased that Professor Walker acknowledges this by stating:

> 'This step (THMPD) severely limited the scope of some herbal practitioners to continue practising, particularly those from the Traditional Chinese Medicine (TCM) and Ayurvedic traditions.'
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> '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.'

This failure of the THMPD to ensure that the public have access to a wide range of herbal medicines has in our view done nothing to protect public health but has in fact negatively impacted public health. The TCM sector has been especially impacted leading many practitioners to consider this directive discriminatory. The European Commission 2008 experience report[ii] agreed that the THMPD was not suitable for TCM by concluding that:

> 'Medical traditions such as those mentioned above (Ayurvedic and traditional Chinese medicine) are based on a holistic approach, and the set of requirements for the simplified registration procedure under Directive 2004/24/EC is **not appropriate** for a global regulation of such medical practices. **The regulation of such traditions would demand a different approach** from that introduced by Directive 2004/24/EC. Therefore, the Commission does not envisage extending the scope of the simplified registration procedure to cover traditional medical systems as such. Nevertheless, independently of this report, **the suitability of a separate legal framework for products of certain traditions should be assessed.'**

We do not think that this conclusion could be expressed more plainly and yet the EU has chosen to ignore its own Commission's advice.

We are therefore pleased that Professor Walker has recommended that:

> 'Recommendation 4
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> 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.'

We are of the opinion that the language of this recommendation is not urgent enough and that the recommendation should be that the UK government SHOULD IMMEDIATELY ASK the European Commission to review the operation of the Herbal Directive as it appears to have failed to meet its stated aims.

4. Product Regulation - Third Party Dispensaries

The CMC fundamentally disagrees with the argument that manufactured herbal medicines are by nature more dangerous than medicine assembled on a practitioner's premises. We agree that adverse incidents have commonly involved manufactured medicine but it is our position that this is because the majority of TCM prescriptions supplied prior to April 2014 were manufactured herbal medicines.

Of course it is essential that the TCM sector provides quality assurance and purchases from respected GMP audited suppliers and we support the creation of a scheme of supplier approval. However, the idea that a medicine produced in state-of-the-art facilities with stringent testing and quality control procedures is somehow inherently more dangerous than a medicine assembled during an appointment by one person (with an increased chance of human error and limited testing controls) is absurd.

In the absence of manufactured products being legally available to herbal practitioners it is essential that we find ways to help practitioners to provide cost effective and quality assured herbal medicines within the law. The CMC wholeheartedly supports the Chairs recommendation:

> 'Recommendation 3
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> 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’.'

We cannot stress enough the importance that any dispensary system does not become corrupted by excessive controls but is simple, inclusive and proportionate to proven risk.

When the consultation documents of the Herbal Directive were first released many years ago it seemed on the surface to be plausible idea - create a simplified registration system for herbal products to ensure public safety and access. The problem was that the scheme became corrupted and complex by lawmakers that began borrowing from pharmaceutical standards and were perhaps excessively influenced by those with self-interests outside the herbal sector. The Directive became unworkable, expensive, excluding and ultimately lost the majority of support from the herbal sector.

We cannot allow the same thing to happen with any herbal dispensary system. Of course any 'dispensary' scheme must offer quality assurances but the **requirements should be commensurate to risk and not be unduly difficult to achieve or expensive to setup and run**. If we fail to achieve this, then the idea will not work and instead it will be taken over by the few who already have connections with pharmacies who will already meet these requirements but may not have any knowledge, consideration or concern for the herbal sector.

It is similarly fundamental that any herbal dispensary system does not preclude the right to assemble herbal medicines on practitioner premises.

5. Practitioner Regulation

It is important to state from the outset that **the CMC has always supported the Statutory Regulation of Chinese medical practitioners.** This position is clear and unwavering. Statutory Regulation of Chinese medical practitioners would offer many advantages to the industry and the public including quality assurance, protected title and standards for education and training.

The government have backtracked from their initial consideration of creating a Statutory Register for 'TCM PRACTITIONERS' including Chinese herbs, acupuncture, cupping, gua sha and tuina. The government, erroneously in our view, decided to instead restrict consideration of SR to all herbalists from varying traditions. For many TCM doctors this is the equivalent of wanting to set up a register for professional tennis players with codes of conduct and rules of play, and subsequently being told that instead you would have to be registered with all racquet sports players (squash, badminton etc). Of course the skills are related but they are so different in so many ways that it would be difficult and reductive to try to agree on common requirements. This one-size-fits-all approach does not sit comfortably with many TCM doctors.

Having said this, the CMC continued to be supportive of the concept of Statutory Regulation of herbal medicine especially since one of the stated government aims for SR was, as mentioned in the report:

> 'to ensure that the public had continued access to herbal products manufactured by a third party in light of European legislation.'

At the first meeting of the Working Group it was made clear by representative of the MHRA that, due to Commission v Poland, **SR would NOT allow practitioners access to manufactured herbal medicines**. The CMC is aware that this legal position is contested by others in the Working Group and we await any clarification should the government position be shown to be incorrect.

It was then made very clear by the Chair that the sole acceptable reason for him to recommend Statutory Regulation would be if a lack of SR of herbal medicine is proven to pose a substantial public safety risk. This is stated in the report:

> '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.**"

The Chair commissioned a review of safety data which was prepared by HMAC in order to assess the proven risk to public safety posed by unregulated herbal medicine. Whilst the HMAC report clearly shows potential and actual risk posed by herbal medicine, the CMC agrees with Professor Walker's conclusion that:

> '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.'

It is our opinion that, as in all foods and medicines, there are clearly some risks to the public posed by consuming herbal medicine. However, the facts are that:

1. TCM has been available to the public in an unregulated environment for nearly 50 years in the UK (and tested over thousands of years in China).

2. Other herbal medicines have been available for hundreds of years.

3. There are officially promoted systems for reporting adverse incidents and agencies dedicated to collecting this data.

It is the CMC's opinion that, whilst any adverse event is regrettable, the number and severity of the adverse events in the HMAC report represent a very low risk to the public when balanced against the decades of unregulated practice of herbal medicine with millions of prescriptions being taken. The CMC agrees that the Working Group has used all available evidence to come to their conclusions and agrees that this evidence shows a good safety record which does not justify Statutory Regulation purely on the grounds of preventing a significant public health risk. This is not dissimilar in approach to the decision not to regulate Acupuncture. The CMC supports the continuous collection and systematic review of safety data to ensure that we monitor the safety of our medicine.

The CMC supports the concept of Statutory Regulation but we are not prepared to artificially inflate the risks posed by herbal medicine in order to achieve Statutory Regulation. This would be untrue and dishonor herbal medicine on public record. We should not have to drag the reputation of our medicine through the mud in order to achieve our aim.

6. Building Unity

The CMC agrees with Professor Walker's recommendation that:

> Recommendation 5
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> 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.

The Chinese Medical Council was set up in 2003 primarily to achieve these goals and we believe that the CMC is perfectly placed to act as this 'umbrella register' for the Chinese Medicine sector. We welcome and invite all other Chinese Medicine groups to join the CMC in order to meet this recommendation.

7. Evidence base of Herbal Medicine

Professor Walker comments on the lack of a strong enough evidence base to support the efficacy of herbal medicine. He refers to herbal medicine as being 'based upon traditional practice rather than science'. The CMC understands the importance of developing an evidence base for herbal medicine but would stress that 'person centred' medicine such as Chinese Medicine is very different to 'condition centred' conventional medicine which seeks to find a standard chemical or mechanical intervention to treat a condition. In Chinese Medicine the same symptoms will be treated in different ways depending on the person. This makes it almost impossible for Chinese Medicine trials to conform to RCT requirements without diluting or generalising the treatment.

The flaws of RCTs have been proven again and again in the divergence between efficacy trials and effectiveness and yet medical science maintains an extremely rigid view of RCT's and systematic reviews as the proof required to be termed 'scientific'. Whilst this is a subject which is not relevant in this paper, the CMC disagrees that herbal medicine is not based on science.

8. Comment on the other recommendations

> Recommendation 1
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> 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.

The MHRA have mechanisms in place to ban any herbs following any adverse incidents. The CMC agrees that the list of banned herbs should be reviewed regularly and would support independent systematic reviews. The CMC is always cautious that these reviews should be done by those that understand herbal medicine and its application. The CMC agrees with Professor Walker's opinion that any review should have the 'overall aim of a minimal level of regulation and restriction'.

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.

It would be very useful if the UK could create or adopt a list of herbs and dosages which could be considered as foods and/or food supplements. The Working Group has shown that there are lists currently being made in the EU and it seems that, given a little effort, the UK could use all of the resources available from these lists and herbal safety data to create our own list. If the industry had such a list then it would immediately take away any argument of whether or not a herbal product could be placed on the market as a food supplement. It is surprising that, given the number of borderline products available, the MHRA does not seem to have the appetite to create this definitive list.

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;
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> • Looks at the case for assurance of herbal practitioners in the wider context of control of herbal medicines.

The CMC agrees that in order to move things forward regarding product and practitioner regulation, the government should support further research in herbal medicine. The CMC would welcome the opportunity to contribute to this recommendation.

9. Conclusions

The CMC has read the Working Group report thoroughly and would like to highlight the following key messages:

1. Herbal Medicine has a very good safety record and the proven risk to the public is low.

2. The Traditional Herbal Medicinal Products Directive has failed to meet its stated aim of ensuring public access to herbal medicines and should be reviewed by the EU commission.

3. The herbal medicine sectors should create umbrella organisations such as the CMC to collaborate on setting standards, collecting safety data and representing the industry with a unified voice. This is especially relevant because there was no recommendation for Statutory Regulation in the report which would have given part of these roles to the HCPC. The CMC will be best placed to set and maintain standards in Chinese Medicine. It is our opinion that other herbal modalities should have similar umbrella organisations for their specific medicine rather than mix modalities.

4. The MHRA should bring more clarity to the herbal medicines industry by creating a UK list of herbs which could be considered to be foods and/or food supplements.

5. The government should create a simple but assured system for herbal dispensaries in order to allow practitioners to commission assembly of herbal prescriptions for their patients.

Many of those involved in herbal medicine will berate the fact that Professor Walker has not recommended Statutory Regulation despite government promises to do so. Whilst the CMC supports Statutory Regulation as a concept we believe that it would have been dishonest, fruitless and counterproductive to wildly exaggerate the risks posed to the public by herbal medicine in order to try to convince the Chair to recommend Statutory Regulation.

Statutory Regulation would NOT have allowed herbalists to supply manufactured medicines routinely and this is the most important issue facing Chinese Medicine practitioners and their patients. The CMC is dedicated to trying to work with the authorities to find a suitable solution to this ridiculous situation.

The CMC would like to thank all those involved in the Working Group who have dedicated so much effort to support the herbal profession and their patients. It is essential that we continue this valuable work to improve public health and patient choice. The CMC stands ready to assist in these aims in any way.

Signatories to this CMC paper:

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For more information or to interview a representative of the CMC please contact Don Mei by calling 0207 388 6704.

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[i] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/417768/Report_on_Regulation_of_Herbal_Medicines_and_Practitioners.pdf

[ii] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0584:FIN:en:PDF