Notification Number: 1995/3/F

Decree relating to the reagents listed in Article L-761-14-1 of the Public Health Code.

Date received	:	05/01/1995
End of Standstill	:	Closed
Invocation of the Emergency Procedure	:	Yes

Message

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TELEX 002

COMMUNICATION FROM THE COMMISSION - SG (95) D/50080/2
DIRECTIVES 83/189/EEC AND 88/182/EEC
TRANSLATION OF TELEX 001

NOTIFICATION 95/0003/F

- 3B1 : 9500080.EN

1. Structured Information Line
TLX 002 IND- 95 0003 F-- EN ------ 950104 --- ---

2. Member State
FRANCE

3. Department Responsible
Secrétariat Général du Comité Interministériel pour les Questions de Coopération Economique Européenne.
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3. Originating Department
Ministère des Affaires Sociales, de la Santé et de la Ville.
Direction Générale de la Santé.
1, place Fontenoy - 75005 PARIS

4. Notification Number
Notification 95/0003/F

5. Title
Decree relating to the reagents listed in Article L-761-14-1 of the Public Health Code.

6. Products Concerned
Medical reagents

7. Notification Under Another Act
-

8. Main Content
The draft decree is aimed at a) replacing the procedure for submitting files currently provided for in the Decree of 8 September 1982 relating to laboratory reagents intended for medical-biological analyses by a registration procedure, and b) supplementing the provisions in force concerning the indications which the reagent registration file must contain together with those given to the user by the manufacturer (instructions, packaging). The registration system, organized by the decree, is similar to the 'EC' type examination linked to the 'EC' verification of Directive 93/42 relating to medical equipment and of the draft proposal for a directive relating to in vitro diagnostic medical equipment currently being assessed.

Furthermore, it allows the Director-General of the Medicines Agency to withdraw a reagent if it does not comply with the rules laid down by the decree or in the event that it poses a

risk to public health. Finally, it lays down the conditions for the composition and stipulates the attributions of a consultative commission for the registration of reagents which sits with the Medicines Agency.

9. Brief Statement of Grounds
The attention of the Minister for Social Security, Health and Urban Affairs has been drawn to the problems of health safety posed by reagents used in laboratories carrying out medical-biological analyses. In particular, a recent report by the Social Security Inspectorate on the functioning of the Medical Biology Department of the National Health Laboratory was submitted to the Minister for Social Security, Health and Urban Affairs and the Minister delegated to health in July 1993. This report found that the registration of reagents for medical-biological analyses constituted a purely declarative action.

10. Reference Documents - Basic Texts
Reference documents - basic texts.

Public Health Code: Articles L 512, L 567-2, L 567-9, L 666-8, L 761-14 and L 761-14-1.

Act 93-5 of 4 January 1993 relating to the safety of blood transfusions and medicines, in particular Article 19 thereof in its amended form.

11. Invocation of the Emergency Procedure
Yes.

12. Grounds for the Emergency
During 1993, the Medicines Agency carried out, with the help of acknowledged experts, a scientific evaluation of a certain number of reagents. It goes without saying that, in terms of public health, the quality of these reagents is of paramount importance. This evaluation involved performing screening tests on the AIDS, Hepatitis B and Hepatitis C viruses. On this occasion, 31 screening bags of anti-HIV antibodies were evaluated: nine of these tests were deemed to be of 'mediocre' sensitivity. A letter was sent to the various manufacturers, who stopped distribution and began recalling any products which had not been used. However, it emerged that the departments of the Minister for Health did not possess the adequate legal instruments if the manufacturers had not accepted to suffer the consequences of the results of this research.

In the light of these serious problems, closely followed by the media and public opinion, it was important to give the authorities the means of acting in the interest of public health. Article 32 of Act No. 94-43 of 18 January 1994

relating to public health and safety and the draft decree were drawn up in this context., given the seriousness of the pathologies in question, the legislator felt and the government feels it is imperative that the quality of this type of reagent be brought up to a high level as a matter of urgency.

D. WILLIAMSON
COMEUR
NNNN