Ministry of Health, Welfare and Sport
Office of Medicinal Cannabis

United Nations International Narcotics Control Board
Mr Herbert Schaepe, Secretary of the Board
Vienna International Centre
P.O. Box 500
A-1400 VIENNA
AUSTRIA

Our reference	Information	Telephone no.	The Hague
CIBG/BMC 2413726	Ms N.V. Barkmeijer	+31 70 340 5863	24 September 2003
Subject		Enclosure(s)	Your reference
Use of cannabis for medicinal purposes in The Netherlands		9	INCB-NAR 210/03

Dear Mr Schaepe,

Thank you for your fax of 9 September 2003, ref. INCB-NAR-210/03, requesting information on the distribution of cannabis to pharmacies in the Netherlands. I would inform you as follows.

- The Office of Medicinal Cannabis (OMC) sells the following two products as pharmaceutical starting materials:
  - Cannabis flos variety Bedrocan (per 5 grams)
  - Cannabis flos variety SIMM 18 (per 5 grams)
- Both products consist of the dried and gamma-irradiated flowers of Cannabis sativa L. Crops are cultivated according to the standardised procedures prescribed in Good Agricultural Practices (GAP) (enclosed). The GAP rules are based on the EMEA Guidelines, but they also include rules for standardisation and the prevention of diversion. The other parties involved in the production process are required to comply with Good Manufacturing Practices. They are all audited by the OMC.
- The laboratory Farmalyse BV in Zaandam analyses samples from each batch to establish identity, strength (dronabinol, cannabidiol and fingerprint), decomposition products (e.g. cannabinol), contaminants (heavy metals, pesticides, microbiology) and moisture content. In the future they will also be tested for cannabichromene and cannabigerol content, and a distinction will be made between dronabinol in acid form and in free form.
- I am also enclosing copies of the release certificates for both products, giving the release specifications. The forms are in Dutch, but I trust that you will be able to understand them. The specifications are in compliance with the requirements of the European Pharmacopoeia for inhalation preparations and herbal teas. As regards permissible deviations for the active constituent content, at present we are aiming at a range of 85% to 115% of the declared values, although we hope to narrow this to a range of 90% to 110% at a later stage.
- We have published guidelines for health care professionals with the format of the Part IB of registered medicines (enclosed). We recommend using cannabis in a nebuliser or as a herbal tea, both of which, along with smoking, are the normal methods of administration. However, we do not recommend smoking because of the associated health hazards (polycyclic aromatic carbohydrates and carbon monoxide).

P.O. Box 16114
2500 BC THE HAGUE
The Netherlands
Telephone +31.70.3405113
Telefax +31.70.3407426

Address:
Wijnhaven 16
2511 GA THE HAGUE
The Netherlands

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

Internet address:
www.minvws.nl

- The guidelines also contain a warning against driving under the influence of cannabis. Dutch law prohibits driving under the influence of any substance that impairs driving ability.
- The Royal Dutch Association of Pharmacists (KNMP) has published a patient information leaflet based on the guidelines for health care professionals. It has also drafted a protocol for pharmacies receiving prescriptions. Unfortunately both are available in Dutch only (enclosed).

You may also be interested to know about the production and distribution processes.
The parties involved are two growers, a laboratory, a transport company, a gamma-irradiation firm and a company responsible for packaging and logistics.
The growers produce one batch a month and keep records of the yield per plant (fresh weight, dried weight and flower yield), which must be constant on average. The OMC collects the harvest from them every month and counts the plants. The harvest is then weighed and a sample is sent to the laboratory. The remainder is packaged in cardboard boxes, which are sealed with uniquely numbered safety tape and then sent for gamma irradiation. The boxes are irradiated without being opened. The are forwarded to the packager on the same day and stored in a safe. There, the cannabis is packed into five- gram containers, which are subsequently sealed (see enclosure). The OMC checks the average net weight of the containers against the total of cannabis received by the packager, and approves the batch for release. The packager is also responsible for logistics. I would emphasise that the cannabis is state property from the time it is collected from the growers until it is sold to a pharmacy.

I hope I have answered all your questions.

Yours sincerely,

L.J.S. Wever, LL.M.
Director, Medicines and Medical Technology Department.