EUROPEAN COMMISSION
GROWTH DIRECTORATE-GENERAL

Single Market for goods
Prevention of Technical Barriers

Notification Number: 2015/215/F

Decree concerning the indication on the external packaging of pharmaceutical products of the therapeutic value taken into consideration to establish the rate of participation of the insured party.

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) 01208
Directive 98/34/EC
Translation of the message 001
Notification: 2015/0215/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: 201501208.EN)

1. Structured Information Line
MSG 002 IND 2015 0215 F EN 23-04-2015 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
d9834.france@finances.gouv.fr
tél : 01 44 97 24 55

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.
Bureau du médicament (PP2).
14, avenue Duquesne - 75350 PARIS 07 SP
jean-noel.dodote@sante.gouv.fr
tél : 01.40.56.54.19 – fax : 01.40.56.47.92

4. Notification Number
2015/0215/F - C00P

5. Title
Decree concerning the indication on the external packaging of pharmaceutical products of the therapeutic value taken into consideration to establish the rate of participation of the insured party.

6. Products Concerned
Medicinal product for human use: reimbursable pharmaceutical products.

7. Notification Under Another Act
-

8. Main Content
The draft decree concerning the indication of therapeutic value on external packaging provides for the addition on the external packaging of reimbursed pharmaceutical products of an indication of the therapeutic value taken into consideration 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.

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;
• the effectiveness and 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
References 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
-

13. Confidentiality
No

14. Fiscal measures
No

15. Impact assessment
-

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.

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European Commission

Contact point Directive 98/34
Fax: +32 229 98043
email: dir83-189-central@ec.europa.eu