EUROPEAN COMMISSION
GROWTH DIRECTORATE-GENERAL

Single Market for goods
Prevention of Technical Barriers

Notification Number: 2017/161/F

Decree laying down the maximum duration for the authorised prescription of antibiotics

Date received	:	25/04/2017
End of Standstill	:	26/07/2017 **(26/10/2017)**
Issue of detailed opinion by	:	Austria

Message

Message 002

Communication from the Commission - TRIS/(2017) 01042
Directive (EU) 2015/1535
Translation of the message 001
Notification: 2017/0161/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: 201701042.EN)

1. Structured Information Line
MSG 002 IND 2017 0161 F EN 25-04-2017 F NOTIF

2. Member State
F

3. Department Responsible
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4. Notification Number
2017/0161/F - C10P

5. Title
Decree laying down the maximum duration for the authorised prescription of antibiotics

6. Products Concerned
Medicinal products for human use

7. Notification Under Another Act
-

8. Main Content
The present draft decree is issued pursuant to Article 146 of Law No 2016–41 on the modernisation of the health system, which creates Article L5132-10 of the French Public Health Code: 'For reasons of public health and especially to prevent the emergence of resistance to antibiotic medicinal products containing one of the substances mentioned in this chapter, regulatory measures shall be taken to combat resistance to said medicinal products.' The purpose of this draft decree is to regulate the procedures for the prescription of antibiotics.
It limits the length of initial prescriptions of antibiotics to seven days.

9. Brief Statement of Grounds
For the past 15 years, France has had to deal with an overall increase in bacterial resistance to antimicrobial agents. This phenomenon is largely due to bacteria having been overexposed to antimicrobial agents, which is the direct result of the overuse and persistent misuse of antibiotics. Despite the initial success of programmes concerning antibiotics implemented in France since 2001 to protect human health, usage of antibiotics remains excessively high compared with the European average.
Limiting the duration of the prescription is part of the wider series of measures from the first Interministerial Committee for Health (Comité Interministériel pour la Santé) for controlling resistance to antibiotics, implemented by the Prime Minister. Thus, this issue has become a health priority for the government by highlighting the challenges and objectives in terms of reducing the use of antibiotics as well as the number of deaths caused by these infections.
Action 8 of the Committee's roadmap states the need to limit the duration of prescriptions for common infections to seven days at most. Indeed, treatment lasting seven days covers the vast majority of common infections and corresponds to the majority of first-line treatments recommended by the French National Authority for Health. An analysis of data from the French National Agency for the Safety of Medicine and Health Products [Agence nationale de sécurité du médicament et des produits de santé- ANSM] with a focus on respiratory infections (which account for 67 % of prescriptions made by local GPs according to a 2015 ANSM report) shows that one quarter of prescriptions are given for too long a period (more than seven days) in the target indications. Limiting these prescriptions to seven days is a pragmatic objective under which the excessively long treatment periods still used too frequently for certain infections can be reduced by 25-30 %.
As regards the above-mentioned observations, it seemed necessary, appropriate and proportionate to limit the

maximum prescription duration for medicinal products to seven days. This measure is even more appropriate and proportionate since the prescribing physician may deviate from this maximum duration of seven days 'for specific reasons relating to the patient or his condition'. In other cases where treatment is necessary for a longer duration, the patient may always ask the prescribing physician to reassess his prescription.

10. Reference Documents - Basic Texts
Reference(s) to basic text(s): Article L5132-10 of the French Public Health Code

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 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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