Notification Number: 2004/530/F

Order laying down rules on performing biochemical analyses concerning predictive serum markers for trisomy 21

Date received : 10/12/2004

End of Standstill : 11/03/2005

Message

Message 002

Communication from the Commission - SG(2004) D/52529
Directive 98/34/EC
Translation of the message 001
Notification: 2004/0530/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 - Määräaika ei ala tästä - Inleder ingen frist.

(MSG: 200402529.EN)

1. Structured Information Line
MSG 002 IND 2004 0530 F EN 11-03-2005 10-12-2004 F NOTIF 11-03-2005

2. Member State
France

3. Department Responsible
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3. Originating Department
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Sous-Direction Qualité du système de santé
Bureau de la Qualité des pratiques
8 Avenue de Ségur - 75350 Paris 07 SP

4. Notification Number
2004/0530/F - S10S

5. Title
Order laying down rules on performing biochemical analyses concerning predictive serum markers for trisomy 21

6. Products Concerned
Reagents and software intended to assess the risk of trisomy 21.

7. Notification Under Another Act
-

8. Main Content
This text is aimed at biologists who perform biochemical analyses allowing them to assess the risk of foetal trisomy 21 in pregnant women, using markers contained in the maternal blood (maternal serum markers). It specifies the reagents and software that can be used to assess this risk; the maternal serum markers to research; the point of pregnancy (amenorrhoea) at which these examinations must be performed; the methods for interpreting the risk for the patient in carrying a foetus with trisomy 21. This text repeals the previous Order laying down conditions for the assessment of this risk, in order to implement Order No 2001-198 of 1 March 2001 transposing Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

Keywords: in vitro diagnostic medical devices, reagents, software, trisomy 21, risk assessment

9. Brief Statement of Grounds
This draft text is one of the measures transposing Directive 98/79/EC on in vitro diagnostic medical devices. Furthermore, it specifies the item on list B in Annex II to the Directive on evaluating the risk of trisomy 21, since it sets the rules for using device that allow this risk to be assessed. For the sake of transparency, it therefore seems preferable to us to also notify the text pursuant to Directive 98/34/EC. This Order enables French biologists to use CE-marked reagents and software to assess the risk of foetal trisomy 21 in pregnant women, whereas the previous text, which it repeals, only authorised the use of reagents and software registered in accordance with French legislation. The previous text also laid down specific regulations for assessing the risk of trisomy 21, which appear essential to the French authorities in order to guarantee the health safety of this screening throughout the national territory. These regulations are reproduced in the new draft text.

10. Reference Documents - Basic Texts
a) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

the Public Health Code and in particular Articles L. 6211-1, L. 6213-2, L. 5133-2 and R. 5133-1, L. 5221-1 and R. 5221-1 et seq., L. 2131-1 and R 2131-2

Order No 2001-198 of 1 March 2001 transposing Directive 98/79/EC of the European Parliament and of the

Council of 27 October 1998 on in vitro diagnostic medical devices, and in particular Articles 9 and 10 thereof

11. Invocation of the Emergency Procedure
No

12. Grounds for the Emergency
-

13. Confidentiality
a) No

14. Fiscal measures
b) No

15. Impact assessment
No

16. TBT and SPS aspects
TBT aspect (Agreement on technical barriers to trade)
a) No
iii) The draft does not have any notable impact on international trade.

SPS Aspect (Agreement on sanitary and phytosanitary measures)
a) No
i) The draft is not a sanitary or phytosanitary measure pursuant to Annex A to the SPS Agreement.

David O'Sullivan
General Secretary
European Commission

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