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## COMMITTEE ON HERBAL MEDICINAL PRODUCTS

### Updated Annexes to the HMPC status report on the implementation of the provisions of Chapter 2a of Directive 2001/83/EC as amended by Directive 2004/24/EC as regards traditional herbal medicinal products (EMEA/HMPC/187219/2006)

(cut-off date 31 July 2007)

The following tables are an update of the Annexes presented in the HMPC status report dated 31 October 2006 (EMEA/HMPC/187219/2006). The updated Annexes provide a more recent (status July 2007) picture of the composition of the Committee and its subgroups, as well as of the HMPC documents published on the EMEA website.

## Annex 1

### Composition of the HMPC and HMPC subgroups, (status July 2007)

Member (state)	HMPC		MLWP	DG Q	ORGAM
	Member	Alternate			
Konstantin Keller (DE)	C		X		
Heribert Pittner (AT)	VC		C		
Wolfgang Kubelka (AT)		X		X	
Arnold J Vlietinck (BE)	X		X		
Heidi Neef (BE)		X		X	
Stefan Nikolov (BU)	X				
Elena Mustakerova (BU)		X			
Panayiotis Triantafyllis (CY)	X				
Maria Stavrou (CY)		X			
Marie Heroutova (CZ)	X		X		
Helena Látalová (CZ)		X			
Steffen Bager (DK)	X				X
Kristine Hvolby (DK)		X		X	
Marje Zernant (EE)	X				
Ain Raal (EE)		X	X		
Anneli Törrönen (FI)	X		X		
Sari Koski (FI)		X		X	
Antoine Sawaya (FR)	X				
Jacqueline Viguet Poupelloz (FR)		X	X		X
Werner Knöss (DE)	X				
Christine Werner (DE)		X	X		
Klaus Reh (DE)				X	X
Ioanna Chinou (GR)	X		VC		
Eleni Skaltsa (GR)		X			
Zsuzsanna Biró-Sándor (HU)	X		X		
Thorbjörg Kjartandsdóttir (IS)	X				
Sesselja Ómarsdóttir (IS)		X			

Member (state)	HMPC		MLWP	DG Q	ORGAM
	Member	Alternate			
Cora Nestor (IE)	X		X		
Sinead Harrington (IE)		X			
Vittorio Silano (IT)	X				
Marisa Delbó (IT)		X	X	X	X
Dailonis Pakalns (LV)	X		X		
Dace Kalke (LV)		X			
Artūras Kažemekaitis (LT)	X				
Mariette Backes-Lies (LU)	X				
Jacqueline Genoux-Hames (LU)		X			
Caroline Attard (MT)	X				
Emiel Van Galen (NL)	X				C
Burt H Kroes (NL)		X	X	C	
Steinar Madsen (NO)	X				
Gro Fossum (NO)		X	X		
Wojciech Dymowski (PL)	X				X
Elzbieta Wojtasik (PL)		X		X	
Ewa Widy Tyszkiewicz (PL)			X		
Ana Paula Martins (PT)	X				X
Maria Helena Pinto Ferreira (PT)		X	X		
Maria do Céu costa (PT)				X	
Maria Niculescu (RO)	X				
Laurentia Ruscan (RO)		X			
Peter Potůček (SK)	X				
Milan Nagy (SK)		X			
Samo Kreft (SI)	X		X		
Barbara Razinger (SI)		X			X
Gloria García Lorente (ES)	X		X		X
Adela Velázquez (ES)		X			
Per Claeson (SE)	X		X		
Ubonwan Claeson (SE)		X			X
Linda Anderson (UK)	X		X	X	
Sue Harris (UK)		X			
Gert Laekeman (BE)	# Pre-clinical pharmacology		#		
Olavi Pelkonen (FI)	# Toxicology		#		
Kurt Widhalm (AT)	# Paediatric medicine		#		
Ulrike Wissinger-Gräfenhahn (DE)	# Clinical pharmacology		#		
	<b>Observer</b>	<b>Alternate</b>			
Josipa Cvek (HR)	O				
Meral Gündoğan (TR)	O				
Melanie Bald (Pharmacopoeia Commission)	O				
Michael Wierer (Pharmacopoeia Commission)		O			

C = Chairperson  
 VC = Vice Chairperson  
 X = Member / Alternate member  
 # = Co-opted member  
 O = Observer / Alternate observer

## Annex 2

### Overview of distribution of HMPC assessment work, (status July 2007)

*Table 1: Distribution of HMPC assessment work related to Community herbal monographs / entries to the Community list (until 31 July 2007)*

Member States	2005-2007	
	R	[Co-R]
Austria (AT)	5	-
Belgium (BE)	4	-
Bulgaria (BG)	-	-
Cyprus (CY)	-	-
Czech Republic (CZ)	1	-
Denmark (DK)	1	-
Estonia (EE)	1	-
Finland (FI)	-	-
France (FR)	2	-
Germany (DE)	16	-
Greece (EL)	1	-
Hungary (HU)	3	-
Ireland (IE)	2	-
Italy (IT)	4	-
Latvia (LV)	1	-
Lithuania (LT)	-	-
Luxembourg (LU)	-	-
Malta (MT)	-	-
The Netherlands (NL)	2	-
Poland (PL)	1	-
Portugal (PT)	3	-
Romania (RO)	-	-
Slovakia (SK)	-	-
Slovenia (SI)	4	-
Spain (ES)	3	-
Sweden (SE)	3	-
United Kingdom (UK)	1	-
Iceland (IS)	1	-
Norway (NO)	4	-
G. Laekeman*	-	1
O. Pelkonen*	-	1
K. Widhalm*	-	-
U. Wissinger-Gräfenhahn*	1	1
<b>Total</b>	<b>64</b>	<b>[3]</b>

R = Rapporteur

Co-R = Co-Rapporteur

\* = co-opted member

Table 2: Distribution of HMPC assessment work related to development of guidance in the areas of quality, safety & efficacy, pharmacovigilance and organisational matters (until 31 July 2007).

Member States	Quality		Safety & Efficacy		Pharmaco-vigilance		ORGAM		TOTAL R and [Co-R]
	R	[Co-R]	R	[Co-R]	R	[Co-R]	R	[Co-R]	
HMPC Chairman			3						3
Austria (AT)	2								2
Belgium (BE)	3				2				5
Bulgaria (BG)									
Cyprus (CY)									
Czech Republic (CZ)									
Denmark (DK)		1							[1]
Estonia (EE)									
Finland (FI)				1					[1]
France (FR)					1		1	1	2 [1]
Germany (DE)	5				7		3	1	15 [1]
Greece (EL)									
Hungary (HU)									
Ireland (IE)	1	1			1			1	2 [2]
Italy (IT)	2								2
Latvia (LV)			1						1
Lithuania (LT)									
Luxembourg (LU)									
Malta (MT)									
The Netherlands (NL)	1	1					2		3 [1]
Poland (PL)							1		1
Portugal (PT)							1	1	1 [1]
Romania (RO)									
Slovakia (SK)									
Slovenia (SI)									
Spain (ES)	1	2					1	3	2 [5]
Sweden (SE)				1	1		3		4 [1]
United Kingdom (UK)	2	1							2 [1]
Iceland (IS)									
Norway (NO)									
G. Laekeman*									
O. Pelkonen*			2	1					2 [1]
K. Widhalm*									
U. Wissinger-Gräfenhahn*									
<b>Total R and [Co-R]</b>	<b>17</b>	<b>[6]</b>	<b>6</b>	<b>[3]</b>	<b>12</b>	<b>[0]</b>	<b>12</b>	<b>[7]</b>	<b>47 [16]</b>

R = Rapporteur

Co-R = Co-Rapporteur

\* = co-opted member

## Annex 3

### Status of documents / publication on EMEA website, (status July 2007)

ORGANISATIONAL MATTERS		
Title	Reference	Status
Guideline on the documentation to be submitted for inclusion in the 'Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products'	EMEA/HMPC/107399/2005 Rev.1	Adopted July 2007
<i>Overview of comments received on draft 'Guideline on the documentation to be submitted for inclusion in the List of herbal substances, preparations and combinations thereof' (EMEA/HMPC/107399/2005)</i>	EMEA/HMPC/309367/2005	Adopted October 2005
Procedure for the appointment by the HMPC of Rapporteur responsible in the simplified procedure for: - The evaluation of a proposal for inclusion in the list of herbal substances, preparations and combinations thereof - The development of a Community herbal monograph	EMEA/HMPC/108877/2005	Adopted September 2005
Structure of the list of herbal substances, preparations and combinations thereof	EMEA/HMPC/100824/2005 Rev.1	Adopted July 2006
<i>Overview of comments received on draft 'Structure of the list of herbal substances, preparations and combinations thereof' (EMEA/HMPC/100824/2005)</i>	EMEA/HMPC/309366/2005	Adopted October 2005
Template for a Community herbal monograph	EMEA/HMPC/107436/2005 Rev.2	Adopted January 2007
Template for a submission of a request for expert advice on herbal medicinal products	EMEA/HMPC/119889/2005	Adopted September 2005
Timetable for the establishment of a Community list entry and/or a Community herbal monograph	EMEA/HMPC/126542/2005 Rev.1	Adopted March 2007
Procedure for the preparation of Community monograph for herbal medicinal products with well-established medicinal use	EMEA/HMPC/182352/2005 Rev.2	Adopted January 2007
Procedure for the preparation of Community monograph for traditional herbal medicinal products	EMEA/HMPC/182320/2005 Rev.2	Adopted January 2007
Concept paper on CTD for traditional herbal medicinal products	EMEA/HMPC/261344/2005	Adopted March 2006
Public statement on the interpretation of the term 'external use' for use in the field of traditional herbal medicinal products	EMEA/HMPC/31897/2006	Adopted May 2006

ORGANISATIONAL MATTERS		
Title	Reference	Status
Assessment report template for the development of Community herbal monographs and for inclusion of herbal substance(s), preparation(s) or combinations thereof in the Community list	EMEA/HMPC/418902/2005	Adopted January 2007
Procedure for calls for scientific data for use in HMPC assessment work	EMEA/HMPC/1004/2006	Adopted October 2006
<i>Overview of comments received on draft 'Procedure for calls for scientific data for use in HMPC assessment work'</i>	EMEA/HMPC/309487/2006	Adopted October 2006
Guidance on documentation to be provided by Member States and applicants/MAHs in support of a simplified registration referral under articles 16c(1)c and 16c(4)	EMEA/HMPC/431129/2005	Adopted September 2006
Procedure for the preparation of an entry to the 'Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products'	EMEA/HMPC/57137/2007	Adopted July 2007
Template for a Community list entry	EMEA/HMPC/439705/2006 Rev.2	Adopted January 2007
Draft 'Guideline on the use of the CTD format in the preparation of a registration application for traditional herbal medicinal products'	EMEA/HMPC/71049/2007	Adopted for release for consultation May 2007

QUALITY		
Title	Reference	Status
Draft 'Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products in the SPC'	EMEA/HMPC/CHMP/CVMP/2875/39/2005	Adopted for release for consultation June 2006
Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products in the SPC	EMEA/HMPC/CHMP/CVMP/2875/39/2005	Adopted May 2007 (HMPC), June 2007 (CHMP), July 2007 (CVMP)
<i>Overview of comments received on draft 'Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products in the SPC'</i>	EMEA/HMPC/230249/2006	Adopted July 2007
Guideline on quality of herbal medicinal products/traditional herbal medicinal products	CPMP/QWP/2819/00 Rev.1, EMEA/CVMP/814/00 Rev.1	Adopted January 2006 (HMPC), March 2006 (CHMP and CVMP)
<i>Overview of comments received on draft 'Guideline on quality of herbal medicinal products/traditional herbal medicinal products' (CPMP/QWP/2819/00 Rev.1, EMEA/CVMP/814/00 Rev.1)</i>	EMEA/CHMP/CVMP/QWP/40683/2006	Adopted June 2006
Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products	CPMP/QWP/2820/00 Rev.1, EMEA/CVMP/815/00 Rev.1	Adopted January 2006 (HMPC), March 2006 (CHMP)
<i>Overview of comments received on draft 'Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products' (CPMP/QWP/2820/00 Rev.1, EMEA/CVMP/815/00 Rev.1)</i>	EMEA/CHMP/CVMP/QWP/40728/2006	Adopted June 2006
Guideline on good agricultural and collection practice (GACP) for starting materials of herbal origin	EMEA/HMPC/246816/2005	Adopted January 2006
<i>Overview of comments received on draft 'Guideline on good agricultural and collection practice (GACP) for starting materials of herbal origin' (EMEA/HMPC/246816/2005)</i>	EMEA/HMPC/11138/2006	Adopted January 2006
Concept paper on quality of combination herbal medicinal products/traditional herbal medicinal products	EMEA/HMPC/CHMP/CVMP/5822/2/2006	Adopted for release for consultation March 2006 (HMPC), June 2006 (CHMP, CVMP)
Draft 'Guideline on quality of combination herbal medicinal products/traditional herbal medicinal products'	EMEA/HMPC/CHMP/CVMP/2148/69/2006	Adopted for release for consultation March 2007 (HMPC), June 2007 (CHMP) July 2007 (CVMP)
Reflection paper on the use of fumigants	EMEA/HMPC/125562/2006	Adopted October 2006

SAFETY & EFFICACY		
Title	Reference	Status
Public Statement on "CPMP List of herbal drugs with serious risks, dated 1992"	EMEA/HMPC/246736/2005	Adopted November 2005
Guideline on the clinical assessment of fixed combinations of herbal substances/herbal preparations	EMEA/HMPC/166326/2005	Adopted January 2006
<i>Overview of comments received on draft 'Guideline on the clinical assessment of fixed combinations of herbal substances/herbal preparations' (EMEA/HMPC/166326/2005)</i>	EMEA/HMPC/419395/2005	Adopted January 2006
Guideline on non-clinical documentation for herbal medicinal products in applications for marketing authorisation (bibliographical and mixed applications) and in applications for simplified registration	EMEA/HMPC/32116/2005	Adopted July 2006
<i>Overview of comments received on draft 'Guideline on non-clinical documentation for herbal medicinal products in applications for marketing authorisation (bibliographical and mixed applications) and in applications for simplified registration' (EMEA/HMPC/32116/2005)</i>	EMEA/HMPC/132154/2006	Adopted July 2006
Guideline on the assessment of clinical safety and efficacy in the preparation of Community herbal monographs for well-established and of Community herbal monographs/entries to the Community list for traditional herbal medicinal products/substances/preparations	EMEA/HMPC/104613/2005	Adopted September 2006
<i>Overview of comments received on draft 'Guideline on the assessment of clinical safety and efficacy in the preparation of Community herbal monographs for well-established and of Community herbal monographs/entries to the Community list for traditional herbal medicinal products/substances/preparations' (EMEA/HMPC/104613/2005)</i>	EMEA/HMPC/314947/2006	Adopted September 2006
Concept paper on the development of a guideline on the assessment of genotoxic constituents in herbal substances/preparations	EMEA/HMPC/413271/2006	Adopted for release for consultation October 2006
Draft 'Reflection paper on the risks associated with furocoumarins contained in preparations of <i>Angelica archangelica</i> L.'	EMEA/HMPC/317913/2006	Adopted for release for consultation January 2007
Draft 'Reflection paper on the adaptogenic concept'	EMEA/HMPC/102655/2007	Adopted for release for consultation July 2007



COMMUNITY HERBAL MONOGRAPHS / COMMUNITY LIST			
Title		Reference	Status
Overview of status of HMPC assessment work (continuously updated)		EMA/HMPC/278067/2006	Published April 2007
Aloe <i>Aloe barbadensis</i> Miller; <i>Aloe</i> (mainly <i>Aloe ferox</i> Miller and its hybrids) (barbados aloes; cape aloes)	Community herbal monograph (26 October 2006)	EMA/HMPC/76310/2006 Corr.	Adopted September 2006
	HMPC assessment report (19 July 2007)	EMA/HMPC/76313/2006	Adopted September 2006
	Opinion of the HMPC on Community herbal monograph	EMA/HMPC/429376/2006 EMA/HMPC/M/H/0006	Adopted September 2006
	List of references (05 July 2007)	EMA/HMPC/76313/2006	Adopted September 2006
	Overview of comments	EMA/HMPC/342482/2006	Adopted September 2006
Anisi fructus <i>Pimpinella anisum</i> L. (aniseed)	Community herbal monograph	EMA/HMPC/137423/2006	Adopted July 2007
	<b>Draft</b> Community list entry	EMA/HMPC/297757/2007	Adopted for release for consultation July 2007
	HMPC assessment report		
	Opinion of the HMPC on Community herbal monograph		
	<b>Draft</b> List of references	EMA/HMPC/359388/2006	Adopted July 2007
	Overview of comments		
Anisi aetheroleum <i>Pimpinella anisum</i> L. (anise oil)	Community herbal monograph	EMA/HMPC/263273/2006	Adopted July 2007
	Community list entry	N/A	
	HMPC assessment report		
	Opinion of the HMPC on Community herbal monograph		
	List of references		
	Overview of comments		
Betulae folium <i>Betula pendula</i> Roth; <i>Betula pubescens</i> Ehrh. (birch leaf)	<b>Draft</b> Community herbal monograph (8 May 2007)	EMA/HMPC/260019/2006	Adopted for release for consultation May 2007
	Community list entry	N/A	
	HMPC assessment report		
	Opinion of the HMPC on Community herbal monograph		
	<b>Draft</b> List of references	EMA/HMPC/207742/2007	Adopted May 2007
	Overview of comments		
Calendulae flos <i>Calendula officinalis</i> L. (calendula flower)	<b>Draft</b> Community herbal monograph	EMA/HMPC/179281/2007	Adopted for release for consultation July 2007
	<b>Draft</b> Community list entry	EMA/HMPC/179283/2007	Adopted for release for consultation July 2007
	HMPC assessment report		
	Opinion of the HMPC on Community herbal monograph		
	<b>Draft</b> List of references	EMA/HMPC/261882/2007	Adopted July 2007
	Overview of comments		

COMMUNITY HERBAL MONOGRAPHS / COMMUNITY LIST			
	Title	Reference	Status
Echinaceae purpureae herba <i>Echinacea purpurea</i> (L.) Moench (purple coneflower herb)	<b>Draft</b> Community herbal monograph (8 March 2007)	EMEA/HMPC/104945/2006	Adopted for release for consultation March 2007
	<b>Draft</b> Community list entry	EMEA/HMPC/189629/2007	Adopted for release for consultation May 2007
	HMPC assessment report		
	Opinion of the HMPC on Community herbal monograph		
	<b>Draft</b> List of references	EMEA/HMPC/111536/2007	Adopted May 2007
	Overview of comments		
Eleutherococci radix <i>Eleutherococcus senticosus</i> (Rupr. et Maxim.) Maxim. (eleutherococcus root)	<b>Draft</b> Community herbal monograph	EMEA/HMPC/244569/2006	Adopted for release for consultation July 2007
	<b>Draft</b> Community list entry	EMEA/HMPC/83756/2007	Adopted for release for consultation July 2007
	HMPC assessment report		
	Opinion of the HMPC on Community herbal monograph		
	<b>Draft</b> List of references	EMEA/HMPC/249428/2007	Adopted July 2007
	Overview of comments		
Foeniculi amari fructus aetheroleum <i>Foeniculum vulgare</i> Miller subsp. <i>vulgare</i> var. <i>vulgare</i> (bitter-fennel fruit oil)	Community herbal monograph	EMEA/HMPC/263292/2006	Adopted July 2007
	Community list entry	N/A	
	HMPC assessment report		
	Opinion of the HMPC on Community herbal monograph		
	<b>Draft</b> List of references	EMEA/HMPC/456740/2006	Adopted January 2007
	Overview of comments		
Foeniculi amari fructus <i>Foeniculum vulgare</i> Miller subsp. <i>vulgare</i> var. <i>vulgare</i> (bitter-fennel fruit)	Community herbal monograph	EMEA/HMPC/137428/2006	Adopted July 2007
	<b>Draft</b> Entry to the Community list	EMEA/HMPC/428817/2006	Adopted for release for consultation October 2006
	HMPC assessment report		
	Opinion of the HMPC on Community herbal monograph		
	<b>Draft</b> List of references	EMEA/HMPC/456740/2006	Adopted January 2007
	Overview of comments		
Foeniculi dulcis fructus <i>Foeniculum vulgare</i> Miller subsp. <i>vulgare</i> var. <i>dulce</i> (Miller) Thellung. (sweet-fennel fruit)	Community herbal monograph	EMEA/HMPC/263293/2006	Adopted July 2007
	<b>Draft</b> Entry to the Community list	EMEA/HMPC/428963/2006	Adopted for release for consultation October 2006
	HMPC assessment report		
	Opinion of the HMPC on Community herbal monograph		
	<b>Draft</b> List of references	EMEA/HMPC/456740/2006	Adopted January 2007
	Overview of comments		

COMMUNITY HERBAL MONOGRAPHS / COMMUNITY LIST			
	Title	Reference	Status
Frangulae cortex <i>Rhamnus frangula</i> L. (frangula bark)	Community herbal monograph (26 October 2006)	EMA/HMPC/76307/2006 Corr.	Adopted September 2006
	HMPC assessment report (5 July 2007)	EMA/HMPC/76306/2006	Adopted September 2006
	Opinion of the HMPC on Community herbal monograph	EMA/HMPC/429405/2006 EMA/HMPC/M/H/0007	Adopted September 2006
	List of references (5 July 2007)	EMA/HMPC/76304/2006	Adopted September 2006
	Overview of comments	EMA/HMPC/342513/2006	Adopted 5 July 2007
Lini semen <i>Linum usitatissimum</i> L. (linseed)	Community herbal monograph (26 October 2006)	EMA/HMPC/340849/2005	Adopted July 2006
	<b>Draft</b> Entry to the Community list	EMA/HMPC/340854/2005	Adopted for release for consultation September 2005
	HMPC assessment report (25 October 2006)	EMA/HMPC/167395/2006	Adopted September 2006
	Opinion of the HMPC on Community herbal monograph	EMA/HMPC/353205/2006 EMA/HMPC/M/H/0002	Adopted July 2006
	List of references (25 October 2006)	EMA/HMPC/167397/2006	Adopted July 2006
	Overview of comments	EMA/HMPC/66042/2006	Adopted October 2005
Lupuli flos <i>Humulus lupulus</i> L. (hop strobiles)	<b>Draft</b> Community herbal monograph	EMA/HMPC/513617/2006	Adopted for release for consultation July 2007
	Entry to the Community list	N/A	
	HMPC assessment report		
	Opinion of the HMPC on Community herbal monograph		
	<b>Draft</b> List of references	EMA/HMPC/262640/2007	Adopted July 2007
	Overview of comments		
Melissae folium <i>Melissa officinalis</i> L. (melissa leaf)	<b>Draft</b> Community herbal monograph (8 May 2007)	EMA/HMPC/5341/2007	Adopted for release for consultation May 2007
	Entry to the Community list	N/A	
	HMPC assessment report		
	Opinion of the HMPC on Community herbal monograph		
	<b>Draft</b> List of references	EMA/HMPC/207739/2007	Adopted May 2007
	Overview of comments		

COMMUNITY HERBAL MONOGRAPHS / COMMUNITY LIST			
	Title	Reference	Status
Menthae piperitae aetheroleum <i>Mentha x piperita</i> L. (peppermint oil)	<b>Draft</b> Community herbal monograph (8 May 2007)	EMEA/HMPC/349466/2006	Adopted for release for consultation May 2007
	Entry to the Community list	N/A	
	HMPC assessment report		
	Opinion of the HMPC on Community herbal monograph		
	<b>Draft</b> List of references (5 July 2007)	EMEA/HMPC/199469/2007	Adopted May 2007
	Overview of comments		
Menthae piperitae folium <i>Mentha x piperita</i> L. (peppermint leaf)	<b>Draft</b> Community herbal monograph	EMEA/HMPC/193909/2007	Adopted for release for consultation July 2007
	Entry to the Community list	N/A	
	HMPC assessment report		
	Opinion of the HMPC on Community herbal monograph		
	<b>Draft</b> List of references	EMEA/HMPC/262645/2007	Adopted July 2007
	Overview of comments		
Passiflorae herba <i>Passiflora incarnata</i> L. (passion flower)	<b>Draft</b> Community herbal monograph	EMEA/HMPC/230962/2006	Adopted for release for consultation March 2007
	Entry to the Community list	N/A	
	HMPC assessment report		
	Opinion of the HMPC on Community herbal monograph		
	<b>Draft</b> List of references	EMEA/HMPC/111180/2007	Adopted March 2007
	Overview of comments		
Plantaginis ovatae semen <i>Plantago ovata</i> Forssk. (ispaghula seed)	Community herbal monograph (26 October 2006)	EMEA/HMPC/340861/2005	Adopted July 2006
	Entry to the Community list	N/A	
	HMPC assessment report (28 February 2007)	EMEA/HMPC/166377/2006	Adopted September 2006
	Opinion of the HMPC on Community herbal monograph	EMEA/HMPC/353198/2006 EMEA/HMPC/M/H/0004	Adopted July 2006
	List of references (28 February 2007)	EMEA/HMPC/167158/2006	Adopted July 2006
	Overview of comments	EMEA/HMPC/65636/2006	Adopted February 2007

COMMUNITY HERBAL MONOGRAPHS / COMMUNITY LIST			
	Title	Reference	Status
Plantaginis ovatae seminis tegumentum <i>Plantago ovata</i> Forssk. (ispaghula husk)	Community herbal monograph (26 October 2006)	EMEA/HMPC/340857/2005	Adopted July 2006
	Entry to the Community list	N/A	
	HMPC assessment report (28 February 2007)	EMEA/HMPC/165838/2006	Adopted September 2006
	Opinion of the HMPC on Community herbal monograph	EMEA/HMPC/353208/2006 EMEA/HMPC/M/H/0005	Adopted July 2006
	List of references (28 February 2007)	EMEA/HMPC/165832/2006	Adopted July 2006
	Overview of comments	EMEA/HMPC/65916/2006	Adopted February 2007
Primulae flos <i>Primula veris</i> L.; <i>Primula elatior</i> (L.) Hill (primula flower)	<b>Draft</b> Community herbal monograph	EMEA/HMPC/64684/2007	Adopted for release for consultation March 2007
	Entry to the Community list	N/A	
	HMPC assessment report		
	Opinion of the HMPC on Community herbal monograph		
	<b>Draft</b> List of references	EMEA/HMPC/111633/2007	Adopted for release for consultation March 2007
	Overview of comments		
Primulae radix <i>Primula veris</i> L.; <i>Primula elatior</i> (L.) Hill (primula root)	<b>Draft</b> Community herbal monograph	EMEA/HMPC/143370/2006	Adopted for release for consultation March 2007
	Entry to the Community list	N/A	
	HMPC assessment report		
	Opinion of the HMPC on Community herbal monograph		
	<b>Draft</b> List of references	EMEA/HMPC/111736/2007	Adopted March 2007
	Overview of comments		
Psyllii semen <i>Plantago afra</i> L.; <i>Plantago indica</i> L. (psyllium seed)	Community herbal monograph (26 October 2006)	EMEA/HMPC/340865/2005	Adopted July 2006
	Entry to the Community list	N/A	
	HMPC assessment report (28 February 2007)	EMEA/HMPC/167338/2006	Adopted September 2006
	Opinion of the HMPC on Community herbal monograph	EMEA/HMPC/353137/2006 EMEA/HMPC/M/H/0003	Adopted July 2006
	List of references (28 February 2007)	EMEA/HMPC/244406/2006	Adopted July 2006
	Overview of comments	EMEA/HMPC/65063/2006	Adopted February 2007

COMMUNITY HERBAL MONOGRAPHS / COMMUNITY LIST			
	Title	Reference	Status
Rhamni purshianae cortex <i>Rhamnus purshianus</i> D.C. (cascara)	<b>Draft</b> Community herbal monograph	EMEA/HMPC/513579/2006	Adopted for release for consultation March 2007
	Entry to the Community list	N/A	
	HMPC assessment report		
	Opinion of the HMPC on Community herbal monograph		
	<b>Draft</b> List of references	EMEA/HMPC/513578/2006	Adopted March 2007
	Overview of comments		
Rhei radix <i>Rheum palmatum</i> L.; <i>Rheum officinale</i> Baillon (rhubarb)	<b>Draft</b> Community herbal monograph	EMEA/HMPC/189624/2007	Adopted for release for consultation July 2007
	Entry to the Community list	N/A	
	HMPC assessment report		
	Opinion of the HMPC on Community herbal monograph		
	<b>Draft</b> List of references	EMEA/HMPC/189625/2007	Adopted July 2007
	Overview of comments		
Sennae folium <i>Cassia senna</i> L.; <i>Cassia angustifolia</i> Vahl (senna leaf)	Community herbal monograph (26 October 2006)	EMEA/HMPC/51869/2006 Corr.	Adopted September 2006
	Entry to the Community list		
	HMPC assessment report (27 April 2007)	EMEA/HMPC/51868/2006	Adopted September 2006
	Opinion of the HMPC on Community herbal monograph	EMEA/HMPC/429415/2006 EMEA/HMPC/M/H/0008	Adopted September 2006
	List of references (27 April 2007)	EMEA/HMPC/343925/2006	Adopted September 2006
	Overview of comments	EMEA/HMPC/237669/2006	Adopted April 2007
Sennae fructus <i>Cassia senna</i> L.; <i>Cassia angustifolia</i> Vahl (senna pods)	Community herbal monograph (26 October 2006)	EMEA/HMPC/51871/2006 Corr.	Adopted September 2006
	Entry to the Community list	N/A	
	HMPC assessment report (27 April 2007)	EMEA/HMPC/51870/2006	Adopted September 2006
	Opinion of the HMPC on Community herbal monograph	EMEA/HMPC/429430/2006 EMEA/HMPC/M/H/0009	Adopted September 2006
	List of references (27 April 2007)	EMEA/HMPC/343925/2006	Adopted September 2006
	Overview of comments	EMEA/HMPC/237716/2006	Adopted April 2007

COMMUNITY HERBAL MONOGRAPHS / COMMUNITY LIST			
	Title	Reference	Status
Thymi herba <i>Thymus vulgaris</i> L.; <i>Thymus zygis</i> L. (thyme herb)	<b>Draft</b> Community herbal monograph (8 May 2007)	EMEA/HMPC/234113/2006	Adopted for release for consultation May 2007
	Entry to the Community list	N/A	
	HMPC assessment report		
	Opinion of the HMPC on Community herbal monograph		
	<b>Draft</b> List of references	EMEA/HMPC/207858/2007	Adopted May 2007
	Overview of comments		
Valerianae radix <i>Valeriana officinalis</i> L. (valerian root)	Community herbal monograph (26 October 2006)	EMEA/HMPC/340719/2005	Adopted July 2006
	<b>Draft</b> Entry to the Community list	EMEA/HMPC/340779/2005	Adopted for release for consultation September 2005
	HMPC assessment report (not yet published)	EMEA/HMPC/167391/2006	Adopted September 2006
	Opinion of the HMPC on Community herbal monograph (not yet published)	EMEA/HMPC/313368/2006 EMEA/HMPC/M/H/0001	Adopted September 2006
	<b>Draft</b> List of references (not yet published)	EMEA/HMPC/167392/2006	Adopted September 2006
	Overview of comments (not yet published)	EMEA/HMPC/50774/2006	Adopted September 2006

PHARMACOVIGILANCE		
Title	Reference	Status
Public statement on the risks associated with the use of herbal products containing Aristolochia species	EMEA/HMPC/138381/2005	Adopted November 2005
Public statement on the use of herbal medicinal products containing asarone	EMEA/HMPC/139215/2005	Adopted November 2005
Public statement on Capsicum/capsaicin containing herbal medicinal products	EMEA/HMPC/138379/2005	Adopted November 2005
Public statement on the use of herbal medicinal products containing estragole	EMEA/HMPC/137212/2005	Adopted November 2005
Public statement on the use of herbal medicinal products containing methyleugenol	EMEA/HMPC/138363/2005	Adopted November 2005
<i>Overview of comments received on 'Public statement on the use of herbal medicinal products containing estragole' (EMEA/HMPC/137212/2005) and on 'Public statement on the use of herbal medicinal products containing methyleugenol' (EMEA/HMPC/138363/2005)</i>	EMEA/HMPC/381090/2005	Adopted November 2005
Public statement on the use of herbal medicinal products containing pulegone and menthofuran	EMEA/HMPC/138386/2005	Adopted November 2005
Public statement on the allergenic potency of herbal medicinal products containing soya or peanut protein	EMEA/HMPC/138139/2005	Adopted January 2006
<i>Overview of comments received on 'Public statement on the allergenic potency of herbal medicinal products containing soya or peanut protein' (EMEA/HMPC/138139/2005)</i>	EMEA/HMPC/381405/2005	Adopted January 2006
Public statement on Chamomilla containing herbal medicinal products	EMEA/HMPC/138309/2005	Adopted March 2006
<i>Overview of comments received on 'Public statement on Chamomilla containing herbal medicinal products'</i>	EMEA/HMPC/379986/2005	Adopted March 2006
EMEA Public Statement on herbal medicinal products containing <i>Cimicifugae racemosae rhizoma</i> (Black cohosh, root)	EMEA/269259/2006	Adopted July 2006
Assessment of case reports connected to herbal medicinal products containing <i>Cimicifugae racemosae rhizoma</i> (Black cohosh, root)	EMEA/HMPC/269258/2006 Rev.1	Adopted May 2007



<b>GENERAL DOCUMENTS</b>		
<b>Title</b>	<b>Reference Rapp</b>	<b>Status</b>
Committee on Herbal Medicinal Products: Rules of Procedure	EMEA/HMPC/139800/2004 Rev.1	Adoption May 2007
Mandate, objectives and rules of procedure for the HMPC Working Party on Community Monographs and Community List (MLWP)	EMEA/HMPC/379153/2005 Rev.1	Adopted March 2007
Overview of Questions and Answers relating to technical/scientific issues	EMEA/HMPC/151144/2006 Corr.	Adopted May 2006
MLWP work programme 2007	EMEA/HMPC/152126/2006	Adopted January 2007
MLWP work programme 2008	EMEA/HMPC/271648/2007	Adopted July 2007

## Annex 4

### List of interested parties to the HMPC, (status July 2006)

<i>Industry Associations</i>	
<b>AEFMUTA</b> <b>European Association of Manufacturers of Medicines for Anthroposophic Therapy</b>	9, rue E. Jung 68330 Huningue France
<b>AESGP</b> <b>The Association of the European Self-Medication Industry</b> Website: <a href="http://www.aesgp.be">http://www.aesgp.be</a>	7, avenue de Tervuren 1040 Brussels Belgium
<b>EFPIA</b> <b>European Federation of Pharmaceutical Industries and Associations</b> Website: <a href="http://www.efpia.org">http://www.efpia.org</a>	108 Rue du Trône, Bte 1 1050 Brussels Belgium
<b>EGA</b> <b>European Generic Medicines Association</b> Website: <a href="http://www.egagenerics.com">http://www.egagenerics.com</a>	PO Box 193 1040 Brussels Belgium
<b>EHGA-EUROPAM</b> <b>European Herb Growers Association</b> Website: <a href="http://www.europam.net">http://www.europam.net</a>	Clakenweg 132 8081 LZ Elburg The Netherlands
<b>EHPM</b> <b>European Federation of Associations of Health Product Manufacturers</b> Website: <a href="http://www.ehpm.org">http://www.ehpm.org</a>	Rue de l'Association, 50 1000 Brussels Belgium
<i>Scientific Societies</i>	
<b>ESCOP</b> <b>European Scientific Cooperative on Phytotherapy</b> Website: <a href="http://www.escop.com/">http://www.escop.com/</a>	ESCOP Secretariat Argyle House Gandy Street Exeter Devon EX4 3LS United Kingdom
<b>GA</b> <b>Society for Medicinal Plant Research</b> Website: <a href="http://www.ga-online.org">http://www.ga-online.org</a>	Institute of Pharmaceutical Sciences Dept. of Pharmacognosy Karl-Franzens-Universitaet Graz Universitaetsplatz 4/I 8010 Graz Austria

<b>PSE</b> <b>The Phytochemical Society of Europe</b> Website: <a href="http://www.phytochemicalsociety.org/about.htm">http://www.phytochemicalsociety.org/about.htm</a>	University of London, The School of Pharmacy Centre for Pharmacognosy and Phytotherapy 29-39 Brunswick Square London WC1N 1AX United Kingdom
<b><i>Healthcare professionals and Consumers &amp; Patients Organisations</i></b>	
<b>BEUC</b> <b>Bureau Européen des Unions de Consommateurs</b> Website: <a href="http://www.beuc.org">http://www.beuc.org</a>	Avenue de Tervuren 36 Bte 4 1040 Brussels Belgium
<b>CPME</b> <b>Standing Committee of European Doctors</b> Website: <a href="http://www.cpme.be">http://www.cpme.be</a>	Rue de la Science 41 1040 Bruxelles Belgium
<b>EFCAM</b> <b>European Forum for Complementary and Alternative Medicine</b> Website: <a href="http://cam.epha.org/">http://cam.epha.org/</a>	39-41 Rue d'Arlon 1000 Brussels Belgium
<b>EFNMU</b> <b>European Federation of Natural Medicine Users</b> Website: <a href="http://www.efnmu.de">http://www.efnmu.de</a>	Gerhard-Kienle-Weg 18 58313 Herdecke Germany
<b>EHPA</b> <b>European Herbal Practitioners Association</b> Website: <a href="http://www.ehpa.eu/index.html">http://www.ehpa.eu/index.html</a>	8 Lion Yard Tremadoc Road London SW4 7NQ United Kingdom
<b>IVAA</b> <b>International Federation of Anthroposophical Medical Associations</b> Website: <a href="http://www.ivaa.info/">http://www.ivaa.info/</a>	Rüttiweg, 4143 Dornach Switzerland  <b>Operational site:</b> <b>(to be used for correspondence)</b> Via Vincenzo Monti 79/4 20145 Milano Italy
<b>PGEU</b> <b>Pharmaceutical Group to the European Union</b> Website: <a href="http://www.pgeu.org">www.pgeu.org</a>	Rue du Luxembourg 19-21 Box 6 1000 Brussels Belgium