Notification Number: 2020/307/F

Order of 15 May 2020 supplementing the Order of 23 March 2020 prescribing the organisational and operational health system measures necessary to deal with the COVID-19 epidemic in the context of the state of health emergency

Date received : 18/05/2020

End of Standstill :

Message

Message 002

Communication from the Commission - TRIS/(2020) 01748
Directive (EU) 2015/1535
Translation of the message 001
Notification: 2020/0307/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 - Não 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: 202001748.EN)

1. Structured Information Line
MSG 002 IND 2020 0307 F EN 18-05-2020 F NOTIF

2. Member State
F

3. Department Responsible
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4. Notification Number
2020/0307/F - S00S

5. Title
Order of 15 May 2020 supplementing the Order of 23 March 2020 prescribing the organisational and operational health system measures necessary to deal with the COVID-19 epidemic in the context of the state of health emergency

6. Products Concerned
Hydro-alcoholic gel/boxes of masks/medicinal products/telecare/medical devices/in vitro diagnostic medical devices

7. Notification Under Another Act
-

8. Main Content
In particular, the draft text provides that:
- the provisions on hydro-alcoholic solutions are now applicable until the end of the state of health emergency. In addition, details are provided on the labelling of these solutions;
- the distribution of masks has been extended to certain professionals and patients;
- the provisions on telecare from certain professionals are specified and extended;
- the provisions on the possibility of using in vitro diagnostic medical devices which do not have CE marking are specified;
- certain provisions on the dispensing of medicinal products or medical devices in the event of an expired prescription are applicable until 11 June 2020 or until the end of the state of emergency.

These measures have already been the subject of previous notifications.

9. Brief Statement of Grounds
The World Health Organization (WHO) declared that the emergence of a novel coronavirus (COVID-19) constitutes a public health emergency of international concern on 30 January 2020.

Firstly, it is necessary to prevent the risks of a shortage of hydro-alcoholic products used for human hygiene in order to limit the infectious risk related to the transmission of the COVID-19 virus. It is also necessary that the labelling imposed for hydro-alcoholic products manufactured under derogation mentions the final concentration of the active substance, which is an essential element for judging the quality and effectiveness of the product.

Secondly, it is necessary to extend the distribution of protection masks to the professionals most exposed to possible or confirmed cases of COVID-19 and to extend it to certain professionals and certain people at risk.

Thirdly, the risk of doctors being unavailable due to managing the crisis could cause interruptions to chronic

treatment that could be detrimental to the health of patients. This risk should be prevented by allowing pharmacies to dispense, within the initially planned dosage and when the period of validity of a renewable prescription has expired, a number of boxes per line of the prescription or a volume of products or services guaranteeing the continuation of the treatment.

Fourthly, telehealth enables the provision of medical and nursing care at home for patients with symptoms of infection or recognised as having COVID-19 and protects health professionals and the patients they care for from infection.

Fifthly, there are still predicted constraints on the supply of in vitro diagnostic medical devices. The European Commission also strongly recommends carrying out additional validation of the clinical performance of the tests, carried out by the competent authorities and reference laboratories in the Member States. It is therefore necessary to introduce such validation.

10. Reference Documents - Basic Texts
Reference(s) to basic text(s): - Article L3131-16 of the Public Health Code

Notifications Nos 2020/107/F, 2020/128/F, 2020/130/F, 2020/134/F, 2020/139/F, 2020/163/F, 2020/224/F, 2020/230/F

11. Invocation of the Emergency Procedure
Yes

12. Grounds for the Emergency
Emergency measure to protect the population against the serious health threat posed by the COVID-19 novel coronavirus

13. Confidentiality
No

14. Fiscal measures
No

15. Impact assessment
-

16. TBT and SPS aspects
TBT aspect

No - the draft has no significant impact on international trade.

SPS aspect

No - the draft is neither a sanitary nor phytosanitary measure.

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European Commission

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