

Ministry of Health, Welfare and Sport



Dr Herbert Schaepe,
Secretary of the International Narcotics Control Board,
Vienna International Centre,
P.O. Box 500,
1400 Vienna
AUSTRIA

| | | | |
|---|-------------|----------------|----------------------|
| Our reference | Information | Telephone no. | The Hague |
| GMT/BMC 2321164 | | +31.70.3406970 | 22th of October 2002 |
| Subject | | Enclosure(s) | Your reference |
| Medical prescription of heroin and cannabis | | | INCB-NAR 071/02 |

Dear Dr Schaepe,

In your letter ref. INCB-NAR 071/02 of 6 June 2002 you informed me that the International Narcotics Control Board is concerned at the possible proliferation of heroin trials and at the medical prescription of cannabis in the Netherlands.

In reply I would like to give you the following information on the current situation, and in so doing allay the INCB's concern.

Medical co-prescription of heroin

By letter of 8 April 2002, the former Minister of Health, Welfare and Sport, Ms E. Borst-Eilers, informed you of the government's position on innovation in the treatment of heroin addiction. However, as you may know, the general election held in the Netherlands in May led to a change of government.

Two debates have since been held in parliament on the former government's position. They resulted in the decision to restrict the medical co-prescription of heroin to the treatment units that took part in the randomised controlled trials. Parliament also expressed an interest in the effects of psychosocial care combined with co-prescription treatment. This element was not included in the trials, since their purpose was only to study the effects of prescribing heroin. Participants were of course able to obtain psychosocial care as usual.

A new project will be launched in the next few months to study the impact of psychosocial care. The results achieved with new patients will be compared with those achieved with patients who participated in the trials. The number of treatment slots will remain unchanged, and the results of the project will be published within a year of its launch.

P.O. Box 20350
2500 EJ THE HAGUE
The Netherlands
Telephone +31.70.3407911
Telefax +31.70.3407834

Address:
Parnassusplein 5
2511 VX THE HAGUE
The Netherlands

All correspondence
addressed to the postal
address quoting date and
reference of this letter.

Internet address:
www.minvws.nl

In the interim, I am planning to set up an independent committee to examine in more detail the many questions to which the possible introduction of heroin on prescription gives rise. Within six months, this committee will submit a proposal to the government on responsible, permanent, high-quality introduction of heroin treatment in the Netherlands, the results of which can be evaluated.

The government will then determine its position on continuing the medical prescription of heroin and present its proposal to parliament.

Medical prescription of cannabis

The government pursues a twin-track policy on medicinal cannabis. Its primary aim is to promote the development of at least one medicine from legally grown cannabis, to be registered by the Medicines Evaluation Board. To this end, the government set up the Office of Medicinal Cannabis in 2000. The Office arranged for a legal supply of medicinal grade cannabis to enable clinicians to carry out high quality trials. By giving priority to clinical research, the Dutch government fully subscribes to the need for evidence-based use of cannabis.

Some important progress has already been made in developing a medicine. A pharmaceutical company in the Netherlands is preparing a research programme that may lead to a registered product. This project has been recognised by the European Council under the Eureka subsidy programme. The Netherlands Organisation for Applied Scientific Research (TNO), a highly respected, government-subsidised institute, has launched "from plant to medicine", an international project in which many scientific institutes are working together to identify standardised cannabis extracts and appropriate pharmaceutical dosage forms. A clinical study on the effects and safety of administering cannabis products to MS patients orally was carried out in a Dutch hospital in 2000 and will be followed by a study on the effects of inhaling the drug in 2002.¹ The Office of Medicinal Cannabis supports all these projects. An intermediary organisation for research and development in medical science (ZONMw) will be contracted to evaluate the need for further research.

Many scientific studies are being carried out internationally and more and more evidence is being gathered to support the use of cannabis in clinical practice. In a report published in 1999, the Institute of Medicine (IOM), under the authority of the White House Office of National Drug Control Policy (ONDCP), emphasizes the need for evidence-based medicine as opposed to belief-based medicine, but also found "substantial consensus among experts in the relevant disciplines on the scientific evidence about potential medical uses of marijuana".² An article in *Drugs* discusses the therapeutic value of cannabinoids in treating a number of diseases. The authors come to the conclusion that cannabis has a potential for clinical use, although this is often obscured by unreliable and purely anecdotal reports. Another conclusion is that, apart from the risks attached to smoking, the safety profile of cannabis is fairly good.³ In a review of the scientific literature commissioned by the British Department of Health (DOH) cannabis and some cannabinoids are considered to be effective anti-emetics and analgesics. Evidence was also found for symptom relief and improved well-being in selected neurological conditions, AIDS and certain cancers.⁴ The exact therapeutic value of cannabis compared to that of conventional medicines is still a subject of discussion in scientific publications. Though it will probably remain so for many years to come, cannabis clearly has potential for various indications.

Greater knowledge of cannabis pharmacology and therapeutic applications may ultimately lead to the development of a medicine. For several years now, nabilone has been registered in some countries as an anti-emetic drug in chemotherapy. GW Pharmaceuticals plc (UK) has

commenced phase III trials with a cannabis preparation to be used sublingually. The development of a medicine is complex and time consuming. It will take at least five years before the Medicines Evaluation Board can register a product based on cannabis. For the pharmaceutical industry, this is not exceptionally long. However, for the general public, the matter is more urgent. This prompted the government to add a second track to its policy, and to make cannabis legally available to patients waiting for a medicine to be developed.

A substantial number of patients already uses cannabis and considers it to be a useful medication in disease management. These are not isolated cases. By analysing the market for medicinal cannabis, the Office of Medicinal Cannabis estimated that approximately 10,000 people in the Netherlands are already using cannabis for medical purposes. They buy it at coffee shops, from patients' associations that act as buyers' clubs, or even from pharmacies. In many cases, doctors are aware that their patients are using cannabis and support them by prescribing it. Marinol (synthetic THC), the legal alternative, is not registered in the Netherlands but can be obtained on special import licence granted by the health care inspector. However, it is considered less effective than cannabis and is very expensive for the patient. Doctors and patients therefore prefer cannabis. Although it is still illegal, cannabis apparently has such a therapeutic value that patients, doctors and pharmacists are willing to break the law.

Legal implications aside, the current situation is also undesirable from the viewpoint of quality. The composition of the cannabis that patients buy from illegal sources is unknown, and it may be contaminated, for instance by pesticides. What is more, medical and pharmaceutical patient care cannot be guaranteed under the present circumstances. If cannabis is made legally available as a prescription drug, the Office of Medicinal Cannabis will act as the wholesaler according to the Single Convention and the pharmacies will be supplied with cannabis that meets all pharmaceutical standards. Doctors and pharmacists will be able to supervise their patients in a more professional way.

An important task for the Office of Medicinal Cannabis is to provide doctors and pharmacists with sound information about the medicinal use of cannabis, stressing that it is not a panacea or cure-all drug, despite the many indications that have been reported. The indications that are labelled as "most promising" by the British Medical Association will be communicated extensively.⁵ Indeed doctors are free to prescribe cannabis for any indication, as you stated in your letter. In fact they have this prescribing freedom for any other drug. Making rational choices in pharmacotherapy is considered to be the doctors' and pharmacists' professional responsibility. No exception will be made for the medicinal use of cannabis. Abuse of cannabis by doctors or pharmacists can be prosecuted by the medical disciplinary court and can lead to claims for compensation under civil law. The Opium Act and other pharmaceutical legislation must warrant a safe use of medicinal cannabis. This implies, for instance, that a special Opium Act prescription will be required. The prescription and use of medicinal cannabis will be carefully monitored and practical experience may provide further input for research.

Under this second track policy, cannabis will be delivered to pharmacists as a starting material. The pharmacist may then dispense it to patients, either as it is or in a suitable pharmaceutical dosage form. Cannabis will thus have the status of a magistral, extemporaneous preparation and will form no exception to normal practice in the Netherlands, where unregistered, pharmacy-made drugs make up a substantial part of pharmacotherapy. This practice is in conformity with EU pharmaceutical legislation. The amount of cannabis needed is roughly estimated at 200 kilos in the first year that distribution to pharmacies will start.

The measures described above are now being fleshed out by the Office of Medicinal Cannabis, and the Opium Act will probably be amended before the end of 2002. Growers of medicinal cannabis are now being asked to quote prices and distribution channels are now being prepared. Policy will be in place in 2003.

Although the Netherlands are the first government to regulate the distribution of cannabis to pharmacies by the Office of Medicinal Cannabis as a government agency, other European countries, Canada, several states of the USA and some Asian countries also allow the use or the culture of cannabis for medical purposes.

To conclude, the aim of Dutch policy is evidence-based therapy with medicinal cannabis. In the near future, patients may be treated with cannabis of standardised quality from their pharmacy, but only on doctor's prescription and in compliance with the Opium Act. The development of a registered medicine based on cannabis still has the highest priority.

Yours sincerely,

Clémence Ross-van Dorp
State Secretary of Health,
Welfare and Sport

1. Killestein J, Hoogervorst ELJ, Reif M, et al., Safety, tolerability, and efficacy of orally administered cannabinoids in MS. *Neurology* 2002; 58; 1404-1407.
2. Joy JE et al., Executive summary (page ES.2). From: *Marijuana and Medicine, Assessing the Science Base*. Institute of Medicine, National Academy Press, Washington D.C., 1999 (www.nap.edu/html/marimed/)
3. Williamson EM, Evans FJ, Cannabinoids in Clinical Practice. *Drugs* 2000; 60(6); 1303-1314.
4. Robson P. Therapeutic Aspects of Cannabis and Cannabinoids. *British Journal of Psychiatry* 2001; 178; 107-115.
5. British Medical Association, *Therapeutic uses of cannabis*. Amsterdam: Harwood Academic Publishers, 1997.