



Notification Number: 2012/229/F

The Decree on the obligation of certifying support medical prescription software and support dispensation software, provided by Article L.161-38 of the Social Security Code

Date received : 11/04/2012

End of Standstill : 12/07/2012

Message

Message 002

Communication from the Commission - SG(2012) D/5976

Directive 98/34/EC

Translation of the message 001

Notification: 2012/0229/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 - Не се предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 201200976.EN)

1. Structured Information Line

MSG 002 IND 2012 0229 F EN 11-04-2012 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

Ministère du travail, de l'emploi et de la santé
Direction de la sécurité sociale



Sous-direction du financement du système de soins
Bureau des produits de santé (1C)
8 Avenue de Ségur
75350 PARIS 07 SP
Tél : 01 40 56 44 23 (secrétariat)- fax 01 40 56 73 95

4. Notification Number

2012/0229/F - S00S

5. Title

The Decree on the obligation of certifying support medical prescription software and support dispensation software, provided by Article L.161-38 of the Social Security Code

6. Products Concerned

Medical prescription support software for proprietary medicines used by medical professionals in private practice in health care institutions and nursing homes and support software for officinal dispensation of proprietary medicines.

7. Notification Under Another Act

-

8. Main Content

The draft decree of the State Council, made under Article 32 of the Law No 2011 - of 29 December 2011 on reinforcement of safety of health products and standardised in Article L. 161-38 of the Social Security Code, defines the conditions under which certification of support software for medical prescription and support software for dispensation is obligatory.

The obligation is fixed for 1 January 2015 for:

- on the one hand, medical prescription support software (LAP) whose at least one functionality is to provide prescribers practicing in town, in a health institution or a nursing home assistance for the effective realisation of medical prescription of proprietary medicines
- and, on the other hand, for dispensation support software (LAD) whose at least one functionality is support to the pharmaceutical analysis of a prescription or whose aim is the provision of information and advice necessary for the proper use of medicines to be dispensed as part of a pharmacist's work.

Certification bodies accredited by the French Accreditation Committee (COFRAC) shall carry out certification of the software concerned under a public certification procedure established by the High Authority of Health (HAS). This procedure describes the certification standards applicable to the software and within which expected technical requirements are defined. This certification shall be renewed every 3 years. The software publisher guarantees, during this period, maintenance of compliance of all potential later versions with the certified software version according to the applicable certification standard. Otherwise, the software version shall be submitted for recertification. The certification standards are the result of multidisciplinary working groups chaired by the HAS and are subject to public consultation on its website.

The deadline of this obligation was set for 1 January 2015 to give publishers necessary time to develop computer applications corresponding to the minimum technical requirements required by the applicable standards. Several standards are so foreseen: an applicable standard for LAP called "ambulatory" validated and made public in 2008, a standard for the LAP called "hospital" in the course of validation by the HAS at the end of April 2012 and a standard for LAP planned for the end of 2012.



9. Brief Statement of Grounds

The French authorities decided to require certification of medical prescription support software, which was previously optional, and also to extend it to cover the drug dispensation software, to help improve the quality, safety and efficiency of drug therapy in general. The software currently on the market does not provide all the minimum requirements of quality and safety in prescription and dispensation of proprietary medicines. This software proved, in addition, to be essential tools in improving and regulating prescription and dispensation practices in the proper use and also efficiency. It is therefore important that this software undergoes a certification procedure that will control and certify compliance with these requirements. The users will thus have an offer of exclusively certified products. At the same time, incentive measures are planned or are under development, to help significantly increase the rate of penetration of certified software to prescribing physicians and pharmacists concerned.

10. Reference Documents - Basic Texts

References to the reference texts: Article L.161-38 of the Social Security Code (resulting from Article 32 of the Law No 2011-2012 of 29 December 2011 on improving safety of medicines and health products).

11. Invocation of the Emergency Procedure

None

12. Grounds for the Emergency

-

13. Confidentiality

None

14. Fiscal measures

None

15. Impact assessment

-

16. TBT and SPS aspects

Aspect OTC

None - The draft has no significant effect on international trade.

Aspect SPS

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

Catherine Day
Secrétaire général



EUROPEAN COMMISSION
GROWTH DIRECTORATE-GENERAL

Single Market for goods
Prevention of Technical Barriers

Commission européenne

Point de contact Directive 98/34

Fax: (32-2) 296 76 60

email: dir83-189-central@ec.europa.eu