



Notification Number: 2010/719/F

Order laying down the conditions for carrying out quick tests for a working diagnosis of the human immunodeficiency virus infection (HIV 1 and 2).

Date received : 10/11/2010

End of Standstill : 11/11/2010

Invocation of the Emergency Procedure : Yes

Message

Message 002

Communication from the Commission - SG(2010) D/52754

Directive 98/34/EC

Translation of the message 001

Notification: 2010/0719/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 - Nao 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: 201002754.EN)

1. Structured Information Line

MSG 002 IND 2010 0719 F EN 10-11-2010 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 – fax : 01 53 44 98 88

3. Originating Department

Ministère de la Santé et des Sports



Direction générale de la Santé
Sous direction « Prévention des risques infectieux »
Bureau des infections par le VIH, les IST et hépatites

4. Notification Number

2010/0719/F - S10S

5. Title

Order laying down the conditions for carrying out quick tests for a working diagnosis of the human immunodeficiency virus infection (HIV 1 and 2).

6. Products Concerned

Screening tests for HIV 1 and 2.

7. Notification Under Another Act

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8. Main Content

This Order regulates the use of quick tests for a working diagnosis (TROD) of the HIV 1 and 2 infection by health professionals (doctors, biologists, midwives, nurses, laboratory technicians) in points of care and by associations involved in preventive structures or associative structures concerned with preventive health-care. The latter may only organise a screening service through TROD within the framework of an authorisation granted by the Regional Health Agency (ARS) by conventional means. The agreement lasts three years.

This text is completed by 4 annexes:

- Annex I describing the specifications to be respected by preventive or associative structures in order to be duly authorised by the ARS to carry out HIV TRODs and setting out the content of the authorisation application file;
- Annex II on the objectives and content of the training imposed on persons carrying out TRODs in these preventive or associative structures;
- Annex III on the recommendations on good practice for carrying out TRODs applicable in a health-care and associative setting;
- Annex IV on the quality assurance procedure to be implemented in order to carry out TRODs in a private practice, in a health establishment or service.

9. Brief Statement of Grounds

Up until the end of 2009, screening for HIV infection, in particular by a TROD, could only be carried out by biologists in medical biology laboratories. The Order of 13 January 2010 reforming medical biology removed all TRODs from the field of biology (L.6211-3 of the Public Health Code) by issuing orders as to the definition of persons authorised to carry out these tests and their conditions for carrying them out. The present Order comes within this context and must allow a TROD screening service for HIV 1 and 2 infection to be organised quickly by health professionals and by health non-professionals.

This text has been drawn up on the basis of the recommendations made in 2008 and in 2009 by the French National Authority for Health.

The purpose of this text is to enable a screening service in addition to that which currently exists to be organised in order to increase recourse to screening for certain members of the public that do not want to or cannot attend



the standard health-care facility. This screening method is aimed in particular at men having sexual relationships with other men (HSH), for which the incidence of HIV is 200 times greater than that of the general heterosexual population. It could also answer specific needs of other populations in a vulnerable situation. It must, in so doing, attract people who sometimes exclude themselves from the health-care facility, without replacing it.

Furthermore, making a quick screening service available in an alternative framework to the health-care system should also limit recourse by people to self-testing via the Internet on a non-prescription basis, tests that present no technical guarantee and which expose individuals to a high risk of wrong results.

10. Reference Documents - Basic Texts

References to the reference texts: "Public Health Recommendations on the Screening of HIV Infection in France: Ways to Carry out Screening Tests" of the French National Authority for Health, October 2008.

- "Public Health Recommendations on the Screening of HIV Infection in France: Strategies and Screening Systems" of the French National Authority for Health, October 2009.

- Order of 28 May 2010 laying down the conditions for carrying out the biological diagnosis of human immunodeficiency virus infection (HIV 1 and 2) and the conditions for carrying out a quick test for a working diagnosis in emergency situations.

The reference texts must be sent in the framework of the previous notification: 2009/0552/F.

11. Invocation of the Emergency Procedure

Yes

12. Grounds for the Emergency

The 2010-2014 National Action Plan against HIV and Sexually Transmitted Infections was officially announced on 4 November 2010.

One of the leading measures of this plan for which the Health Minister, Roselyne Bachelot, has committed to implement quickly (from November 2010), is to develop screening services in a community environment in order to respond to:

- the urgency to develop new prevention strategies for men having sexual relationships with other men (HSH) in the light of the increase in the number of new diagnoses among the HSH population between 2000 and 2007 and the results of the Prevagay Investigation carried out by the Institute for Health Surveillance (InVS) in Parisian gay establishments showing that 20% of HIV-infected persons are unaware of their serological status;
- the urgency to deploy over the whole territory and in particular in Guiana, an area with a high prevalence of HIV, a facilitated screening service by reaching out to members of the public that are isolated from the traditional health-care system.

Since 2008, several experiments using TRODs have been carried out in the community environment. The initial results are positive. Publication of this Order is indispensable to enable a quick implementation of this screening service.

13. Confidentiality

No

14. Fiscal measures

No



15. Impact assessment

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16. TBT and SPS aspects

TBT aspect

No – The draft has no significant impact on international trade.

SPS aspect

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

Catherine Day
Secrétaire général
Commission européenne

Point de contact Directive 98/34
Fax: (32-2) 296 76 60
email: dir83-189-central@ec.europa.eu

sent to :

Työ- ja elinkeinoministeriö
Ms. Leila Vilhunen

Malta standards Authority
Sarah Jane Meli

Ministry of Economy and Commerce Division for Internal Market
Catalina Groza

CU N Lovseth Hanne Leen
.

European Free Trade Association
Mr. Robert Murphy

AGENCIA ESPAÑOLA DE SEGURIDAD ALIMENTARI Comisión Interministerial para la Ordena
M^a Luisa Aguilar Zambalamberri

NSAI
Mr Tony Losty

Undersecretariat of Foreign Trade General Directorate of Standardisation



Mr Mehmet COMERT

EFTA Surveillance Authority
Mr. Gunnar Thor PETURSSON

Représentation Permanente du Royaume-Uni

.

Department for Business, Innov. & Skills
Mr Philip Plumb

State Agency for Metrological and Technical Surveillance
Violetta Veleva

SL

.

Hungarian Notification Centre Ministry of National Development and Eco
Mr Zsolt Fazekas

Représentation Permanente de l'Irlande
Denis Colfer