Notification Number: 2010/587/F

DECREE No. [ ] on the toxicovigilance of [ ]

Date received	:	24/08/2010
End of Standstill	:	25/11/2010 **(25/02/2011)**
Issue of comments by	:	Commission,Portugal,Romania,United Kingdom
Issue of detailed opinion by	:	Commission,Italy

Message

Message 002

Communication from the Commission - SG(2010) D/52164
Directive 98/34/EC
Translation of the message 001
Notification: 2010/0587/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 - Не се предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 201002164.EN)

1. Structured Information Line
MSG 002 IND 2010 0587 F EN 24-08-2010 F NOTIF

2. Member State
F

3. Department Responsible
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3. Originating Department
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4. Notification Number
2010/0587/F - C10C

5. Title
DECREE No. [ ] on the toxicovigilance of [ ]

6. Products Concerned
Substances and preparations (mixtures), particularly those classified as dangerous, within the meaning of Directive 1999/45/EC and/or Regulation (EC) No 1272/2008.

7. Notification Under Another Act
-

8. Main Content
This draft enhances toxivigilance and its organisation coordinated by the Sanitary Surveillance Institute, in accordance with Article L. 1413-4 established by Law No. 2009-879 of 21 July 2009 on hospital reform and relating to patients and healthcare. The draft also lays down new provisions with respect to applicable rules on, firstly, the mandatory declaration by persons responsible for marketing of information on all dangerous preparations and within thirty days following them being placed on the market and, secondly, on the mandatory declaration by health professionals of cases of intoxication. This information must be available to bodies responsible for toxicovigilance, principally poison and toxicovigilance centres responsible for responding to toxicological emergencies and for toxicovigilance (monitoring, expertise and alerting of toxic risks). These bodies must be able to have all information on the composition of products that have been placed on the market, in particular in case of emergency; if
the information has not been provided to these bodies, they can request it from persons responsible for marketing in case of emergency. This information is moreover forwarded, pursuant to existing provisions, to the National Research and Safety Institute responsible for the prevention of occupational risks. The draft also provides for the saving, use and distribution of information among the authorities and bodies responsible for toxicovigilance, as part of secure information systems.

Keywords: toxicovigilance, declaration, composition, preparations, mixtures, dangerous, intoxication

9. Brief Statement of Grounds
The draft text is in application of new laws introduced by Article 106 of Law No. 2009-879; it also takes account of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, by means of Article 45. This draft text will amend Articles R. 1341-1 - R. 1343-2 of the Public Health Code (established by Decree No 99-841) as to take account of the new laws, namely the declaration by health professionals of intoxication cases to bodies responsible for toxicovigilance and, to these same bodies, the declaration of information on preparations classified as very toxic, toxic, corrosive, carcinogenic, mutagenic or

toxic to reproduction, harmful or sensitising (a spreading out over time is laid down for application of this declaration depending on danger class). The draft law will also allow for the adaptation of regulatory activity to the evolution of informatic resources (in particular with the establishment of a portal for the declaration of chemical products).

10. Reference Documents - Basic Texts
References to basic texts: - Directive relating to the classification, packaging and labelling of dangerous substances;
- Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations;
- Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, and in particular Article 45 thereto;
- Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, and in particular Article 13 thereto;
- Law No. 2009-879 of 21 July 2009 on hospital reform and relating to patients and healthcare, and Article 106 thereto;
- the Employment Code, and in particular Articles L. 4411-4 and L. 4411-2;
- the Public Health Code, and in particular Articles L. 1341-3 thereto, L. 1342-3 and L. 6141-4;
- Decree No 99-841 of 28 September 1999 organising toxicovigilance and amending the Public Health Code (second half: Decrees in Council of State)
- the Order of 18 December 1996, empowering the National Research and Safety Institute, pursuant to Articles L. 231-7 (subparagraph 4) the Employment Code and L. 626-1 of the Public Health Code;
- the Order of 18 June 2002, on the joint computer system for poison centres.

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 will not have a notable impact on international trade.

SPS Aspect

NO - The draft will not have a notable impact on international trade.

Catherine Day
Secrétaire général
Commission européenne

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