Notification Number: 2014/210/F

Decree on the symbol mentioned in section 19 of Article R. 5121-138 of the Public Health Code.

Date received	:	05/05/2014
End of Standstill	:	06/08/2014
Issue of comments by	:	Germany
Issue of detailed opinion by	:	Commission

Message

Message 002

Communication from the Commission - TRIS/(2014) 01272
Directive 98/34/EC
Translation of the message 001
Notification: 2014/0210/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 - 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: 201401272.EN)

1. Structured Information Line
MSG 002 IND 2014 0210 F EN 05-05-2014 F NOTIF

2. Member State
F

3. Department Responsible
Délégué interministériel aux normes – SQUALPI – Bât. Sieyès -Teledoc 151 – 61, Bd Vincent Auriol - 75703 PARIS Cedex 13
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3. Originating Department
Ministère des affaires sociales et de la santé

Direction générale de la santé.
Sous-direction de la politique des produits de santé et de la qualité des pratiques et des soins.
Bureau du médicament (PP2).
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4. Notification Number
2014/0210/F - C10P

5. Title
Decree on the symbol mentioned in section 19 of Article R. 5121-138 of the Public Health Code.

6. Products Concerned
Medication for human use: reimbursable medicinal specialities

7. Notification Under Another Act
-

8. Main Content
The draft decree on the symbol mentioned in section 19 of Article R. 5121-138 of the Public Health Code establishes the characteristics of said symbol.

9. Brief Statement of Grounds
The medical service rendered (MSR) is a criterion that informs the authorities responsible for the approval of the reimbursement of medications on the clinical benefit of medications. More specifically, it enables a question to be answered: does the medication have sufficient clinical interest to be supported by national solidarity? It shall be evaluated by the Transparency Committee of the High Authority of Health, on the basis of scientific data. It helps set the rate of support for the medication by the National Union of Health Insurance Funds (UNCAM).
It takes into account:
• the severity of the condition;
• the efficacy and adverse effects of the drug;
• the preventative, healing and symptomatic nature of the medication;
• its place in the therapeutic strategy in relation to other available therapies;
• its interest in terms of public health.
It is qualified as major or significant, moderate, low or insufficient.

The inclusion of the level of medical service rendered for each indication on the packaging of medications helps to foster patient access to reliable, scientific and independent data. For the protection of public health, this measure forms part of a process of transparency and equal access to medical information, and promotes the proper use of medication.

10. Reference Documents - Basic Texts
References to basic texts: Articles L. 5121-20, R. and R. 5121-138 5121-149 of the 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 has no significant impact on international trade.

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European Commission

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