Notification Number: 2012/51/F

Pro Pharmacopoea technical notes subject to public enquiry No 1231: Bacteriological and fungal test on corneal grafts stored in tissue culture

Date received : 27/01/2012 End of Standstill : 30/04/2012

Issue of comments by: Italy

Message

Message 002

Communication from the Commission - SG(2012) D/5200

Directive 98/34/EC

Translation of the message 001

Notification: 2012/0051/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 késéseket - Ma' jiftaħx il-perijodi ta' dawmien - Geen termijnbegin - Nie otwiera opóźnień - Nao inicia o prazo - Neotvorí oneskorenia - Ne uvaja zamud - Мääräaika ei ala tästä - Inleder ingen frist - Не се предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 201200200.EN)

1. Structured Information Line

MSG 002 IND 2012 0051 F EN 27-01-2012 F NOTIF

2. Member State

F

3. Department Responsible

Délégué interministériel aux normes – SQUALPI – Bâtiment Le Bervil - 12, rue Villiot – 75572 PARIS Cedex 12 d9834.france@finances.gouv.fr

tél: 01 53 44 98 24

3. Originating Department

Agence française de Sécurité Sanitaire des Produits de Sante -

DLC/Unité Pharmacopée – 143-147, boulevard Anatole France – F-93285 SAINT-DENIS CEDEX pharmacopeefrançaise@afssaps.sante.fr tél. 01 55 87 41 41 – fax. 01 55 87 41 32

4. Notification Number

2012/0051/F - C30P

5. Title

Pro Pharmacopoea technical notes subject to public enquiry No 1231: Bacteriological and fungal test on corneal grafts stored in tissue culture

6. Products Concerned

Monograph

7. Notification Under Another Act

8. Main Content

French Pharmacopoeia, 10th edition. The text will be published by way of an Order in the Official Journal of the French Republic with the remark: "Having regard to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules concerning information society services, and in particular notification No ..."

9. Brief Statement of Grounds

Pro Pharmacopoea technical notes subject to public enquiry prior to publication in the Official Journal of the French Republic.

10. Reference Documents - Basic Texts

There is no reference text

11. Invocation of the Emergency Procedure

No

12. Grounds for the Emergency

13. Confidentiality

No



| 14. Fiscal measu | ures |
|------------------|------|
|------------------|------|

No

15. Impact assessment

-

16. TBT and SPS aspects

TBT aspects

No – the draft is not a technical regulation or a conformity assessment.

SPS aspects

No – the draft is not a sanitary or phytosanitary measure.

Catherine Day Secrétaire général Commission européenne

Point de contact Directive 98/34

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