28 January 2015
EMA/HMPC/769631/2014
Procedure Management and Business Support Division

Committee on Herbal Medicinal Products (HMPC)

Minutes of the 24 November 2014 meeting

FINAL

Chair: Werner Knöss

24 November 2014, 09:00 – 19:00, room 3E, *plenary*
(Assessors training on 25 November 2014, 09:00-17:00, 3E)

- **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 Creston 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.

- **Announcement of new nominations, changes to composition**

Resignation of Mariette Backes-Lies (LU member)

- **Election of Co-opted member to the HMPC with expertise in:**

- Paediatric medicine
See I.1.3

- **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.

- Draft annex to the minutes for the November 2014 HMPC meeting, documenting anticipated restriction on involvement in relation to agenda topics and declarations of interest from members and alternates (EMA/HMPC/639151/2014)

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

- **Note on access to documents**

Some documents mentioned in the agenda/minutes cannot be released at present within the framework of Regulation (EC) No 1049/2001 on access to documents because they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents

I. Introduction	
I.1 Agenda, minutes	
I.1.1 Agenda of 24 November 2014 HMPC meeting - timetable, for order of topics *For adoption*	Adopted
I.1.2 Minutes of 29-30 September HMPC meeting *For adoption*	Adopted
I.1.3 Election of co-opted member - procedure for nomination/election of co-opted members for HMPC - Overview of expertise available in the HMPC, MLWP, ORGAM, Q DG - Nomination received for Paediatric medicine: S. Girotto *For adoption*	Report: HMPC Chair S. Girotto was re-appointed as co-opted member to the HMPC for Paediatric medicine for a 3 year term starting 27 Jan 2015. Members to provide information for completion of the overview of expertise by 15 December 2014.
I.2 Legislation and regulatory affairs	
I.2.1 Revision procedure for List entries - email from legal department 7 November 2014 - draft list of minor/major changes *For discussion*	*See also I.6* and *V.1.3* Art. 16f(3) of the Dir. 2001/83/EC provides the legal basis for LE revision as it suggests that a herbal substance, preparation or a combination thereof can be removed from the list and implies that there should be a procedure established in order to prevent LE from becoming outdated. In order to establish a differentiation based on the magnitude of the modification to trigger a revision process or not, the procedure EMA/HMPC/124695/2011 and RP EMA/HMPC/326440/2007 Rev.2 need to be amended. The list of minor/major changes was agreed as first approach, however, an exhaustive listing of all cases was not considered possible. Considerations to be given on time for implementation with transmission of revised LE to the Commission.

	HMPC asked ORGAM DG to review the list, implement necessary changes in the current procedural guidance and report at the HMPC January 2015 meeting.
A legal basis for possible LE revision was confirmed although not equivalent to the need for renewal as common for individual MA. Therefore in case of no necessary changes no new opinion or voting is necessary. The use and exhaustiveness of the list of minor/major changes was discussed. While principally seen in accordance with the legislation to trigger the revision only in case of major relevance (but not minor template adaptions) it was also acknowledged that slightly different standards can co-exist with an updated TU part of a monograph alongside the 'old list entry' (example Echinacea purpurea herba see II.3.1; Anisi aetheroleum). In view of currently few LEs a 'case by case' decision was considered feasible based on main principles to be implemented in existing guidance documents. The Commission representative asked for clarification on implementation in case of revisions and eventually necessary transition periods as well as whether there are any products already registered based on a LEs.	
I.2.2 New terminology for herbal monographs and list entries - email from legal department 8 October 2014 *For information*	'Community herbal monographs' will be renamed into 'Union herbal monographs' (or 'European Union herbal monographs'). The change will be implemented on any supporting documents, scientific, regulatory and procedural guidelines or monographs which will be adopted/revised from now on. There is no need to change adopted documents retrospectively. HMPC agreed to the immediate change by the secretariat for all adopted templates in use. All information on the EMA website mentioning 'Community herbal monographs' are being replaced by the term 'European Union herbal monographs' to align with the terminology as proposed.
I.3 Questions raised by HMPC members	
I.4 Questions raised by companies	
I.5 Referral procedures	
I.6 Co-ordination with Eur. Com.	
I.6.1 Revision procedure for List entries *For discussion*	Report: E. van Galen *See I.2.1* and *V.1.3*
I.7 Co-ordination with EFSA	
I.7.1 Report from 'HMPC strategic presidency meeting' held in Rome on 4-5 November 2014 - agenda - presentations *For information*	Report: M. Delbó, HMPC Chair HMPC noted first report on meeting together with representatives from EFSA and the Eur. Com. The meeting report will be made available for information once finalised.

Under the Italian presidency the Italian agency had chosen the topic of borderline between food supplements and medicines originating from plant sources. Existing legislative frameworks, their implementation, assessment methodology of claims and safety as well as the use of assessment outcomes by national competent authorities and patients, consumers and health professionals were discussed from a public health perspective.	
I.8 Other external Co-ordination	
II. Safety & efficacy	
II.1 Report on MLWP activities	
II.1.1 Report on progress achieved Overview of status of MLWP assessment work *For information*	Report: MLWP Chair
II.1.2 MLWP work plan 2015 *For adoption*	Report: MLWP Chair *See V.2.1*
II.2 European Union list entries transmitted to European Commission	
II.3 European Union herbal monographs for public consultation / final adoption after systematic review / revision	
II.3.1 Monograph on Echinaceae purpureae herba (and supporting documents: AR, LoR) *For adoption*	Rapporteur: S. Kreft/B. Razinger Peer-reviewer: J. Wiesner *MLWP proposed no changes to the existing LE.* Final revised **monograph** with changes in several sections and supporting documents adopted by majority vote (21 out of 29). Divergent position: E. v. Galen, A. Cunney, M. Nagy, A. Núñez Velázquez, M. Delbo, L. Anderson, S. Girotto, G. Calapai NO expressed a favourable position. HMPC agreed not to change the existing **list entry**.
Members discussed the scope of the monograph (pressed juice from fresh plant) and necessary clarity in the titles and footnotes vis-à-vis the Ph.Eur. monograph). The use in children and adolescents was scrutinized because of more available clinical data on use in children than for most other herbal substances, relevant guidelines in this respect and subsequent agreed wordings by the MLWP. In addition, all necessary changes in the monograph were discussed in view of general considerations on monograph and list entry revision procedure (see 1.2.1). Members accepted the proposal by the Rapporteur in the TU part of the monograph but did not consider those changes as that substantial requiring LE revision as it referred mostly to template and current practice alignments. Changes had been introduced in monograph sections 2, 4.2, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 5.1 and 5.3 predominantly in the WEU part of the monograph. Divergent positions were mainly related to the debate on the recognised efficacy for WEU acceptance. The HMPC Chair reminded that as part of the supporting documents, the references should be available at time of adoption. Outstanding full text copies should be provided to the secretariat before publication for closure of the package.	

II.3.2 Monograph Betulae folium (and supporting documents: AR, LoR) *For adoption*	Rapporteur: R. Länger Peer-reviewer: M. Heroutová Final revised monograph with change in section 4.2 and supporting documents adopted by majority vote (28 out of 29). Divergent position: E. v. Galen. NO expressed a favourable position.
While newly available data had been included in the AR, they triggered no major changes in the monograph. The revision adhered primarily to template and current practice adaptations. Members discussed mainly the possible inclusion of adolescents based on available market data for the different preparations taking into account the indication, safety considerations and analogies to comparable substances, which was agreed by a majority. Some improvement in wordings were proposed but not accepted. The divergent opinion referred to doubts on the evidence of plausibility for urine increase due to the herbal substance alone.	
II.4 European Union herbal monographs (post finalisation)	
II.5 European Union herbal monographs, European Union list entries and public statements for adoption after public consultation	
II.5.1 Monograph and list entry on Melaleucae alternifoliae aetheroleum (and supporting documents: AR, LoR, OoC) *For adoption*	Rapporteur: M. Delbò Peer-reviewer: J. Viguet-Poupelloz Final **monograph** with changes in section 4.2 and supporting documents adopted by majority vote (24 out of 29). Divergent positions: E. Leinonen, O Pelkonen, M. Nagy, W. Dymowski, A. Le NO expressed a favourable position. Draft **list entry** with changes in the posology section and supporting documents adopted by majority vote (21 out of 29) for transmission to the Eur. Com. Divergent positions: E Leinonen, O Pelkonen, M. Nagy, W. Dymowski, A. Le, E. v. Galen, A. Núñez Velázquez, I. Chinou NO expressed a favourable position.
The HMPC discussed the inclusion of the undiluted oil as regards available evidence on 15/30 years of safe medicinal use. In this respect the suitability of available non-scientific evidence to prove 15 years in the EU was discussed as well as the irritant potential of undiluted essential oil. Aspects taken into account were: the wide use outside the medicines framework (such as cosmetic), expert evidence on the allergenic potential and reported contact dermatitis also on intact skin, the posology and linked plausibility to achieve the same effects within the range of 0.5%-100%, the bibliographic evidence that irritation is mainly linked to oxidised but not fresh and properly stored high quality tea tree oil, but also	

the value of studies performed with fresh oil showing an irritant potential, while the oil is rapidly oxidising after container opening and therefore likely to be used in oxidised form. Some members requested a differentiation of indications (such as Acne) as regards the use of the undiluted oil from a safety perspective. The risk of accidental poisoning due to overdose was not considered as relevant for the defined medicinal use by a majority of members. It was agreed to accept sound information from medicinal text books as evidence on the medicinal use, while non-scientific journal articles might be somewhat supportive within the totality of data and mentioned in the AR, but not be recognised as stand-alone evidence nor included in the LoR. A majority agreed to include the undiluted essential oil in the monograph and the Rapporteur was also asked to adapt the list entry accordingly. Divergent positions were all safety-related due to the sensitising and allergenic potential.	
II.5.2 Monograph on Lichen islandicus (and supporting documents: AR, LoR, OoC) *For adoption*	Rapporteur: M. Heroutová Peer-reviewer: A. Vlietinck Final monograph with change in sections 4.2 and 4.4 and supporting documents adopted by consensus. NO expressed a favourable position.
No major changes had been introduced after public consultation. The use in children and adolescents was discussed given the wide use of the substance in other product categories (starting at age 1) and also the use of marketed medicinal products from 6 years on. The rationale for the Rapporteur and MLWP proposal was explained and several aspects discussed including the risks due to the pharmaceutical form, general considerations on use of cough medicines in children, the content in lichen acids, analogies to other herbal medicinal products, and available data versus actual use in marketed products. A majority agreed to an acceptable use in adolescents but not in children. The Rapporteur was asked to provide the justification (available data, safety aspects and possible extrapolation) in the AR to explain the changes in the monograph as per preparation/ route of administration and indication.	
II.6 European Union herbal monographs, European Union list entries and public statements for adoption for release for public consultation	
II.6.1 Monograph on Carvi aetheroleum (and supporting documents: AR, LoR) *For adoption*	Rapporteur: P. Claeson Peer-reviewer: M. Delbò Draft monograph with change in section 4.2 and supporting documents adopted by consensus for release for 3 months public consultation.
The Carvi monographs had been rediscussed at MLWP for consideration of new safety data on carvone published by EFSA leading to changes in the AR but not the monograph. The only change was the inclusion of infants for the cutaneous use of the essential oil.	
II.6.2 Monograph on Carvi fructus (and supporting documents: AR, LoR) *For adoption*	Rapporteur: P. Claeson Peer-reviewer: M. Delbò *See II.6.1* Draft monograph without change and supporting documents adopted by consensus for release for 3 months public consultation.

II.6.3 Monograph on Sabalis serrulatae fructus (and supporting documents: AR, LoR) For adoption	Rapporteur: G. Laekeman/A. Vlietinck Peer-reviewer: L. Anderson Draft monograph without changes and supporting documents adopted by majority vote for release for 3 months public consultation.
The Committee discussed the indications in particular the evidence for WEU, BPH symptoms, the difference to the TU indication and posology as well as the warnings section in the monograph. No changes were introduced. Some members did not support the draft AR (such as missing clarity in presentation of clinical data) but a majority agreed to the release for public consultation now (to support the understanding for IPs), while shortcomings of the AR should be corrected for the final AR after public consultation.	
II.7 European Union herbal monographs, European Union list entries and public statements for discussion	
II.7.1 MLWP recommendation to cancel the assessment work on Cyani flos (and supporting documents: presentation) *For adoption*	Rapporteur: J. Wiesner Peer-reviewer: C. Purdel HMPC agreed with MLWP recommendation to cancel the assessment work on Cyani flos because of insufficient data.
II.7.2 MLWP recommendation to cancel the assessment work on Myrtilli folium (and supporting documents: Mo and AR) *For adoption*	Rapporteur: E. Widy-Tyszkiewicz Peer-reviewer: G. Calapai; M. Delbò HMPC agreed with MLWP recommendation to cancel the assessment work on Myrtilli folium because of insufficient data.
II.8 Guidelines and other guidance documents	
II.8.1 Public statement on the use of herbal medicinal products containing toxic, unsaturated pyrrolizidine alkaloids (PAs) - final public statement - overview of comments *For adoption*	Rapporteurs: J. Wiesner and O. Pelkonen *For final adoption.* Adopted with changes by consensus for publication on EMA website.
Following a second public consultation, the rationale for changes in the PS following the agreement at MLWP was explained by the Rapporteur. In principle the EFSA risk assessment on an acceptable daily PA intake is followed as the upper limit for short term use of PA-containing medicinal products. The potential additional exposure via parallel food intake is considered acceptable during this limited period (maximum 14 days – specified in the conclusions). Calculations for children are to be done as per body weight. The oral use follows the same principle unless product specific data (including suitable absorption data) justify a higher amount in the product. The applicability for final products vis-à-vis the magisterial use (e.g. preparation in pharmacies) was discussed and necessary requirements (e.g. certificate of analysis) and legal implications considered.	
II.8.2 Public statement on the use of herbal medicinal products containing estragole - letter by SWP Chair - draft revised public statement *For adoption*	*Draft adoption for public consultation.* Adopted with changes by consensus for publication on EMA website.

The background for the intended revision of the 2005 PS was explained by the Rapporteur due to newly available data from the last 10 years. The consideration of estragole as genotoxic carcinogen has been established as well as the importance of metabolic activation. The extrapolation of animal data to human risk assessment had been confirmed by SWP. The HMPC discussed the necessary safety factors to be applied, short term use, possible repeated use and the double exposure via medicine and food. The suitability of some references was discussed and a different approach to the EFSA assessment was noted as regards consideration of the extracted and absorbed amounts from the source (concentration in the product and likely intake versus acceptable limits for the human organism).	
II.8.3 Public statement on the use of herbal medicinal products containing pulegone and menthofuran - letter by SWP Chair - draft revised public statement *For adoption*	*Draft adoption for public consultation.* *See also IV.3.1* Adopted with changes by consensus for publication on EMA website.
Equally to estragole, a series of new data over the last 10 years triggered the revision of the PS on pulegone and menthofurane and the assessment approach had been scrutinised by SWP. In contrast to estragole, the genotoxic potential of pulegone is more controversial. Common standard tests do probably not capture genotoxicity sufficiently in this case. Some contradictory data from animal studies and the SWP advice on metabolic activation were considered. The acceptable safety margin was questioned. It was asked to clarify some references, to specify the short term use and to make clear that the content of pulegone and menthofuran (main metabolite of pulegone) has always to be considered together. Members acknowledged that proposed limits would affect some peppermint oil preparations on the market and would require regulatory action. The coordination with PRAC will, however, only be sought after public consultation because further coordination and decision should be based on final recommendations.	
III. Quality	
III.1 Quality Drafting Group	
III.1.1 Meeting report from Q DG meeting held on 12 November 2014 *For adoption*	Report: Q DG Chair Adopted
The Q DG Chair reported that mostly the reflection paper on benzene had been discussed (see below) followed by a discussion on the chemical comparability of virgin and refined castor oil regarding safety, efficacy/plausibility and classification as herbal preparation. In principle it was concluded that both can be regarded as herbal preparations with a comparable profile allowing their potential inclusion into the monograph currently under development at MLWP, without need to distinguish in all cases whether data are available for the one or the other. In addition, considerations have been given to the draft work plan 2015. The additional face to face meeting on 10 December will be used to finalise the mock-up for the amendment of the CTD guideline.	
III.1.2 Reflection paper on Benzene (class 1 solvent) as a potential impurity in solvents used for the manufacture of herbal preparations *For adoption*	Report: Q DG Chair Postponed. HMPC recommended inclusion of guidance developed into the quality Q&A document.
The document had been considered finalised from a content perspective at the last Q DG meeting but after written procedure post-meeting questions were raised both on the content as well as the format and objective of the elaborated guidance. After request it was confirmed that benzene in ethanol is	

indeed a general issue from the quality perspective for non-herbal medicines that needs also clarification for herbal products. Secretariat and HMPC advised to consider the inclusion into the anyway to be updated HMPC quality Q&A document as originally intended, before it became clear that different scenarios are more complicated than expected.	
III.1.3 Q DG work plan 2015 *For adoption*	Report: Q DG Chair *See V.2.1*
III.2 Co-ordination European Pharmacopeia	
III.2.1 EDQM Expert Group 13A meeting to be held on 2-3 December 2014 - agenda *For information*	EDQM: M. Bald, U. Rose HMPC Observer: I. Chinou
III.2.2 EDQM: 50 years of leadership in the quality of medicines – paving the way for the future meeting held on 6-8 October 2014 - presentations *For information*	EDQM: M. Bald, U. Rose
III.2.3 HMPC observers at Ph. Eur. Expert groups 13A, 13B and TCM -email *For discussion*	I. Chinou, H. Neef and R. Länger were confirmed for 2015 as HMPC observers at Ph. Eur. expert groups 13A, 13B and TCM, respectively, for regular reporting to the HMPC.
The HMPC confirmed the need having observers at all three European expert groups to ensure the important coordination between groups from a regulatory perspective in addition to EDQM observers at HMPC and Q DG and some personal overlaps. The objective is a regular reporting at HMPC meetings to establish necessary action for HMPC and Q DG.	
IV. Internal Co-ordination with committee and working parties	
IV.1 Observers at other Committees	
IV.1.1 Overview of HMPC coordination/observers with other committees *For discussion*	Postponed.
IV.2 Co-ordination with CHMP	
IV.3 Co-ordination with SWP	
IV.3.1 Revision public statement on the use of herbal medicinal products containing pulegone and menthofuran *For discussion*	*See II.8.3*
IV.4 Co-ordination with HCPWP/PCWP	
IV.4.1 Draft Work plan for the European Medicines Agency Human Scientific Committees' Working Party with Healthcare Professionals' Organisations (HCPWP) - presentation *For adoption*	HMPC observer: S. Bager Adopted.

IV.4.2 Draft Work plan for the European Medicines Agency Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) 2015 - presentation *For adoption*	HMPC observer: S. Bager Adopted.
Main features of the work plans for HCPWP and PCWP were briefly presented. No questions were raised by HMPC members to the secretariat or HMPC observer whether herbal medicinal products or the work of the HMPC should be considered in the 2015 plans apart from support with the identification of experts from PCOs to provide input on draft summaries of herbal ARs.	
IV.5 Co-ordination with Working Group on Quality Review of Documents (QRD)	
IV.5.1 QRD template modifications tailored for THMPs - Annex III, SmPC, labelling and PL - w*ith minor changes submitted to QRD* *- email* - Annex III, SmPC, labelling and PL - *with further proposed changes by ORGAM* *For discussion/adoption*	Rapporteurs: E. Svedlund, P. Claeson, R. Laenger, E. v. Galen *See also V.1.2* Submitted proposals for minor changes could not be taken into account by QRD group anymore for ongoing template revision. ORGAM DG to finalise an overall proposal for discussion with QRD representatives at HMPC January 2015 meeting.
According to the agreed two steps at the September meeting, the first proposed minor changes were transmitted to the QRD group but it was too late to be considered for the ongoing revision. Clarification on timelines for the next revision has not yet been obtained. For the second more detailed proposal ORGAM had extensively discussed and principle agreement had been reached on most points. The ORGAM Chair proposed that once ready and agreed from ORGAM/HMPC side, the proposals should also be presented in presence of a QRD representative to explain the rationale behind and find agreement on the level of detail that is suitable for the generally applicable template. The current focus of the template on centralised procedure and the existing modified template used by CMDh was mentioned. Members discussed the emphasis on THMP so far (but not HMP) as well as common and different features compared to herbal monographs - both points to be considered for the next ORGAM discussion.	
V. Organisational matters	
V.1 Organisational Matters Drafting Group	
V.1.1 Meeting report from ORGAM DG meeting held on 10 November 2014 *For adoption*	Report: ORGAM DG Chair Adopted
The ORGAM Chair reported from an extensive discussion on the QRD template (Annex III, SmPC, labelling and PL) with good progress but some remaining controversial points, which will be further debated at the next meeting 9 December (see IV.5.1). In addition the revision procedure for List entries and requested major/minor list (see I.2.1) has been initiated and a draft proposal agreed as basis for HMPC discussion and possible review by MLWP for completeness. Other topics were the 'change of terminology implementation' (see I.2.2) already initiated by the secretariat and proposals for the 2015 work plan.	
V.1.2 QRD template modifications tailored for THMP *For discussion/adoption*	Rapporteurs: E. Svedlund, P. Claeson, R. Laenger, E. v. Galen *See IV.5.1*

V.1.3 Revision procedure of List entries *For discussion*	Report: ORGAM DG Chair *See I.2.1*
V.1.4 ORGAM DG work plan 2015 *For adoption*	*See V.2.2*
V.2 Working methodology	
V.2.1 HMPC work plan 2015 and input for EMA work programme - HMPC work programme 2012-2015, current status - HMPC work plan 2015 - work plan 2015 MLWP - work plan 2015 Q DG - work plan 2015 ORGAM DG Add as per discussion *For adoption*	*See also* II.1.2, *III.1.3 and V.1.4* HMPC noted work plans as proposed by HMPC Chair MLWP, Q DG and ORGAM DG. Specification of Rapporteurs/ activities and further proposals according to available resources recommended. After finalisation of the MLWP work plan 2015 HMPC secretariat to distribute to all HMPC members. Members to send comments by 08 December 2014 and before final adoption by written procedure by 15 December 2014.
Based on the HMPC work programme 2012-15 the most important topics had been identified by Chair and secretariat and compiled into the HMPC work plan 2015. Beside core business of monograph and guideline development with reference to the respective annual work plans of MLWP, Quality and ORGAM DG, 4 main projects were specified covering revision strategy, assessment needs including combinations and non-European substances, and European and international collaboration. Apart from previously appointed observers in other relevant groups of the agency no new horizontal activities, specific coordination projects or activities focussing on partners and stakeholders were proposed for 2015 but a specific cooperation (such as with PDCO) in the future was suggested to be explored for implementation in 2016. The draft MLWP work plan was proposed to be finalised during the following MLWP meeting. Some modifications for the drafting group plans were requested as regards content, possibility for completion within 2015 and priorities, specific actions and Rapporteur appointment and distribution.	
V.2.2 '2015 EMA policy on the handling of declarations of interests of scientific committees' members and experts' - presentation *For information*	Reasons and main new provisions of the policy revision were presented. Members noted timelines for new DOI submission (end of January) and consequences for meeting participation. In case no requests have been received yet, members to double-check with the secretariat.
The objective and rationale for changes was provided referring to transparency but also the aim to obtain the best possible expertise in the EU. Therefore improvements have been introduced also based on a public workshop in 2013 and endorsed at the MB in March 2014. The implementation and subsequent format has now been finalised. Main changes were highlighted such as interest levels with differentiation of role, assessment of funding (e.g. research grants) according to beneficiary, time periods for consideration, competitor products, or change in terminology. An impact assessment has been performed in 2 committees.	

The new electronic format is already available (incl. helpdesk) and has to be completed by 30 January, otherwise the expert status will be changed to 'non-active' and participation in meetings not possible. Questions on the provisions as regards relatives and research grants were clarified.	
V.2.3 Election of MLWP Chair in January 2015 - Mandate, objectives and rules of procedure for the HMPC Working Party on European Union Monographs and European Union List (MLWP) (EMEA/HMPC/379153/2005 Rev.2) *For information*	
With the expiring 3 year mandate the MLWP Chair for the next 3 year term has to be elected in January and possible candidatures should be considered. The HMPC secretariat will send out beginning of January a reminder and request for nominations.	
V.2.4 Assessors' training 'European Union monographs- development and usages' on 25 November 2014 - agenda *For information*	Report: HMPC Chair
V.2.5 Quality and finalisation of documents transmitted to HMPC for adoption - examples *For discussion*	Postponed
V.2.6 Survey on implementation of Dir. 2004/24/EC (status 2014) - Timetable - List of questions *For discussion*	Postponed
V.2.7 Minor change of time schedule for January 2015 meeting - email dated 18 November 2014 *For discussion*	Members noted minor shift with HMPC starting Tuesday 27/01/2015 1pm.
VI. Other relevant business	
VI.1 Conferences, presentations & research projects	
VI.1.1 Paving the way towards a coherent system, AESGP meeting in Brussels 7-8 October 2014 - report *For information*	Report: W. Knöss, I. Chinou, M. Delbó http://www.aesgp.eu/media/reports/London_report.pdf
VI.2 International cooperation, collaboration with non-EU regulatory authorities	
VI.2.1 7th annual meeting of IRCH to be held in Lisbon, Portugal on 2-4 December 2014 - draft agenda - programme *For information*	Report: HMPC Chair

VI.3 Documents for information	
VI.3.1 Table of Decisions from HMPC meeting held on 29-30 September 2014	
VI.3.2 Meeting report from HMPC meeting held on 29-30 September 2014	http://www.ema.europa.eu/docs/en_GB/document_library/Committee_meeting_report/2014/10/WC500175755.pdf
VI.3.3 Draft agenda of MLWP meeting to be held on 26 - 28 November 2014	
VI.3.4 Table of Conclusions from MLWP meeting held on 30 September – 2 October 2014	
VI.3.5 Draft Minutes from MLWP meeting held on 30 September – 2 October 2014	
VI.3.6 Overview of status of HMPC assessment work – priority list	http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/12/WC500017724.pdf
VI.3.7 Inventory of herbal substances for assessment work	http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/12/WC500017723.pdf
VI.3.8 Common names of herbal substances in all EU official languages	
VI.3.9 PCWP - Training session for patients and consumers involved in EMA activities (25 November 2014) - draft agenda	Observer: S. Bager
VI.3.10 PCWP - EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) meeting with all eligible organisations (26 November 2014) - draft agenda	Observer: S. Bager
VI.3.11 News item on 10th anniversary HMPC at the EMA website	http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/11/news_detail_002211.jsp&mid=WC0b01ac058004d5c1
VI.3.12 NTP project: Report on Carcinogens (RoC) Concept: Goldenseal Root Powder	
VI.4 Any other information	
VI.4.1 Abbreviations in HMPC minutes	http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/11/WC500155666.pdf
VI.4.2 Proposal by Kew Gardens to map a plant list - email from M. Delbò 14 November 2014 - proposal from Kew Gardens	Report: M. Delbò Postponed
VI.4.3 Non-European traditional herbal medicines in Europe: A community herbal monograph perspective. L. Que *et al.*, *Journal of Ethnopharmacology* 156(2014) 107–114	

List of participants

Chair of the HMPC
Werner Knöss

HMPC members

Reinhard Länger (AT)
Heidi Neef (BE)
Elena Mustakerova (BG)
Ivan Kosalec (HR)
Marie Heroutová (CZ)
Steffen Bager (DK)
Eeva Sofia Leinonen (SF)
An Lê (FR)
Jacqueline Wiesner (DE)
Ioanna Chinou (GR)
Zsuzsanna Biró-Sándor (HU)
Anna Cunney (IE)
Marisa Delbó (IT)
Dace Kalke (LV)
Everaldo Attard (MT)
Emiel van Galen (NL)
Steinar Madsen (NO)
Wojciech Dymowski (PL)
Ana Paula Martins (PT)
Nadia Grigoras (RO)
Barbara Razinger (SL)
Adela Núñez Velázquez (ES)
Per Claeson (SE)
Linda Anderson (UK)
Gioacchino Calapai (co-opted)
Silvia Girotto (co-opted)
Gert Laekeman (co-opted)
Olavi Pelkonen (co-opted)

Apologies
Maria Stavrou (CY)
Evelin Saar (EE)
Jacqueline Genoux-Hames (LU)
Arturas Kažemekaitis (LT)
Martina Hudecová (SK)
Melanie Bald (EDQM)
Ulrich Rose (EDQM)
Maria Helena Pinto Ferreira (co-opted)

HMPC alternate members
Astrid Obmann (AT)
Wim Vervaet (BE)
Kapka Kaneva (BU)
Markéta Příhodová (CZ)
Marje Zernant (EE)
Zoi Karampourmpouni (GR)
Baiba Jansone (LT)
Erika Svedlund (SE)
Milan Nagy (SK)
Burt Kroes (NL)
Sue Harris (UK)

Observer
Gabriela Duchajová (SK)