6 February 2014
EMA/HMPC/196834/2014

Committee on Herbal Medicinal Products (HMPC)

Minutes of the 27-28 January 2014 meeting

Chair: Werner Knöss

- **Health & Safety Information**

In accordance with Agency policy, delegates are to be shown a slide show with health and safety and emergency information and procedures. This is to be displayed at the start of this meeting using the Crestron system as delegates are entering the meeting room. In addition, the meeting secretariat is to draw the delegates' attention to the slideshow and point out the nearest fire exit(s), which are marked where the room has two or more exits. Should there be an evacuation during the meeting staff will guide delegates out of the building via the nearest fire exit.

- **Welcome to new participants**

New AST member in HMPC secretariat.
New trainee in HMPC secretariat.

- **Transfer of voting rights from members to the alternate members**

From Barbara Razinger to Samo Kreft, from Panayiotis Triantafyllis to Maria Stavrou.

- **Apologies**

Apologies received from Artūras Kažemekaitis, Gert Laekeman and Gioacchino Calapai.

- **Declaration of conflict of interests**

In accordance with the Agency's Policy and Procedure on the handling of conflicts of interests, participants in this meeting are asked to declare any conflict of interests on the matters for discussion (in particular any changes, omissions or errors to the already declared interests).
Discussions, deliberations and voting will take place in full respect of the restricted involvement of Scientific Committee members and, where relevant, experts attending the plenary meeting, as announced by the Scientific Committee secretariat at the start of the meeting.

- No new or revised conflict of interests was declared and no restriction in the involvement of members in relation to agenda topics was identified.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7455
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Election of Chair of ORGAM DG

The HMPC renewed the mandate of E. van Galen as chair of the ORGAM DG, for a new 3-year mandate starting on 27 January 2014.

I. Introduction	* = Change introduced following last pre-meeting mailing
I.1 Agenda, minutes	
I.1.1 Agenda of 27-28 January 2014 HMPC meeting (EMA/HMPC/782373/2013): **for adoption**	Adopted. HMPC secretariat to publish the document after redaction (see VI.3.20). ***Post-meeting note: published on 30 January.***
I.1.2 Time schedule of 27-28 January 2014 HMPC meeting (EMA/HMPC/782372/2013): **for adoption**	Adopted.
I.1.3 Draft minutes of 11-12 November 2013 HMPC meeting (EMA/HMPC/742564/2013): **for adoption**	Adopted. HMPC secretariat to publish the document after redaction. ***Post-meeting note: published on 3 February.***
The draft minutes had been circulated to HMPC members on 11 December 2013, with a deadline for comments by 6 January. The same version had been included in the first pre-meeting mailing sent on 14 January. The HMPC Chair invited all members to pay attention to the highlighted parts, which are intended for deletion in the public version of the minutes, in line with the principles adopted by the Management Board (link circulated under agenda point VI.3.20). Experience is being gained within the HMPC and the EMA secretariat with the implementation of these principles.	
I.2 Legislation and regulatory affairs	
I.3 Questions raised by HMPC members	
I.3.1 Question by R. Länger dated 12 August 2013 in relation to estragole amounts in herbal extracts and average intake of estragole by food - Discussion paper on possible revision public statement (EMEA/HMPC/137212/2005): **for discussion** - Presentation by O. Pelkonen given at HMPC informal meeting in Vilnius: **for discussion** - preliminary draft reflection paper on assessment of estragole and alkenyl benzenes: **for discussion**	*Rapporteurs: O. Pelkonen and J. Wiesner* See VI.3.11 HMPC discussions to be brought to the attention of the SWP secretariat with a request for the topic to be added to the agenda of one of their next meetings, with the CHMP secretariat informed in parallel.

The HMPC Chair reminded the members about the discussion held at the November plenary meeting as well as during the informal HMPC meeting in December 2013. O. Pelkonen provided a brief overview of the content of his presentation and the conclusions that can be drawn from the non-clinical testing results. The assessment must be continued and brought into perspective vis-à-vis the conclusions reached in 2005 and current, state-of-the-art knowledge in estragole's metabolic pathways and the relevance to human beings of findings from non-clinical testing. Estragole is found in food and further assessment must integrate knowledge and views from experts in the food sector. Before consideration of the need for cooperation with bodies established in the EU (e.g. EFSA), a consolidation of a scientific opinion on studies' results within the Agency shall be sought first. The matter will be brought to the attention of the SWP secretariat with a request for the topic to be added to the agenda of one of their next meetings, with the CHMP secretariat informed in parallel.

I.4 Questions raised by companies

I.5 Referral procedures

II. Co-ordination issues

II.1 General co-ordination issues

II.2 Co-ordination with CHMP

II.2.1 Coordination on request for eligibility to CP received by CHMP: **for discussion** - letter of intent - eligibility request	*Report by J. Wiesner*

II.3 Co-ordination with SAWP

N/A

II.4 Co-ordination with SWP

II.4.1 Feedback on SWP virtual meeting held on 3 December 2013	*Report by O. Pelkonen*

The HMPC observer in the SWP considered that none of the items addressed at the meeting deserve any particular mentioning to the Committee and reference was made to the topics highlighted in November.

II.4.2 Report on draft agenda for SWP virtual meeting scheduled for 28 January 2014	*Report by O. Pelkonen*

The HMPC observer in the SWP did not consider that the items on the agenda require specific reporting to the Committee.

II.5 Co-ordination with PDCO

II.6 Co-ordination with PRAC

II.6.1. PRAC recommendation on labelling of efavirenz-containing medicinal products concerning potential deleterious pharmacokinetic interaction with Ginkgo biloba extracts (EMA/PRAC/606660/2013/Adopted): **for information**	*See V.6.1* *http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/11/WC500153952.pdf*

II.7 Co-ordination with PCWP

II.7.1 PCWP Work plan for 2014 (EMA/552003/2013): **for adoption**	*Presentation on 28 January at 11.30 - See also VI.3.16* Adopted.
The HMPC noted the highlights provided on the expectations in 2014 concerning the PCWP area of work, with a strengthening of the framework under which the enlarged network of 36 eligible organisations operates. The work plan includes the organisation in 2014 of two workshops, one on benefit-risk methodologies and one on risk communication.	
II.8 Co-ordination with HCPWP	
II.8.1 HCPWP Work plan for 2014 (EMA/549571/2013): **for adoption**	*Presentation on 28 January at 11.45 - See also VI.3.16* Adopted.
The HMPC was informed about developments in the interactions of HCP in EMA activities and the growing network on now 26 eligible organisations represented in the HCPWP. Future interactions with HCP representatives include their involvement in the establishment of scientific guidelines. The framework of interactions is being reinforced to create more robust interactions with the eligible organisations, as sought in the legislation.	
II.9 Co-ordination with MIS	
II.10 Co-ordination with COMP	
II.11 Co-ordination with CMDh	
II.12 Co-ordination with Eur. Com.	
II.12.1 HMPC questions WEU and TU provisions: **for discussion** - draft Questions and draft answers (EMA/HMPC/724649/2013) - Discussion on how to improve the genotoxicity data situation	

The HMPC Chair reminded members of the context in which a number of questions on TU and WEU provisions had arisen. The Eur. Com. representative then reported on the different issues and responded to the questions from the HMPC members. however this summary cannot be assumed to represent an interpretation of legal provisions.

- Clarifications were provided on the circumstances surrounding the revision of conclusions on the benefit-risk ratio established for a given HS/HP. If safety issues have arisen since the first publication of the final HMPC monograph, the HMPC may change its scientific conclusions at the time of the revision of the monograph. If a new scientific consensus has emerged in the wide, international scientific community, the HMPC may reconsider its scientific conclusions.
- Data protection provisions (whereby a period of exclusivity is set out vis-à-vis data, which can be relied upon by applicants for generics at the end of that period) are not relevant to the establishment of monographs on the basis of the WEU provisions (whereby the HMPC establishes a monograph upon review of published scientific literature that include literature describing clinical trials results).
- The HMPC assesses a large range of data, including information on marketed medicinal products and published literature; within the concept of an overall set of data, the HMPC will evaluate this set in order to conclude that '10 years of medicinal use' is proven and, *separately*, will decide if the set of data (which may include one or more scientific publications, published less than 10 years before the time of the HMPC assessment) allow to establish 'a recognised efficacy'. The congruence across the data in the set, in relation of the therapeutic indication in the monograph, is key.

II.13 Co-ordination with EFSA

II.13.1 Discussion on EFSA scientific opinion related to hydroxyanthracene derivatives

http://www.efsa.europa.eu/en/efsajournal/doc/3412.pdf

The HMPC Chair reminded members of the discussion held in November and pointed to correspondence that had been exchanged between HMPC members. Clarification was given on the steps of elaboration of a Commission decision on a health claim after an application to EFSA according to Article 13(5) of Regulation (EC) No 1924/2006. The application for a health claim had been submitted in France and EFSA had been asked to deliver a scientific opinion. The application dossier contained proprietary data, including two unpublished randomised controlled trials, pertinent to the proposed claim 'improvement of the bowel function' in 'general population experiencing disturbed defecation'. The food subject to the claim is a food supplement, in the form of a tablet containing powdered dried underground parts of Rhubarb, powdered dried expressed juice from leaves of Artichoke, dried plant material from *Rosa centifolia*, *Althaea officinalis*, *Ocimum basilicum*, *Coriandrum sativum* as well as 3 bacteria. The HMPC noted that the EFSA had released a scientific opinion on hydroxyanthracene derivatives, listing the different plant species in which they are found, beyond the Rhubarb and Artichoke contained in the tablet. The EFSA opinion thus appears wide in scope, vis-à-vis the composition of the food supplement in the application; the HMPC noted in the EFSA opinion that "the evidence provided by the applicant did not establish that any of the other food constituents in the tablet exert an effect on bowel function over and above the effect of hydroxyanthracene derivatives". The Eur. Com. representative reminded the HMPC members about the legislative framework for food. She clarified that France was legally obliged to seek an opinion from EFSA, upon receipt, on a national level, of the application. She explained that the Commission in order to proceed with the authorisation of a claim would take into account the scientific opinion of EFSA but also other legitimate factors relevant to the issue concerned. In that regard, the HMPC considered important that the EMA shares with the Eur. Com. the committee's concerns associated with the idea that consumption of hydroxyanthracene derivatives-containing products could be supplementation of the normal diet and not medicinal use.	
II.13.2 Scientific assessment of estragole **for discussion**	*See I.3.1*
III. Organisational matters	
III.1 Organisational Matters Drafting Group	
III.1.1 ORGAM DG (virtual) meeting held on 14 January 2014	*Report by ORGAM DG Chair*
III.1.1.1 Agenda (EMA/HMPC/739161/2013): **for information**	
III.1.1.2 draft Meeting report (EMA/HMPC/22724/2014): **for adoption**	Adopted. HMPC members were invited to send nominations for members for appointment in the ORGAM DG.

The ORGAM DG Chair reported on the different topics discussed at the virtual meeting on 14 January. A review of the AR template allowed making substantial progress, which was complemented after the meeting by an editorial review by the secretariat to bring the documents close to finalisation. The Committee noted that the template would be presented by the Rapporteur to the MLWP on 29 January aiming at collection of the last request for amendments which would then be taken on board by the ORGAM DG on 10 February. The ORGAM DG Chair was confident that progress would allow circulation to the HMPC in March 2014 of this 4th revision that contains instructions to assessors and a revised AR structure, for adoption.

The ORGAM DG Chair invited the Committee to consider that there are three vacant positions in the ORGAM DG. Considering the meetings are held virtually, membership into the ORGAM DG does not represent a commitment to participate physically in meetings at the EMA premises. The meetings are organised during morning sessions of 3-hour duration, from 9.00 to 12.00 (UK time), using Adobe Connect as a platform. The nominations would be discussed at the March 2014 meeting, with a view to appointing the new members, either in March or in May.

III.1.2 Progress on establishment of a draft Q & A on non-European traditional herbal medicinal products (EMA/HMPC/402684/2013): **for discussion**	*Report by ORGAM DG Chair* Adoption scheduled for HMPC March 2014, after finalisation at ORGAM DG on 10 February.

The ORGAM DG Chair informed the HMPC on the expected progress at the next ORGAM DG virtual meeting on 10 February, when the final review of the comments from RA and Legal EMA colleagues will take place. The HMPC secretariat had circulated on 21 January a new version that attempted to account for the original, intended scope of the document and the input received from EMA staff members from the RA and Legal services. Again, the ORGAM DG Chair considered that progress would allow circulation to the HMPC in March 2014 for adoption.

III.1.3 Revised 'HMPC procedure on publication of public statements when no monographs are established' (EMA/HMPC/84530/2010 Rev.2): **for adoption**	*Report by ORGAM DG Chair* Adopted. HMPC secretariat to publish the document.

The ORGAM DG Chair presented the scope of the revision, which had been discussed during the hearing of AESGP held at the May 2013 MLWP meeting. The procedure now clarifies that, at any point of time, interested parties are welcome to submit new data/information on a plant covered by a final public statement. Such new data might allow the HMPC/MLWP to modify the original conclusion and lead to the establishment of a monograph. The assessment of the new data would be integrated in the annual work programme of the MLWP, current or next, depending on the time and volume of the submission and considering the priorities given to on-going assessment works by the concerned Rapporteurs.

III.1.4 Revision of guidance on systematic review/revision of monographs and related documents concerning the nature of the changes that trigger a release for public consultation: **for discussion** - proposal from HMPC Chair and MLWP Chair	*Report by HMPC Chair and MLWP Chair* Proposal endorsed.

The HMPC Chair presented the proposal, which contains a list of changes, which depending on their status as 'minor' or 'major', would justify that a monograph (and the supportive documents) is published for a new public consultation, after the systematic review/revision. In any case, the original versions (when first published as final) remain always accessible for reference (access via the EMA search function, using the documents reference numbers).

III.1.5 Progress for the ORGAM DG contribution to the revision of the CTD guideline: **for discussion**	*Report by A. Cunney* See II.1.1.2

The HMPC Chair thanked the Irish colleagues for taking the lead of the CTD guideline revision, after comments from interested parties had been discussed during the informal HMPC meeting organised during the Irish EU presidency. The ORGAM DG Chair pointed to the identification of all existing HMPC documents which would be considered during the revision exercise. He indicated that the ORGAM DG members had been invited to send comments to A. Cunney in advance of the next ORGAM DG virtual meeting on 10 February.

III.2 Working methodology

III.2.1 Timetable for the next survey (2013 data) of the 'Uptake of traditional use registration scheme and implementation of the provisions of Directive 2004/24/EC in EU Member States' (EMA/HMPC/28645/2014): **for discussion**	*Report by HMPC secretariat* Adopted. HMPC secretariat to send questionnaires to national contact points.

The HMPC endorsed the proposed timetable, which foresees the circulation of the questionnaire to the national contact points on 10 February 2014. No change to the questionnaire was deemed necessary, so the HMPC secretariat was instructed to circulate the same questions (as done in February 2013 to collect the end-of-2012 data). The timetable anticipates the results to be presented at the May 2014 HMPC meeting.

III.2.2 Update on support in 2014 to HMPC coordination activities, especially with EDQM: **for discussion** *- Presentation	*See also VI.3.10* HMPC secretariat to support the participation of the HMPC observers into the agreed Ph. Eur. Expert Group meetings. HMPC members to send proposals on the possible scope of the assessors' training.

The HMPC welcomed the presentation given on the budget allocation foreseen in 2014 to support the activities of the HMPC and its subgroups. The Committee welcomed the re-stating of a FtF meeting for the Q DG (see IV.1.1.2). The HMPC supported the organisation of this FtF on 12-13 February. The HMPC secretariat was invited to promptly send the invitations for this meeting to facilitate rapid transport and accommodation bookings.
The HMPC supported the need for budgetary planning to allow:
- participation of I. Chinou into the meetings of the EDQM Expert Group 13A on 4-5 March and 2-3 December 2014 (I. Chinou signalled her unavailability for the meeting on 3-4 June);
- participation of H. Neef into the meetings of the EDQM Expert Group 13B on 8-9 April and 23-24 September 2014.
The HMPC welcomed the participation of R. Länger as HMPC observer into the next meeting of the EDQM Expert Group TCM on 11-12 February 2014 (without however any financial implication for the EMA considering the primary invitation of R. Länger as expert sent by the Austrian authorities).

The HMPC welcomed the information that budget had been anticipated for an assessors' training (see III.2.8). HMPC members were invited to send proposals on the possible scope of such assessors' training, which is anticipated as a stand-alone event; experience from the past with the organisation of such training on the Friday after the HMPC & MLWP meeting from Monday to Thursday had been taken

into consideration. Beyond the 20 assessors who can physically attend the training at the EMA offices, additional participation via a webinar platform will be offered to many more assessors in the NCAs. The HMPC will decide in March 2014 on the intended scope & format for this training, in order to allow sufficient planning and organisation.

III.2.3 Meeting of EMA Scientific Coordination Board held on 9 December 2013: **for discussion** — *Report by HMPC Chair*

The HMPC noted the report from the HMPC Chair on the various topics addressed during the Scientific Coordination Board meeting, which he had taken part in, via audioconferencing from Vilnius.
Besides a presentation on the 'Move 2014' project, the chairs of the 7 scientific committees of the EMA and that of the SAWP had been invited to highlight, for their respective committee/WP, the key developments and deliverables expected during the 2014-2015 period. The Chair indicated that he had circulated in writing the key elements of the HMPC 2012-2015 work programme, pointing to his comments he raised in relation to the timing of communication by EMA on financial provisions, which make the planning of the committee's work more difficult when the committee is confronted with the news of budget cuts. An alignment of the work programmes' duration e.g. to 2-year periods would be sought across the committees.
The chairs had also received information about a project within the Agency to rationalise the committee secretariats. Whilst all chairs understood and supported that 'best practices' should be shared across the different secretariats, there was also a demand for acknowledgements of each committee's specific competence as laid down in the EU legislation and not all tasks undertaken by the secretariats can be considered as 'generic' tasks, that can be easily performed by interchangeable staff members. Overall the new Agency re-structuration announced publicly in September 2013 is ongoing and internal work is still required to bring about the expected benefits. Within the Department of A. Nolte, a methodology-based review of processes is undertaken to make efficiency gains and allow a re-allocation of human resources within the EMA secretariat, with the ultimate goal for the Agency to meet its objectives and fulfil its mission.
Although less relevant for the HMPC, the Chair reported on analyses being made when cross-committee responsibility exists to ascertain a positive benefit-risk for a medicinal product under assessment.
In the context of this report to the HMPC, the Chair expressed the view that he would appreciate if A. Nolte could present to the HMPC in March (or May) an intermediate progress report on the so-called 'Review & Reconnect' exercise, with a focus on the projects affecting the committees and their secretariats.

III.2.4 Introduction to MMD: **for information**

III.2.4.1 Progress with the establishment of HMPC folders' structure in MMD — *Report by HMPC Chair/HMPC secretariat*

III.2.4.2 Timetable for next steps in implementation, including training of delegates in March 2014 (EMA/HMPC/28836/2014) — HMPC noted the timetable.

The HMPC received a second information session on the implementation of MMD and IT support was made available to the delegates, at the margins of the meeting, to connect with the MMD platform and to access the different folders. The structure under MMS had been built to mirror the current agenda structure. Some members reported very positive experience with the access to the documents. The HMPC secretariat confirmed that all documents for this meeting would be posted, representing a formal 'meeting record' of all documentation pertaining to the meeting. As such, the MMD is a repository of official, plenary meeting documentation, allowing the EMA to stop keeping prints

gathered in a so-called 'master file'. This supports the evolution of the EMA to become as much as possible a paperless functioning organisation. The Committee also noted the timetable circulated; it was confirmed that, as of May 2014, the meeting's documentation will only be made available via MMD. EMA ICT colleagues pointed to the various training material available on the landing page of the application. Members were also informed that the CHMP and PRAC for examples had already successfully migrated to MMD and guidance could also be sought from colleagues in the national competent authorities. HMPC members not associated to NCAs (e.g. working at a university) were invited to inform the HMPC secretariat of any difficulty encountered. The March 2014 HMPC meeting would represent the last opportunity to have FtF meeting with ICT colleagues who could assist with connection issues. As of April, the two pre-meeting documentation will be posted via MMD (22 & 29 April respectively for pre-mail 1 and pre-mail 2).

III.2.5 Report on informal HMPC meeting held in Vilnius in December 2013: **for information**	*Postponed to March 2014* *See also VI.3.11*
III.2.6 Update on organisation of informal HMPC meetings in 2014 during Greek and Italian presidency: **for information** - Informal HMPC meeting in Rome on 4-5 November 2014	*Report by I. Chinou and M. Delbò* HMPC members were invited to contact M. Delbò to indicate their intention to participate.

I. Chinou indicated that the NCA in Greece had not transmitted information that would indicate an ongoing organisation of an informal meeting during the EU Greek presidency; the HMPC therefore anticipated that no informal meeting would take place during the first half of 2014.
M. Delbò confirmed the dates for the informal HMPC meeting during the EU Italian presidency and informed the committee of confirmed/contacted participants & lectures. A significant part of the meeting would be devoted to the borderline with food/food supplements; speakers from the Eur. Com. will be invited as well Prof. Silano, Chair of the EFSA Scientific Committee. Two co-opted members of the HMPC will be invited to present the results on ongoing survey activity on the use of herbal product in pregnancy and on the use of herbal products in children in the Members States. The researchers in faculties of the University of Rome are being approached to deliver lectures on works relevant to the HMPC competence and scientific duties. HMPC members willing to give a presentation at the meeting were invited to contact M. Delbò.

III.2.7 Meeting dates in 2016-2017-2018: **for discussion**	HMPC members to consider the proposed dates. For adoption in March.

The HMPC noted the dates proposed by the HMPC secretariat, taking into account availabilities in the EMA meetings' schedule and the 2-monthly pattern for HMPC meetings. Members were invited to signal any conflict with known important events that would be considered a sufficient reason to amend the proposed dates.
The dates will be put for formal adoption at the March meeting.

III.2.8 Organisation of a training in 2014 for 20 rapporteurs /assessors on the revised assessment report template with instructions on the intended content of the various sections of HMPC ARs (objective 'high quality standards and consistency for monographs, list entries and supporting documents'): **for discussion**	*Rapporteur for AR template revision and Topic Leader for the 'high quality standards and consistency' objective in 2012-2015 HMPC work programme: M. Delbò*

III.2.9 Move to new EMA offices in July 2014

III.2.9.1 Presentation on EMA move to 30 Churchill Place

The HMPC was informed about the progress in the Agency project to move to new premises in July

2014. A presentation was given to the Committee by the Head of the EMA Infrastructure Service Department, covering information on the features of the future meeting rooms, the audio/video/teleconferencing equipment in support of virtual meetings as well as a range of facts relevant to the work of the delegates in their capacity of representatives from NCA (e.g. work station, delegates lounge, etc.). The Committee was informed about the environment-friendly features of the building itself and the paper-less evolution for the whole EMA secretariat. EMA staff members will operate in large, open-space areas and teams will be organised in relation to their structural interdependency.

IV. Quality

IV.1 Quality Drafting Group

IV.1.1 Q DG (virtual) meeting to be held on 15 January 2014	*Report by Q DG Chair*
IV.1.1.1 Agenda (EMA/HMPC/791200/2013)	
IV.1.1.2 Draft Meeting report (EMA/HMPC/32635/2014): **for adoption**	Adopted.

The Q DG Chair reported on the main outcomes of the virtual QDG meeting held on 15 January (re-schedule of the December 2013 meeting cancelled due to conflicting dates with the informal HMPC meeting held in Vilnius).
Besides the conclusions reached on the documents presented to the HMPC for adoption at the present meeting, the Q DG had discussed the choice of date for the FtF meeting planned in 2014. The HMPC was informed (see III.2.2) that such FtF meeting had been budgeted for 1.5 day for 15 delegates; this is why the HMPC secretariat had initially suggested 12-13 November 2014 for this FtF. The 5 additional delegates reimbursed for participants would include the 3 chairs from the EDQM Expert Groups, the HMPC Chair and the MLWP Chair. The HMPC endorsed the Q DG request for the FtF meeting to be scheduled for February to meet the need (CTD mock up to be discussed); the joint meeting with EDQM chairs was considered equally important and the budget expenditure would be closely monitored against the forecast, in the expectation that sufficient funding would sustain the invitation of the 3 EDQM chairs to attend a meeting at the EMA offices, possibly organised in conjunction with a plenary HMPC meeting.

IV.1.2 Quality of essential oils as active substances in herbal medicinal products/traditional herbal medicinal products	*Rapporteur: K. Reh* *Q&A, after adoption, to be added to General quality Q&A for HMP/THMP (EMA/HMPC/41500/2010 Rev.2)*
- draft Q&A (EMA/HMPC/462429/2013): **for adoption** - final reflection paper (EMA/HMPC/84789/2013): **for adoption**	Adopted. HMPC secretariat to publish the documents.

The HMPC Chair reminded the Committee that the adoption of the Q&A had been postponed in November 2013 until the reflection paper was finalised by the Q DG, to synchronise their adoption as final documents. The HMPC secretariat was asked to publish the reflection paper as final and to integrate the questions & answers on essential oils into the general Q&A on quality for HMP/THMP.

IV.1.3 Proposal to establish guidance (e.g. Q&A) regarding HS or HP which are covered by a pharmacopoeia monograph that does not contain an assay: **for discussion**	*Report by R. Länger and Q DG Chair* *See also VI.3.10*
- impact on MRP - timelines for guidance drafting	Proposal endorsed. R. Länger was appointed Rapporteur.

The HMPC endorsed the Q DG recommendation to establish guidance for NCAs and applicants on a European view how to address the cases where a pharmacopoeia monograph that does not contain an assay. The example of Althaea radix had been given, as some NCAs insist on the development of an assay by the applicant, others accept the absence of the assay in the pharmacopoeia monograph.
R. Länger was appointed Rapporteur. Upon request from the secretariat, the HMPC considered that it was not necessary to amend the 2014 Q DG work programme.

IV.1.4 Draft 'Reflection paper on microbiological aspects of HMP and THMP' (EMA/HMPC/95714/2013): **for adoption**	*Rapporteurs: K. Hvolby, M. Delbò* *For release for public consultation until 15 June 2014* Adopted. HMPC secretariat to publish the document.

The HMPC noted that microbiologist experts at EDQM had been consulted and their comments integrated during the preparation of the document. The committee noted the comment raised by the Austrian HMPC member, however it was agreed that this would be considered during the public consultation. The Committee thanked the Rapporteurs for the establishment of such integrated, comprehensive document, in cooperation with EDQM experts.

IV.2 European Pharmacopoeia

~~IV.2.1 Update on Pharmacopoeia Commission decisions and publications in Pharmeuropa~~	~~*Report by M. Bald*~~
IV.2.2 Progress report from Expert Groups 13A, 13B and TCM - Summary of decisions Extract WP Nov 2013 - Summary of decisions 13B WP Nov 2013 - Summary of decisions TCM WP Nov 2013	*Report by M. Bald* *See also VI.1.2 and VI.4.2*

The HMPC welcomed the report from M. Wierer and M. Bald, EDQM observers in the HMPC, who participated by audioconference. The observers thanked the Committee for the excellent cooperation between HMPC and EDQM on the finalisation of the Ph. Eur. revised monograph on extracts.
The EDQM observers drew the members' attention to the Expert Group 13B's intention to make proposals towards a greater use of quantitative approach and five Ph. Eur. monographs will serve as example. They will be published in Pharmeuropa (Betulae folium, Calendulae flos, Chamomillae romanae flos, Hyperici herba and Hyperici herbae extractum siccum). The next meeting of the group 13 B is scheduled for 8-9 April 2014. As for the Expert group 13A, their next meeting is scheduled for 4-5 March. Participation of the respective HMPC observer in these meetings was hoped for (see III.2.2).

IV.2.3 Ph. Eur. monograph on herbal drug extracts and corresponding information: **for information**

The HMPC noted that the monograph will be submitted for adoption by the Pharmacopoeia Commission in March 2014.

V. Safety & efficacy

V.1 MLWP

The next meeting of the MLWP will be held on 28-30 January	*See VI.3.2*

Status on Community herbal monographs, Community list entries, public statements, appointment of new Rapporteurs and Peer-reviewers

V.1.1 Overview of status of MLWP assessment work (EMA/HMPC/519580/2007): **for discussion**	*Report by MLWP Chair*

V.1.1.1 Appointment of Rapporteurs/Peer-reviewers

Balsamum peruvianum
Calendulae herba
Cinnamomi camphorae (folium/cortex)
Cisti cretici folium/resinum
Cyani flos
Epilobii herba
Glycine max, lecithin
Helichrysi flos
Juniperi communis summitates
Origani majoranae herba
Paeoniae radix
Pistacia lentiscus, resinum (mastix)
Polygoni avicularis herba
Ricini oleum
Saccharomyces cerevisiae/S. boulardii
Salviae trilobae folium
Sideritis herba

Endorsed by HMPC.
Post-meeting note: although all HS/HP will be added to the priority list, a call for submission of scientific data will only be published by the HMPC secretariat upon signal by the Rapporteur that he/she is ready to spend time on the assessment work. This was discussed at the MLWP meeting on 28-30 January and the HMPC secretariat will publish 12 calls for data.

Other relevant topics

N/A

V.2 Community list entries transmitted to European Commission

V.3 Community herbal monographs for public consultation/final adoption after systematic review/revision

N/A

V.4 Community herbal monographs (post finalisation)

V.4.1 Corrigendum to monograph on Plantaginis lanceolata folium: **for information**	*http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000182.jsp&mid=WC0b01ac058001fa1d*

V.4.2 Corrigendum to monograph on Origani dictami herba: **for information**	*http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/herbal/medicines/herbal_med_000182.jsp&mid=WC0b01ac058001fa1d*
V.5 Community herbal monographs, Community list entries and public statements for adoption after public consultation	
V.5.1 Sambuci fructus	*Rapporteur: G. Fossum* *Peer-reviewer: M. Heroutová*
V.5.1.1 Assessment report	Adopted by consensus.
V.5.1.1.1 List of references - available references xx/xx	HMPC secretariat to publish the documents.
V.5.1.2 Public statement	
V.5.1.3 Overview of comments	
V.5.2 Ginseng radix	
V.5.2.1 Assessment report	*Rapporteur: R. Länger* *Peer-reviewer: W. Knöss*
V.5.2.1.1 List of references - available references xx/xx	HMPC decided to return the monograph on Ginseng radix and supporting documents to MLWP for further discussion. With a view to be adopted at HMPC in March 2014.
V.5.2.2 Monograph	
V.5.2.3 Overview of comments	
V.5.3 Curcumae xanthorrhizae rhizoma	*Rapporteurs: E. van Galen/B. Kroes* *Peer-reviewer: P. Claeson* *No comments received during public consultation*
V.5.3.1 Assessment report	Adopted by consensus.
V.5.3.1.1 List of references - available references xx/xx	HMPC secretariat to publish the documents.
V.5.3.2 Monograph	
V.5.4 Rubi idaei folium	*Rapporteur: G. Fossum; Peer-reviewer: P. Claeson* *No comments received during public consultation*
V.5.4.1 Assessment report	Adopted by a majority vote (28 out of 29) without changes to the monograph.
V.5.4.1.1 List of references - available references xx/xx	Divergent position – N. Curran (Ireland)
V.5.4.2 Monograph	NO expressed a favourable position.
	HMPC secretariat to publish the documents.

V.6 Community herbal monographs, Community list entries and public statements for adoption for release for public consultation

V.6.1 Ginkgo folium V.6.1.1 Assessment report V.6.1.1.1 List of references - available references V.6.1.2 Monograph	*Rapporteur: J. Wiesner; Peer-reviewer: O. Palomino; Expert: E.-M. Eibl* *For release for public consultation until 15 June 2014* *See II.6.1* Draft monograph and supporting documents adopted. HMPC secretariat to publish the documents.

The HMPC Chair reported on the compromise reached in the MLWP on the WEU part of the monograph, referring to the range of literature available publicly and presented in the AR, with an extensive set of clinical studies results as well as some reviews. The Chair reminded that the draft monograph was presented to the Committee for adoption for release for public consultation. There was consensus in the committee to release the draft monograph and supporting documents, as tabled, for 3-month public consultation until 15 June 2014. Two editorial changes were introduced in the AR.

V.7 Community herbal monographs, Community list entries and public statements for discussion

N/A

V.8 Guidelines

N/A

VI. Other relevant business

VI.1 Conferences, presentations & research projects

VI.1.1 Report from International Symposium 'Regulation of herbal and traditional medicinal products – European and global strategies' held on 31 September-2 October 2013 in Bonn, Germany: **for information**	*Report by Organising Committee members*

The HMPC Chair reported on successful organisation of the event and the positive feedback received from participants. The event represented a valuable opportunity for exchange of information between several key regulators in the field of herbal medicines. The dialogue is expected to be continued with more of such symposium to be organised regularly in the future. The Committee was informed of the initiative to obtain from all speakers manuscripts of their presentation/lecture, with a view to getting them published in a special issue of the Journal of Ethnopharmacology (with J. Wiesner, I. Chinou and the HMPC Chair being guest editors).

VI.1.2 Report from EDQM Symposium on traditional Chinese medicines held on 14-15 November 2013 in Strasbourg, France: **for information** - Summary outcome of Symposium	*Report by M. Bald and HMPC participants*

The HMPC had welcomed the circulation of the summary outcome from the symposium, which

represented a unique opportunity for European experts to meet representatives from the Chinese Pharmacopoeia who shared their expertise and knowledge on the establishment of specifications for Chinese herbal material.	
VI.2 International cooperation, collaboration with non-EU regulatory authorities	
N/A	
VI.3 Documents for information	
VI.3.1 HMPC meeting held on 11-12 November 2013	
VI.3.1.1 Table of Decisions (EMA/HMPC/694378/2013)	
VI.3.1.2 Meeting report (EMA/HMPC/702025/2013)	*http://www.ema.europa.eu/docs/en_GB/document_library/Committee_meeting_report/2013/11/WC500156450.pdf*
VI.3.2 Draft agenda of MLWP meeting to be held 28-30 January 2014 (EMA/HMPC/790056/2013)	
VI.3.3 MLWP meeting held on 12-14 November 2013	
VI.3.3.1 Table of Conclusions (EMA/HMPC/698330/2013 Ver.2)	
VI.3.3.2 Draft Minutes (EMA/HMPC/730474/2013)	***Post-meeting note: adopted by MLWP with corrections (spelling errors + change to topics IV.6 and IV.13 + inclusion of list of participants).***
VI.3.4 Overview of status of HMPC assessment work – priority list (EMA/HMPC/278067/2006)	*Status November 2013 (post-meeting)* *http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/12/WC500017724.pdf*
VI.3.5 Inventory of herbal substances for assessment work – alphabetical order (EMA/HMPC/494079/2007)	*Status November 2013 (post-meeting)* *http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/12/WC500017723.pdf*
VI.3.6 Common names of herbal substances in all EU official languages (EMA/HMPC/95087/2011)	*Status December 2013*
VI.3.7 HMPC Letter dated 18 December 2013 on BSS and further considerations	*Rapporteur: G. Calapai*
VI.3.8 Published MLWP 2014 work programme	*http://www.ema.europa.eu/docs/en_GB/document_library/Work_programme/2009/12/WC500020087.pdf*
VI.3.9 Published ORGAM DG 2014 work programme	*http://www.ema.europa.eu/docs/en_GB/document_library/Work_programme/2009/12/WC500020090.pdf*

VI.3.10 Published Q DG 2014 work programme	http://www.ema.europa.eu/docs/en_GB/document_library/Work_programme/2009/12/WC500020089.pdf
VI.3.11 Presentations given at informal HMPC meeting held in Vilnius in December 2013	
VI.3.12 Progress with ARSP establishment	*Report by HMPC secretariat*
The HMPC secretariat informed the HMPC on the expected progress concerning the publication of the ARSP that had been transmitted for publication and checking of linguistic versions in the autumn 2013.	
VI.3.13 Helmstädter A, Staiger C. Traditional use of medicinal agents: a valid source of evidence. *Drug Discovery Today* 2014, 19(1):4-7	*Circulated to HMPC on 8 January*
VI.3.14 Vlachojannis C, Magora F, Chrubasik-Hausmann S. Pro and contra duration restriction of treatment with willow bark extract – letter to the editor. *Phytother. Res.* 2014, 28:148–149	*Circulated to HMPC on 8 January*
VI.3.15 Danish Food Agency information rapid alerts on Ayurvedic products sold as food supplements with high levels of toxic heavy metals	*Report by S. Bager*
S. Bager reported on the information received from the Danish Food Agency concerning food supplements containing high levels of heavy metals, present in the products in support of their intended use rather than as a result of contamination. The Committee had already been confronted with similar rapid alerts in the past, circulated by competent authorities in the EU but also by non-EU regulators (e.g. FDA, Health Canada).	
VI.3.16 Minutes from the joint PCWP-HCPWP meeting held on 25 September 2013 (EMA/618027/2013)	
VI.3.17 Maggini V, Gallo E, Vannacci A, Gori L, Mugelli A, and Firenzuoli F. e-Phytovigilance for misleading herbal information. *Trends in Pharmacological Sciences* 2013, 34(11):594-595	
VI.3.18 Pelkonen O, Xu Q, Fan T-P. Why is research on herbal medicinal products important and how can we improve its quality? *Journal of Traditional and Complementary Medicine* 2014, 4(1):1-7	*Circulated to HMPC on 11 January*
VI.3.19 Presentations given at the EDQM Symposium on traditional Chinese medicines held on 14-15 November 2013 in Strasbourg, France	Available at http://www.edqm.eu/en/proceedings-international-conference-83.html
VI.3.20 EMA Principles for publication of agendas and minutes of EMA scientific committees	Available at http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/12/WC500158538.pdf
VI.4 Any other information	
VI.4.1 HMPC New Year function on 27 January 2014 at 19.00 in the lobby outside 3A	

The HMPC Chair, on behalf of the Committee, thanked the EMA secretariat for enabling the members to get the opportunity for an informal exchange between the delegates and members of the EMA secretariat, celebrating the achievements for 2013 and reflecting on the challenges of the year 2014.
VI.4.2 Announced changes in EDQM observers to HMPC and farewell to M. Wierer
The HMPC Chair, on behalf of the Committee, thanked M. Wierer, EDQM observer in the HMPC since the Committee was created, for the substantial contribution to the strengthening of the EDQM-HMPC cooperation. With a personal commitment to transparent communication and support to the Ph. Eur. activities on monographs' establishment for HS/HP, M. Wierer was a fundamental actor in raising the collaboration beyond a mere exchange of information to achieve a true dialogue on the pharmacopoeial requirements that complement the safety & efficacy conclusions found in the HMPC monographs. The Chair wished M. Wierer every success in his new function at EDQM.

VI.4.3 Abbreviations in HMPC minutes	
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/11/WC500155666.pdf	To be added at next revision: SA = scientific advice PA = protocol assistance PR = peer-review ICT = Information and Communication Technology

The Chair thanked all participants (list in Annex) and closed the meeting.