22 November 2011
EMA/HMPC/501139/2011
Committee on Herbal Medicinal Products (HMPC)

HMPC work programme for 2012-2015

Besides the management of HMPC's core-tasks as defined in Directive 2004/24/EC which are reflected in the annual work programmes of the HMPC working party (monographs) and drafting groups (quality, organisational matters), a number of the activities presented in this HMPC work programme 2012-2015 represent actions which support the objectives outlined in the 'EMA Road Map to 2015' and the associated implementation plan, some of which stem from the 'Action plan for herbal medicines 2010-2011'.
The HMPC work programme elaborates on objectives and deliverables identified in the context of the **harmonisation of procedures and provisions laid down in EU Member States** concerning herbal medicinal products, whilst some focus on those aspects specifically relating to the **work of the HMPC**.

'Road map to 2015: The European Medicines Agency's contribution to science, medicines and health' (EMA/299895/2009)
'Implementing the European Medicines Agency's Road map to 2015: The Agency's contribution to Science, Medicines, Health – From vision to reality' (EMA/MB/550544/2011)
'Action plan for herbal medicines 2010-2011' (EMA/831327/2009)

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7051
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

List of future/ongoing HMPC activities

Priority/Project type/Deadline	Objectives/deliverables	HMPC Sponsor(s) and Lead sponsor (in bold)
High – Improvement of best practice guidance – **2012-2013**	Improve templates, SOP and other procedural guidance so as to produce monographs, list entries and supporting documents of high quality and consistency. Organise an assessors training via a webinar on the revised assessment report template with instructions on the intended content of the various sections of HMPC ARs.	M. Delbò
High – Monographs' revision – **2012-2014**	Implement the procedure (1) for the 5-year review and revision of monographs according to the agreed pilot phase. Report on the experience gained and finetune the long-term strategy for the systematic review & revision.	**I. Chinou**, M. Delbò W. Knöss
High – Network/Reporting on TUR and MA – **2012-2015**	Publish regular updates on the registration of traditional herbal medicinal products and the marketing authorisation of well established use herbal medicinal products.	*In collaboration with CMD-h, with joint publication on EMA and HMA websites.* W. Knöss
Medium – Network/Impact analysis – **2013-2014**	Survey on usage of monographs and benefits of the system. Report on the impact of monographs and list entries	W. Knöss, **R. Länger**
Medium – Network/Impact analysis – **2013-**	Assess the impact of harmonisation on reducing workload/worksharing at national competent	W. Knöss, **R. Länger**

Priority/Project type/Deadline	Objectives/deliverables	HMPC Sponsor(s) and Lead sponsor (in bold)
2014	authorities' level.	
High – Regulatory guidance for non-European interested parties – **2012**	Initiate pilot projects for herbal substances with a non-European traditional background. Identify central questions or obstacles and provide specific information in conjunction with a training for assessors. Develop a specific guidance document aimed at non-European interested parties, i.e. a 'Guideline on Regulatory Essentials' which summarises all available guidance established by the HMPC. Such document should clarify the main issues related to the registration procedures, the establishment and use of monographs, quality issues, combinations, safety, referrals etc. The document may be translated in Chinese and other relevant languages.	W. Knöss, **E. van Galen**
High – Harmonisation of assessment practice for herbal substances of non-European origin – **2012-2015**	Contribute to establish a harmonised view on the assessment of herbal substances of non-European origin at the level of the national competent authorities. Identify existing centres of expertise.	W. Knöss, **E. van Galen**
High – Coordination with EU bodies – **2012-2015**	Provide orientation to the Quality Drafting Group on the coordination/harmonisation activities with the relevant Expert Groups of the European Directorate for the Quality of Medicines (EDQM)	I. Chinou, B. Kroes, **H. Neef**
High – Coordination with EU bodies – **2012-**	Coordinate with relevant bodies within the European Union's medicine and health system	**W. Knöss**, A. P. Martins, H. Neef

Priority/Project type/Deadline	Objectives/deliverables	HMPC Sponsor(s) and Lead sponsor (in bold)
2015	concerning issues arising at the interface of the different frameworks under which herbal ingredients can be regulated.	
Medium – International collaboration – **2012-2014** *HMPC Chair was appointed as 'International Regulatory Cooperation on Herbal medicines (IRCH) Information Focal Point acting as coordinator') in November 2010*	Define an EMA/HMPC approach to international collaboration in the field of herbal medicines.	*In liaison with E. Cooke, the EMA International Liaison Officer* S. Bager, M. Delbò, **W. Knöss**, E. van Galen
Medium – Communication **- 2013**	Publish HMPC monographs and list of references as a book. With respect to globalisation in this field, the European monographs should take over the role of monographs that were formerly acknowledged as standards.	G. Calapai, I. Chinou, **G. Laekeman**
Medium – Communication **- 2013**	Organise an international workshop on herbal medicines synchronised with the release of the book containing the first 100 monographs.	I. Chinou, **W. Knöss**, G. Laekeman
Medium – Forward planning & prioritisation – **2012**	Initiate a pilot project to define a pragmatic solution for tea combinations, e.g. establish monograph(s) on usual combinations of teas.	W. Knöss
High – Forward planning & prioritisation – **2012**	Define the set of European herbal substances, preparations and combinations for which a monograph should be established in the next years. Improve the transparency on the prioritisation of	**W. Dymowski,** W. Knöss

Priority/Project type/Deadline	Objectives/deliverables	HMPC Sponsor(s) and Lead sponsor (in bold)
	assessment works by Rapporteurs, upon establishment of clear criteria.	
High – Legislation – **2012-2015**	Contribute to the development of new/revised legislation as required.	W. Knöss
High – Legislation – **2012-2015**	Support implementation of European procedures (MRP, DCP). Develop initiatives to improve the communication and exchange of information between competent authorities, in particular regarding the initial phase of new national procedures for THMP or MA. The aim should be to establish more mutual consistency between Member States' practices on validation, the mandatory character of MRP/DCP, and the role which Community herbal monographs play.	W. Knöss, H. Neef, **E. van Galen**
Medium – Network/Information sharing on genotoxicity – **2012-2015**	Follow-up on the availability of genotoxicity data. Prepare a reflection paper on herbal substances with known genotoxic concerns, with a regular update via the network of NCAs. Prepare an overview on knowledge about data of genotoxicity of the herbal substances/preparations. Redefine strategy for the establishment of list entries.	**O. Pelkonen**, J. Wiesner
Medium – Communication/Scientific	Support the publication activities of the HMPC. Both scientific publications and publications aimed	**E. Attard**, G. Calapai, I. Chinou, S. Girotto, S. Kreft, W. Knöss, G. Laekeman,

Priority/Project type/Deadline	Objectives/deliverables	HMPC Sponsor(s) and Lead sponsor (in bold)
Publications – **2012-2015**	at consumers and interested parties should be considered.	R. Länger, O. Pelkonen, J. Wiesner
High – Communication/Patient information – **2012-2015**	Collaborate with the Medical Information Sector (MIS) on the provision of clear and consistent information on herbal medicinal products to the general public. Implement the procedure (2) on establishment of assessment summaries for the public, for new monographs and for all monographs already published.	**S. Bager**, E. Attard, S. Kreft. G. Laekeman, S. Madsen
High – Integrated Quality Management – **2012-2013**	Rediscuss Key Performance Indicators (KPI) on the number of monographs and list entries established. Define a target for the KPI on the time required to establish a monograph/list entry. Define KPI(s) on the revision of adopted monographs and list entries.	I. Chinou, **M. Delbò**, W. Knöss
High – Integrated Quality Management – **2012-2013**	Investigate opportunity for efficiency gains in the operations of the HMPC and its subgroups.	I. Chinou, M. Delbò, **W. Knöss**, B. Kroes E. van Galen

References:

(1) 'Procedure for the systematic review of adopted Community herbal monographs and supporting documents' – draft (EMA/HMPC/124695/2011)

(2) 'Procedure for the preparation of an HMPC assessment report summary for the public (ARSP)' – under preparation (EMA/HMPC/448825/2011)