EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 April 2017
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Inspections, Human Medicines, Pharmacovigilance and Committees Division

Uptake of the traditional use registration scheme and implementation of the provisions of Directive 2004/24/EC in EU Member States

Status: 31 December 2016

Summary

The provisions for registration of traditional herbal medicinal products in the European Union can be found in Chapter 2a of Directive 2001/83/EC that was introduced by Directive 2004/24/EC in April 2004.

Regular reports on the uptake of the traditional use registration (TUR) scheme in the EU Member States[1] are published following the adoption of an 'Action plan for herbal medicines 2010-2011' by the management board of the European Medicines Agency and the Heads of Agencies (HMA) in 2010.

During the latest survey (status 31 December 2016), National competent authorities (NCAs) provided the number of TUR granted for traditional herbal medicinal products (THMP) according to Art. 16a of Directive 2001/83/EC (Figures 1 and 3) and on marketing authorisations for herbal medicinal products (HMP) on the basis of 'well-established use' (WEU MA) according to Art. 10a of Directive 2001/83/EC (Figures 2 and 4). Information was collected for both, monocomponent and combination products (products that contain more than one herbal substance/preparation as active substance). Furthermore it was specified for each Member State how many applications have been received, are under assessment, have been refused by NCAs, or withdrawn by applicants before authorisation (Tables 1 and 2, Figures 5 and 6).

Based on additional information such as registration/authorisation dates, the active substance, and the indication, overviews are presented on the herbal substances used in monocomponent products (Tables 3 and 4), the number of components in combination products (Figure 7) and the traditional therapeutic areas to which granted indications can be allocated (Figures 8 and 9).

All data are summarised in the report as received from NCAs of the EU Member States. For questions with respect to presented numbers or background information the NCAs may be contacted directly.

General information on the registration of THMP can be found at the European Commission website:

http://ec.europa.eu/health/human-use/herbal-medicines/index_en.htm

https://ec.europa.eu/health/human-use/herbal-medicines/developments_en

[1] EEA countries (European Economic Area) are included in this report

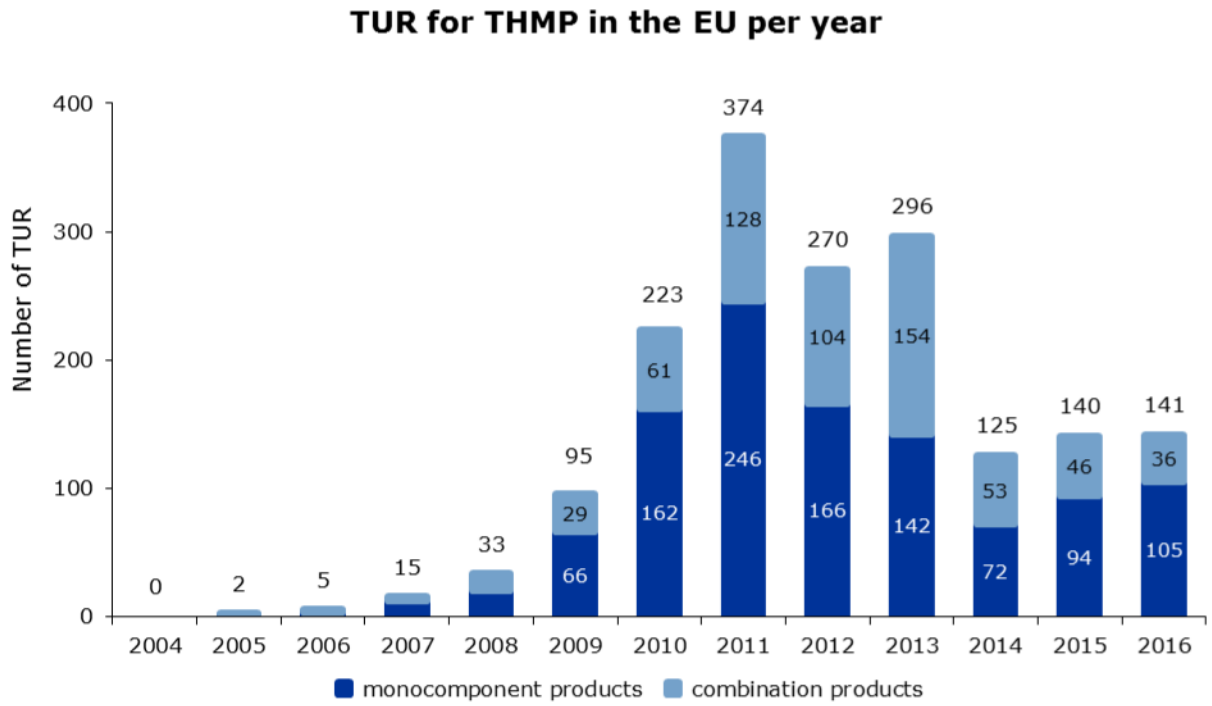


Figure 1

Number of traditional use registrations (TUR) for THMP in the EU grouped by year of registration for monocomponent and combination products (2004 until December 2016; total 1719).

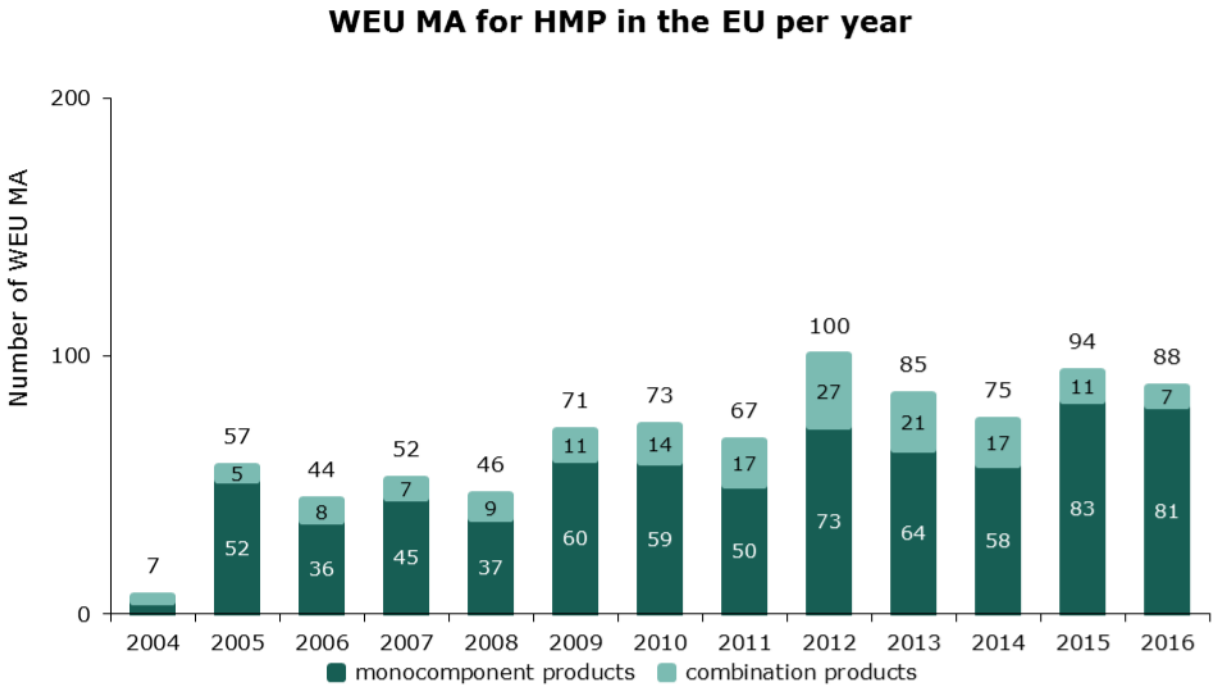


Figure 2

Number of well-established use marketing authorisations (WEU MA) for HMP in the EU grouped by year of authorisation for monocomponent and combination products (2004 until December 2016; total 859).

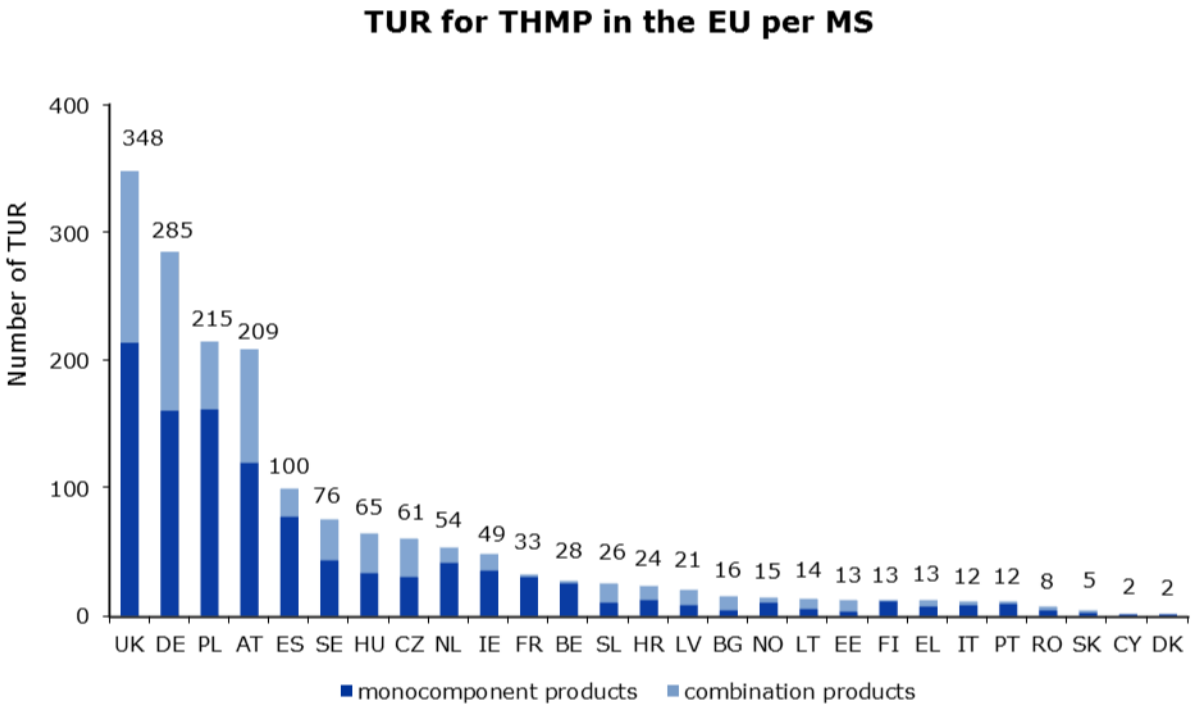


Figure 3

Number of granted TUR for monocomponent and combination THMP in EU Member States (since implementation of Dir. 2004/24/EC until 31 December 2016). Total 1719: 1089 for monocomponent products, 630 for combination products (No TUR granted for IS, LI, LU and MT).

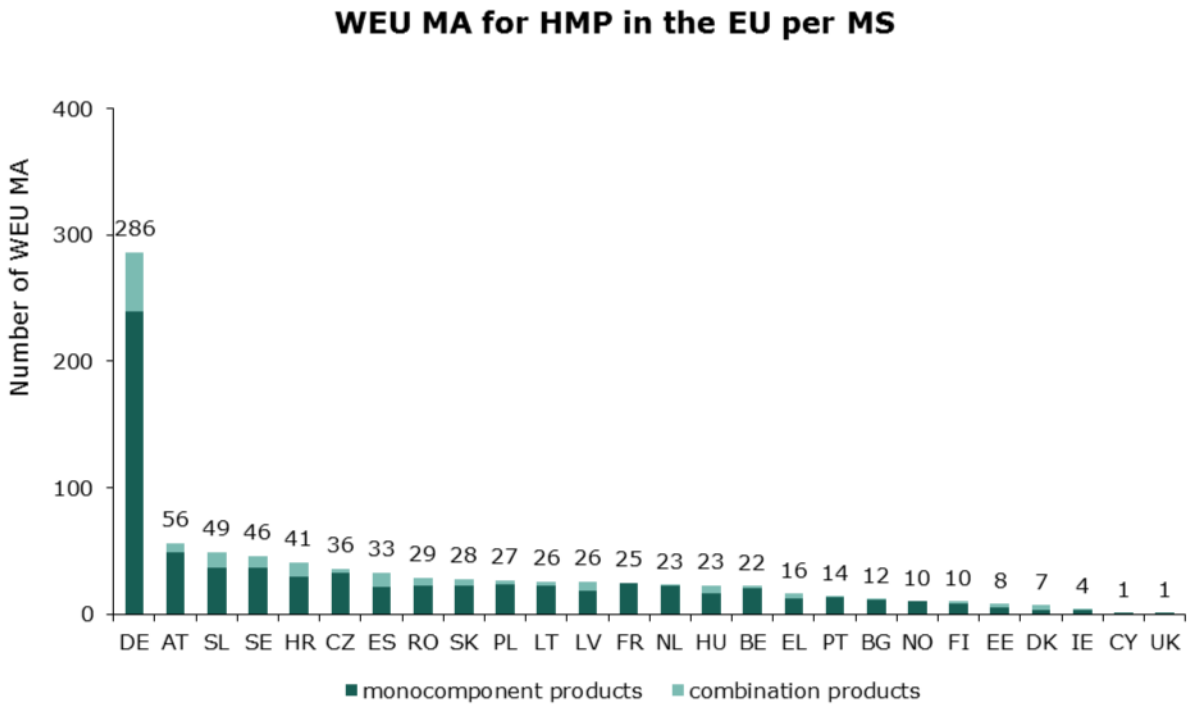


Figure 4

Number of granted WEU MA for monocomponent and combination HMP in EU Member States (since implementation of Dir. 2004/24/EC until 31 December 2016). Total 859: 704 for monocomponent products, 155 for combination products (No WEU MA granted for IS, IT, LI, LU and MT).

Table 1

Number of **TUR applications** for THMP according to Art. 16a Directive 2001/83/EC received, under assessment, granted, refused and withdrawn in EU Member States since national implementation of Directive 2004/24/EC until 31 December 2016.

Member State	Received	Under assessment	TUR granted	TUR refused	Withdrawn [1]
Total	**2730**	**574**	**1719**	**240**	**197**
Austria	224	14	209	0	1
Belgium	72	26	28	7	11
Bulgaria	33	14	16	2	1
Croatia	38	12	24	0	2
Cyprus	8	6	2	0	0
Czech Republic	76	6	61	3	6
Denmark	18	11	2	4	1
Estonia	14	1	13	0	0
Finland	30	6	13	1	10
France	171	127	33	0	11
Germany	513	61	285	106	61
Greece	34	8	13	5	8
Hungary	115	50	65	0	0
Ireland	85	35	49	0	1
Italy	19	1	12	2	4
Latvia	25	0	21	0	4
Liechtenstein [2]	0	0	0	0	0
Lithuania	32	0	14	15	3
Luxembourg[3]	0	0	0	0	0
Malta	0	0	0	0	0
Netherlands	80	13	54	2	11
Poland	315	62	215	19	19
Portugal	20	7	12	0	1
Romania	33	25	8	0	0
Slovakia	16	5	5	2	4
Slovenia	34	4	26	0	4
Spain	162	7	100	54	1
Sweden	87	5	76	0	6
United Kingdom	450	58	348	18	26
(Norway)	*26*	*10*	*15*	*0*	*1*
(Iceland)	*0*	*0*	*0*	*0*	*0*

[1] Withdrawn by applicant before registration
[2] Liechtenstein has an agreement with Austria regarding recognition of registration issued by Austria
[3] No response received

Table 2

Number of **WEU MA applications** for HMP according to Art. 10a Directive 2001/83/EC received, under assessment, granted, refused and withdrawn in EU Member States since national implementation of Directive 2004/24/EC until 31 December 2016.

Member State	Received	Under assessment	WEU MA granted	WEU MA refused	Withdrawn[1]
Total	**1354**	**303**	**803**	**64**	**181**
Austria	74	18	56	0	0
Belgium	39	12	22	1	4
Bulgaria	15	3	12	0	0
Croatia	73	13	41	7	12
Cyprus	6	5	1	0	0
Czech Republic	73	16	36	6	15
Denmark	21	13	7	1	0
Estonia	13	0	8	0	5
Finland	35	8	10	0	17
France	59	30	25	0	4
Germany[2]	447	67	286	24	67
Greece	26	5	16	1	4
Hungary	44	16	23	0	5
Ireland	7	2	4	0	1
Italy	3	0	0	2	1
Latvia	32	4	26	0	2
Liechtenstein[3]	0	0	0	0	0
Lithuania	61	10	26	9	16
Luxembourg[4]	0	0	0	0	0
Malta	0	0	0	0	0
Netherlands	35	4	23	1	7
Poland	65	24	27	2	12
Portugal	28	5	14	6	3
Romania	66	37	29	0	0
Slovakia	35	3	28	4	0
Slovenia	53	4	49	0	0
Spain	45	12	33	0	0
Sweden	56	4	46	0	6
United Kingdom	4	3	1	0	0
(Norway)	*13*	*3*	*10*	*0*	*0*
(Iceland)	*0*	*0*	*0*	*0*	*0*

[1] Withdrawn by applicant before authorisation
[2] 3 MAs ceased because of sunset clause
[3] Liechtenstein has an agreement with Austria regarding recognition of MA issued by Austria
[4] No response received

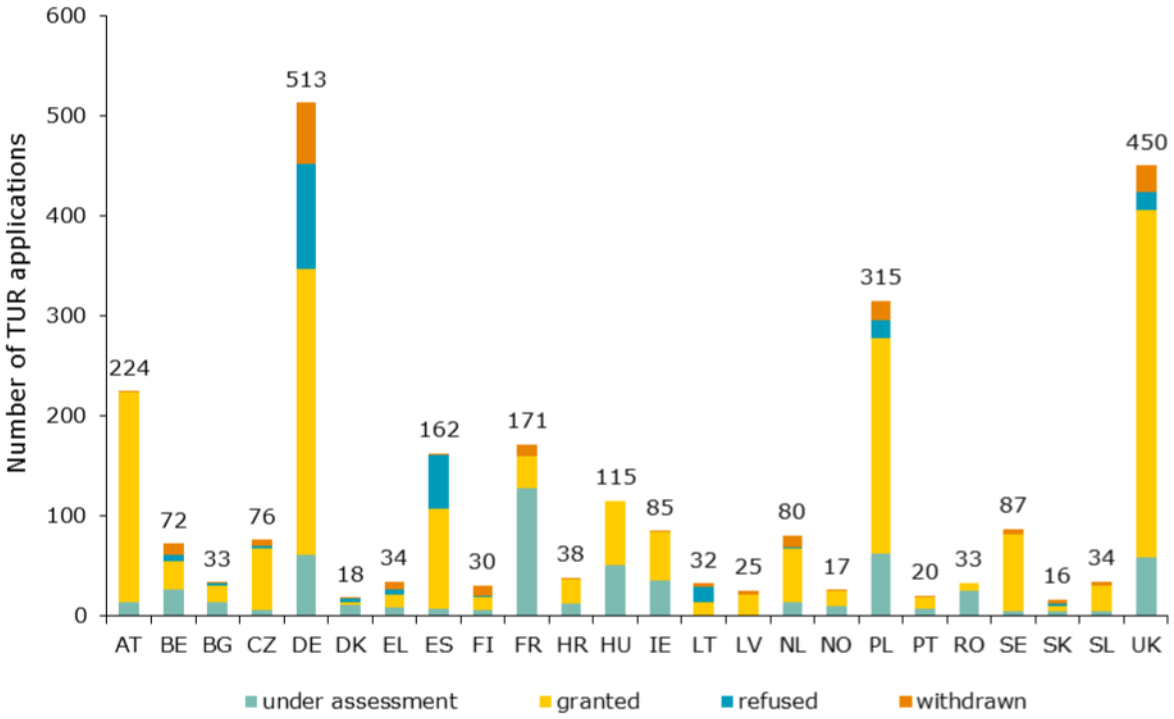


Figure 5

Number of TUR applications for THMP received (total bar height), divided according to the current status (under assessment, granted, refused and withdrawn) in EU Member States (status 31 December 2016; see also **Table 1**). Figure includes only EU Member States with at least 30 applications for TUR and / or WEU MA.

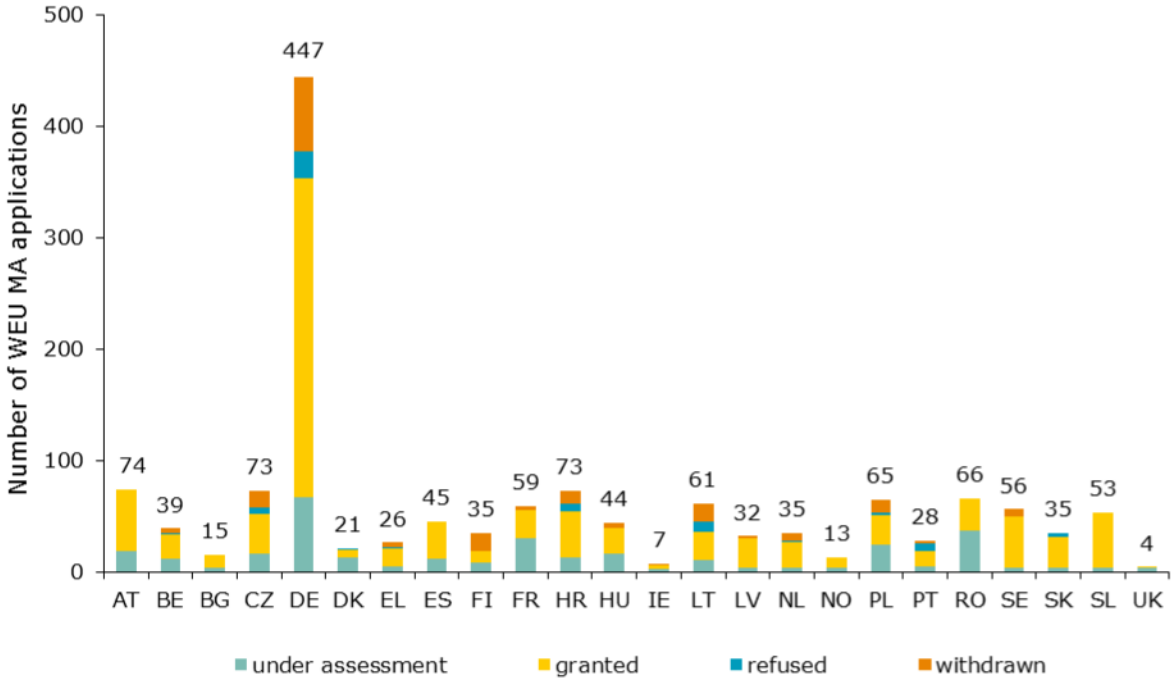


Figure 6

Number of WEU MA applications for HMP received (total bar height), divided according to the current status (under assessment, granted, refused and withdrawn) in EU Member States (status 31 December 2016; see also **Table 2**). Figure includes only EU Member States with at least 30 applications for TUR and / or WEU MA.

Table 3

Number of TUR for herbal substances used in monocomponent THMP in the EU by 31 December 2016 and current status/outcome of the corresponding HMPC assessment.

Herbal substances[1]	TUR[2]	Status HMPC assessment[3]	Draft monograph publication date[4]	Final monograph publication date	Outcome (TU/WEU)[5]	Outcome (MO/LE/PS)[6]
Total (162)	**1066**					
Harpagophyti radix	65	F	10/01/2008 (15/02/2016)	06/11/2008 (14/11/2016)	TU	MO
Pelargonii radix	61	F	26/04/2011 (26/10/2015)	04/02/2013	TU	MO
Valerianae radix	54	F	20/09/2005 (23/07/2015)	26/10/2006 (27/04/2016)	TU+WEU	MO
Hyperici herba	46	F	06/11/2008	20/12/2009	TU+WEU	MO
Thymi herba	42	F	08/05/2007 (12/11/2013)	30/10/2007 (02/06/2014)	TU	MO
Passiflorae herba	40	F	07/03/2007 (25/01/2014)	07/09/2007 (18/06/2014)	TU	MO
Ginseng radix	26	F	16/04/2013	22/05/2014	TU	MO
Salviae officinalis folium	26	F	16/07/2009	28/01/2011	TU	MO
Echinaceae purpureae radix	25	F	14/01/2009	03/02/2010	TU	MO
Silybi mariani fructus	25	PF	23/07/2015			
Crataegi folium cum flore	23	F	14/10/2014	17/06/2016	TU	MO
Cucurbitae semen	22	F	17/10/2011	25/03/2013	TU	MO
Hippocastani semen	21	F	04/09/2008	16/07/2009	TU+WEU	MO
Cynarae folium	20	F	18/01/2011	21/12/2011	TU	MO
Melissae folium	20	F	08/05/2007	31/10/2007 (05/08/2013)	TU	MO
Agni casti fructus	19	F	17/09/2009	05/08/2011	TU+WEU	MO
Rhodiolae roseae rhizoma et radix	19	F	22/08/2013	22/07/2014	TU	MO
Arnicae flos	17	F	20/09/2011	29/05/2012	TU	MO
Ginkgo folium	16	F	14/02/2014	08/04/2015	TU+WEU	MO
Matricariae flos	16	PF	24/07/2014			
Plantaginis lanceolatae folium	14	F	15/11/2008	24/02/2012	TU	MO
Echinaceae purpureae herba	13	F	08/05/2007 (09/2014)	08/05/2008 (13/04/2015)	TU+WEU	MO+LE
Equiseti herba	13	F	30/10/2007 (27/07/2015)	03/07/2008 (17/03/2016)	TU	MO
Vitis viniferae folium	13	F	20/12/2009	03/01/2011	TU+WEU	MO+LE
Hederae helicis folium	12	F	08/03/2010 (12/02/2015)	19/04/2011 (18/01/2016)	TU+WEU	MO
Menthae piperitae folium	12	F	05/07/2007	05/07/2007	TU	MO
Visci albi herba	12	F*				PS
Tanaceti parthenii herba	11	F	28/05/2010	20/01/2011	TU	MO
Cimicifugae rhizoma	10	F	17/09/2009	20/01/2011	WEU	MO
Lichen islandicus	10	F	19/05/2014	11/02/2015	TU	MO
Urticae folium	10	F	08/05/2008	17/01/2011	TU	MO

[1] Herbal substance or preparation thereof used as single active substance in products with TUR
[2] May include several TUR in different EU Member States for the same product
[3] Status by April 2017 (R: Rapporteur assigned, D: Draft under discussion, P: Draft published, PF: Assessment close to finalisation [pre-final], F: Final opinion adopted, F*: Final Public Statement, C: Call for scientific data, n.p.: not on the HMPC priority list (EMA/HMPC/278067/2006)
[4] In brackets the publication date of the revised monograph
[5] Existing monograph for traditional use (TU), well-established use (WEU) or both (TU + WEU)
[6] HMPC assessment outcome (MO: monograph, LE: list entry, PS: public statement)

Table 3 (continued)

Herbal substances[1]	TUR[2]	Status HMPC assessment[3]	Draft monograph publication date[4]	Final monograph publication date	Outcome (TU/WEU)[5]	Outcome (MO/LE/PS)[6]
Uvae ursi folium	10	F	16/06/2008	19/04/2011	TU	MO
Zingiberis rhizoma	10	F	20/09/2011	04/06/2012	TU+WEU	MO
Rosmarini aetheroleum	9	F	16/07/2009	28/01/2011	TU	MO
Sabalis serrulatae fructus	9	F	19/08/2013	06/08/2014	TU	MO
Rusci aculeati rhizoma	8	F	07/09/2007	04/09/2008	TU	MO
Fucus vesiculosus	8	F	10/09/2014	14/01/2016	TU+WEU	MO
Tiliae flos	8	F	20/10/2011	10/07/2012	TU	MO
Calendulae herba	7	C				
Menthae piperitae aetheroleum	7	F	31/10/2007	08/05/2007	TU+WEU	MO+LE
Orthosiphonis folium	7	F	16/07/2009	03/01/2011	TU	MO
Althaeae radix	6	F	03/07/2008 (11/12/2015)	14/05/2009 (04/11/2016)	TU	MO
Urticae radix	6	F	19/10/2011	05/11/2012	TU	MO
Allii sativi bulbus	5	P	25/07/2016			
Eleutherococci radix	5	F	05/07/2007 (25/03/2014)	08/05/2008 (06/10/2014)	TU	MO+LE
Lavandulae aetheroleum	5	F	11/02/2011	13/06/2012	TU	MO
Liquiritiae radix	5	F	19/08/2011	24/08/2012	TU	MO
Millefolii herba	5	F	09/11/2010	30/09/2011	TU	MO
Myrtilli fructus recens	5	F	09/02/2015	09/12/2015	TU	MO
Taraxaci radix	5	n.p.				
Damianae folium	5	n.p.				
Absinthii herba	4	F	06/11/2008	16/07/2009	TU	MO
Arctii radix	4	F	08/03/2010	03/01/2011	TU	MO
Betulae folium	4	F	08/05/2007 (24/11/2014)	08/05/2008 (13/03/2015)	TU	MO
Calendulae flos	4	F	05/07/2007	08/05/2008	TU	MO+LE
Hamamelidis cortex	4	F	05/11/2008	23/03/2010	TU	MO
Lupuli flos	4	F	05/07/2007	11/07/2008 (07/08/2014)	TU	MO
Piceae summitates	4	n.p.				
Quercus cortex	4	F	08/03/2010	28/01/2011	TU	MO
Solidaginis virgaureae herba	4	F	31/10/2007	04/09/2008	TU	MO
Trigonellae foenugraeci semen	4	F	10/06/2010	23/02/2011	TU	MO
Boldi folium	4	F	08/05/2008 (09/2016)	13/01/2009 (12/01/2017)	TU	MO
Other 12 substances with 3 registrations	12 x 3	(F: 7, F*: 1, PF: 0, P: 0, D: 0, R: 0, C: 1, n.p.: 3)				
Other 30 substances with 2 registrations	30 x 2	(F: 21, PF: 0, P: 0, D: 0, R: 0, C: 0, n.p.: 9)				
Other 58 substances with 1 registration	58 x 1	(F: 26, F*: 3, PF: 0, P: 0, D:2, R: 0, C: 1, n.p.: 26)				

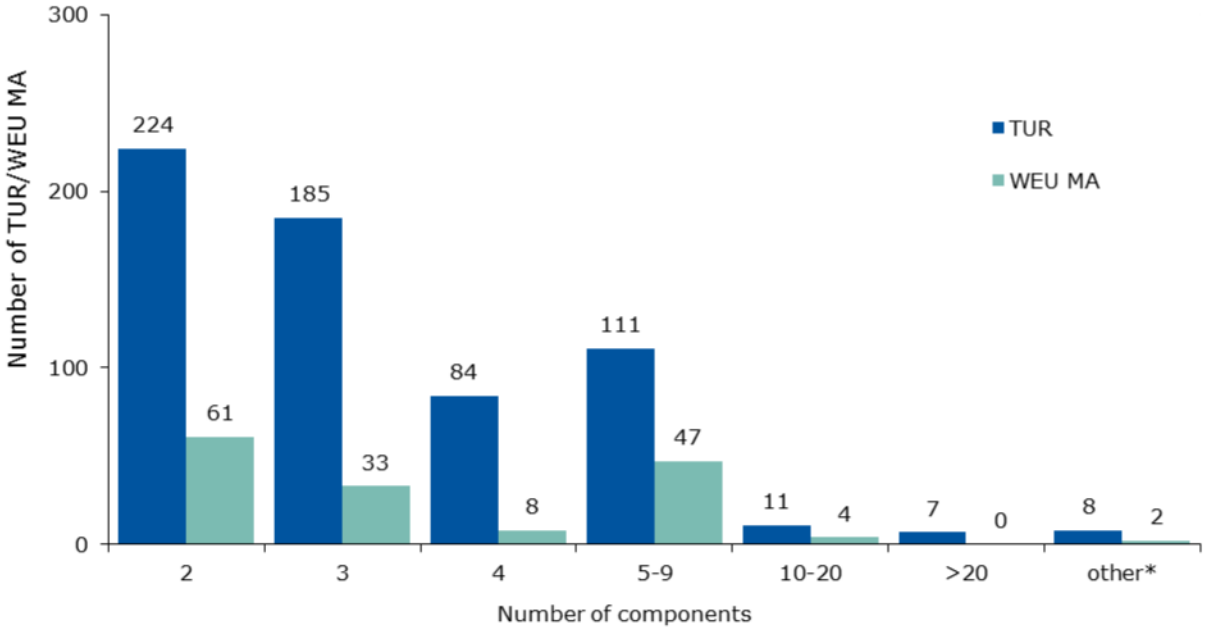
[1] Herbal substance or preparation thereof used as single active substance in products with TUR
[2] May include several TUR in different EU Member States for the same product
[3] Status by April 2017 (R: Rapporteur assigned, D: Draft under discussion, P: Draft published, PF: Assessment close to finalisation [pre-final], F: Final opinion adopted, F*: Final Public Statement, C: Call for scientific data, n.p.: not on the HMPC priority list (EMA/HMPC/278067/2006)
[4] In brackets the publication date of the revised monograph
[5] Existing monograph for traditional use (TU), well-established use (WEU) or both (TU + WEU)
[6] HMPC assessment outcome (MO: monograph, LE: list entry, PS: public statement)

Table 4

Number of WEU MA for herbal substances used in monocomponent HMP in the EU by 31 December 2016 and current status/outcome of the corresponding HMPC assessment.

Herbal substances[1]	WEU MA[2]	Status HMPC assessment[3]	Draft monograph publication date[4]	Final monograph publication date	Outcome (TU/WEU)[5]	Outcome (MO/LE/PS)[6]
Total (61)	**694**					
Hederae helicis folium	115	F	08/03/2010 (12/02/2015)	19/04/2011 (18/01/2016)	TU+WEU	MO
Ginkgo folium	111	F	14/02/2014	08/04/2015	TU+WEU	MO
Valerianae radix	57	F	20/09/2005 (23/07/2015)	26/10/2006 (27/04/2016)	TU+WEU	MO
Hyperici herba	50	F	06/11/2008	20/12/2009	TU+WEU	MO
Silybi mariani fructus	33	PF	23/07/2015			
Cimicifugae rhizoma	30	F	17/09/2009	20/01/2011	WEU	MO
Echinaceae purpureae herba	29	F	08/05/2007 (09/2014)	08/05/2008 (13/04/2015)	TU+WEU	MO+LE
Vitis viniferae folium	21	F	20/12/2009	03/01/2011	TU+WEU	MO+LE
Glycini semen	19	D	28/02/2017			
Pelargonii radix	18	F	26/04/2011 (26/10/2015)	04/02/2013	TU	MO
Sabalis serrulatae fructus	17	F	10/09/2014	14/01/2016	TU+WEU	MO
Sennae folium	17	F	10/01/2006	26/10/2006	WEU	MO
Crataegi folium cum flore	13	F	14/10/2014	17/06/2016	TU	MO
Hippocastani semen	12	F	04/09/2008	16/07/2009	TU+WEU	MO
Capsici fructus	10	F	12/09/2014	26/06/2015	WEU	MO
Visci albi herba	8	F*				PS
Plantaginis ovatae semen	8	F	24/10/2005 (11/2012)	26/10/2006 (23/07/2013)	WEU	MO
Psyllii semen	8	F	24/10/2005 (03/2013)	26/10/2006 (29/07/2013)	WEU	MO
Sennae fructus	8	F	10/01/2006	26/10/2006	WEU	MO
Agni casti fructus	7	F	17/09/2009	05/08/2011	TU+WEU	MO
Eucalypti aetheroleum	7	F	31/07/2013	13/05/2014	TU	MO
Passiflorae herba	6	F	07/03/2007 (25/01/2014)	07/09/2007 (18/06/2014)	TU	MO
Betulae folium	6	F	08/05/2007 (24/11/2014)	08/05/2007 (13/03/2015)	TU	MO
Solidaginis virgaureae herba	6	F	31/10/2007	04/09/2008	TU	MO
Camelliae sinensis non fermentatum folium	6	F	19/04/2013	29/04/2014	TU	MO
Thymi herba	5	F	08/05/2007 (12/11/2013)	30/10/2007 (02/06/2014)	TU	MO
Cynarae folium	5	F	18/01/2011	21/12/2011	TU	MO
Symphyti radix	5	F	19/08/2011	05/06/2015	TU	MO
Menthae piperitae aetheroleum	4	F	31/10/2007	08/05/2007	TU+WEU	MO+LE
Rhei radix	4	F	05/07/2007	30/10/2007	WEU	MO
Other 5 substances with 3 MA	5 x 3	(F: 4, PF: 0, P: 0, D: 0, R: 0, C: 1, n.p.: 0)				
Other 8 substances with 2 MA	8 x 2	(F: 4, PF: 0, P: 1, D: 0, R: 0, C: 0, n.p.: 3)				
Other 18 substances with 1 MA	18 x 1	(F: 10, F*: 1, PF: 0, P: 0, D: 0, R: 0, C: 1, n.p.: 6)				

[1] Herbal substance or preparation thereof used as single active substance in products with WEU MA
[2] May include several WEU MA in different EU Member States for the same product
[3] Status by April 2017 (R: Rapporteur assigned, D: Draft under discussion, P: Draft published, PF: Assessment close to finalisation [pre-final], F: Final opinion adopted, F*: Final Public Statement, C: Call for scientific data , n.p.: currently not on the HMPC priority list EMA/HMPC/278067/2006)
[4] In brackets the publication date of the revised monograph
[5] Existing monograph for traditional use (TU), well-established use (WEU) or both (TU + WEU).
[6] HMPC assessment outcome (MO: monograph, LE: list entry, PS: public statement)



(* 'other' includes e.g. combinations with ancillary vitamins or minerals)

Figure 7

Number of TUR and WEU MA in the EU by 31 December 2016 for herbal combination products (total: 630 TUR; 155 WEU MA) grouped according to number of components (herbal substances and/or preparations) included.

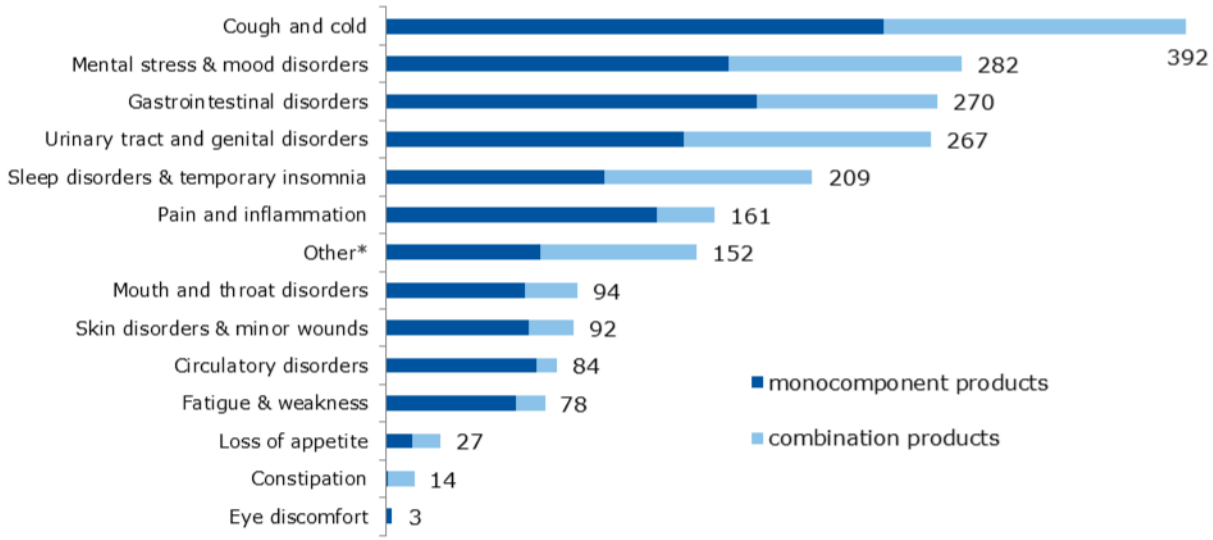


Figure 8

Number of indications[1] granted in TUR for THMP grouped by typical traditional therapeutic areas[2] for monocomponent and combination products in the EU by 31 December 2016.

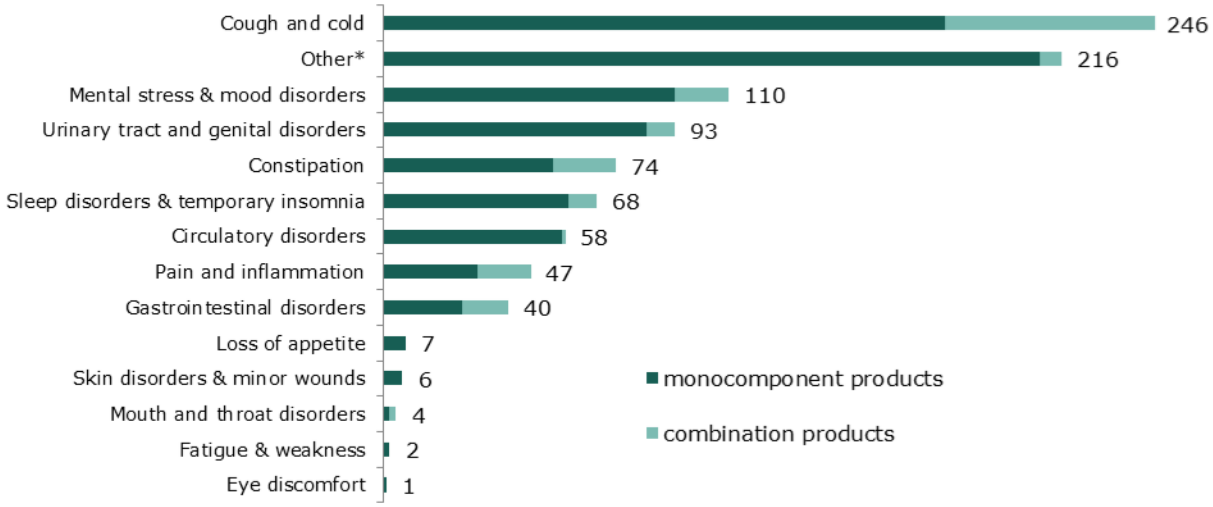


Figure 9

Number of indications[1] granted in WEU MA for HMP grouped by typical traditional therapeutic areas[2] for monocomponent and combination in the EU by 31 December 2016.

[1] May include several indications per registration/authorisation
[2] May include several registrations/authorisations in different Member States for the same product
Allocations of indications to the therapeutic areas in line with document EMA/568320/2009 Rev.1 used for 'browse by use' function at the EMA website. (* 'Other' includes indications in therapeutic areas so far not covered in document EMA/568320/2009 Rev.1 such as cardiovascular, improving liver function, mild cerebral insufficiencies)