Regulation of the Minister of Health,
Welfare and Sport of ____ November 2002,
GMT/BMC 2340685, containing policy guidelines
for the decision on applications for Opium Act
exemptions (Policy guidelines Opium Act
exemptions)

Reference The Hague, the Netherlands

GMT/BMC 2340685

The Minister of *Volksgezondheid, Welzijn en Sport* [Health, Welfare and Sport],

The Minister of Health, Welfare and Sport

Decrees:

Adopts the following policy guidelines:

1. The Opium Act and Opium Act exemptions

The Opium Act makes it illegal to bring into and outside the territory of the Netherlands, grow, prepare, treat, process, sell, supply, provide, transport, possess and manufacture substances falling under the regime of List I or List II of the Act (Opium Act drugs). Only pharmacists, doctors, dentists and veterinary surgeons may perform certain acts with Opium Act drugs without an exemption within the normal practice of their professions.

Under Article 5, second paragraph, of the Opium Act, some institutions (for example, those providing care for addiction) may also perform certain acts with Opium Act drugs without an exemption insofar as they have been designated by an order in council. An Opium Act exemption is necessary, however, to conduct scientific research (for example, clinical trials). Under Article 6 of the Opium Act, the Minister of Health, Welfare and Sport may grant an application for an exemption to perform one or more acts with Opium Act drugs. In the light of Article 8 of the Opium Act, these exemptions may only be granted for certain purposes and to certain persons or institutions. These policy guidelines have been drawn up with a view to deciding applications for an Opium Act exemption. They further develop the criteria mentioned in the Act which will be applied in the decision on an application for an exemption. They also indicate the restrictions and conditions which may be attached to an exemption. The fees which are associated with obtaining an exemption are also mentioned.

2. Applying for Opium Act exemptions

A distinction is made between, on the one hand, applications for an Opium Act exemption regarding cannabis, cannabis resin or the preparations thereof and, on the other hand, other applications. Applications for an Opium Act exemption regarding cannabis, cannabis resin or the preparations thereof will be handled by the *Bureau voor Medicinale Cannabis (BMC)* [Office of Medicinal Cannabis],

which, since 1 January 2001, has been acting with the authority of a government agency within the meaning of Article 28 in conjunction with Article 23 of the Single Convention on Narcotic Drugs (1961).
To apply for an Opium Act exemption regarding cannabis, cannabis resin or the preparations thereof, a fully completed application form with the requested annexes needs to be sent in. An application form may be obtained from the Ministry of Health, Welfare and Sport, Office of Medicinal Cannabis of the *directie Geneesmiddelen en Medische Technologie (GMT)* [Department of Pharmaceutical Affairs and Medical Technology], Room A-1412, Postbus 20350, 2500 EJ The Hague.
To apply for an Opium Act exemption regarding other Opium Act drugs besides cannabis, cannabis resin or the preparations thereof, an application form may be obtained from the *CIBG* [Central Health Professions Information Centre], Pharmacy Technology Department, Room M-0306, Postbus 16114, 2500 BC The Hague.
If applications are made both regarding cannabis, cannabis resin or the preparations thereof as well as regarding other Opium Act drugs, these will be considered two separate applications, to be handled separately. If granted in such a case, separate Opium Act exemptions will be issued.

3. Purposes for which an Opium Act exemption may be granted

Article 8 of the Opium Act states when an exemption may be granted. This is possible if the applicant has demonstrated:

a. that this will serve the interest of public health or that of the health of animals (article 8, first paragraph, under a);
b. that he needs the exemption to perform scientific or analytical chemical research or for instructional purposes, insofar as the interest of public health does not dictate otherwise (article 8, first paragraph, under b), or
c. that he needs the exemption to bring into or outside the territory of the Netherlands, grow, prepare, treat, process, sell, supply, provide, transport, possess and manufacture Opium Act drugs, and he has an agreement with:
    1. another person who has an exemption;
    2. a pharmacist or a doctor operating a pharmacy;
    3. a veterinary surgeon;
    4. a designated institution or person;
    5. a holder of an exemption granted in another country to import the drugs in question into that country, insofar as the interest of public health does not dictate otherwise (article 8, first paragraph, under c)

An exemption may also be granted if the applicant needs this to grow cannabis pursuant to an agreement with the Minister of Health, Welfare and Sport (see under Point 6).
Of course, the purpose indicated may never be contrary to other laws, regulations or policy guidelines.

4. Criteria attached to the aforementioned purposes

The criteria which will be applied in the decision on an application for an exemption are the following.

Re: 4, under a.

Generally speaking, Opium Act exemptions in the interest of public health or of the health of animals will fall under the general exemption for, for example, doctors, veterinary surgeons, pharmacists or special institutions. Applications for acts with Opium Act drugs may also be filed, however, which do

not fall under this exemption, but are nevertheless deemed to be in the interest of public health or that of the health of animals. In that case, an exemption may be granted under this category.

Re: 4, under b.
With regard to an application for an Opium Act exemption to perform scientific or analytical chemical research or for instructional purposes, the necessity of the permit must be demonstrated. In principle, if there are alternative options – that is, the purpose may reasonably be achieved without using Opium Act drugs -, necessity has not been demonstrated.
With regard to an application to perform scientific or analytical chemical research, the purpose must be supported in a scientific manner (for example, through a scientific research protocol for a clinical study or for improving plants).
If applicable, various quality requirements, such as GMP, GLP, GCP or GCLP, or various certification standards (for example, ISO and NEN) must be met. If these cannot be met (or not yet), this has to be supported. If experimental subjects will be involved in the research, a statement must be submitted showing that the experimental design has been reviewed favourably by a competent medical-ethical commission.
A standardised preparation (standardised, for example, regarding one or more of the substances contained) must be used. It must be indicated how the preparation will be prepared and from whom this preparation will be purchased.

The following distinction will apply to applications for instructional purposes:
1. Training dogs to detect narcotics
   Opium Act exemptions to train dogs to detect narcotics will only be granted for detection of narcotics in the Netherlands. Only the police and customs are authorised to engage in these detection activities. They train dogs internally in this regard.
2. Other instructional purposes.

Re: 4, under c.
The commercially-related purposes have been included under c. This provision pertains to, for example, natural or legal persons that trade in Opium Act drugs as a fixed business activity (such as for production or distribution) or to natural or legal persons that wish to conclude a once-only contract to supply an Opium Act drug. Under c, there is a list of those with whom such a contract may be concluded. The possibility is created under 1 to grant exemptions for mutual trade, for example, between traders and researchers. Under 5, the Convention requirement is implemented that an export exemption may only be granted if this is to supply someone in a foreign country who already has an import permit for that country.

5. Growing cannabis
An exemption is necessary under the Opium Act to grow cannabis. BMC is the institution which grants all exemptions regarding cannabis on the Minister's behalf. BMC, which, since 1 January 2001, has been acting as a government agency within the meaning of the Single Convention on Narcotic Drugs, has a monopoly with regard to the import and export of, wholesale trade in, and maintenance of stocks of cannabis and cannabis resin, and must purchase all crops and actually seize these.
BMC's task is two-fold. On the one hand, BMC must research or arrange for research regarding whether cannabis or cannabis products may be used as medicines; on the other hand, BMC must provide pharmacies in the course of 2003 with medicinal cannabis, so that patients can obtain this with a doctor's prescription.
For the first task, developing a medicine, clinical research is not only necessary, but also scientific research into the plant cannabis and into the production process. In the case of scientific research, not

only must the criteria referred to in article 8, first paragraph, under b, of the Opium Act, be met, it must also be demonstrated that the research serves a need, given the state of the art.
For the second task, supplying pharmacies, a small number of growers will be approached. In deciding on exemption applications regarding cannabis under Article 8, second paragraph, of the Opium Act, BMC will apply the following criteria. In that case, Article 8i, first paragraph, will be applicable: an exemption will only be granted if BMC concludes a contract to grow and supply cannabis. Thus, growers directly supplying the market will not be granted an exemption to grow cannabis.
In connection with administrative prevention of crime, applicants may be subjected to a security screening, which will include a request to submit administrative and financial data through annual reports with explanations and a so-called Declaration concerning the conduct of the applicant or – in the case of legal persons – of the legal person's directors and actual managers. For a proper evaluation, additional information will have to be provided on request regarding the data supplied. Once the Public Administration Probity in Decision-making Act (the BIBOB Act) has taken effect, probity screening within the meaning of that Act can constitute part of the screening. ′
If growers apply for an exemption, extensive screening of the applicant will be part of the procedure. In some cases, the Office of Medicinal Cannabis may decide to forego the screening if an application from an institution is involved whose trustworthiness may be assumed beforehand. If necessary, other natural or legal persons involved in the application or in growing the cannabis will be screened as well. This will enable the Office of Medicinal Cannabis to make the risk of cannabis and other Opium Act drugs disappearing to illegal markets as small as possible. The purpose of the screening is to limit the Minister's political risk as much as possible.
All applicants must meet special requirements relating to security around the cannabis, for example, regarding transport and storage. These requirements will be determined on a case-by-case basis and will be recorded contractually.
In addition, BMC will impose special requirements for prospective growers in terms of quality. Hence, the cannabis to be supplied must be produced according to the Regulations for Cultivating Cannabis for Medicinal Purposes (annex), or requirements which are equivalent in BMC's judgment. The Regulations are derived from the Points to Consider on Good Agricultural and Collection Practice for Starting Materials of Herbal Origin (EMEA/HMPWP/31/99 rev. 2) of the Working Group on Herbal Medicinal Products of the European Medicines Evaluation Agency (EMEA). The regulations help ensure that the product's quality is consistent. Depending on the further treatment, the product must also meet other specifications. For example, the production method must guarantee that the product contains a consistent level of active substances.
The prospective grower must also have a quality file for the product. The product characteristics must be carefully recorded in that file. It must include a description of what the growing conditions are (for example, intensity of light, temperature, dampness and fertilisation), what the specifications are of the product grown under these conditions and how there can be monitoring that the product meets these specifications. These requirements regarding composition and the possibility of monitoring are conditions for being able to develop a reproducible medicine. In addition, a prospective grower must be able to demonstrate that he is able to deliver such a standardised product within a reasonable time.
In the event that they are equally suitable, not all prospective growers will obtain an exemption. BMC will compare the growers' offers with each other, with aspects such as the degree to which the requested specifications can be met and the most favourable delivery terms and conditions being decisive, as well as the security which may be provided that none of the cannabis will end up in illegal circuits.

6. Restrictions and conditions in granting an Opium Act exemption

An exemption may be granted which is subject to restrictions. Moreover, conditions may be attached to an exemption. The restrictions and conditions will depend on the nature of the application and may

differ in each case. Each Opium Act exemption will include restrictions and conditions regarding the number and type of Opium Act drugs to which the exemption relates, the acts which may be performed, the purpose for which the exemption has been requested, adequate security regarding the Opium Act drugs present, proper records, cooperation with the Health Inspector in monitoring compliance with the exemption and the duration of the exemption.
Additional restrictions and conditions will apply to cannabis growers. For example, growers will be required to sell their entire harvest to BMC. This will be verified by comparing the size of the harvest with the size of the built-up land, the number of plants and through other monitoring measures. This will be further fleshed out in a contract that BMC will conclude with the growers concerned. Another condition that will be imposed on the exemption is that the unnecessary crops be destroyed.
The *Inspectie voor de Gezondheidszorg* [Health Care Inspectorate] will make visits to growers who have received an exemption in connection with monitoring the conditions imposed on the exemption. BMC employees will also visit companies to ensure that there is compliance with the agreed contract terms and conditions.

7. Provisions regarding the exemption for import and export

7.1 Generally

With regard to bringing Opium Act drugs into or outside the territory of the Netherlands (Article 2, under A, and 3, under A, of the Opium Act), an import or export exemption is required. Applications for an import or export exemption will be handled by a special inspector of the Health Care Inspectorate. This inspector will have authority to act for the Minister of Health, Welfare and Sport.
In handling applications for an import and export Opium Act exemption, a distinction will be made between an application regarding an Opium Act drug from List I (Article 2 of the Opium Act) and an application regarding an Opium Act drug from List II (Article 3 of the Opium Act). An exemption will always relate to drugs from either List I or List II; a combined exemption will not be possible. This means that the fee referred to under Point 10 of these policy guidelines will be charged per exemption.
An exemption will apply solely to a particular lot or lots of Opium Act drugs as described in the application. The import or export act must be completed within six months after the exemption is granted; if this is not the case, a new exemption will have to be requested.
Applications for an exemption to bring Opium Act drugs into or outside the territory of the Netherlands must be directed to: Health Care Inspectorate, Opium Act Matters Section, Postbus16119, 2500 BC The Hague.

7.2 Data to be provided in connection with import

If the exemption is intended to bring Opium Act drugs into the territory of the Netherlands, the following data must be provided:

- for each drug to be brought into the territory of the Netherlands, the name, the quantity and its pharmaceutical form; if the drug to be imported concerns a preparation with a special name, that name must also be stated;
- for each drug to be brought into the territory of the Netherlands that comes from a country requiring an export document for the export, a copy of that document;
- name and address of the person, including legal persons, outside the Netherlands from whom the drug or drugs will be purchased;
- the time period within which the drug or drugs will be brought into the territory of the Netherlands;
- a statement of the type of transport by which the drug or drugs will be transported to the Netherlands.

7.3 Data to be provided in connection with export

If the exemption is intended to bring Opium Act drugs outside the territory of the Netherlands, the following data must be provided:

- for each drug to be brought outside the territory of the Netherlands, the name, the quantity and its pharmaceutical form; if the drug to be exported concerns a preparation with a special name, that name must also be stated;
- a document issued by the competent government agency in the country to which the drug is to be exported, to the effect that the drug may be imported there;
- name and address of the person, including legal persons, or the government agency outside the Netherlands which will purchase the drug or drugs from the applicant;
- -the statement "export to customs warehouse", in the event that storage in a customs warehouse in the country of destination has been approved, as evidenced by a declaration placed on the import document by the competent government agency in the country of destination;
- the time period within which the drug or drugs will be brought outside the territory of the Netherlands;
- a statement of the type of transport by which the drug or drugs will be brought to the country of destination.

8. Varying provisions regarding the exemption for import and export of cannabis and cannabis resin

Varying provisions will apply for the import and export of cannabis and cannabis resin (Article 3, under A). Under Article 8i, fifth paragraph, under a, only the Minister of Health, Welfare and Sport has authority to import and export. This provision means that a person wishing to import or export cannabis or cannabis resin must enter into an import or export agreement with the Office of Medicinal Cannabis, acting on the authority of the Minister. To enter into an import or export agreement with the Office of Medicinal Cannabis, the data mentioned in Section 8.2 or 8.3 must be provided. In connection with this agreement, the fee owed for the import or export (see Point 11) will be passed on. In practice, the person wishing to import or export will already have an Opium Act exemption from the prohibitions of Article 3, under B to D inclusive: preparation, processing, treatment, provision, transport, possession, manufacturing. In such cases no in-depth screening will be conducted.

9. Denial or revocation of Opium Act exemption

An exemption may be denied or revoked. The reasons for denial or revocation are listed in Articles 8b to 8e inclusive of the Opium Act.

10. Fees

Fees will be set by ministerial regulation, the Opium Act Implementation Regulations. The point of departure in calculating the fees incurred to obtain an Opium Act exemption is that the user pays. These fees will be subject to change if the costs related to granting the exemption change. At the time these policy guidelines take effect, a fee of EUR 1225 will be charged to process an application for an exemption or a modification, supplementation or extension thereof, and an annual fee of EUR 350 will be charged during the term of the exemption. In deviation from the foregoing, in the case of an exemption for bringing a drug into or outside the territory of the Netherlands, a fee of EUR 40 will be charged to process an exemption application.

11. Final provision

These policy guidelines shall be cited as: Policy guidelines Opium Act exemptions. These policy guidelines will take effect at the same time that the Act amending the Opium Act (Act of 13 July 2002, *Stb.* [Bulletin of Acts and Decrees] 2002, 520) takes effect.

12. Repeal of earlier policy guidelines

The policy guidelines of 11 May 1998, *Stcrt.* [Government Gazette] 1998, 92, amended on 18 May 2001, Stcrt. 2002, 96 and on 6 December 2001, Stcrt. 2002, 237, are repealed.

The Minister of Health, Welfare and Sport

A.J. De Geus

Annex: Regulations for Cultivating Cannabis for Medicinal Purposes