



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

6 May 2014  
EMA/HMPC/36949/2014  
Committee on Herbal Medicinal Products (HMPC)

## Overview of comments received on Community herbal monograph on *Arnica montana* L., flos (EMA/HMPC/198793/2012)

Table 1: Organisations and/or individuals that commented on the draft Community herbal monograph on *Arnica montana* L., flos as released for public consultation on 09 July 2013 until 15 December 2013.

	Organisations and/or individuals
1	Association of the European Self-Medication Industry (AESGP)
2	Coopération Pharmaceutique Française (COOPER)
3	Dr. Theiss Naturwaren GmbH, Germany



Table 2: Discussion of comments

**General comments to draft document**

Interested party	Comment and Rationale	Outcome
AESGP	<p>AESGP in principle welcomes the development of the above-mentioned Community herbal monograph which, by providing harmonised assessment criteria for arnica-containing products, should facilitate mutual recognition in Europe.</p>	<p>The welcome note by AESGP is appreciated.</p>
COOPER	<p>We propose to include “Arnica Chamissonis Less subsp. Foliosa (Nutt.) Maguire, flos” and herbal preparation “Liquid extract (1:1), extraction solvent: ethanol 60% (v/v)” in this Community Herbal monograph.</p> <p>The rationale is provided in the second document attached to this document.</p>	<p>Not endorsed.</p> <p>The Community Monograph on <i>Arnica montana</i> L., flos is referring to the herbal substance included in the definition of the relevant monograph of the European Pharmacopoeia.</p> <p>The provided justification to support the inclusion of <i>Arnica chamissonis</i> Less subsp. <i>Foliosa</i> (Nutt.) Maguire, flos and herbal preparations derived thereof was assessed but considered not suitable to change the Community Monograph. The justification could be taken into account in an application to a National Competent Authority.</p>

## SPECIFIC COMMENTS ON TEXT

Section number and heading	Interested party	Comment and Rationale	Outcome
2. Qualitative and quantitative composition	COOPER	<p><i>Arnica montana</i> L., flos</p> <p>We propose to include <i>Arnica chamissonis</i> Less subsp. <i>Foliosa</i> (Nutt.) Maguire, flos <b>[A]</b>.</p> <p>ii) Herbal preparation</p> <p>a) Tincture (1:10), extraction solvent: ethanol 70% (v/v)</p> <p>b) Tincture (1:5), extraction solvent: ethanol 60% (v/v)</p> <p>c) Liquid extract of fresh flowers (1:20), extraction solvent: ethanol 50% (m/m)</p> <p>We propose to include:</p> <p>d) Liquid extract (1:1), extraction solvent: ethanol 60% (v/v) <b>[B]</b></p>	<p>Not endorsed.</p> <p>The Community Monograph on <i>Arnica montana</i> L., flos is referring to the herbal substance included in the definition of the relevant monograph of the European Pharmacopoeia.</p> <p>The provided justification to support the inclusion of <i>Arnica chamissonis</i> Less subsp. <i>Foliosa</i> (Nutt.) Maguire, flos and herbal preparations derived thereof was assessed but considered not suitable to change the Community Monograph. The justification could be taken into account in an application to a National Competent Authority.</p>
3. Pharmaceutical Form	AESGP	<p>One of our member companies ran three searches respectively in 2009, 2011 and 2013.</p> <p>The following remarks may allow the addition and/or correction of the information regarding products on the market listed in the Assessment Report for 9 Member States: AT, BE, FR, DE, HU, IR, PL, SE and UK.</p> <p>We would like to point out the case of pure solutions / pure tincture sold as is for use in liquid form (following dilution) as “cutaneous solutions” – cf. product No. 4 in Austria, product No. 11 in Germany and to the French product No. 4, which exactly is a dressing, but a dressing impregnated with arnica tincture, so it is a solution that is coming into direct contact with the skin.</p>	<p>The additional information is appreciated. Additions or corrections of monograph and assessment report are only made if the information is relevant. The monograph is defining a harmonised view. As the availability of information is differing, the objective of monograph and assessment report is not to provide an exhaustive overview about divergences of labelling of product before adoption of the monograph.</p>

Section number and heading	Interested party	Comment and Rationale	Outcome
		<p>Respective references (SPCs, leaflets, further information) are supplied and accompany this submission of comments.</p> <p><b>Austria /AT: Traditional use</b></p> <p>1. Ointment (registration in 2008), <b>doc Arnika Salbe</b>, HERB-00006 [<i>Hermes 2010</i>]:</p> <p><u>Composition:</u> 100 g ointment contain 21.5 g tincture (1:10), extraction solvent 70 % (v/v) <u>Indication:</u> THMP for external use at blunt traumas, sprain, bruise, contusion and dislocation, and at painful muscle and joint disorders. <u>Posology:</u> apply 3-5 times daily to the affected area in slight massage, not for persons under 18 years recommended</p> <p>In the case of "doc Arnika Salbe" we do not understand why posology b) of the draft monograph ("<i>21.5% tincture in ointment base</i>") is restricted to "<i>ointment</i>" only. We suggest allowing all types of semi-solid forms as it is the case in posology b) of the draft monograph ("<i>...tincture in base</i>").</p> <p>2. Gel (registration in 2011), <b>Atrogel Arnika Gel</b>, HERB-00082 [<i>Aponova 2011</i>]:</p> <p><u>Composition:</u> 100 g contain 50 g liquid extract from fresh Arnica flowers (1:20), extraction solvent: ethanol 50 % (m/m) <u>Indication:</u> THMP for external use at blunt traumas, sprain, bruise, contusion and dislocation, and at painful muscle and joint disorders. <u>Posology:</u> apply 2 times daily 4 cm to the affected area in slight massage, not for persons under 18 years recommended</p> <p>Additionally, we point to the following third product whose registration under §17a [Ö]AMG expired in 2011 and which we believe to be suitable for support of the tradition of liquid products containing arnica. Particularly, we remind the so-called</p>	<p>Corresponding to herbal preparation a).</p> <p>The comment is referring to posology a) of the monograph. The suggestion is accepted and the monograph changed accordingly.</p> <p>Corresponding to herbal preparation d).</p>

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		<p>grandfathering once expressed by the BfArM for positive evaluation of the 30 years tradition period, supposing that a bought product is stored e.g. in the drawer cabinet of bedroom for use until expiry.</p> <p>3. Tincture (registered since 1999)  <b>Arnikatinktur "Wernigerode"</b>, Z-Nr. 7-01052 [AGES 2011]</p> <p><u>Composition:</u> Flos Arnicae (extract)  <u>Indication / ATC:</u> M02AX: Other topical products for joint and muscular pain</p> <p><b>Belgium /BE: Traditional Use</b></p> <p>The draft assessment report tables the existence of traditional use registration(s) in Belgium, but does not give details on at least one product. Below, we do so:</p> <p>1. Cream for cutaneous use (registered since 2002):  <b>Arnican crème</b> (N.F. de arnican pomade) , no. 0160IS0024F007 [Melisana 2003a, Melisana 2003b]</p> <p><u>Composition:</u> 100 g contain 25 g <i>Arnicae</i> tincture.  <u>Indication:</u> Locally acting anti-inflammatory and antiphlogistic remedy in the event of sprains or for administration onto haematoma or oedema caused by acute injuries. Any serious condition must be excluded.  <u>Posology:</u> apply generously 2 to 3 times daily onto the affected skin area and massage gently until cream is completely absorbed. A string of ointment of 3 cm is sufficient for the treatment of an area of the size of the palm.</p> <p><u>Patient groups:</u> not specified  <u>Adverse drug reactions:</u> prolonged use on wounds and ulcers may elicit a skin inflammation with oedema and blisters. Prolonged use can cause eczema.</p>	<p>The tradition of 30 years is not covered by this specific product. Details on extraction solvent and DER are not provided. The product may be supportive to demonstrate the traditional use of liquid formulations.</p> <p>Corresponding to herbal preparation a)</p> <p>The posology for this herbal preparation is extended accordingly.</p>

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		<p>Registration took place before Directive 2004/24/EC and must therefore have followed a national, probably traditional registration scheme (as can be assumed from the formulation “any serious condition must be excluded”).</p> <p><b>France /FR: Traditional Use</b></p> <p>Taken from the draft assessment report, with little supplementation and differences in Nos. 1 and 4:</p> <p>1. Cream for cutaneous use (since 1959),  <b>Arnican 4 pour cent</b>, # 34009 341 638 5 2 (15 g) ou # 34009 341 639 1 3  (50 g) [<i>Coopération Pharmaceutique Française 2008</i>]:</p> <p><u>Composition:</u> 100 g cream contains 4 g arnica fluid extract.  <u>Indications:</u> Traditionally used in the symptomatic treatment of bruises.  <u>Posology:</u> Apply and massage gently until complete penetration. Repeat administration 2 to 3 times within 24 hours.  <u>Adverse drug reactions:</u> allergic reactions may give reason to stop the treatment. Due to the presence of terpenic derivatives, as well as of certain excipients, and when the recommended doses are exceeded, risks of convulsion in babies and children and of agitation and confusion in the elderly arise.</p> <p>2. Gel for cutaneous use (since 2006),  <b>Arnica Médiflor</b>, # 34009 376 220 7 3 (50 g) and # 34009 376 221 3 4 (100 g) [<i>Médiflor 2011</i>]:</p> <p><u>Composition:</u> 100 g gel contains 20 g arnica tincture (1:9), extraction solvent 70 % (v/v).  <u>Indications:</u> Traditionally used in the symptomatic treatment of bruises.  <u>Posology:</u> As soon as possible, apply a nut-like portion of gel onto the</p>	<p>For this product it is unknown whether the active substance was derived from <i>Arnica montana</i> or <i>Arnica chamissonis</i>. The tradition is not demonstrated.</p> <p>According to the clarification of the declaration the active substance is corresponding to herbal preparation a). The section on posology is modified according to the suggestion.</p>

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		<p>skin area to treat and massage gently until gel is completely absorbed. Apply 2 to 3 times daily.</p> <p><u>Adverse drug reactions:</u> some cases of erythema have been observed. Propylene glycol can cause skin irritation.</p> <p>In the case of "Arnica Mediflor", the declaration of the tincture gives the ratio of the <b>herbal substance to the herbal preparation</b>, which is 1:9, whereas the <b>ratio of herbal substance to extraction solvent</b> is 1:10 (which is to be declared for a tincture). Thus the API of Arnica Mediflor conforms to Herbal preparation a) given in the draft monograph and therefore posology b) ("<i>semi-solid dosage form with 20% tincture in base</i>") should be allowed for Herbal preparation a) of the draft monograph as well.</p> <p>3. Gel for cutaneous use (since 2004), <b>Arnicagel</b>, # 34009 377 540 5 7 (25 g) [<i>Weleda 2006c</i>]:</p> <p><u>Composition:</u> 100 g gel contains 20 g arnica tincture (1:5), extraction solvent: ethanol 60 % (v/v).</p> <p><u>Indications:</u> Traditionally used in the symptomatic treatment of bruises.</p> <p><u>Posology:</u> Apply immediately following a trauma. Massage gently until complete penetration. Repeat administration 1 hour later, then 3 to 4 times daily until complete disappearance of the symptoms.</p> <p><u>Adverse drug reactions:</u> allergic reaction may give reason to stop the treatment. Due to the presence of alcohol, frequent cutaneous administrations may cause irritations and skin dryness. Risk of dermatoses for persons sensitive to arnica.</p> <p>4. Dressing impregnated with solution for cutaneous use (since 1982), <b>Teinture d'Arnica Gilbert</b> (formerly: Pharmadose teinture d'arnica), # 34009 318 653 1 5 [<i>Laboratoires Gilbert 2008</i>]:</p> <p><u>Composition:</u> One (1) impregnated dressing contains 2.5 ml solution. 100 ml solution contains 100 ml arnica tincture (1:10), extraction</p>	<p>Corresponding to herbal preparation c)</p> <p>The tradition of the liquid herbal preparation is sufficiently demonstrated. The specific herbal preparation is introduced into the monograph.</p>

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		<p>solvent: ethanol 60 % (v/v).  <u>Indications:</u> Traditionally used in the symptomatic treatment of bruises.  <u>Posology:</u> Take the dressing out of its package and apply it locally.  <u>Adverse drug reactions:</u> Particularly allergy to arnica.</p> <p><b>Germany /DE: Well established use</b></p> <p>Taken from the draft assessment report, we reprint with little modifications but add an eleventh product:</p> <p>1. Gel for cutaneous use (as a compress and liniment) (since 1976), <b>Arnikafit-Gel</b>, Zul.-Nr. 6153206.00.00 [<i>Kraeuterhaus 2013</i>].</p> <p><u>Composition:</u> 100 g contain 25 g tincture from Arnica flowers (1:10), extraction solvent: ethanol 70 %  <u>Indication:</u> For external administration (as layer/compress and as rub) in the event of consequences of injuries and accidents, e.g. haematoma, sprains, bruises and contusion.  <u>Posology:</u> Apply 3 times daily a string of gel of 3-5 cm length per area of the size of the palm and massage gently, in adults and adolescents over 12 years. Compresses covered slightly with gel can be applied overnight.</p> <p>2. Gel for cutaneous use (since 1976), <b>Kneipp Arnika Kühl- &amp; SchmerzGel</b>, Zul.-Nr. 6993946.00.00 [<i>Kneipp 2011</i>]:</p> <p><u>Composition:</u> 100 g contain 25 g tincture from Arnica flowers (1:10), extraction solvent: ethanol 70 % (v/v).  <u>Indication:</u> For external use after injuries and accidents, i.e. haematoma, sprains, bruises, contusion.  <u>Posology:</u> apply 2 times daily a string of gel of 3 cm length per area of the size of the palm and massage gently, in adults and adolescents over 12 years.</p>	<p>Corresponding to herbal preparation a)</p> <p>Corresponding to herbal preparation a)</p>



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		<p>3. Gel for cutaneous use (since 1976), <b>Arnikamed-Gel</b> (formerly Mobil Arnika Schmerz-Gel), Zul.-Nr. 6681684.00.00 [<i>Dr. Theiß 2010</i>):</p> <p><u>Composition:</u> 10 g gel contains 2.4 g tincture from Arnica flowers (1:10), extraction solvent: ethanol 70 % (v/v). <u>Indication:</u> For external use after injuries and accidents, i.e. haematoma, sprains, bruises, contusion. <u>Posology:</u> apply up to 2 times daily a string of gel of size of a pea per area of the size of the palm and massage gently into the affected parts of the skin, in adults and adolescents over 12 years.</p> <p>4. Gel for cutaneous use (since 1976), <b>Medizinisches Sport Gel</b>, Zul.-Nr. 6232472.00.00 [<i>IMG 2005</i>):</p> <p><u>Composition:</u> 100 g gel contains 25 g tincture from Arnica flowers (1:10), extraction solvent: ethanol 70 % (v/v). <u>Indication:</u> For external use after injuries and accidents, i.e. haematoma, sprains, bruises, contusion. <u>Posology:</u> apply 2 times daily, best in the morning and in the evening, a string of gel of 3 cm length per area of the size of the palm and massage gently, in adults and adolescents over 12 years.</p> <p>5. Cream (yes!) for cutaneous use (since 1976), <b>Medizinische Sport Salbe aktiv</b>, Zul.-Nr. 6354666.00.00 [<i>IMG 2004b</i>):</p> <p><u>Composition:</u> 10 g cream contain 2 g tincture from Arnica flowers (1:10), extraction solvent: ethanol 70 % (v/v). <u>Indication:</u> For external use at blunt trauma, i.e. haematoma, sprains, bruises, contusion. <u>Posology:</u> apply up to 3 times daily a string of cream of 3 cm length per area of the size of the palm and massage gently, in adults and adolescents over 12 years.</p> <p>6. Cream for cutaneous use (since 1976),</p>	<p>Corresponding to herbal preparation a)</p> <p>Corresponding to herbal preparation a)</p> <p>Corresponding to herbal preparation a)</p> <p>Corresponding to herbal preparation a)</p>

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		<p><b>Doc<sup>®</sup>-Salbe</b>, Zul.-Nr. 6318914.00.00 [<i>Hermes 2012</i>]:</p> <p><u>Composition</u>: 10 g cream contain 2.15 g tincture from Arnica flos (1:10), extraction solvent: ethanol 70 % (v/v).  <u>Indication</u>: For external use after injuries and accidents, i.e. haematoma, sprains, bruises, contusions.  <u>Posology</u>: apply 2-3 times daily a string of cream of 3 cm length per area of 10 x 10 cm, in adults and adolescents over 12 years.</p> <p>7. Cream for cutaneous use (since 1976),  <b>profelan Salbe nach Müller-Wohlfahrt</b>, Zul.-Nr. 6314483.00.00 [<i>Mueller-Wohlfahrt 2004</i>]:</p> <p><u>Composition</u>: 100 g contain 20 g tincture from Arnica flowers (1:10), extraction solvent: ethanol 70 % (v/v)  <u>Indication</u>: For external use after injuries and accidents, i.e. haematoma, sprains, bruises, contusion.  <u>Posology</u>: apply up to 3 times daily a string of ointment of size of 3 cm per area of the size of the palm and massage gently, in adults and adolescents over 12 years.</p> <p>8. Cream for cutaneous use (since 1976),  <b>Klosterfrau Arnika Schmerz-Salbe</b>, Zul.-Nr. 6883235.00.00 [<i>Klosterfrau 2009</i>]:</p> <p><u>Composition</u>: 100 g contain 25 g tincture from Arnicae flos (1:1<sup>0</sup>), extraction solvent: ethanol 70 % (v/v)  <u>Indication</u>: For external use after injuries and accidents, i.e. in case of haematoma and sprains.  <u>Posology</u>: apply up to 2-3 times daily a string of cream of 3 cm length per area of the size of the palm and massage gently, in adults and adolescents over 12 years.</p> <p>9. Cream for cutaneous use (since 1990),  <b>Medizinische Arnika Salbe</b>, Zul.-Nr. 3000769.00.00 [<i>IMG 2004a</i>]:</p>	<p>Corresponding to herbal preparation a)</p> <p>Corresponding to herbal preparation a)</p> <p>Corresponding to herbal preparation a)</p>

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		<p><u>Composition:</u> 1 g cream contains 80 mg tincture from Arnica flowers (1:10), extraction solvent: ethanol 70 % (v/v).  <u>Indication:</u> For external use after injuries and accidents, i.e. oedema, haematoma, distorsion, bruises, contusion.  <u>Posology:</u> apply 2-3 times daily to the affected parts of the skin and massage gently, in adults and adolescents over 12 years.</p> <p>10. Ointment for cutaneous use (since 1993),  <b>Kneipp Arnika Salbe S</b>, Zul.-Nr. 23101.00.00 [<i>Kneipp 2013</i>]:</p> <p><u>Composition:</u> 100 g contain 10 g extract from Arnica flowers (1:3.5-4.5), extraction solvent: sunflower oil.  <u>Indication:</u> For external use after injuries and accidents, i.e. haematoma, sprains, bruises, contusion, oedema in tissues as a result of fractures; rheumatic muscle and joint pain; inflammation from insect bites.  <u>Posology:</u> apply several times daily and massage gently, for instance a string of ointment of 8 cm length for the area of the lower leg, for bigger or smaller areas more or less, respectively; in adults and adolescents over 12 years.</p> <p>We add:</p> <p>11. Solution for cutaneous use (since 1985),  <b>Arnikatinktur Standardzulassung</b>, Zul.-Nr. 5799.99.99 [<i>BfArM 2004</i>]:</p> <p><u>Composition:</u> 100 ml contain 100 ml arnica tincture (1:10), extraction solvent: ethanol 70 % (v/v).  <u>Indications:</u> For external treatment of consequences of injuries and accidents, e.g. haematoma, sprains, bruises or contusions, oedema as a consequence of fractures, in the event of rheumatic muscular and joint complaints; furunculosis and inflammations as a consequence of insect bites; superficial vein inflammations.  <u>Posology:</u> use water to dilute arnica tincture 3 to 10 fold and thereof prepare humid compresses to apply onto wounds. In the event of</p>	<p>The herbal preparation is not covering a period of 30 years of traditional use.</p> <p>A defined liquid herbal preparation is introduced into the monograph based on a specified product from France. The information according the "Standardzulassung" may be useful to support individual applications for evaluation by the national competent authorities. The posology should be specified in more detail.</p>

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		<p>blunt injuries, sprains, muscular and joint pains, affected body areas can be rubbed using diluted tincture, in adults and adolescents above 12 years.</p> <p>The possibility offered to MAHs to refer to this Standardzulassung and to market such products dates back to 1985. However, detailed facts about early use of this possibility are not known. We allow ourselves to underline that there is very high interest in using this Standardzulassung as can be depicted from <b>187</b> (!) entries of users of the said Standardzulassung, now available since its use must be obligatorily notified.</p> <p><b>Hungary / HU: Traditional use</b></p> <p>The draft assessment report lists two traditional products, respectively of 1992 and 1996).</p> <p>Following our own thorough research activities, we propose a slightly different result:</p> <p><b>Hungary: Traditional use</b>  1. Ointment (since 1992)  Based on the information found, the product <b>RHEUDOL forte reumakrém</b>, marketed by <i>In vitro</i> Kutató-Fejlesztő (Dunakeszi, HU), Nytsz. Sz. OGYI 307/92 (a non-medicinal product), formerly was a <u>combination product</u> containing 5.0 g alcoholic tincture from <i>Arnica montana</i> per 100 g, 600 mouse units honey bee toxin per 100 g and 3.0 g camphor per 100 g ("50 g vízzel lemosható krém: házi méh méreg (<i>Apis mellifera</i> toxin): 300 MU (mouse unit - egér egység), <i>Arnica montana</i> L. vizes-alkoholos kivonat: 2,5 g, kámfor: 1,5 g" [In vitro w/o year]). It had been granted in 1992 (as can be depicted from registration number). Following a decision of 2011, the product was renewed on 11.04.2011 in a modified form <u>no longer containing arnica</u> [OGYI 2011]. It is therefore not useful.</p>	<p>The comment is making reference to a combination product.</p>

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		<p>2. Cream for cutaneous use (since 1996), <b>Naturland Árnika krém</b>, OGYI 611/96 [<i>Naturland 2013</i>]:</p> <p><u>Composition</u>: 60 g contain 6 g Arnica tincture (1:10), extraction solvent: ethanol 70 % (v/v) and 1.56 mg betacarotene.</p> <p><u>Indications</u>: Treatment of closed lesions, sprain, bruise, distortion, luxation. To decrease inflammation due to lesions, to promote resorption of local swelling of suffusion. To alleviate articular or muscular pain. Warming up before sport activities. Relief of insect bites.</p> <p><u>Posology</u>: after cleaning the affected area apply the cream in thin layer and rub it 2-3 times daily.</p> <p><u>Risk</u>: Allergic skin reaction can occur. Long term use can cause eczema.</p> <p>In spite of the small amount of betacarotene (as second active substance), the product may be mentionable here (?).</p> <p><b>Ireland / IE: Well established use</b></p> <p>We do not recognise the following product in the draft assessment report:</p> <p>1. Ointment for cutaneous use (since 1992), “marketed for over 35 years”, <b>Arnica ointment</b>, # PA0407/001/001 [<i>Weleda 2009a</i>]:</p> <p><u>Composition</u>: 100 g gel ointment contain 10 ml of tincture from <i>Arnica montana</i> L., whole plant (1:2), extraction solvent ethanol 30 % (W/V).</p> <p><u>Indication</u>: For the symptomatic relief of muscular pain, stiffness, sprains, bruises and swelling after contusions. Immediate application at the site of a contusion helps to prevent the development of bruising.</p> <p><u>Posology</u>: muscular pain, stiffness, sprains and bruises: apply</p>	<p>The comment is making reference to a combination product. The Arnica tincture described is corresponding with herbal preparation a).</p> <p>The herbal preparation is extracted from the whole plant. The Community monograph is addressing the herbal substance as defined according to the relevant Ph. Eur. monograph.</p>

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		<p>sparingly to the affected area with gentle massage three to four times daily; contusions: apply a small amount immediately at the sit of the injury, for adults, children and elderly.  <u>Adverse drug reactions:</u> contact sensitisation has been reported very rarely.</p> <p><b>Latvia / LV</b></p> <p>1. Ointment for cutaneous use (marketed since 2002),  <b>Terra-sport ziede</b>, # 02-0378 [<i>Rigas farmaceitiska fabrika 2007</i>]:</p> <p><u>Composition:</u> Ointment 10 % contains tincture (1:10), extraction solvent: ethanol 70 %.  <u>Indications:</u> Antiseptic, anti-inflammatory and local irritant for the reduction of pain and inflammation of joints and muscles; for the treatment of bruises, dislocations, sprains, mild frostbites and burns, inflammation after insect bites; for the relief of subcutaneous haemorrhages and hematomas.  <u>Posology:</u> Apply 3-4 times daily to the affected area of skin by massaging gently.</p> <p><b>Netherlands / NL: Traditional use</b></p> <p>The draft assessment report mentions the following product which we describe like this:</p> <p>1. Gel for cutaneous use (registration since 2009),  <b>A.Vogel Atrosan spier- en gewrichtsgel</b>, # RVG 100903 [<i>Biohorma 2012</i>]:</p> <p><u>Composition:</u> 1 g gel contains 500 mg arnica montana flos extract (1=20) (corresponding to 120-200 mg of fresh arnica flowers), extraction solvent: ethanol 58 % /v/v).  <u>Indications:</u> Traditional herbal medicinal product for external use in the event of muscular pain following strain, stiff muscles and joints,</p>	<p>Corresponding to herbal preparation a)</p> <p>Corresponding to herbal preparation d)</p>

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		<p>pain by contusion, sprains or distorsion and in the event of bruises following traumata {THMP}.</p> <p><u>Posology:</u> apply 2 to 4 times daily in thin layer onto the painful bruise.</p> <p><u>Adverse drug reactions:</u> Itching, dry skin and erythema occur commonly.</p> <p><b>Poland / PL</b></p> <p>The draft assessment report lists two traditional products, respectively of 1992 and 1994, that we reprint with modifications and supplementation of a third one</p> <p><b>Poland: Traditional use</b></p> <p>1. Tincture for cutaneous use only (since 1992)  <b>Nalewka z arniki</b>, # 13690 [<i>Amara 2013</i>]:</p> <p><u>Composition:</u> 100 g of the preparation contain 100 g Arnica tincture, Ethanol content 66-69 %. Dilution before use.</p> <p><u>Indication:</u> applied onto injuries with intact skin and without external bleedings, as compress onto contusions, haematoma and sprains, as mouth rinsing solution in case of gingivitis or ulcers of the oral cavity.</p> <p><u>Posology:</u> Topical use. For dressings, dilute the tincture 3 to 10 times with water. For mouth rinsing solution dilute 10 times. Do not swallow.</p> <p><u>Adverse drug reactions:</u> Prolonged use as dressing, particularly on injured skin, may cause symptoms of burns with swelling and blisters. Use of dressing on big body areas may cause increase of temperature.</p> <p>2. Extract for cutaneous use (since 1994)  We could only identify a similar combination product, <b>Arnica Gel żel z arniki</b>, Kod Nazwa 6339401. Not useful (combination product).</p> <p>3. Ointment for cutaneous use (since 2005, or 1982?),</p>	<p>The product is derived from <i>Arnica chamissonis</i> which is not covered by the monograph.</p> <p>The product is derived from <i>Arnica chamissonis</i> which is not covered by the monograph.</p> <p>Data provided are not sufficiently demonstrating a</p>

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		<p><b>Maść arnikowa</b>, # R/ 0476 (registered acc. former rules) [<i>Elissa 2013</i>].</p> <p><u>Composition</u>: 1 g ointment contains 200 mg extract from meadow arnica flowers (<i>Arnica montana</i> L.) DER 1:1; extraction solvent: ethanol 70 % (v/v).</p> <p><u>Indication</u>: Supportive in case of contusions (bruises), for relief of post-traumatic swellings, symptoms of insect bites and rheumatic complaints.</p> <p><u>Posology</u>: Ointment for cutaneous use. Apply 2-4 time daily onto sick, inflamed skin.</p> <p><u>Adverse drug reactions</u>: Allergic skin reactions may occur (e.g. contact allergy).</p> <p><b>Slovenia / SI: Well established use</b></p> <p>The draft assessment report mentions the following product that we describe like this:</p> <p>1. Gel for cutaneous use only (registration in 2007)  <b>Atrogel® 0,5 g/g gel</b>, # 5363-II-038/08 [<i>Farmedica 2007</i>]:</p> <p><u>Composition</u>: 1 g contains 0.54 g of tincture of fresh Arnica flowers (<i>Arnica montana</i> L.) (1:20), extraction solvent 57.9 % (v/v)</p> <p><u>Indications</u>: Herbal medicinal product for cutaneous use: for supportive treatment of rheumatic complaints (osteoarthritis) and other conditions with muscular aches, pains and stiffness symptomatic relief of aches, pains and stiffness, sprains, after contusions, exclusively based on long-standing use.</p> <p><u>Posology</u>: apply the gel gently to the affected area 2-3 times daily.</p> <p><b>Spain / ES: Traditional use</b></p> <p>The draft assessment report mentions the following product that we describe like this:</p>	<p>tradition of 30 years for this herbal preparation.</p> <p>Corresponding to herbal preparation d)</p>



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		<p>1. Gel for cutaneous use (registration in 2008)  <b>Arnicated gel de árnica</b>, # 662298 [<i>Flor de loto 2009</i>]:</p> <p><u>Composition</u>: 1 g gel contains 500 mg extract (as liquid extract) of fresh Arnica Flowers (<i>Arnica montana</i> L.) (equivalent to 120 - 200 mg fresh Arnica Flowers); extraction solvent: ethanol 58 % (v/v)  <u>Indications</u>: Traditional herbal medicinal product for the symptomatic relief of localised muscular conditions like pain and stiffness, distorsion, contusion and swellings as consequences of a trauma, exclusively based on long standing-use.  <u>Posology</u>: adults apply 2-10 cm to the affected area 2-4 times daily. Children over 6 years and elderly use the same dose as adults.  <u>Adverse drug reactions</u>: Contact dermatitis, eczema, itching, dry skin.</p> <p><b>Sweden / SE: Traditional use</b></p> <p>The draft assessment report does not mention the following product. This may be due to the fact that its indication applies the expression "to be used in anthroposophic medicine". But we have the impression that a closer view allows understanding the product as common traditional herbal product, the latter expression is used two times within indication:</p> <p>1. Ointment for cutaneous use (registration in 2009)  <b>Arnica Weleda</b>, # MT nr. 26935 [<i>Weleda 2009b</i>]:</p> <p><u>Composition</u>: 1 g ointment contains: 300 mg liquid extract of <i>Arnica montana</i> L., whole plant, arnica, corresponding to 100 mg fresh arnica herb; extraction solvent: ethanol 43 % (m/m).  <u>Indications</u>: Traditional herbal medicinal product to be used in anthroposophic medicine for the relief of occasional joint and muscle pain, sprain, stiffness, bruises or swelling after a trauma. The indications of this THMP exclusively base on experience and long standing-use.  <u>Posology</u>: Adults, elderly and children over 12 years apply Arnika</p>	<p>Corresponding to herbal preparation d)</p> <p>The herbal preparation is extracted from the whole plant. The Community monograph is addressing the herbal substance as defined according to the relevant Ph. Eur. monograph.</p>

Section number and heading	Interested party	Comment and Rationale	Outcome
		<p>Weleda ointment onto the hurting skin area 3 to 5 times daily. Treatment shall continue until symptoms have disappeared. Following use, hands should be cleaned with soap. Immediate use prevents development of bruises.</p> <p><u>Adverse drug reactions:</u> contact dermatitis, itching, skin eczema or skin dryness. Frequencies are not known.</p> <p><b>United Kingdom / UK: Traditional use</b></p> <p>The draft assessment report does not mention the following traditional product:</p> <p>1. Gel for cutaneous use (registration in 2006)  <b>Atrogel arnica gel</b>, THR 13668/0009 [<i>Bioforce 2006</i>]:</p> <p><u>Composition:</u> 1 g gel contains 500 mg extract (as liquid extract) of fresh Arnica Flowers (<i>Arnica montana</i> L.) (equivalent to 120 - 200 mg fresh Arnica Flowers); extraction solvent: ethanol 58 % (v/v).</p> <p><u>Indications:</u> A traditional herbal medicinal product for the symptomatic relief of muscular aches, pains and stiffness, sprains, bruises and swelling after contusions, exclusively based on long-standing use</p> <p><u>Posology:</u> Adults apply 2 - 10 cm gently to the affected area 2 to 4 times daily. Children and the elderly apply similarly as described for adults.</p> <p><u>Adverse drug reactions:</u> common: contact dermatitis, itching, rash, dry skin.</p>	Corresponding to herbal preparation d).
<p><b>Clinical particulars</b></p> <p>4.2 Posology and method of administration</p>	Dr. Theiss Naturwaren GmbH	<p>Based on the Assessment Report on Arnica Montana L., flos, we propose to include under "traditional use" Tincture (1:10), extraction solvent: ethanol 70% (v/v)</p> <p style="padding-left: 40px;">- semi-solid dosage form (<b>24% tincture in base</b>)</p> <p>Please refer to section 2.2 "Information on traditional/current</p>	The specific herbal preparation may be included.

Section number and heading	Interested party	Comment and Rationale	Outcome
		indications and specified substances/preparation" – Germany Point 3.: "Gel for external use (since 1976)".	
4.2. Posology and method of administration	COOPER	<p>Adolescent, adults and elderly</p> <p>a) Semi-solid dosage form (21.5% tincture in ointment base) Apply a thin layer on the affected area, two to three times daily</p> <p>b) Semi-solid dosage form (20% tincture in base) Apply a thin layer on the affected area, two to three times daily</p> <p>c) Semi-solid dosage form (50% liquid extract in base) Apply a thin layer on the affected area, two to four times daily</p> <p>We propose to apply:</p> <p>d) Semi-solid dosage form (4% fluid extract in base) Apply a thin layer on the affected area, two to three times daily</p> <p><b>[B]</b></p> <p>The use in children under 12 years of age is not recommended.</p> <p>We propose the use in children from 30 months <b>[C]</b></p>	<p>Not endorsed.</p> <p>The Community Monograph on <i>Arnica montana</i> L., flos is referring to the herbal substance included in the definition of the relevant monograph of the the European Pharmacopoeia.</p> <p>The provided justification to support the inclusion of <i>Arnica chamissonis</i> Less subsp. <i>Foliosa</i> (Nutt.) Maguire, flos and herbal preparations derived thereof was assessed but considered not suitable to change the Community Monograph. The justification could be taken into account in an application to a National Competent Authority.</p>
4.4. Special warning and precautions for use	COOPER	<p>We propose to remove this warning: <b>[C]</b></p> <p>The use in children under 12 years of age has not been established due to the lack of adequate data</p>	<p>Not endorsed.</p> <p>The Community Monograph on <i>Arnica montana</i> L., flos is referring to the herbal substance included in the definition of the relevant monograph of the the European Pharmacopoeia.</p> <p>The provided justification to support the inclusion of <i>Arnica chamissonis</i> Less subsp. <i>Foliosa</i> (Nutt.) Maguire, flos and herbal preparations derived thereof was assessed but considered not suitable to change the Community Monograph. The justification could be taken into account in an</p>

Section number and heading	Interested party	Comment and Rationale	Outcome
			application to a National Competent Authority.