

TRANSMISSION TO HMA for release for consultation	15 December 2016
DEADLINE for comments	27 February 2017
DISCUSSION WITHIN THE SUBGROUP	23 May 2017
ADOPTION BY THE HMPWG for publication on HMA-website	27 June 2017

Overview of comments received

Table 1: Origin of comments

HMPWG – Fifth list entries of stocks for which homeopathic use is justified as released for public consultation on the HMA website until 27/02/2017

	Organisation and/or individual
1	AESGP
2	BPI e.V. - Bundesverband der Pharmazeutischen Industrie e.V.
3	ECH - European Committee for Homeopathy
4	ECHAMP – European Coalition on Homeopathic and Anthroposophic Medicinal Products

Remark

“New entry, in a list of stocks for which homeopathic use is justified, is possible if sufficient homeopathic use references (copy of full text) for the concerned stock are sent to the HMPWG chair. This literature will be assessed during the next sub-WG meeting”.

Information is needed to justify the homeopathic use of the different stocks:

- *Aesculus hippocastanum fleurs (FP)*
- *Berberis vulgaris e fructibus (GHP)*
- *Crataegus (FP)*
- *Hamamelis virginiana ex cortice summitatibusque (GHP)*
- *Hamamelis virginiana e foliis; Hamamelis, Folium (GHP)*
- *Humulus lupulus siccum (FP)*
- *Valeriana officinalis recens (FP)*

Table 2: Discussion of comments

GENERAL COMMENTS		
Interested party	Comment and Rationale	Outcome
AESGP	<p>The Association of the European Self-Medication Industry (AESGP) represents the manufacturers of non-prescription medicines – including herbal and homeopathic medicinal products –, food supplements and self-care medical devices in Europe. AESGP welcomes the fifth list of stocks for which homeopathic use is justified, because reference to the list may facilitate application within the simplified registration procedure according to Article 14 of CD 2001/83/EC.</p> <p>However, it was found that some references to the GHP / FP were missing and must be added. For some substances, the Latin name/ homeopathic synonyms are missing. The synonyms of the HAB (GHP) and FP are established and recognized and in use in regulatory documents and labels. Therefore, all synonyms should be listed in the relevant column of the table. Some spelling errors, incorrect numbering of Ph. Eur monographs and deviations from direct English translations were also noted.</p>	<p>Homeopathic names mentioned in the GHP: missing synonyms were added.</p> <p>Homeopathic names mentioned in the FP: According to the preamble to the consolidated list of justified homeopathic stock, the name(s) of the stocks is the <u>first</u> traditional Latin name as in the French Pharmacopoeia (FP) monograph and sometime a second name (FP monograph) if applicable.</p> <p>The name followed by “ad praeparationes homoeopathicas” is not considered as a traditional name used in France.</p>
ECHAMP	Commentating the list required much time because of formal mistakes like incomplete reference or names or wrong numbers of Ph. Eur. monographs. We would appreciate very much if future lists for commenting were made more carefully.	
BPI e.V.	Is it possible to list the monographs of GHP and FP separately?	<p>The priority of this subgroup is to have a list including a majority of the stocks for which the homeopathic use can be justified.</p> <p>However we are aware that the use of the updated consolidated list including more than 100 stocks (lists 1-4) would be easier if it was available under an Excel table enabling to sort and/or filter the stocks according to the different possible synonyms or Pharmacopoeias.</p> <p>We propose to discuss this point further.</p>
ECHAMP	We would prefer to list the monographs of GHP and FP separately.	

GENERAL COMMENTS		
Interested party	Comment and Rationale	Outcome
BPI e.V.	The used stock should be the same as described in the homeopathic drug picture.	See the strategy in the preamble to the consolidated list of justified homeopathic stock.
ECHAMP	The used stock should be the same as described in the homoeopathic drug picture.	

SPECIFIC COMMENTS ON TEXT			
Concerned stock (first column of the table)	Interested party	Comment and Rationale (red writing = to be added)	Outcome
Agaricus muscarius, Agaricus / Agaricus muscarius	AESGP BPI e.V. ECH ECHAMP	<u>Column 1</u> Amanita muscaria, Agaricus muscarius, Agaricus / Agaricus muscarius <u>Comment/Rationale</u> “Amanita muscaria” is the main name according to the GHP	Agree
	ECH	<u>Column 1</u> Amanita muscaria, Agaricus muscarius, Agaricus / Agaricus muscarius, Amanita muscaria <u>Comment/Rationale</u> See in FP: <i>Amanita muscaria ad praeparationes homoeopathicas (FP)</i>	Not agree See the first outcome in the section “general comment”. Amanita muscaria is not considered as a traditional name used in France.
	AESGP	<u>Column 3</u> "Lam." <u>Comment/Rationale</u> As Lam. is an abbreviation, we recommend to add a full stop and an apostrophe (".") i.e. "Lam."	Partially agree Addition of a full stop as mentioned in the HAB There is no apostrophe in the HAB ⇒ Lam.

Agaricus phalloides, Agaricus bulbosus	AESGP BPI e.V. ECH ECHAMP	<u>Columns 1 and 2</u> Agaricus phalloides, Amanita phalloides , Agaricus bulbosus Ph. Eur. 2290 (GHP) <u>Comment/Rationale</u> Agaricus phalloides is the only name used in the Ph. Eur., Amanita phalloides is the main name in GHP, Agaricus phalloides and Agaricus bulbosus are synonyms in the GHP, we ask to include all three names. In the GHP, the substance is also monographed, please add "GHP".	Agree
	ECH	<u>Comment/Rationale</u> Typing error: Whole fresh mushroom (fruiting body) of ...	Not agree See the definition in the Ph. Eur.
Aletris farinosa / Aletris farinosa	BPI e.V. ECHAMP	<u>Comment/Rationale</u> GHP has listed the fresh underground parts, which are also mentioned in the drug picture. The dried rhizome is only listed in the FP.	Not agree According to the preamble to the consolidated list of justified homeopathic stock, in the case where it is not possible to know if concerned literature is related to the fresh or the dried part of a plant and both states are already being used in clinical practice without evidence to conclude a significant difference, it was decided that both states can be considered as similar forms.
Ammonium bromatum	ECH	<u>Column 1</u> Ammonium bromatum, Ammonii bromidum <u>Comment/Rationale</u> Latin Ph.Eur name	Not agree See the first outcome in the section "general comment". Ammonii bromidum is not considered as a traditional name used in France.
Apisinum	AESGP ECHAMP	<u>Column 1</u> Apisinum/ Apium virus <u>Comment/Rationale</u> We recommend that the first traditional French Latin name.	Agree.

Apocynum cannabinum / Apocynum	AESGP ECHAMP	<u>Column 3</u> Fresh underground parts of Apocynum cannabinum L. / Dried underground parts of Apocynum cannabinum L.	Not agree. Only fresh underground parts are described in the homeopathic section of an official Pharmacopoeia.
Apomorphinum hydrochloricum/ Apomorphinum muriaticum	ECH	<u>Column 1</u> Apomorphinum hydrochloricum/ Apomorphinum muriaticum/ Apomorphini hydrochloridum (hemihydricum) <u>Comment/Rationale</u> Latin Ph.Eur name	Not agree See the first outcome in the section “general comment”. Apomorphini hydrochloridum (hemihydricum) is not considered as a traditional name used in France.
Arisaema triphyllum, Arum triphyllum / Arum triphyllum	BPI e.V. ECHAMP	<u>Comment/Rationale</u> GHP has listed the fresh underground parts, which are also mentioned in the drug picture. The dried underground parts are only listed in the FP.	Not agree According to the preamble to the consolidated list of justified homeopathic stock, in the case where it is not possible to know if concerned literature is related to the fresh or the dried part of a plant and both states are already being used in clinical practice without evidence to conclude a significant difference, it was decided that both states can be considered as similar forms.
Artemisia cina, Cina / Cina	ECHAMP	<u>Column 3</u> / Dried, non blooming capitulum of Artemisia cina O. Berg <u>Comment/Rationale</u> The French monograph is officially translated into English and published on the ANSM website. Please note that the direct translation of the raw material is: Dried, non blooming capitulum of <i>Artemisia cina</i> Berg.	Agree
Atropinum sulfuricum	ECH	<u>Column 1</u> Atropinum sulfuricum, Atropini sulfas <u>Comment/Rationale</u> Latin Ph.Eur name	Not agree See the first outcome in the section “general comment”. Atropini sulfas is not considered as a traditional name used in France.

Baptisia tinctoria	BPI e.V. ECH ECHAMP	<u>Column 1</u> Baptisia tinctoria / Baptisia <u>Comment/Rationale</u> The raw material Baptisia tinctoria (acc. to FP) is also the raw material for the homeopathic substance Baptisia in the German homeopathic tradition. The preparation of the mother tincture is not specified in the current GHP (HAB 1), but in the GHP 34. We ask to amend “Baptisia” as synonym, because this term is used in the in the Kommission D Monograph and in the GHP 1934 Monograph (please find both literature references attached).	Not agree. On basis of literature provided homeopathic use of the stock described in the Monograph of Commission D is justified. Taking into account that the raw material used in German tradition to manufacture the mother tincture is different (fresh underground parts instead of dried underground organ), it was decided to postpone the assessment of this stock to the following sub-wg meeting.
Calcium sulfuricum	ECHAMP	Ph. Eur. N° 0892 (GHP/FP) Calcium sulfate dihydrate $\text{CaSO}_4 \cdot 2 \text{H}_2\text{O}$	Not agree. Calcium sulfuricum is in the second list (see the consolidated list and the Ph. Eur. monograph number is 0982.
Carbolicum acidum	ECH, ECHAMP	<u>Column 1</u> Carbolicum acidum / Phenolum <u>Comment/Rationale</u> We recommend to include the first traditional Latin name as in the French Pharmacopoeia (FP) monograph.	Agree (GHP). Used names in German tradition are accepted on basis of received literature. <u>Column 1:</u> Carbolicum acidum / Acidum carbolicum, Phenolum Not agree (FP) See the first outcome in the section “general comment”. Phenolum is not considered as a traditional name used in France.

Caulophyllum thalictroides, Caulophyllum / Caulophyllum thalictroides	BPI e.V. ECHAMP	<u>Comment/Rationale</u> GHP has listed the fresh underground parts, which are also mentioned in the drug picture. The dried underground parts are only listed in the FP.	Not agree According to the preamble to the consolidated list of justified homeopathic stock, in the case where it is not possible to know if concerned literature is related to the fresh or the dried part of a plant and both states are already being used in clinical practice without evidence to conclude a significant difference, it was decided that both states can be considered as similar forms.
Chondrodendron, Pareira brava / Pareira brava	BPI e.V. ECH ECHAMP	<u>Column 1</u> Please change name of the stock: Chondrodendron <u>Comment/Rationale</u> Typing error	Agree
Collinsonia canadensis / Collinsonia canadensis	BPI e.V. ECHAMP	<u>Comment/Rationale</u> GHP has listed the fresh underground parts, which are also mentioned in the drug picture. The dried underground parts are only listed in the FP.	Not agree According to the preamble to the consolidated list of justified homeopathic stock, in the case where it is not possible to know if concerned literature is related to the fresh or the dried part of a plant and both states are already being used in clinical practice without evidence to conclude a significant difference, it was decided that both states can be considered as similar forms.

Conyza canadensis, Erigeron canadensis / Erigeron canadensis, Erigeron	BPI e.V. ECH ECHAMP	<u>Columns 1 and 3</u> Conyza canadensis (in name of the stock) GHP: Fresh aerial parts of Conyza canadensis (L.) Cronquist, collected at flowering time. (in definition of the raw material) FP: Fresh, blooming aerial part of Conyza canadensis (L.) Cronq. (Erigeron canadensis L.). <u>Comment/Rationale</u> Spelling in the GHP Conyza, not Coniza. This is the correct botanical name	Agree
Corallium rubrum	AESGP BPI e.V. ECH ECHAMP	<u>Column 3</u> Fragments of the calcareous skeletons of Corallium rubrum L. <u>Comment/Rationale</u> Typing error: Corallium -> Corallium.	Agree
Crocus, Crocus sativus	AESGP BPI e.V. ECHAMP ECH	<u>Column 2</u> Ph. Eur. 1624 (GHP) <u>Comment/Rationale</u> The number of the Ph. Eur. monograph 2092 (GHP) is not correct. We recommend to amend to the following: Ph. Eur. 1624 (GHP).	Agree
Crocus, Crocus sativus	ECH	<u>Column 1</u> Crocus stigma ad praeparationes homoeopathicas (Ph. Eur Name) <u>Comment/Rationale</u> Ph.Eur name	Not agree See the first outcome in the section “general comment”. Crocus stigma is not considered as a traditional name used in France.

Dioscorea villosa / Dioscorea villosa	BPI e.V. ECHAMP	<u>Comment/Rationale</u> GHP has listed the fresh underground parts, which are also mentioned in the drug picture. The dried underground parts are only listed in the FP.	Not agree According to the preamble to the consolidated list of justified homeopathic stock, in the case where it is not possible to know if concerned literature is related to the fresh or the dried part of a plant and both states are already being used in clinical practice without evidence to conclude a significant difference, it was decided that both states can be considered as similar forms.
Euphorbium	AESGP ECHAMP	<u>Column 1</u> Euphorbium / <i>Euphorbia resinifera</i> <u>Comment/Rationale</u> We recommend to include the first traditional French Latin name.	Agree.
Euphrasia, Euphrasia officinalis / Euphrasia officinalis	AESGP BPI e.V. ECHAMP	<u>Column 1</u> Euphrasia, Euphrasia officinalis / Euphrasia officinalis / <i>Euphrasia ferm 33c</i> <u>Column 2</u> (ECH) GHP/FP/ <i>GHP</i> <u>Column 3</u> / Whole fresh plants of Euphrasia stricta D. Wolff ex J.F. Lehm. and Euphrasia officinalis L. subsp. rostkoviana (Hayne) F. Towns., their hybrids and mixtures thereof, collected at flowering time <u>Comment/Rationale</u> We ask to amend “Euphrasia ferm 33c” as synonym or include on a separate row, because this term/monograph is also used in the GHP (see reference).	33c: Not agree Currently, we do not have any literature to support homeopathic use of this kind of preparation.

Euphrasia, Euphrasia officinalis/ Euphrasia	ECH	<u>Column 1</u> Euphrasia, Euphrasia officinalis/ Euphrasia , Euphrasia stricta, Euphrasia rostkoviana <u>Comment/Rationale</u> Euphrasia stricta and Euphrasia rostkoviana ad praeparationes homoeopathicas (FP name)	Not agree See the first outcome in the section “general comment”. „Euphrasia stricta, Euphrasia rostkoviana“ is not considered as a traditional name used in France.
Ferrum sesquichloratum solutum, Ferrum sesquichloratum /Ferrum muriaticum	AESGP ECHAMP	<u>Column 1</u> (Other name: Ferrum muriaticum) <u>Comment/Rationale</u> Ferrum muriaticum is a homeopathic name traditionally used in France but this name does not come from the FP (i.e there is no monograph). We therefore recommend to leave this name as (other name: Ferrum muriaticum)	Not agree. See similar presentation: Euphorbium, Natrium nitricum, Aurum chloratum
Ferrum sulfuricum	AESGP BPI e.V ECH ECHAMP	<u>To be added in column 2</u> Ph. Eur. 2340 (GHP) <u>Comment/Rationale</u> In the GHP reference is made to the Ph. Eur. monograph for Ferrous Sulfate, dried. We suggest mentioning both, the Ph. Eur. and GHP, analogous to the rest of the list.	Agree
Ferrum sulfuricum	ECH	<u>Column 1</u> Ferrum sulfuricum, Ferrosi sulfas desiccatus <u>Comment/Rationale</u> Latin Ph.Eur name	Not agree See the first outcome in the section “general comment”. Ferrosi sulfas desiccatus is not considered as a traditional name used in France.

Filipendula ulmaria, Spirea ulmaria	AESGP	<u>Column 1</u> Filipendula ulmaria, Spiraea ulmaria / Filipendula ulmaria ferm 34c <u>Comment/Rationale</u> We recommend adding "Filipendula ulmaria ferm 34c" as a synonym because this term/monograph is also used in the GHP (see reference). Typing error: Spirea should read Spiraea.	34c: Not agree Currently, we do not have any literature to support homeopathic use of this kind of preparation. Spiraea: agree
Filipendula ulmaria, Spirea ulmaria	BPI e.V. ECHAMP	<u>Column 1</u> Filipendula ulmaria, Spirea ulmaria / Filipendula ulmaria ferm 34c <u>Column 2</u> GHP/GHP <u>Column 3</u> Fresh aerial parts of Filipendula ulmaria (L.) Maxim., collected at flowering time.	34c: Not agree Currently, we do not have any literature to support homeopathic use of this kind of preparation.
Spiraea ulmaria (FP)	ECH	<u>Column 1</u> (FP): Spiraea ulmaria, Filipendula ulmaria <u>Comment/Rationale</u> Little typo, the correct name in FP is Spiraea ulmaria Filipendula ulmaria ad praeparationes homoeopathicas (FP name)	Spiraea: agree Filipendula ulmaria: not agree See the first outcome in the section "general comment". Filipendula ulmaria is not considered as a traditional name used in France.
Spirea ulmaria	AESGP ECHAMP	<u>Column 3</u> / Fresh blooming flower heads of Filipendula ulmaria (L.) Maxim. (= Spiraea ulmaria L.) <u>Comment/Rationale</u> The French monograph is officially translated into English and published on the ANSM website. The translation of the raw material is: Fresh, blooming flower heads.	Agree

Fucus vesiculosus / Fucus vesiculosus, Fucus	BPI e.V. ECHAMP	<u>Comment/Rationale</u> GHP has listed the dried thallus, which is also mentioned in the drug picture. The fresh thallus is only listed in the FP.	Not agree According to the preamble to the consolidated list of justified homeopathic stock, in the case where it is not possible to know if concerned literature is related to the fresh or the dried part of a plant and both states are already being used in clinical practice without evidence to conclude a significant difference, it was decided that both states can be considered as similar forms.
Gentiana lutea / Gentiana lutea	AESGP ECHAMP	<u>Column 1</u> Gentiana lutea, ethanol. Decoctum <u>Comment/Rationale</u> We recommend to add in the name's column "Gentiana lutea, ethanol. Decoctum." Indeed there is another stock monograph in the GHP with the exactly same raw material. The method of preparation is homeopathic acc. to Ph.Eur. (2371 method 1.2.11). In the homeopathic literature, the method of preparation is less significant (even not known) compared to the raw material definition.	Ethanol decoctum: not agree Currently, we do not have any literature to support homeopathic use of this kind of preparation.
	AESGP ECHAMP	<u>Column 3</u> Fresh underground parts of Gentiana lutea L. / Fresh underground parts of Gentiana lutea L.; harvested in spring <u>Comment/Rationale</u> To be added at the end as included in FP definition	Agree. ⇒ Harvested in spring
	ECH	<u>Column 3</u> collected at springtime	
Geranium robertianum	AESGP ECHAMP	<u>Column 3</u> Fresh aerial parts of Geranium robertianum L. Collected at flowering time / Whole fresh flowering plants of Geranium robertianum L.	Not agree. Literature only refers to the fresh aerial parts.

Ginkgo biloba / Ginkgo biloba	AESGP BPI e.V. ECH ECHAMP	<u>Column 1</u> Ginkgo biloba, Ginkgo / Ginkgo biloba <u>Comment/Rationale</u> Please add “Ginkgo” as synonym, according to the GHP monograph.	Agree
Hedera helix	AESGP BPI e.V. ECH ECHAMP	<u>Column 2</u> Ph. Eur. 2092 (GHP) <u>Comment/Rationale</u> The number of the Ph. Eur. monograph 2030 (GHP) is not correct. We recommend to amend to the following: Ph. Eur. 2092 (GHP).	Agree
Hydrargyrum chloratum, Mercurius dulcis / Mercurius dulcis, Hydrargyri subchloridum	AESGP BPI e.V. ECH ECHAMP	<u>Column 2</u> GHP / FP <u>Comment/Rationale</u> Please add the missing reference to the relevant monographs.	Agree
Hydrargyrum chloratum, Mercurius dulcis / Mercurius dulcis, <i>Hydrargyri subchloridum</i>	ECH	<u>To be added as synonym (FP):</u> Mercurius dulcis, Hydrargyri subchloridum, Hydrargyri chloridum <u>Comment/Rationale</u> Hydrargyri chloridum ad praeparationes homoeopathicas (FP name)	Not agree See the first outcome in the section “general comment”. Hydrargyri chloridum is not considered as a traditional name used in France.
Lycopus europaeus / Lycopus europaeus	AESGP ECHAMP ECH	<u>Column 1</u> Lycopus europaeus/ Lycopus <u>Comment/Rationale</u> The name in FP is only Lycopus	Not agree. Given that different literature can justify the homeopathic use of Lycopus virginicus and Lycopus europaeus, it was decided to have two entries: one for Lycopus virginicus and one for Lycopus europaeus. The name “Lycopus” is not considered as sufficient because it corresponds on two different stocks.
Lycopus virginicus / Lycopus virginicus	AESGP ECHAMP ECH	<u>Column 1</u> Lycopus virginicus / Lycopus <u>Comment/Rationale</u> The name in FP is only Lycopus	

Lycopus europaeus or virginicus / Lycopus	AESGP ECHAMP	<u>Comment/ Rationale</u> The FP name is only "Lycopus" in both cases. Indeed the FP permits both species. We recommend to correct to be in accordance with the FP name.	
Berberis aquifolium, Mahonia aquifolium	AESGP BPI e.V. ECHAMP	<u>column 2</u> GHP <u>column 3</u> Dried bark from branches and twigs and dried tips of twigs of Mahonia aquifolium (Pursh) Nutt. <u>Comment/Rationale</u> The substance is not only considered in the FP, a monograph also exists in the GHP. According to the German tradition, the bark of the aerial parts is used, as is already written in GHP 34. We also ask for the addition of the material Berberis aquifolium according to GHP. To prove the use in homeopathy, literature is attached (= commission D document). <u>Other comments (AESGP, ECHAMP)</u> There is also a monograph for Mahonia aquifolium at the GHP that concerns the bark of <i>Mahonia aquifolium</i> Nutt. (but not from the root). We would like to make sure that it is not an omission.	Agree on basis of received literature. Part of the plant described in the FP differs from the part of the plant mentioned in the GHP ⇒ two entries for the stock (see the strategy in the preamble to the consolidated list). <u>Column 1:</u> Mahonia aquifolium, Berberis aquifolium <u>column 2</u> GHP <u>column 3</u> Dried bark from branches and twigs and dried tips of twigs of Mahonia aquifolium (Pursh) Nutt.
Melilotus officinalis / Melilotus officinalis, Melilotus	AESGP BPI e.V. ECH ECHAMP	<u>Column 3</u> Fresh aerial parts of Melil og tus officinalis (L.) Lam., without woody stems, collected at flowering time / Fresh aerial flowering part of Melilotus officinalis (L.) Lam. <u>Comment/Rationale</u> Typing error: Melilogus -> Melilotus.	Agree

Menyanthes trifoliata	AESGP BPI e.V. ECH ECHAMP	<u>Column 1</u> Menyanthes trifoliata / Menyanthes <u>Comment/Rationale</u> The raw material Menyanthes trifoliata (acc. to FP) is also the raw material for the homeopathic substance Menyanthes in the German homeopathic tradition. The preparation of the mother tincture is not specified in the current GHP (HAB 1), but in the GHP 34. We ask to amend “Menyanthes” as synonym, because this term is used in the Kommission D Monograph and in the GHP 1934 Monograph (both literature references are attached B(PI e.V. + ECHAMP)).	Agree. Used names in German tradition are accepted on basis of received literature. <u>Column 1:</u> Menyanthes trifoliata / Menyanthes trifoliata, Menyantes
Moschus	AESGP BPI e.V. ECH ECHAMP	<u>Column 1</u> Moschus / Moschus moschiferus <u>Comment/Rationale</u> The raw material Moschus (acc. to FP) is also the raw material for the homeopathic substance Moschus / Moschus moschiferus in the German homeopathic tradition. The preparation of the mother tincture is not specified in the current GHP (HAB 1), but in the GHP 34. We ask to amend “Moschus moschifera” as synonym, because this term is used in the Kommission D Monograph and in the GHP 1934 Monograph (both literature references are attached B(PI e.V. + ECHAMP)).	Agree. Used names in German tradition are accepted on basis of received literature. <u>Column 1:</u> Moschus / Moschus moschiferus, Moschus
Nasturtium officinale	AESGP BPI e.V. ECH ECHAMP	<u>column 1</u> Nasturtium officinale, Nasturtium aquaticum <u>Comment/Rationale</u> We recommend to add “Nasturtium aquaticum” as a synonym, in accordance with the GHP monograph	Agree

Natrium chloratum/ Natrium muriaticum	ECH	<u>Column 1</u> <u>To be added</u> as synonym (Ph.Eur) Natrii chloridum	Not agree See the first outcome in the section “general comment”. Natrii chloridum is not considered as a traditional name used in France.
Natrium chloratum / Natrum muriaticum	AESGP BPI e.V. ECH ECHAMP	<u>Column 2</u> Ph. Eur. 0 193 <u>Comment/Rationale</u> The Ph.Eur number is written with 4 digits, as "0193": “0” is missing in number of the monograph	Agree

Natrium chloratum / Natrum muriaticum	AESGP	<p><u>Column 1</u></p> <p>Natrum muriaticum naturale</p> <p><u>Column 2</u></p> <p>FP</p> <p>Ph. Eur. 0193 (GHP/FP)</p> <p><u>Column 3</u></p> <p>Unrefined sea salt, from Atlantic</p> <p><u>Comment/Rationale</u></p> <ul style="list-style-type: none"> In neither the GHP nor the Ph. Eur. monograph sea salt is specified for the stock, this requirement can only be found in the FP. Therefore, we ask to assign it to the FP. Both naturally occurring form and synthetic chemical form of NaCl are allowed. Therefore, we recommend to add in the names "Natrum muriaticum naturale" and the correct definition acc. to FP ("Unrefined sea salt, from Atlantic") in the column "Definition of the raw material" The cited French definition is an old one and was superseded by revision. <p>Natrum muriaticum PPH / Sodium (chlorure de) PPH (2010) (06/01/2016):</p> <p>“Le chlorure de sodium pour préparations homéopathiques satisfait aux exigences de la monographie Sodium (chlorure de) (0193).“</p> <p>Therefore we ask for the deletion and assignment of NaCl to the Ph. Eur. only.</p>	<p>Deletion of (GHP/FP): not agree</p> <p>Natrum muriaticum naturale: a new entry is added.</p> <p>During the discussion in the subgroup (20/09/2016), it was decided to add the definition “The stock corresponds to the sea salt that complies with the requirements of the sodium chloride” for the stock Natrum muriaticum because all literature on the stock “Natrum muriaticum” is related to the sea salt.</p> <p>However given that there is also literature justifying the use of the chemical (see Commission D monograph), it is decided to have two list entries: one for Natrum chloratum and one for Natrum muriaticum (= sea salt).</p>
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Natrium chloratum / Natrum muriaticum	BPI e.V.	<u>Column 3</u> <p>FP: The stock corresponds to the sea salt that complies with the requirements of the sodium chloride.</p> <p><u>Comment/Rationale</u> In neither the GHP nor the Ph. Eur. monograph sea salt is specified for the stock, this requirement can only be found in the FP. Therefore we ask to assign it to the FP.</p>	See above
Natrium chloratum / Natrum muriaticum	ECHAMP	<u>Column 3</u> <p>The stock corresponds to the sea salt that complies with the requirements of the sodium chloride</p> <p><u>Comment/Rationale</u> In neither the GHP, the FP nor the Ph. Eur. monograph sea salt is specified for the stock, therefore we ask to delete this definition.</p>	
Pilocarpus, Jaborandi/ Jaborandi	ECH	<u>Column 1</u> <p>Pilocarpus, Jaborandi/ Jaborandi, <u>Pilocarpus</u></p> <p><u>Comment/Rationale</u> Pilocarpus ad praeparationas homoeopaticas (synonym in FP)</p>	<p>Not agree</p> <p>See the first outcome in the section “general comment”.</p> <p>Pilocarpus is not considered as a traditional name used in France.</p>
<u>Stock to be added</u> Pini aetheroleum	BPI e.V. ECHAMP	Pini aetheroleum DAB <p>Fresh pins, tips of twigs or fresh branches with pins and tips of twigs of Pinus silvestris L. or other pine species</p>	<p>Not agree.</p> <p>There is no monograph of the Commission D to confirm the homeopathic use.</p> <p>The substance is not listed in the GHP either.</p> <p>⇒ the substance is no homeopathic stock.</p>

Podophyllum peltatum, Podophyllum / Podophyllum peltatum, <i>Podophyllum</i>	BPI e.V. ECHAMP	GHP has listed the fresh underground parts, which are also mentioned in most of the drug pictures (some only mention the fresh rhizome). The dried rhizome is only listed in the FP.	Not agree According to the preamble to the consolidated list of justified homeopathic stock, in the case where it is not possible to know if concerned literature is related to the fresh or the dried part of a plant and both states are already being used in clinical practice without evidence to conclude a significant difference, it was decided that both states can be considered as similar forms.
Rhododendron	AESGP ECHAMP	<u>Column 1</u> Rhododendron / <i>Rhododendron chrysanthum</i> <u>Column 2</u> GHP / <i>French tradition</i> <u>Column 3</u> Dried leafy twigs of <i>Rhododendron campylocarpum</i> Hook. f. or <i>Rhododendron aureum</i> Georgi, their hybrids, or mixture thereof (change: update GHP 2014)/ Fresh leafy branches with flower buds of <i>Rhododendron aureum</i> Georgi or <i>Rhododendron campylocarpum</i> Hook. f. <u>Comment/Rationale</u> There should be no reference to pharmacopoeia version.	Not agree. On basis of available literature homeopathic use of the stock used in French tradition is justified. Taking into account that the raw material used in French tradition to manufacture the mother tincture is different (fresh leaves of <i>Rhododendron chrysanthum</i> instead of dried leafy twigs), it was decided to postpone the assessment of this stock to the following sub-wg meeting.
<u>Stock to be added</u> <i>Rhododendron ferrugineum</i>	AESGP ECH	<i>Rhododendron ferrugineum</i> FP Fresh young leafy branches of <i>Rhododendron ferrugineum</i> L. <u>Comment/Rationale</u> (ECH) The raw material <i>Rhododendron ferrugineum</i> (acc. to FP) is also the raw material for the homeopathic substance <i>Rhododendron ferrugineum</i> in the German homeopathic tradition. The preparation of the mother tincture is not specified in the current GHP (HAB 1), but in the GHP 34 and there is also a Kommission D monograph for <i>Rhododendron ferrugineum</i> .	Addition of the stock described in the FP: agree on basis of provided literature. Addition of the stock described in the Kommission D monograph: taking into account that the raw material used in German tradition to manufacture the mother tincture is different (dried branches with leaves instead of fresh young leafy branches), it was decided to postpone the assessment of this stock to the following sub-wg meeting.

Salvia officinalis (FP)	AESGP	<u>Column 3</u> Fresh flowering aerial part of Salvia officinalis L. <u>Comment/Rationale</u> Written as "flowering aerial" in the official English translation of the monograph COMMON SAGE FHP on ANSM website.	Agree
<u>Stock to be added</u> Salviae aetheroleum	BPI e.V. ECHAMP	Salviae aetheroleum DAC/Ph. Helv. Aerial parts of Salvia officinalis L.	Not agree. There is no monograph of the Commission D to confirm the homeopathic Use. The substance is not listed in the GHP either. Currently, we do not have any literature to support homeopathic use of this kind of preparation.
Scrophularia nodosa FP	ECH	<u>Column 1</u> Scrofulosa nodosa and Scrophularia nodosa <u>Column 3</u> "flowering part of" into "flowering plant " <u>Comment/Rationale</u> Scrofulosa nodosa and Scrophularia nodosa are synonyms in FP Typing error. Correct: Whole, fresh, flowering plant , Scrophularia nodosa L.	Not agree See the first outcome in the section "general comment". "Scrofulosa nodosa and Scrophularia nodosa" is not considered as a traditional name used in France. Scrofularia nodosa is the only traditional name used in France ⇒ typing error is corrected
Serenoa repens, Sabal serrulatum / Sabal serrulata	AESGP	<u>Column 3</u> Fresh ripe fruits of Serenoa repens (W. Bartram) Small . / Dried ripe fruit of Serenoa repens (W. Bartram) Small (syn. Sabal serrulata (Michaux) T. Nuttall ex Schultes & Schultes) <u>Comment/Rationale</u> Typing error (see GHP)	Agree

Serenoa repens, Sabal serrulatum / Sabal serrulata	BPI e.V. ECHAMP	<u>Comment/Rationale</u> GHP has listed the fresh ripe fruit, which is also mentioned in the drug picture. The dried ripe fruit is only listed in the FP.	Not agree According to the preamble to the consolidated list of justified homeopathic stock, in the case where it is not possible to know if concerned literature is related to the fresh or the dried part of a plant and both states are already being used in clinical practice without evidence to conclude a significant difference, it was decided that both states can be considered as similar forms.
Serenoa repens, Sabal serrulatum/ Sabal serrulata	ECH	<u>Column 1</u> Serenoa repens, Sabal serrulatum/ Sabal serrulata, Sabal, Serenoa repens <u>Comment/Rationale</u> Sabal pour preparations homeopathiques and Serenoa repens ad praeparationes homoeopathicas are synonyms in FP	Sabal: agree Serenoa repens: not agree See the first outcome in the section “general comment”. Serenoa repens is not considered as a traditional name used in France.
Silicea	ECHAMP	Definition of the raw material according to 2nd list: Ph. Eur. 0434 (FP) Silica, colloidal anhydrous SiO ₂ (ignited substance) It should be added the following definition of the raw material: HAB / DAB: [German Homeopathic Pharmacopoeia and German Pharmacopoeia: Gefälltes Siliciumdioxid (precipitated silica SiO ₂)]	Agree See following change in the updated consolidated list: Acidum silicicum / Silicea DAB (GHP) / Ph. Eur. 0434 (FP) Precipitated silica SiO ₂ / Silica, colloidal anhydrous SiO ₂ (ignited substance)

Silicea (Acidum silicicum, precipitate)	AESGP	<u>Substance to be added to the fifth list</u> Definition of the raw material according to 2nd list: Ph. Eur. 0434 (FP) Silica, colloidal anhydrous SiO ₂ (ignited substance) The following definition of the raw material should be added: GHP / DAB: [German Homeopathic Pharmacopoeia and German Pharmacopoeia: Acidum silicicum, precipitate ("Gefälltes Siliciumdioxid")] <u>Comment/Rationale</u> To prove the use in homeopathy, literature of Commission D is attached (see annex II).	See above
Silybum marianum, Carduus marianus/ Carduus marianus, Silybum marianum	ECH	<u>Column 1</u> To be added as synonym (Ph.Eur) Silybi mariani fructus	Not agree See the first outcome in the section "general comment". Silybi mariani fructus is not considered as a traditional name used in France.
Silybum marianum, Carduus marianus / Carduus marianus, Silybum marianum	AESGP ECHAMP	<u>Column 3</u> Mature fruit, devoid of the pappus, of Silybum marianum L. Gaertn. et <u>Comment/Rationale</u> To be compliant with the monograph this should read: "Gaertn."	Agree
Smilax, Sarsaparilla / Sarsaparilla, Smilax medica	AESGP ECHAMP	<u>Column 3</u> Dried underground parts of Smilax regelii Killip. et C. V. Morton, Smilax medica Schlechtend. et Cham. or other related species / Dried underground parts of Smilax aristolochiifolia Mill. (S. medica Schltdl et Cham.) and related species <u>Comment/Rationale</u> To be compliant with monograph it should read: "Killip" not Kill. and "Schltdl." not Schlechtend.	Agree

Solanum dulcamara, Dulcamara/ Dulcamara	ECH	<u>Column 1</u> Solanum dulcamara, Dulcamara/ Dulcamara, Solanum dulcamara <u>Comment/Rationale</u> Solanum dulcamara ad_preparationes homeopathicas (Synonym in FP)	Not agree See the first outcome in the section “general comment”. Solanum dulcamara is not considered as a traditional name used in France.
Solanum dulcamara, Dulcamara / Dulcamara	AESGP ECHAMP	<u>Column 3</u> Fresh shoots of Solanum dulcamara L., collected prior the flowering / Fresh young blooming leafy-stem with leaves of Solanum dulcamara L. <u>Comment/Rationale</u> The French monograph is officially translated into English and published on the ANSM website. The translation of the raw material is: Fresh, young, blooming leafy-stem	Agree
Solanum dulcamara, Dulcamara/ Dulcamara	ECH	<u>Column 3</u> Flowering stems <u>Comment/Rationale</u> Typing error	Agree (see above)
Solidago virgaurea/ Solidago virga aurea, Solidago	ECH	<u>Column 1</u> Solidago virgaurea/ Solidago virga aurea, Solidago, Solidago virgaurea <u>Comment/Rationale</u> Solidago virgaurea ad_praeparationes homoeopathicas (Synonym in FP)	Not agree See the first outcome in the section “general comment”. Solidago virgaurea is not considered as a traditional name used in France.
Teucrium scorodonia / Teucrium scorodonia	AESGP ECHAMP	<u>Column 3</u> Fresh aerial parts of flowering plants of Teucrium scorodonia L. / Fresh flowering aerial parts of Teucrium scorodonia L. <u>Comment/Rationale</u> "Part" is singular in the FP.	Agree

Urtica dioica	AESGP BPI e.V. ECH	<u>Column 2</u> Ph. Eur. 2030 (GHP) <u>Comment/Rationale</u> The number of the Ph. Eur. monograph 1626 (GHP) is not correct. We recommend modifying to the following: Ph. Eur. 2030 (GHP).	Agree
Urtica urens/ Urtica urens	AESGP BPI e.V. ECH	<u>Column 1</u> Urtica urens, Urtica / Urtica urens, <u>Comment/Rationale</u> Please add "Urtica" as synonym, according to the GHP monograph."	Agree
Ustilago maydis/ Ustilago maidis	ECH	<u>To be changed:</u> Ustilago maydis in Ustilago maidis (FP): Ustilago maydis/ Ustilago maidis <u>Comment/Rationale</u> Typing error	Agree
Valeriana officinalis, Valeriana/ Valeriana officinalis	AESGP ECHAMP	<u>Column 2</u> GHP / FP <u>Column 3</u> Dried, whole or fragmented underground parts of Valeriana officinalis L. s.l., including the rhizome surrounded by the roots and stolons. / Fresh underground parts of Valeriana officinalis L.	Not agree. <u>Rationale during the discussion in the subgroup (20/09/2016):</u> Concerning the stock "Valeriana officinalis recens" described in the FP, the literature is insufficient. Therefore the assessment of the stock described in the FP is postponed to the next sub-wg meeting.
Veronica officinalis, Veronica	AESGP ECHAMP	<u>Column 2</u> GHP / French tradition <u>Column 3</u> Fresh aerial parts of Veronica officinalis L. Collected at flowering time / Whole fresh flowering plants of Veronica officinalis L	Not agree. Up to now only stocks described in an official Pharmacopoeia are mentioned in the lists. The assessment of this stock used in French tradition is postponed to the next sub-wg meeting.

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Annex I

- Baptisia, German Homeopathic Pharmacopoeia (Homöopathisches Arzneibuch) 1934
- Baptisia tinctoria (Baptisia), Commission D, 1987
- Berberis aquifolium, German Homeopathic Pharmacopoeia (Homöopathisches Arzneibuch) 1934
- Berberis aquifolium, Leasers Lehrbuch der Homöopathie, Band III: Pflanzliche Arzneistoffe 1, 1973
- Mahonia aquifolium (Berberis aquifolium), Commission D, 1987
- Euphrasia ferm 33c, German Homeopathic Pharmacopoeia (Homöopathisches Arzneibuch)
- Filipendula ulmaria ferm 34c, German Homeopathic Pharmacopoeia (Homöopathisches Arzneibuch)
- Menyanthes, German Homeopathic Pharmacopoeia (Homöopathisches Arzneibuch) 1934
- Menyanthes trifoliata (Menyanthes), Commission D, 1987
- Moschus, German Homeopathic Pharmacopoeia (Homöopathisches Arzneibuch) 1934
- Moschus (Moschus moschiferus), Commission D, 1987

Annex II

For the substances “Acidum silicicum precipitate”, “Calcium sulfuricum” and “Natrium chloratum” homeopathic use is verified by the pharmacopoeia listed above and by the following bibliographic references:

Name of the stock	Bibliographic references			
	Monographs of Kommission D, “Description of the homeopathic remedy” [1]	Homoeopathic materia medica [2]	A dictionary of practical materia medica [3]	The encyclopedia of pure materia medica [4]
Acidum silicicum precipitate	x	x	x	x
Calcium sulfuricum	x	x	x	x
Natrium chloratum	x	x	x	x

Literature

- [1] Germany, BfArM, German Federal Gazette – 10. October 1985, BAnz 190a (documents as attachment)
- [2] William Boericke and Oscar E. Boericke, 1927, Homeopathic Materia Medica, ISBN 0766183882, <http://www.homeoint.org/books/boericmm/index.htm>
- [3] John Henry Clarke ,M.D.A Dictionary of Practical Materia Medica,third Edition 1991, Homoeopathic Book Service, Sittingbourne
<http://www.homeoint.org/clarke/index.htm>
- [4] Timothy F. Allen, A.M., M.D., Encyclopedia of pure materia medica, 11 Bände, Boericke and Tafel, New York, 1874-1879 <http://homeoint.org/allen/index.htm>

BPI e.V.

Cited (and sometimes attached) documents

- Aletris farinosa, Kommission D, 1995
- Aletris farinosa, Stauffer, Klinische Homöopathische Arzneimittellehre, 1998
- Arum triphyllum, Kommission D, 1995
- Arum triphyllum, Stauffer, Klinische Homöopathische Arzneimittellehre, 1998
- Baptisia Homöopathisches Arzneibuch 1934
- Baptisia tinctoria (Baptisia), Kommission D, 1987
- Berberis aquifolium, Homöopathisches Arzneibuch 1934
- Berberis aquifolium, Leesers Lehrbuch der Homöopathie, Band III: Pflanzliche Arzneistoffe 1, 1973
- Mahonia aquifolium (Berberis aquifolium), Kommission D, 1987
- Caulophyllum, Kommission D, 1990
- Caulophyllum, Stauffer, Klinische Homöopathische Arzneimittellehre, 1998
- Collinsonia canadensis, Kommission D, 1990
- Collinsonia canadensis, Stauffer, Klinische Homöopathische Arzneimittellehre, 1998
- Dioscera villosa, Kommission D, 1990
- Dioscera villosa, Stauffer, Klinische Homöopathische Arzneimittellehre, 1998
- Euphrasia ferm 33c, GHP, 8th Supplement 2011
- Filipendula ulmaria ferm 34c, GHP, 11th Supplement 2014
- Fucus vesiculosus, Kommission D, 1990
- Fucus vesiculosus, Stauffer, Klinische Homöopathische Arzneimittellehre, 1998
- Menyanthes Homöopathisches Arzneibuch 1934
- Menyanthes trifoliata (Menyanthes), Kommission D, 1987
- Moschus Homöopathisches Arzneibuch 1934
- Moschus (Moschus moschiferus), Kommission D, 1987
- Pini aetheroleum, DAB, 2002
- Podophyllum, Stauffer, Klinische Homöopathische Arzneimittellehre, 1998
- Podophyllum, Wiesenauer, Praxis der Homöopathie
- Sabal serrulatum, Kommission D, 1990
- Sabal serrulatum, Stauffer, Klinische Homöopathische Arzneimittellehre, 1998
- Salviae aetheroleum, DAC, 2011