



Notification Number : 2021/0222/F (France)

Draft Decree dated 10 April 2021 amending the Decree dated 10 July 2020 setting out the organisational and operational health system measures necessary to deal with the COVID-19 epidemic as part of the health emergency

Date received : 10/04/2021

End of Standstill : Not applicable (closed)

Message

Message 002

Communication from the Commission - TRIS/(2021) 01326

Directive (EU) 2015/1535

Translation of the message 001

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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' jiftaħ il-perijodi ta' dawmien - Geen termijnbegin - Nie otwiera oóźnień - 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: 202101326.EN)

1. MSG 002 IND 2021 0222 F EN 10-04-2021 F NOTIF

2. F

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4. 2021/0222/F - S10S

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6. Autotests on nasal sampling and vaccination

7. -



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8. The mainland draft text of the provisions on nasal self-testing, army hospitals, SARS-CoV-2 vaccination and accreditation of medical biology laboratories.

9. On 30 January 2020, the World Health Organisation (WHO) declared that the emergence of a new coronavirus (COVID-19) was a global public health emergency.

In France, the Decree dated 14 October 2020 declared the state of health emergency throughout the territory as of 17 October 2020 and two laws extended the state of emergency until 1 June 2021.

Military hospitals take in patients with covid-19 under the same conditions as health facilities and, as such, bear expenses for benefits not included in the basket of care that require additional care.

Vaccination against SARS-CoV-2 is essential to contain the epidemic, and the special conditions for the implementation of this vaccination, in which military hospitals are involved, require, as is the case for health facilities, to provide specific remuneration for these hospitals.

It is necessary to update and harmonise the proposed remuneration according to the expansion of the list of health professionals, health students and other professionals who may intervene to prescribe, administer and/or inject the anti-Covid vaccines and the manner in which they may carry out such actions.

The simplicity of the deployment of self-tests, which does not require the presence of healthcare professionals, and their less invasive method of sampling, will allow for more frequent testing; the conditions for the distribution and use of these tests should therefore be laid down; in addition, sales price standards must be laid down in order to ensure that testing is accessible to the general population and to provide for free availability for certain categories of audiences that require it; finally, it is necessary to lay down the conditions for their coverage by health insurance.

In order to accompany the dispensation of these self-tests by pharmaceutical advice, this dispensation should be limited to the pharmacy and its sale on the Internet should be prohibited; in order to ensure reliable information, advertising must comply with a specification defined by the National Agency for the Safety of Medicinal Products and Health Products and that intended for the general public must be subject to the prior authorisation of that agency and be limited to pharmacies.

The mobilisation of medical biology laboratories in the detection of the epidemic is incompatible with the preparation of accreditation files by 1 May 2021; this date should be extended to 1 November 2021.

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

11. Yes

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

13. No

14. No

15. -

16. TBT aspect

NO – The proposal does not have a significant impact on international trade.



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SPS aspect

NO - The proposal does not have a significant impact on international trade.

European Commission

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