European Commission
Enterprise and Industry

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Directive 98/34/EC

Notificación - Oznámení - Notifikation - Notifizierung - Teavitamine - Γνωστοποίηση - Notification - Notification - Notifica - Pieteikums - Pranešimas - Bejelentés - Notifika - Kennisgeving - Zawiadomienie - Notificacão - Hlásenie-Obvestilo - Ilmoitus - Anmälan - Нотификация

Country
IS - Iceland

Language
EN - English

3A. Department Responsible

Ministry for Foreign Affairs
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3B. Originating Department

Ministry of Welfare
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5. Title

Regulations on granting of licences for parallel import of medicinal products.

6. Products and/or Services Concerned

C00P - PHARMACEUTICALS AND COSMETICS

These Regulations apply to granting of licences for parallel import of medicinal products to Iceland.

7. Notification under another Community Act

- ☐ Regulation (EC) nº 315/93 on contaminants in food
- ☐ Regulations (EC) nº 852/853/854/2004 relating to the hygiene of foodstuffs
- ☐ Regulation (EC) nº 1924/2006 concerning nutrition and health claims made on foods
- ☐ Regulation (EC) nº 1925/2006 concerning the addition of vitamins and minerals and certain other substances to foods
- ☐ Directive 94/62/EC on packaging and packaging waste
- ☐ Directive 2000/13/EC on the labelling and presentation and advertising of foodstuffs
- ☐ Directive 2006/123/EC on services in the internal market
  - ☐ 98/48/EC information society services only

    or specify provisions

    - ☐ quantitative or territorial restrictions
    - ☐ obligation to take a specific legal form
    - ☐ requirements which relate to the shareholding of a company
    - ☐ requirements which reserve access to particular providers
    - ☐ a ban on having more than one establishment in the territory of the same State
    - ☐ requirements fixing a minimum number of employees
    - ☐ fixed tariffs with which the provider must comply
    - ☐ obligation to supply other specific services

☐ Other/Additional Information

8. Main Content

These Regulations apply to granting of licences by the Icelandic Medicines Agency for parallel import of medicinal products. The regulations apply to both human and veterinary medicines, whether they have been granted a central marketing authorisation (MA) within the European Union (EU), or a national MA within the European Economic Area (EEA). A licence for parallel import of medicinal products is granted on the basis that the parallel-imported medicinal product is of equal quality, and meets all the conditions which apply to the granting of a marketing authorisation to the directly-distributed medicinal product.

9. Brief Statement of Grounds

The procedure in these Regulation requires an IS marketing license for parallel import of centrally authorised medicinal products.
There is a fundamental difference between the validity of a community marketing authorisation (issued in accordance with Regulation (EC) No 726/2004) in EU Member States and the three EEA-EFTA states. According to point 1 of Annex to the EEA Joint Committee Decision No 61/2009 which incorporated Regulation 726/2004 into the EEA Agreement,"when decisions on approval of medicinal products are taken according to the Community procedures laid down in Regulation (EC) No 726/2004 [...], the EFTA States shall simultaneously and within 30 days of the Community Decision, take corresponding decisions on the basis of the relevant acts." The issuance of a marketing authorisation in the EEA-EFTA states on the grounds of the aforementioned point 1 the Annex to the EEA Joint Committee Decision No 61/2009 constitutes a national marketing authorisation. In Iceland such a marketing authorisation is issued on the grounds of the provision granted to the Icelandic Medicines Agency in Article 67, Paragraph 7 of Regulation No. 141/2011. For parallel import of a centrally authorised product into Iceland (Norway and Lichtenstein) the national procedures for parallel import apply.

10. Reference Documents, Basic Texts

☐ No Basic Text exists

☐ Limit the marketing or use of a chemical substance, preparation or product

☑ References of the Basic Texts

These Regulations are issued on the basis of provisions of paragraph 9, Article 7, and paragraph 7, Article 33 of the Medicinal Products Act No 93/1994, with subsequent amendments.

http://www.althingi.is/lagas/nuna/1994093.html

☐ Basic Texts have been forwarded within the framework of a previous notification

Reference of previous notification(s)

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[ ] / [ ] / [ ]

11. Invocation of the Urgency Procedure

☐ Yes

12. Grounds for the Urgency

13. Confidentiality

☐ Yes

14. Fiscal measures

☐ Yes

15. Impact assessment

☐ Yes (in a separate file)

or specify

The impact of these Regulation on the market is at this time not forseen as major.

16. TBT and SPS aspects

TBT aspect

☑ Yes

☐ No - The draft is not a technical regulation nor a conformity assessment

☐ No - The draft is in conformity with an international standard

☐ No - The draft has no significant impact on international trade

SPS aspect

☐ Yes

☑ No - The draft is not a sanitary or phytosanitary measure

☐ No – Content is the same as that of an international standard, directive or recommendation

☐ No - The draft has no significant impact on international trade