



Notification Number: 2006/153/F

Draft Decree on the sale to the public of medicinal plants entered in the Pharmacopoeia

Date received : 27/03/2006

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Message

Message 002

Communication from the Commission - SG(2006) D/50762

Directive 98/34/EC

Translation of the message 001

Notification: 2006/0153/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: 200600762.EN)

1. Structured Information Line

MSG 002 IND 2006 0153 F EN 28-06-2006 27-03-2006 F NOTIF 28-06-2006

2. Member State

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4. Notification Number

2006/0153/F - C10P

5. Title

Draft Decree on the sale to the public of medicinal plants entered in the Pharmacopoeia

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 Decree is laid down in implementation of Article L. 4211-1 of the Public Health Code, which lays down that "the sale of medicinal plants entered in the Pharmacopoeia subject to the exceptions laid down by Decree" shall be the preserve of pharmacists.

The list of plants that may be sold outside the monopoly of pharmacists is an integral part of Article D. 4211-11 of the Public Health Code, and is limited to only 34 plants. In order to simplify the management of this list of plants, it is proposed to transfer the list to an interministerial Decree and to extend it to include other medicinal plants entered in the Pharmacopoeia, used for food and condiment purposes.

Thus, the first subparagraph of Article D. 4211-11 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, without prejudice to the legislation applicable to these plants or parts of plants as well as to products in which they may be incorporated. This last sentence responds to the concern that there is a risk the text could be interpreted as a green light to the marketing of medicinal plant-based food supplements, without it being necessary to comply with the other legislation.

According to the second subparagraph of the same Article, 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. At present, the 34 plants decontrolled by Article D. 4211-11 may only be sold as is. This subparagraph allows other forms of plants included on the list to be decontrolled, which will thus be assessed by the National Pharmacopoeia Committee.

Pursuant to Article D. 4211-12 of this draft, medicinal plants or parts of plants entered in the Pharmacopoeia as is or in the form of preparations that do not appear on the list referred to in Article D. 4211-11, use of which in a food supplement has been authorised in implementation of the Decree on food supplements, may be sold by persons other than pharmacists, provided that they are incorporated in these food supplements.

However, the second subparagraph of this Article lays down that this provision does not apply to medicinal plants or parts of plants and preparations thereof which have potential undesirable effects that exceed the expected therapeutic benefits and which appear on a list published by the French Pharmacopoeia, under the



conditions laid down in Article R. 5112-2 of the Public Health Code. Only some of these may be used within the specific context of homeopathy and its rules on dilution. It is inconceivable for reasons of health safety that, considering their undesirable effects, they can be used in the context of food supplements.

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)
Draft Decree on food supplements

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

a) No

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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