

Report to EHTPA Council re the Working Group meeting on Thursday 31st January

The Working Group (WG) met on 31st January attended by the following WG members invited by the MHRA, under whose auspices this meeting was arranged.

Chair - Professor David Walker, Deputy Chief Medical Officer: vice chair - David Tredinnick MP

Working Group Members

Kate Hoey MP	
Jamie Hayes,	Department of Pharmacology, Therapeutics & Toxicology
Dr Lezley-Anne Hanna	Lecturer (Education) School of Pharmacy Queen's University Belfast
Alasdair Mearns	ATCM UK - Scottish Representative
Michael McIntyre	Chair of the European Herbal and Traditional Medicine Practitioners Association (EHTPA).
Alison Denham	Herbal Medicines Advisory Committee (HMAC) NIMH member
Emma Farrant	CEO, Register of Chinese Herbal Medicine
Huijun Shen	Association of Traditional Chinese Medicine (ATCM UK)
Dr Richard W Middleton	Chairman, British Herbal Medicine Association
Mathew Speers	PAGB
Simon Mills	Fellow of College of Practitioners of Phytotherapy and Fellow of Nat Inst Medical Herbalists
Christine Braithwaite	Director of Standards and Policy Professional Standards Authority
Professor Elizabeth Williamson	Director, Pharmacy Practice Reading University
Marc Seale	Chief Executive Health and Care Professions Council
Penny Viner	Chair Herbal Forum
Dr Indira Anand	Chairperson British Association of Accredited Ayurvedic Practitioners.
Dr Mike Dixon,	NHS Alliance
Prof Phil Routledge	Professor of Clinical Pharmacology (School of Medicine)
Helen Gordon	Chief Executive Royal Pharmaceutical Society
Professor Bo-Ying Ma	Chair, Federation of Traditional Chinese Medicine Practitioners (UK) FTCMP
Adam Smith	Association of Master Herbalists
Don Mei	Chinese Medicine Institute and Register
Dr Gaier	General Naturopathic Council

Also present were a number of officials from the MHRA including, the Director of the Policy Division, Jonathan Mogford, Dr Linda Anderson (MHRA Licensing Division) and Andrea Farmer (herbal medicines policy). Others attending are mentioned below.

The meeting began at 10 am with introductions which were then followed by two presentations. The first, 'scene setting - background to date,' was by Julie Bishop (MHRA Team Leader, Policy Co-ordination). She gave a brief history of regulation of the herbal sector since 2000.

The second presentation was from Mark Wilson (MHRA legal adviser). He explained that legal action taken by the European Commission v Poland over that Member State's (MS) use of Article 5.1 had found Poland in breach of European medicines law (April 2012). In the light of this, he said that the Commission had advised the MHRA that use of Article 5.1 of directive 2001/83/EC for permitting third party supply of manufactured herbal medicines to practitioners following SR would also breach EU law. Mark Wilson said that the Commission had advised that the exemptions provided by Article 5.1 (so-called 'specials' legislation) could only be used in exceptional circumstances.

There remain many important questions to be asked about this presentation as its detail was unclear in several respects, not the least because legal advice taken by the EHTPA provides opinion that apparently diametrically opposes this point of view. Members of the WG will be asking for written responses to a number of questions about this presentation.

There then followed a presentation by the Chair, Professor David Walker, regarding the purpose of this review. He said that he understood that there was considerable frustration about the delay on regulation of the herbal sector but that Dr Dan Poulter, the Minister responsible for regulation, needed to review the case for SR again in view of the ruling about article 5.1 by the Commission.

During a scheduled roundtable discussion, a series of comments from the members of the WG followed. It was pointed out that the 2000 report from the House of Lords' Select Committee on Science and Technology and subsequent two Pittilo reports had all recommended that SR for herbalists should go ahead immediately on the basis of providing public safety whilst maintaining public choice to consult a herbal practitioner. The matter of medicines provision was also of vital importance but SR was not dependent on the outcome of the discussion about this matter. Throughout the meeting, all who spoke appeared in favour of SR and, at the end of the WG meeting, the Chair acknowledged that, whilst everyone's view had not been heard, there appeared to be general support for SR in the WG.

The Chair also heard that there were concerns about the draft terms of reference (ToR) as circulated. In particular, it was pointed out that the proposed timetable would have the Committee report to the Minister just before the next General Election and this would effectively add further unacceptable delay. The Chair replied that the WG must do its designated job and that this would take as long as it needed.

It was also pointed out by members of the WG that the statement in the ToR that there were 'constraints preventing statutory regulation which are posed by existing EU legislation' was misleading as the regulation of health professionals was not determined by European law but was left to each MS to decide. The point was also made that voluntary regulation (VR) could not prevent any unqualified person from setting themselves up to practise and VR also

provided no reliable quality assurance of herb supply by practitioners to their patients. On the other hand, SR could enable both these issues to be resolved.

There followed two Group Discussions led by Chair and Vice-chair regarding the ToR. One group focused on medicines law and the other on SR itself. The outcome of these deliberations led the Chair to say that all options were open and that the MHRA officials would redraft the ToR in the light of comments made about them and represent the ToR at the next meeting to be held sometime in April. The Chair also said that the matter of public safety leading to the need for SR should also be revisited at the next meeting.

The meeting closed at midday.

Michael McIntyre