

Steering Group Stakeholders Meeting **10.30am, 31 July 2006 at The King's Fund**

Present:

Mike Pittilo, Steering Group Chair
Mercy Jeyasingham, ASG Chair
Michael McIntyre, EHPA Chair
Mike O'Farrell, CMWG Chair

Val McKie, Steering Group Lay member
Amrit Ahluwalia, EHPA
Richard Woodfield, MHRA
Andrea Farmer, MHRA

Medicines Legislation

RW introduced work of the MHRA within the context of the DH initiatives to regulate acupuncture and herbal medicine. The MHRA and DH are working together to ensure proposals for regulation are in line with S12 (1) reform. Consultations on both will run simultaneously.

An MHRA paper was circulated in advance of this meeting for discussion: 'Reforms of s12(1) of the Medicines Act 1968: linkages with statutory regulation of the herbal medicine profession'.

Reform of S12 (1) legislation will, in effect, protect function as well as title by restricting access to some herbal products to those on the statutory register. The timing of the introduction of the S12(1) reforms will not depend simply on the date when a statutory register first opens; it will also need to have regard to any transitional period which existing practitioners are given to join the register and to those undergoing training at the time of the transition. This is particularly applicable if the s12 (1) reforms prevent unregistered practitioners from carrying out activities they were previously able legally to undertake.

It is also essential that the reform of S12(1) legislation be implemented before the end of the transitional period for the Directive on Traditional Herbal Medicinal Products (April 2011). There are several issues that need to be considered here.

1. Many practitioners use manufactured multi component products within their practice that will require registration under the Directive. Currently, it is very difficult to get these products registered because of the nature of the products (not designed for direct OTC sale to the public) and the demanding tests required of them to gain registration. (Note current EMEA consultation on multi component products.)
2. Statutory registration is likely to grant herbal practitioners access to Specials as Authorised Healthcare Professionals which will allow them to have multi component products made up for them by a third party for practitioner use only, ie not OTC.
3. If there is no route to registration under the Directive for multi component products by the end of the transitional period AND herbal practitioners are not statutorily regulated and thus cannot access these products through other means, the products will be inaccessible and the practice of herbal medicine, particularly by TCM and Ayurveda practitioners, will be under threat.

There is also a need to consider other issues including:

- Other practitioners who access S12 (1), eg naturopaths.
- How SMEs e.g. herb shops will deal with the legislation
- Access to restricted products via the internet
- Possible extension of S12.(1) to include animal and mineral products

- An extended Grandparenting period, which could affect access to restricted products by those not yet on the register
- Delegation of some S. 12(1) tasks within the clinic/dispensary environment or by other professionals by a herbal practitioner to someone not on the statutory register.

It was agreed that detailed discussions regarding the medicines related issues should take place at Stakeholder meetings rather than at Steering Group meetings. At an appropriate time the results of these deliberations would then be taken forward to the main Steering Group for final review.

Action: MM & RW to put a paper together highlighting the issues to the next Steering Group meeting

Action: RW to work with MOF & CMWG with regard to the access to medicines by Chinese Medicine clinics and related matters.

The Home Office

MM has written to three consecutive Home Secretaries about the need to restrict access of TCM practitioners from China who do not have the requisite English language skills, to work in the UK. There is a significant safety risk in allowing practitioners with little or no English to work in the UK. The Home Office has recently responded that it considers it the DH's responsibility to provide legislative processes to ensure the safe practice of TCM so little progress has been made on this front.

Grandparenting

It was agreed that it would be for acupuncture and herbal medicine to determine minimum standards for access to the register during the grandparenting period, which should be as inclusive as possible. Revalidation will ensure practitioners continue to meet necessary training standards as it will confirm suitability to remain on the register.

Action: Chairs should consider the grandparenting arrangements currently in place for the HPC and use this as a benchmark for further development.

Foster Review

While there was concern about the quality of the review, the most important recommendation in the Review for the Steering Group is that new professions will go into the HPC.

This raised a number of concerns including

1. HPC criteria include the requirement of an evidence base that may not easily be provided by herbal medicine, acupuncture, TCM, Ayurveda etc.
2. There is a queue of professions (51?) waiting to get on the HPC
3. Acupuncture and herbal medicine are not currently ready to enter a regulatory body with such a 'light touch' approach as it will not be able to adequately protect the public

Action: MP to draft a response to the Review for discussion at the next Steering Group meeting

Action: MP to meet with Chief Executives of the General Chiropractic Council and General Osteopathic Council to understand their views

Educational standards

Refer to Kate Ling's paper on the Work Programme for the Stakeholder Groups. Acupuncture and herbal medicine have many of the required educational standards in place. Outstanding items include gaining agreement on an Ayurvedic curriculum and National Professional Standards for Ayurveda. Acupuncture may need to reconsider a distinction between TCM Acupuncture and Five Element to ensure patients know what type of practitioner they are seeing and researchers know exactly what kind of acupuncture they are evaluating. These two models of acupuncture should be mapped and appropriate curricula developed.

There needs to be agreement within Stakeholder groups about standards. Where new members have joined existing groups, it may be necessary to get them to sign off on the standards.

Acupuncture, herbal medicine and TCM each need to develop Scope of Practice statements for each profession/tradition.

Accreditation arrangements and codes for each profession/tradition need to be agreed within and between groups and then considered in light of what the HPC is currently doing.

Action: All Chairs need to ensure there is full agreement within their stakeholder groups about standards of training and education (curricula and National Professional Standards)

Action: All Chairs need to develop a Scope of Practice statement for each profession/tradition they represent to ensure it is clear to everyone exactly what constitutes that profession/tradition

Action: MOF to ensure members of the CMWG sign up to minimum standards developed by the acupuncture and herbal medicine professions as agreed in the ARWG/HMRWG reports

Action: All Chairs need to provide agreed accreditation arrangements that can be mapped against each other and compared with the HPC's processes

Action: All Chairs to provide agreed codes (ethics, safe practice, etc) to be mapped and compared with the HPC's codes

Action: It was agreed that no work would be done on dual registration for the time being.

Action: All Chairs to outline existing registers and highlight areas where there are possible gaps

Resource

The lack of resources available to fund the work of both the Steering Group and the Stakeholders Group has been raised a number of times in the past. Unfortunately, the DH has never been able to provide the required level of funding. (Ref Andy Burnham's letter to David Tredinnick) However, it was agreed that there was a significant amount of work to be done that had direct costs and required co-ordination.

MM had circulated a draft costing that was considered. However, during the discussions it transpired that the CMWG was funded entirely by the BAcC, that MJ was only paid to chair four ASG meetings annually and there was an obvious need for the Stakeholders to meet on a

regular basis. Given this, it was agreed that the costing should be redrafted taking these and any other issues into account.

It was also agreed that the Stakeholders should write to Kate Ling at the DH regarding funding.

Action: MM draft a letter from the Stakeholder Chairs to the DH and circulate for comment

Action: MP write to Andy Burnham, the Minister responsible for regulation, requesting a meeting and funding for the Group

Future Meetings

It was agreed that today's meeting was very useful. Possible dates for next meeting to be circulated.