



Notification Number: 2001/36/F

Draft Decree on cells of human origin and on products of gene and cell therapies of human or animal origin with regard to the conditions for authorising the establishments and bodies carrying out the activities governed by Articles L.1243-1 and L.1261-2, the conditions for authorising the processes and products specified in Articles L.1243-6 and L.1261-3 and the conditions for authorising the clinical trial protocols specified in Articles L.1125-1 and L.1125-4.

Date received : 24/01/2001

End of Standstill : Closed

Message

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Représentation Permanente du Royaume-Uni

Message 002

Communication from the Commission - SG(2001) D/50232

Directive 98/34/EC

Translation of the message 001

Notification: 2001/36/F

(MSG: 200100232.EN)

1. Structured Information Line

MSG 002 IND 2001 0036 F EN 24-01-2001 F NOTIF

2. Member State

FRANCE

3. Department Responsible

Délégué interministériel aux normes

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3. Originating Department

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Sous-direction de la politique des produits de santé

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4. Notification Number

2001/36/F - COOP

5. Title

Draft Decree on cells of human origin and on products of gene and cell therapies of human or animal origin with regard to the conditions for authorising the establishments and bodies carrying out the activities governed by Articles L.1243-1 and L.1261-2, the conditions for authorising the processes and products specified in Articles L.1243-6 and L.1261-3 and the conditions for authorising the clinical trial protocols specified in Articles L.1125-1 and L.1125-4.

6. Products Concerned

- products of cell therapy: cells of human or animal origin having undergone certain transformations (selection - sorting - multiplication - expansion) for the purpose of giving them therapeutic properties prior to transplanting or administering them to a patient registered in a cell therapy protocol (therapeutic technique consisting of transplanting to or injecting into a recipient autologous cells (from the recipient's own body), allogeneic cells (from a third party donor) or xenogeneic cells (of animal origin)).
- product of gene therapy: product intended to alter the genetic material of cells by introducing into them a gene which is intended either to correct a genetic disease or to modulate certain biological responses of the cells.

7. Notification Under Another Act

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8. Main Content

This text is adopted pursuant to Articles L.1243-1, L.1261-2, L.1243-6, L.1261-3, L.1125-1 and L.1125-4 of the Public Health Code.

These various legislative provisions provide for, in the field of cells and products of gene and cell therapies, the implementation of certain regulatory provisions intended to authorise the activities which to date have been carried out without any particular supervision. This draft Decree therefore sets out the terms and conditions for authorising:

- the establishments and bodies carrying out the activities of preparing, transforming, storing, distributing and transferring the products of gene and cell therapies;
- the products themselves;
- the clinical trials.

a) Sub-section 1 (Articles R.672-40 to R.672-59) sets out the conditions for authorising the establishments and bodies carrying out the activities of preparation, transformation, storage, distribution and transfer. It is adopted pursuant to Articles L.1243-1 and L.1261-2 of the Public Health Code.

The system of authorisation differs according to whether or not the products of gene and cell therapies have the status of proprietary medicinal products or industrially manufactured medicinal products. Sub-section 1 is therefore subdivided into 2 paragraphs:

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9. Brief Statement of Grounds

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[illegible]

10. Reference Documents - Basic Texts

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11. Invocation of the Emergency Procedure



12. Grounds for the Emergency

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13. Confidentiality

 

14. Fiscal measures

