



Notification Number: 2016/520/F

Decree on the obligation of certifying dispensation support software for in-house pharmacies provided for in Article L161-38 of the Social Security Code

Date received : 30/09/2016

End of Standstill : 03/01/2017

Message

Message 002

Communication from the Commission - TRIS/(2016) 03030

Directive (EU) 2015/1535

Translation of the message 001

Notification: 2016/0520/F

No abre el plazo - Nezaahajuje 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 - Não 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: 201603030.EN)

1. Structured Information Line

MSG 002 IND 2016 0520 F EN 30-09-2016 F NOTIF

2. Member State

F

3. Department Responsible

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4. Notification Number

2016/0520/F - S00S

5. Title

Decree on the obligation of certifying dispensation support software for in-house pharmacies provided for in Article L161-38 of the Social Security Code

6. Products Concerned

Dispensation support software for in-house pharmacies

7. Notification Under Another Act

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8. Main Content

An obligatory certification system for publishers of medical prescription support software and dispensation support software was introduced by Law No 2011-2012 of 29 December 2011 on improving the safety of medicines and health products, supplemented by a decree notified under the Transparency Directive (notification No 2012/229/F). The certification procedure for dispensation support software initially concerned software used in pharmacies. The draft decree aims to extend the certification obligation to all dispensation support software used by in-house pharmacies (i.e. pharmacies in healthcare facilities). This is the purpose of this new draft implementing text (Article 1 of the draft decree). This certification system for dispensation support software provides for a scheme similar to that applied to software used in retail pharmacies detailed in Articles R161-76-1 et seq. of the Social Security Code. Software certification will be based on guidelines drawn up and published by the French National Authority for Health. Certified software must, in particular, meet the minimum technical safety requirements. It must be able to handle prescriptions using international non-proprietary names and to ensure interoperability with the prescription software that will be used in the facility where the in-house pharmacy is located. The certification software must also be able to handle internal messages concerning pharmacovigilance the correct use of medicine. Certification shall be done by certifying bodies accredited by COFRAC (or by any body covered by a mutual recognition agreement at European level). Certification is valid for three years and is renewable. If there are doubts as to the conformity of the software with the guidelines, new certification is required. The date of application of the certification obligation for dispensation support software for in-house pharmacies has been set for 1 January 2018, which gives private operators sufficient time to comply with these new regulations.

9. Brief Statement of Grounds

The reason the certification system is being expanded to include dispensation support software for in-house



pharmacies is to cover and secure the entire medication chain, from prescription to dispensation. Certification helps ensure that the software offered complies with the minimum safety, compliance and efficiency requirements for prescriptions. This draft decree supplements the decree on software used in retail pharmacies. It thus helps ensure that healthcare professionals are provided with fully certified product offerings. The measure is justified on public health grounds and provides a reasonable period to enable private operators to comply with the new requirements.

10. Reference Documents - Basic Texts

Reference(s) to basic text(s): Article 148 of Law No 2016-41 of 26 January 2016 for the modernisation of our health system (Official Journal of 27 January 2016), amending Article L161-38 of the Social Security Code

Article 32 of Law No 2011-2012 of 29 December 2011 on improving the safety of medicines and health products.

Decree No 2014-1359 of 14 November 2014 on the obligation of certifying medical prescription support software and dispensation support software, provided for in Article L161-38 of the Social Security Code (Official Journal of 15 November 2014), notification No 2012/229/F

The basic texts were forwarded with an earlier notification: 2012/229/F

11. Invocation of the Emergency Procedure

No

12. Grounds for the Emergency

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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 has no significant impact on international trade.

European Commission



EUROPEAN COMMISSION
GROWTH DIRECTORATE-GENERAL

Single Market for goods
Prevention of Technical Barriers

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