



Notification Number: 2006/154/F

Draft Order laid down in implementation of Article D. 4211-11 of the Public Health Code, laying down the list of medicinal plants or parts of plants entered in the Pharmacopoeia, which may be sold to the public by persons other than pharmacists

Date received : 27/03/2006

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Message

Message 002

Communication from the Commission - SG(2006) D/50764

Directive 98/34/EC

Translation of the message 001

Notification: 2006/0154/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 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.

(MSG: 200600764.EN)

1. Structured Information Line

MSG 002 IND 2006 0154 F EN 28-06-2006 27-03-2006 F NOTIF 28-06-2006

2. Member State

France

3. Department Responsible

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3. Originating Department

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4. Notification Number

2006/0154/F - C30P

5. Title

Draft Order laid down in implementation of Article D. 4211-11 of the Public Health Code, laying down the list of medicinal plants or parts of plants entered in the Pharmacopoeia, which may be sold to the public by persons other than pharmacists

6. Products Concerned

Medicinal plants

7. Notification Under Another Act

This notification is made in application of Article 8 of the amended Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998, laying down a procedure for the provision of information in the field of technical standards and regulations.

8. Main Content

This draft has been drafted to implement the future Article D. 4211-11 (draft Decree), which lays down that a Decree of the Ministers responsible for Health, Consumer Affairs, Agriculture and Food, drafted on the proposal of the Director-General of the French Agency for the Safety of Health Products, after receiving the opinion of the National Pharmacopoeia Committee referred to in Article R. 5112-6, shall establish the list of medicinal plants or parts of medicinal plants entered in the Pharmacopoeia which may be sold by persons other than pharmacists. These plants or parts of plants may be sold as is or in the form of preparations comprising, in particular, the extracts and powders identified in the aforementioned list.

Having referred to a Decree to lay down the forms of preparations makes amendments easier.

This draft Order enables the liberalisation of 147 plants as is. At present, only 34 plants are liberalised. This draft Order also enables the liberalisation, among the 147 aforementioned plants, of 70 plants in the form of powder and 11 in the form of dry aqueous extract.

9. Brief Statement of Grounds

At present, exceptions to the monopoly for medicinal plants entered in the Pharmacopoeia are laid down by Articles D. 4211-11 and D. 4211-12 of the Public Health Code, according to which 34 plants may be sold by persons other than pharmacists or herbalists, provided that they are sold as is.

However, the pharmaceutical monopoly on the sale of medicinal plants is not respected, giving rise to a significant dispute before the courts. In this regard, case-law is somewhat contradictory. The Court of cassation both considers that all medicinal plants entered in the Pharmacopoeia are medicinal, and that there are mixed plants that cannot be considered medicinal solely on the basis of their entry in the Pharmacopoeia. It is therefore necessary to put an end to this legal confusion and to take advantage of the transposal of the Directive on food supplements in order to clarify the situation of medicinal plants entered in the Pharmacopoeia.



10. Reference Documents - Basic Texts

a) Public Health Code (Articles L. 4211-1, D. 4211-11, D. 4211-12 and R. 5112-6)

11. Invocation of the Emergency Procedure

NO

12. Grounds for the Emergency

-

13. Confidentiality

NO

14. Fiscal measures

NO

15. Impact assessment

-

16 TBT aspect

a) No

b) iii) The draft will not have any notable impact on international trade.

SPS aspect

a) No

b) iii) The draft will not have any notable impact on international trade.

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