



Notification Number: 2018/10/F

## Pro Pharmacopoeia Technical Note No 1271: Aluminium in parenteral nutrition solutions

Date received : 10/01/2018

End of Standstill : 11/04/2018

Issue of comments by : Germany

### Message

Message 002

Communication from the Commission - TRIS/(2018) 00054

Directive (EU) 2015/1535

Translation of the message 001

Notification: 2018/0010/F

No abre el plazo - Nezaahajuje 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: 201800054.EN)

#### 1. Structured Information Line

MSG 002 IND 2018 0010 F EN 10-01-2018 F NOTIF

#### 2. Member State

F

#### 3. Department Responsible

Direction générale des entreprises – SQUALPI – Bât. Sieyès -Teledoc 151 – 61, Bd Vincent Auriol - 75703 PARIS Cedex 13

d9834.france@finances.gouv.fr

tél : 01 44 97 24 55

#### 3. Originating Department

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

Direction des Politiques d'Autorisation et d'Innovation

Pôle pilotage et sécurisation des métiers, des processus et pharmacopée



143-147, boulevard Anatole France – F-93285 SAINT-DENIS CEDEX  
contactspharmacopeefrançaise@ansm.sante.fr  
tél. 01 55 87 41 57 – fax. 01 55 87 35 82

**4. Notification Number**

2018/0010/F - C30P

**5. Title**

Pro Pharmacopoeia Technical Note No 1271: Aluminium in parenteral nutrition solutions

**6. Products Concerned**

Draft monograph for pharmaceutical products

**7. Notification Under Another Act**

-

**8. Main Content**

This draft will be one of the texts implemented in the 11th edition of the French Pharmacopoeia. Said texts will be published by way of a decision of the Director-General on the website of the French National Agency for the Safety of Medicines and Health Products, with reference to the procedure for the provision of information, as laid down in Directive (EU) 2015/1535.

**9. Brief Statement of Grounds**

The aim of this draft monograph submitted for public inquiry is to determine the amount of aluminium in parenteral nutrition solutions in order to limit the risk of patient exposure.

**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.

\*\*\*\*\*

European Commission

Contact point Directive (EU) 2015/1535

Fax: +32 229 98043

email: [grow-dir2015-1535-central@ec.europa.eu](mailto:grow-dir2015-1535-central@ec.europa.eu)