



Notification Number: 2017/561/F

## Technical notes pro pharmacopoeia subject to public inquiry

Date received : 29/11/2017

End of Standstill : 01/03/2018

Issue of comments by : Germany

### Message

Message 002

Communication from the Commission - TRIS/(2017) 03120

Directive (EU) 2015/1535

Translation of the message 001

Notification: 2017/0561/F

No abre el plazo - Nezahajuje odklady - Fristerne indledes ikke - Kein Fristbeginn - Viivituste perioodi ei avata - Καμμία έναρξη προθεσμίας - Does not open the delays - N'ouvre pas de délais - Non fa decorrere la mora - Neietekmē atlikšanu - Atidėjimai nepradedami - Nem nyitja meg a késések - Ma' jiftaħ il-perijodi ta' dawmien - Geen termijnbegin - Nie otwiera opóźnień - Não inicia o prazo - Neotvorí oneskorenia - Ne uvaja zamud - Määräaika ei ala tästä - Inleder ingen frist - He ce предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 201703120.EN)

#### 1. Structured Information Line

MSG 002 IND 2017 0561 F EN 29-11-2017 F NOTIF

#### 2. Member State

F

#### 3. Department Responsible

Direction générale des entreprises – SQUALPI – Bât. Sieyès -Teledoc 151 – 61, Bd Vincent Auriol - 75703

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#### 3. Originating Department

Agence nationale de sécurité du médicament et des produits de santé –

Direction de l'Évaluation / Pôle Qualité pharmaceutique sécurité virale et non clinique

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#### 4. Notification Number

2017/0561/F - C30P

#### 5. Title

Technical notes pro pharmacopoeia subject to public inquiry

#### 6. Products Concerned

Draft monograph for pharmaceutical products:

#### 7. Notification Under Another Act

-

#### 8. Main Content

The monographs listed below will be implemented in the 11th edition of the French Pharmacopoeia by Decision of the Director-General and will be published on the French National Agency for the Safety of Medicine and Health Products (ANSM) website:

- No 1268: American spikenard PPH, *Aralia racemosa* PPH (rev.)
- No 1269: Lemon balm PPH, *Melissa officinalis* PPH (rev.)
- No 1270: *Clematis vitalba* PPH, *Clematis vitalba* PPH (rev.)

#### 9. Brief Statement of Grounds

It is proposed that these monographs be revised in order to improve techniques or specifications in relation to the quality of substances authorised on the market.

#### 10. Reference Documents - Basic Texts

No basic text(s) available.

#### 11. Invocation of the Emergency Procedure

No

#### 12. Grounds for the Emergency

-

#### 13. Confidentiality

No

#### 14. Fiscal measures

No



## 15. Impact assessment

-

## 16. TBT and SPS aspects

TBT aspect

No - the draft is neither a technical regulation nor a conformity assessment procedure.

SPS aspect

No - the draft is neither a sanitary nor phytosanitary measure.

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European Commission

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