CMC THMPD Legislation Forum

12 November 2010
The Old Refectory, UCL, London

Summary of Proceedings

Press Release

The impact of the THMPD (EU Traditional Herbal Medicinal Products Directive 2004/24/EC) on 30 April 2011 will be felt by the consumers of herbal medicine, patients and practitioners. To assess the challenge, the CMC (Chinese Medical Council, UK) organised the Forum to bring together practitioners, researchers and consumers in a search for clarification from the MHRA and other authoritative representatives who are closely connected with the regulations in this field. At the same time, an attempt was made to seek a united voice from professional organisations of various herbal disciplines ranging from Chinese Medicine, Ayurvedic tradition, Western herbal medicine to practitioner organisations of other complementary medicines.

The Forum was attended by over 30 organisations with the participation of more than 100 individual doctors, scientists, patients and interested consumers. The discussion was conducted in a friendly, problem-solving manner to achieve consensus. The session began with an inductive focus on issues, strategy and actions from the Chairs Professor Man Fong Mei and David Tredinnick MP. The key issues were the practical difficulties in licensing applications and the style of enforcement of the THMPD upon its implementation next year. The other issues are regulation of the practitioners in relation to Article 5.1 of the EU Directive 2001/83/EC and the 1968 Medicine Act Section 12(1) in relation to the "authorised healthcare professional" status for practitioners in order to enable legal prescribing of unlicensed herbal products. The general consensus was to form a "united strategic alliance" from different professional organisations to face the challenges of THMPD implementation and to speak with one voice to the Government. The aim is to ensure the continued development of these systems of medicine while protecting the safety of the general public. The suitability and amendment of the THMPD was discussed as was the forthcoming judicial review of the Directive.

Professor Man Fong Mei, Chairman of the Chinese Medical Council (CMC, UK) and David Tredinnick MP, Chairman of the UK All-Party Parliamentary Group for Integrated and Complementary Healthcare, initiated the Forum as a timely platform for dialogues amongst the various professions affected by the directive and the Government. Possible solutions were presented to minimise negative impacts after the implementation of the THMPD.

Richard Woodfield, who represents the MHRA as Group Manager for herbal policy, gave an hour long Q & A sessions at the Forum. Many questions were raised by panellists and audience. Issues mainly concerned the scope of the Directive and its quality standards. Richard Woodfield answered that 170 THR applications had been received so far, with 80 granted. None of the products so far were from the TCM or Ayurvedic traditions. A particular challenge for the TCM sector in submitting products for THR was quality standards. The European quality guidelines were based on good practice in the

herbal industry and he noted that a wide range of herbal companies was meeting these standards, having applied successfully for THRs. He thought it possible in time that some products from these traditions would come forward for registration. However, the Directive was intended for OTC products and many used in these traditions were not suitable for registration as they were intended for practitioners' use in consultation. The key to future accessibility of manufactured unlicensed products in this sector lay in the possibility of practitioner regulation and a UK medicines regulatory scheme for registered herbal practitioners under the Art 5.1 derogation. Such a scheme could not be introduced until practitioners are coming through into professional regulation. If the MHRA is able to set up an Art 5.1 scheme for practitioners this will require standards, one of which is that products will be manufactured under European or equivalent GMP standards. Enforcement after April 2011 will be robust but proportionate. Richard Woodfield reminded the Forum that there was guidance on the MHRA website about the distinction between products and ingredients. David Tredinnick MP informed the audience that after his recent meeting with Secretary of Health, statutory regulation as recommended by the Steering Group report chaired by Professor Pittilo will be a factor for the Department's decision.

The contributions from other Panelists including Maggy Wallace, Chair of Complementary and Natural Healthcare Council (CNHC); Prof. Michael Heinrich, Head of Centre for Pharmacognosy and Phytotherapy, University of London, and also a member of HMAC, Tony Booker from Herbal Medicines Advisory Committee (HMAC); Acupuncture Sector representatives Mike O'Farrel, CEO of British Acupuncture Council (BAcC), and Merian Denning, Chair of Acupuncture Association of Chartered Physiotherapists (AACP); Chinese Medicine Sector representatives, vice chairs of the Chinese Medical Council - Prof. Boying Ma, President of Federation of Traditional Chinese Medical Practitioners (FTCMP), Prof. Duo Gao, President, Anglo Chinese Medical Doctors Society (ACMDS), Dr. Minghua Jia, President of Association of Chinese Medicine Practitioners (ACMP); Chinese Herbal Medicine Sector representative Dr. Ji Liang, vice president of Register of Chinese Herbal Medicine (RCHM); Western Herbal Medicine Sector representative Mr. Peter Bradley, Chair of British Herbal Medicine Association (BHMA); Western Medicine practitioner representatives Dr. Victor Selwyn (GP), Dr. Phillip Vernon (GP) and Dr. Barry Graham (GP)； Ayurvedic Medicine representatives Amarjeet Bhamra, Founder of Save Herbal Medicine and Roopesh Sakaria, Secretary of British Association of Ayurvedic Practitioners (BAAP); other CAM representative Dr. Harald Gaier, President of General Naturopathic Council (GNC); Manufacture and Supplier representative Jin Jiang from Tong Ren Tang (UK) Ltd.; Bio-medicine Industry representatives Marc Weinzweig, Director of Biotec Services International and Douglas Andrews, CEO of Stravencon; Research Sector representatives Dr. Qihe Xu, Chair of The FP7 Good Practice in Traditional Chinese Medicine Research Consortium (GP-TCM) and Dr. Sophie Chen, Research Director of Surrey Technology Centre, University of Surrey, as well as leaders of Chinese Community Councillor Thomas Chan and Chinese Embassy representative. Dr. Robert Verkerk, Director of Alliance for Natural Health (ANH), also informed us that his organisation is preparing to lodge a judicial review application on the THMPD together with European Benefyt Foundation represented by Chris Dhaenens.

There are many comments expressing concerns of the different sectors of the communities and industries. Those with expertise in manufacturing also expressed the importance of quality standards that traditional medicines are required to obtain according to the THMPD. The relevant quality and standards of manufacturing should be improved in order to ensure licensing approval. Comments were made that smaller companies

should form strategic alliance with other companies and research scientists to overcome difficulties in obtaining licences.

The immediate purpose of the Forum was not to debate the merits of the EU Directive, but to discuss practical ways of dealing with its consequences and forging productive alliances within the profession and industry in order to protect public health, consumer choice and professional development. In this respect the Forum was a clear success. The discussions were very lively and involved enthusiastic questions from a large audience consisting of practitioners, students, scientists and Western medical doctors as well as consumers. The only way towards a consensus was through honest debate. The event was immediately followed by positive networking.

The Forum was concluded with an announcement of the results of a post-forum poll to gauge the views on the directive. The results clearly showed that the opinion of the vast majority of participants was that the directive needs to be amended in order to fulfil its aim of protecting public health from the dangers of unregulated herbal medicines while ensuring that a wide choice of safe and beneficial natural medicines is available for patients.

The results sent a strong message that the THMPD is not suitable for the non-European tradition of herbal medicine as identified by the EC Experience reports (COM 2008 584) which stated that the THMPD is not suitable for holistic traditions including TCM, Ayurvedic and other traditions and recommended that "suitability of a separate legal framework" for these traditions should be further assessed.

It was also revealed during the Forum that the Department of Health decision on regulation of "authorised healthcare professionals" of herbal medicine, acupuncture and Chinese Medicine will be announced shortly, before April 2011 or even within 2010. The decision will be either statutory regulation with the HPC or the CNHC. Maggy Wallace, Chair of the CNHC, stated during the proceedings that her organisation is ready to take on the task as the statutory regulating body for these professions.

The full results of the poll and the list of panellists are available on request.

End of summary.

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