

Page
2
Reference
GMT/BMC

shall be written in non-erasable letters and signed by the person placing the order, stating the date of signature. The order shall contain:

- a. the name and initials, the address and the telephone number of the person placing the order;
 - b. the name of the particular Opium Act drug as well as, expressed fully in words, the quantity thereof.
2. If a drug is intended for administration in an institution as referred to in Article 16, first paragraph, under c, of the Opium Act Decree, the order shall also contain the name, address and location of the institution as well as the words "for the practice of medicine in", adding the name and address of the institution.
3. If a drug is intended for administration in the practice of the person who issued a prescription for the drug, the order shall also contain the words "for the practice of medicine" or "for the practice of veterinary medicine".
4. For every order for an Opium Act drug placed with a pharmacist, a separate form shall be used.
5. The first to fourth paragraphs inclusive shall not apply to preparations as referred to in Article 8 of the Opium Act Decree.

Section 4 Final provisions

Article 4

The Import, Export and Transport of Opium Act Drugs Decree and the Prescription of Opium Act Drugs Decree are repealed.

Article 5

This Regulation shall be cited as: 'the Opium Act Implementation Regulations'.

Article 6

This Regulation shall take effect at the time that the Act of 13 July 2002 amending the Opium Act (*Stb.* [Bulletin of Acts and Decrees] 2002, 520) takes effect.

The Minister of Health,
Welfare and Sport,

A.J. de Geus

Page

3

Reference

GMT/BMC

Explanatory Memorandum

Article 2

In determining the amount of the fee owed pursuant to the first paragraph for processing the application for an exemption from the prohibition to perform one or more of the acts referred to in Articles 2 and 3 of the Opium Act, with the exception of the import or export act, the point of departure used is that the costs of processing a new application fall under the application fee and the costs of modifying existing exemptions, the costs of maintaining the system and the overhead costs have been calculated into the annual fee. Briefly stated, the components of the application fee are the costs of the various stages of processing an application for an exemption by the particular employees of the Ministry of Health, Welfare and Sport. The application costs include the costs of investigations to be conducted by the *Inspectie voor de Gezondheidszorg* [Health Care Inspectorate] in order to assess whether the applicant will meet the requirements imposed by or pursuant to the Opium Act. "Pursuant to the requirements imposed by the Opium Act" also refers to the requirements attached to a permit. The application costs further include all related and ensuing administrative costs and the costs of applying for and obtain an advisory opinion from the Office referred to in Article 9 of the Public Administration Probity in Decision-making Act, the so-called BIBOB Office.

The same fee that is charged for a new application will apply to an application to extend an exemption for the maximum term.

Briefly stated, the components of the annual fee are the costs of:

- managing the computerised system;
- consulting with the relevant departments of the Ministry of Health, Welfare and Sport, such as the Office of Medicinal Cannabis and the Health Care Inspectorate;
- calculating and collecting the annual fee and processing changes;
- developing standard letters;
- legal and administrative support;
- accommodation and other overhead.

The number of changes for each exemption is calculated by dividing the average number of changes for each year by the average number of exemptions for each year.

Page

4

Reference

GMT/BMC

Before the present Regulation took effect, a differentiated system of fees applied. What was determinative was the nature of the act for which an exemption was requested and the locations where that act was performed. That system has been abandoned. The new system is based on the average costs for each type of act. For that matter, it is rarely the case that an exemption is requested to perform only one type of act. A combination of acts is nearly always involved.

It follows from the second paragraph that no annual fee will be owed for administering the exemptions granted for import and export. That is related to the provision in Article 7 of the Opium Act that the import and export exemption in each case – that is, for a certain lot of medicines containing Opium Act drugs or a certain lot of Opium Act drugs as such – will be granted for at most six months.

The amount of EUR 40 takes into account the costs of administratively processing the application and the decision (personnel plus overhead) and the costs of assessing and deciding the application. In the Opium Licences Decree which is to be repealed and which dates from October 1976 and was last amended in 1995, the fee for an import or export licence was set at NLG 70. That amount has not changed since 1995. The amount of the fee set forth in the present Regulation (EUR 40) is determined to be NLG 70, converted into euros and adjusted for inflation over the past seven years.

The amounts included here were included before the legislative amendment in the Decree Containing Rules regarding Fees for Opium Licences.

Article 3

The first three paragraphs of this Article include the content of Article 7 of the Prescription and Ordering of Opium Act Drugs Decree. Pursuant to the relevant delegation provisions of the Opium Act, the content of that Decree has been divided between the Opium Act Decree, regulating the prescribing of Opium Act drugs, and the present Regulation, regulating the ordering of Opium Act drugs.

Paragraph 4 provides that every order placed with pharmacists as referred to in the fourth paragraph of this Article must be made with a separate form. This provision is a consequence of the risky nature of the drugs and, in particular, the carelessness seen by the Health Care Inspector in the past. That makes it necessary to build in good monitoring possibilities. Registration for each order is an aspect of this. For prescriptions, these extra monitoring possibilities have been built in through imposing additional rules in the Opium Act Decree, entailing that prescriptions, arranged successively by the name of the person issuing the prescription, the name of the substance and the date of supply, must be kept. More generally, Article 7 of the Opium Act Decree also contains strict administrative provisions, including the authority of the Health Care Inspector to provide further instructions.

The present Regulation is based on Article 4, second paragraph, of the Opium Act and is less stringent than the provisions applicable to registration of prescriptions, contained in Article 5, first paragraph, of the Opium Act Decree. Substantively, the old regulation is not being changed, so that there is no change in the administrative burden.

Article 4

The content of the ministerial regulation Import, Export and Transport of Opium Act Drugs Decree will be part of the conditions which will be attached to an import or export exemption under Article 8a, first paragraph, of the Opium Act. That ministerial regulation must therefore be repealed. The present Article provides for this.

In the amendment of the Opium Act by the Act of 16 December 1998 (*Stb.* 1999, 10), Article 4, first paragraph, of the Opium Act was amended in such a manner that the statutory basis for the ministerial regulation Prescription of Opium Act Drugs Decree disappeared and no longer was applicable as a result. This was pointed out in the general part of the Explanatory Memorandum to the Prescription and



Page

5

Reference

GMT/BMC

Ordering of Opium Act Drugs Decree. The content of that ministerial regulation was included in the Prescription and Ordering of Opium Act Drugs Decree. That Decree is being repealed by the Opium Act Decree.

Because the ministerial regulation was never formally repealed, it did not sufficiently become known that that regulation was no longer applicable. In order to remove any doubt in this respect, the present Regulation formally repeals the Prescription of Opium Act Drugs Decree.

The *adviescollege toetsing administratieve lasten (Actal)* [Advisory Board on Administrative Burden] decided in its meeting of 21 November 2002 not to select the present Decree for an Actal test of the consequences for businesses in terms of administrative burden.

The Minister of Health, Welfare and Sport,

A.J. de Geus