



Notification Number: 2015/216/F

Order concerning the pictogram mentioned in paragraph 15 of article R. 5121-138 of the Public Health Code.

Date received : 23/04/2015
End of Standstill : 24/07/2015 (26/10/2015)
Issue of detailed opinion by : Commission

Message

Message 002

Communication from the Commission - TRIS/(2015) 01211
Directive 98/34/EC
Translation of the message 001
Notification: 2015/0216/F

No abre el plazo - Ne zahajuje 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 - 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: 201501211.EN)

1. Structured Information Line

MSG 002 IND 2015 0216 F EN 23-04-2015 F NOTIF

2. Member State

F

3. Department Responsible

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3. Originating Department

Ministère des affaires sociales, de la santé et des droits des femmes
Direction générale de la santé.



Sous-direction de la politique des produits de santé et de la qualité des pratiques et des soins.

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4. Notification Number

2015/0216/F - C00P

5. Title

Order concerning the pictogram mentioned in paragraph 15 of article R. 5121-138 of the Public Health Code.

6. Products Concerned

Medicinal product for human use: reimbursable pharmaceutical products.

7. Notification Under Another Act

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8. Main Content

The draft order concerning the pictogram mentioned in paragraph 15 of article R. 5121-138 of the Public Health Code establishes the characteristics of this pictogram.

9. Brief Statement of Grounds

The therapeutic value (service médicale rendu) is a criterion which provides information for the authorities responsible for approving medicinal products for reimbursement on the basis of their clinical relevance. In particular, it answers the question: is the medicinal product of sufficient clinical relevance to be paid for by the taxpayer? It is evaluated by the Committee on Transparency of the National Health Authority, on the basis of scientific data. It is taken into consideration to establish the percentage of the cost of the medicinal product that will be paid for by the National Union of Health Insurance Funds (UNCAM).

It takes into consideration:

- The seriousness of the illness;
- Its effectiveness and the adverse effects of the medicinal product;
- The preventive, remedial, and symptomatic nature of the medicinal product;
- Its role in the therapeutic strategy compared with other available therapies;
- Its relevance for public health.

The rating levels are strong, moderate, poor or insufficient. The evaluation of the level of therapeutic value determines the rate of reimbursement of the medicine (65%, 30%, 15% or 0%).

The indication of the level of therapeutic value taken into consideration by the Director General of the National Union of Health Insurance Funds to establish the rate of participation of the insured party in the cost of the medicinal product in accordance with article R. 163-10-1 of the Social Security Code, provides an indication for the patient of the level of therapeutic value taken into consideration to establish the rate of reimbursement of the medicinal product in question.

This indication also gives the patient access to reliable, scientific and independent data on the evaluation of the medicinal product. In the interest of the protection of public health, this measure also seeks to ensure transparency and equal access to medical information and promotes a proper use of the medicinal product.



10. Reference Documents - Basic Texts

Reference to basic texts: Articles L. 5121-20, R. 5121-138 and R. 5121-149 of the Public Health Code.
Articles L. 162-17, R. 161-71 and R. 163-3 of the Social Security Code.

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

OTC 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

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