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 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for each Member State how many applications have been received, are under assessment, have been refused by NCAs, or withdrawn by applicants before authorisation (Tables 1 and 2, Figures 5 and 6).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:


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.

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<th>Member State</th>
<th>Received</th>
<th>Under assessment</th>
<th>TUR granted</th>
<th>TUR refused</th>
<th>Withdrawn 1</th>
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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.

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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.

Uptake of the traditional use registration scheme and implementation of the provisions of Directive 2004/24/EC in EU Member States
EMA/HMPC/322570/2011 Rev. 7
Page 6/11
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.

<table>
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<tr>
<th>Herbal substances</th>
<th>TUR</th>
<th>Status HMPC assessment</th>
<th>Draft monograph publication date</th>
<th>Final monograph publication date</th>
<th>Outcome (TU/WEU)</th>
<th>Outcome (MO/LE/PS)</th>
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<td>MO</td>
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<td>17/09/2009</td>
<td>20/01/2011</td>
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<td>08/05/2008</td>
<td>17/01/2011</td>
<td>TU</td>
<td>MO</td>
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</table>

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)

<table>
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<tr>
<th>Herbal substances1</th>
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<th>Status HMPC assessment3</th>
<th>Draft monograph publication date4</th>
<th>Final monograph publication date</th>
<th>Outcome (TU/WEU)5</th>
<th>Outcome (MO/LE/PS)6</th>
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<td>14/05/2009 (04/11/2016)</td>
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<td>MO+LE</td>
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<td>09/12/2015</td>
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<td>Taraxaci radix</td>
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<td>F</td>
<td>06/11/2008</td>
<td>16/07/2009</td>
<td>TU</td>
<td>MO</td>
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<td>Arcii radix</td>
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<td>F</td>
<td>08/03/2010</td>
<td>03/01/2011</td>
<td>TU</td>
<td>MO</td>
</tr>
<tr>
<td>Betulaceae folium</td>
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<td>F</td>
<td>08/05/2007 (24/11/2014)</td>
<td>08/05/2008 (13/03/2015)</td>
<td>TU</td>
<td>MO</td>
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<td>F</td>
<td>05/07/2007</td>
<td>08/05/2008</td>
<td>TU</td>
<td>MO+LE</td>
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<td>Hamamelidis cortex</td>
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<td>F</td>
<td>05/11/2008</td>
<td>23/03/2010</td>
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<td>MO</td>
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<td>Lupuli flos</td>
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<td>05/07/2007</td>
<td>11/07/2008 (07/08/2014)</td>
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<td>MO</td>
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<td>n.p.</td>
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<td>F</td>
<td>08/03/2010</td>
<td>28/01/2011</td>
<td>TU</td>
<td>MO</td>
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<td>Solidaginis virgaureae herba</td>
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<td>F</td>
<td>31/10/2007</td>
<td>04/09/2008</td>
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<td>Trigonelae foenugraeci semen</td>
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<td>F</td>
<td>10/06/2010</td>
<td>23/02/2011</td>
<td>TU</td>
<td>MO</td>
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<tr>
<td>Boldi folum</td>
<td>4</td>
<td>F</td>
<td>08/05/2008 (09/2016)</td>
<td>13/01/2009 (12/01/2017)</td>
<td>TU</td>
<td>MO</td>
</tr>
<tr>
<td>Other 12 substances with 3 registrations</td>
<td>12 x 3</td>
<td>(F: 7, F*: 1, PF: 0, P: 0, D: 0, R: 0, C: 1, n.p.: 3)</td>
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<td>Other 30 substances with 2 registrations</td>
<td>30 x 2</td>
<td>(F: 21, PF: 0, P: 0, D: 0, R: 0, C: 0, n.p.: 9)</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Herbal substances</th>
<th>WEU MA</th>
<th>Status HMPC assessment</th>
<th>Draft monograph publication date</th>
<th>Final monograph publication date</th>
<th>Outcome (TU/WEU)</th>
<th>Outcome (MO/LE/PS)</th>
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<tr>
<td>Total (61)</td>
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<td>08/03/2010 (12/02/2015)</td>
<td>19/04/2011 (18/01/2016)</td>
<td>TU+WEU</td>
<td>MO</td>
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<tr>
<td>Ginkgo folium</td>
<td>111</td>
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<td>14/02/2014</td>
<td>08/04/2015</td>
<td>TU+WEU</td>
<td>MO</td>
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<td>Hyperici herba</td>
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<td>06/11/2008</td>
<td>20/12/2009</td>
<td>TU+WEU</td>
<td>MO</td>
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<td>Silybi mariani fructus</td>
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<td>PF</td>
<td>23/07/2015</td>
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<td></td>
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<td>Cimicifugae rhizoma</td>
<td>30</td>
<td>F</td>
<td>17/09/2009</td>
<td>20/01/2011</td>
<td>WEU</td>
<td>MO</td>
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<td>Echinacea purpurea herba</td>
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<td>08/05/2007 (09/2014)</td>
<td>08/05/2008 (13/04/2015)</td>
<td>TU+WEU</td>
<td>MO+LE</td>
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<td>20/12/2009</td>
<td>03/01/2011</td>
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<td>MO+LE</td>
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<td>Glycini semen</td>
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<td>Pelargonii radix</td>
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<td>F</td>
<td>26/04/2011 (26/10/2015)</td>
<td>04/02/2013</td>
<td>TU</td>
<td>MO</td>
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<td>Sabalis serrulatae fructus</td>
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<td>10/09/2014</td>
<td>14/01/2016</td>
<td>TU+WEU</td>
<td>MO</td>
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<td>Sennae folium</td>
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<td>10/01/2006</td>
<td>26/10/2006</td>
<td>WEU</td>
<td>MO</td>
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<td>Crataegi folium cum flore</td>
<td>13</td>
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<td>14/10/2014</td>
<td>17/06/2016</td>
<td>TU</td>
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<td>16/07/2009</td>
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<td>12/09/2014</td>
<td>26/06/2015</td>
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<td>MO</td>
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<td>24/10/2005 (03/2013)</td>
<td>26/10/2006 (29/07/2013)</td>
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<tr>
<td>Sennae fructus</td>
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<td>10/01/2006</td>
<td>26/10/2006</td>
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<td>17/09/2009</td>
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<td>07/03/2007 (25/01/2014)</td>
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<td>19/08/2011</td>
<td>05/06/2015</td>
<td>TU</td>
<td>MO</td>
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<tr>
<td>Menthae piperitae aetheroleum</td>
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<td>F</td>
<td>31/10/2007</td>
<td>08/05/2007</td>
<td>TU+WEU</td>
<td>MO+LE</td>
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<td>Rhei radix</td>
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</tbody>
</table>

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)
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Uptake of the traditional use registration scheme and implementation of the provisions of Directive 2004/24/EC in EU Member States
EMA/HMPC/322570/2011 Rev. 7
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.

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