



International Conference on Medicinal Cannabis

**22nd and 23rd November 2001
The Hague**

Report

Preface

Herewith, you will find the minutes and the final version of the reader which was used to prepare for the international Conference of Medicinal Cannabis policy which was held in The Hague, the Netherlands, on 22 and 23 November.

Although this conference was an initiative of the Dutch government, it was not a particular Dutch conference. All the participating countries contributed to the contents of the conference and to the reader. It is important to understand the political environment and cultural circumstances of a country to understand why and how policy is being made on a certain topic. The conference (the presentations, the discussions held and the reader) gave us this opportunity.

The conference had not an official status. This means that it can be that views represented in the minutes and the reader can deviate from the official policies of the attending countries.

I want to thank the participants to the conference and the contributors to the reader once again for their effort. I found it a productive meeting and I hope it has been the start for further cooperation.

Mr. Willem K. Scholten, MSc., Pharm., MPA.
Head, Office of Medicinal Cannabis,
Ministry of Health, Welfare and Sport,
The Netherlands

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Participants to the conference

See annex for titles and addresses

Chairperson:

Mrs. Annemiek van Bolhuis (Deputy director, Ministry of Health, Welfare and Sport
Department of Mental Health and Addiction policy, the Netherlands)

Vice-chairperson:

Mrs. Cindy Cripps-Prawak (Director, Office of Cannabis Medical Access, Health Canada,
Canada)

Delegates

Mrs. Birgit Frommer	Vienna General Hospital, Abt. Für Anaesthesie u. Allg. Intensivmedizin B, Austria
Mr. Bernard Vandenbosch	farmaceutical inspector, Ministry of Health, Belgium
Mr. Frans Gosselinckx	counsellor, Office of the minister of Health, Belgium
Mrs. Cindy Cripps-Prawak	director office of cannabis medical access, Health Canada
Mrs. Suzanne Desjardins	Manager, Evaluation and Research Coordination Division, Office of Controlled Substances, Health Canada
Mr. Bertrand Lebeau	president French Association for Harm Reduction Service d'Infectiologie de l'Hopital Saint Antoine, France
Mr. William Lowenstein	director Hopital Européen Georges Pompidou (HEGP) Centre Monte Cristo, Médecine des Addictions, France
Mrs. Carola Lander	Federal Institute for Drugs and Medical Devices - Federal Opium Agency, , Germany
Mr. Horst Möller	Federal Ministry of Public Health, Germany
Mr. Willem Scholten	head of the Office of Medicinal Cannabis, Ministry of Health, Welfare and Sport, the Netherlands
Mrs. Ingrid Horst-Vermaas	senior policy advisor, Ministry of Health, Welfare and Sport, Office of Medicinal Cannabis, the Netherlands
Mrs. Myra Klee	policy advisor, Ministry of Health, Welfare and Sport Office of Medicinal Cannabis, the Netherlands
Mrs. Annemiek Smulders	policy advisor, Ministry of Health, Welfare and Sport Office of Medicinal Cannabis, the Netherlands
Mr. Jorg Morland	professor of Pharmacology, MD, National Institute of Forensic Toxicology, Norway
Mr. Tomoz Koren	Konoplja.Org (NGO), Slovenia
Mr. Matej Kosir	Government Office for Drugs, Slovenia
Mr. Christian Stamm	deputy head division of pharmacy, Swiss Federal Office of Public health, control and licences section, Switzerland
Mr. John Gerrard	Home Office Drugs Branch, United Kingdom

Abstract of the conference

To the International Conference on Medicinal Cannabis in The Hague, the Netherlands, on 22 and 23 November 2001 participated delegations of the following countries: Austria, Belgium, Canada, France, Germany, The Netherlands, Norway, Slovenia, Switzerland and the United Kingdom.

In the first session of the conference the participating countries presented their views and their activities on the subject of the conference. They all agreed on the necessity to have research on the efficacy and safety of cannabis. They also agreed that the long-term objective should be to develop a medicine that complies to the same standards, as other medicines have to comply to.

The conference found that –regarding the subject- there are differences between them, but also similarities.

The situation regarding the use of cannabis plant and or cannabis extracts

All countries allow clinical trials or will allow them in the near future.

Clinical trials are going on in the UK, Germany, the Netherlands and Switzerland. Canada is funding two trials but they have not started yet. Canada allows the use of medicinal cannabis already; the Netherlands will do so in the near future. Switzerland plans to allow limited use. In Norway and Slovenia is no or almost no discussion on the issue. Germany would allow the medical use of cannabis extract if preconditions are met. In France there was a discrepancy until last year between the public opinion supporting the medicinal use and the politicians who did not.

Regarding the use of pure cannabinoids (mainly dronabinol and nabilone) the conference found:

In Germany and Austria dronabinol is available for magisterial preparation. In most countries the special use of dronabinol (Marinol) and nabilone (Cesamet) are allowed on a special allowance of the authorities, but it is not used in most countries very frequently. In Canada these products are licensed medicines.

The situation regarding the cultivation of cannabis and the manufacturing of products out of it (as the legal definition in the Convention) is:

Canada and the Netherlands have a national agency (aside from US' NIDA) for the control of cultivation of cannabis. France is well positioned to create a national agency, if required. Production for research purposes is going on in the UK. It is ongoing or planned in Canada, Germany and the Netherlands for either research purposes, therapeutic purposes or for the production of dronabinol.

Plant based pharmaceutical dosage forms are developed at GW Pharmaceutical (THC/ CBD) and Merck & Co UK (natural dronabinol) in the UK, at the Berlin Institute for Oncological and Immunological Research in co-operation with the Swiss. In Germany several companies are developing an extract as starting material for magisterial preparation. In the UK there is cannabis cultivation for the purposes of developing cannabis based medicine.

On public opinion:

Some countries have the problem that some citizens use the medicinal cannabis discussion for their purpose of legalising recreational use of cannabis. As a consequence most countries respond to that by separating the discussion in two issues (medicinal and recreational use). Aside from this reason they agree that these two issues are separate indeed.

Concerning article 28 of the Single Convention on narcotic drugs

Article 28 (in connection to article 23) of the Single Convention requires a government agency for cannabis as soon as a country admits the culture of cannabis. This agency should at least

- be the licensing authority that buys all crops,

- have a monopoly on the import and export of cannabis and
- have a monopoly on the wholesale of it.

On the question whether a country needs to establish a national agency there are two different views. Some countries have the opinion that an agency is required as soon as a country allows the culture. Other countries have the standpoint that countries are exempted from this requirement as long as they are in the stage of cultivation for clinical trials and not trade. This view has been put to the INCB. It is expected that the INCB will respond soon. It was discussed whether a joint action for clarification from the INCB on this point would be undertaken, but it was decided against.

The delegates agreed that if a country does not want to grow the cannabis itself, it can buy and import cannabis for its needs at the agencies of other countries that did establish an agency. Countries exporting cannabis to other countries should do this always in concert with the authorities of the importing country, as already required by the importing and exporting procedures for narcotics of the Single Convention.

There was also a discussion on the possibility of establishing a European agency, but this seems amongst other things not to be possible because of the fact that individual countries are parties to the Convention and not the EU.

Discussions on product standardisation, quality and so on

All participants stressed the importance of product standardisation. It has the aspects of product quality, and reproducibility in itself. It is a regular requirement made to all medicinal products.

It would be good if the products and methods used to standardise were universal to make the outcomes of clinical trials in different countries comparable to each other.

Canada has been working already on the chemical-technical part but is not yet ready with it. Germany made monographs for the plant and for dronabinol. Very soon there will be a monograph on cannabis extract too. All these German monographs will be published respectively their drafts. The Netherlands need a monograph for cannabis and, if not yet available, will have one made. It is assumed that GW Pharmaceuticals will have similar documentation but probably it is proprietary information.

The participants all agreed that it is useful to have a common monograph to describe test methods and requirements for medicinal cannabis. The conference considered that it is better to make a common document on quality of cannabis in this early stage of research, than to have each country make its own testing methods first (which will not be interchangeable), and have it harmonised after many years. The Commission of the European Pharmacopoeia may play a role in this.

Such a monograph should be comparable to a pharmacopoeia monograph. The monograph should describe uniform testing methods:

- to make the results of testing comparable to each other
- to give boundaries for approval

Issues to be dealt with are among others:

- content of specific cannabinoids
- fingerprinting methods for verifying plant varieties
- absence of pesticides
- absence of heavy metals
- limits of deterioration products
- moist content

The monograph (or monographs) should be applicable on all thinkable cannabis varieties for all applications (e.g. extraction purposes for whole cannabis extract, as well as isolated cannabinoids; use as simplex for instance for making tea or for vaporising.)

An other aspect of standardisation and varieties is the fact that the experience with cannabis so far is that not all varieties are equally good in different conditions. So the challenge is to find the optimal combination of variety and condition to treat. Much information is based on the illicit experience of users; in most cases it is not science-based and/or based on case reports.

The conference also addressed the placebo issue. It is hard to find a placebo for inhalation of the plant. The Netherlands develop a placebo plant in which are no or almost no cannabinoids present which will still have the characteristic smell. Suggestions were made to use male or young plants for this purpose.

Clinical trials

The conference made an inventory of the clinical trials going on and discussed possible priorities for research (see annex with the complete overview of ongoing clinical trials). It concluded that there is no sufficient scientific evidence as yet for proving the efficacy of medical use of cannabis. However, there are enough indications that justify further clinical research.

The conference was informed about a paper on clinical trials describing research priorities for certain conditions. This paper will be presented on the responsibility of the Netherlands to the EU scientific conference of 25 February 2002. After hearing the comments of the conference it will be rewritten by the Netherlands.

The conference also discussed the role of governments and available budgets for research. For most countries clinical research is not a government responsibility. However, France, Canada and the Netherlands are involved in (future) clinical trials on medicinal cannabis. Furthermore, the European Parliament adopted an amendment to include the subject of medicinal cannabis in the 6th Frame Work Program. It still has to be approved by the European Commission. Projects can be submitted only by a consortium of at least three parties from different countries.

Conclusions and ending

Presentation of the outcome

The conference decided that the amended reader (without chapter 10 and the indication list annex) and the reports of the conference will be made available to others, after commenting by the participators in two rounds. They will be presented by the Netherlands as organising country to:

- those government organisations that showed interest in the conference but could not send representatives for various reasons (New Zealand, the USA, Australia and Spain)
- the INCB and CND
- the scientific EU-conference, organised by Belgium on 25 February 2002 next year with the co-operation of Germany, France, Switzerland and the Netherlands.

Additionally, each delegation can share the report with interested parties.

Cooperation and follow up

The conference concluded that the exchange of views and information is very useful to enhance the development of evidence based, cannabis based medicines. It exchanged contacts for finding clinical investigators in each others countries. For this reason it will also give a follow up to this conference in the second half of 2002, preferably in September. Canada will see if this is feasible.

All participants thanked and congratulated the organisers, commenting that the conference had been very professionally organised.

Goal of this document

This document presents the information gathered on the International Conference on Medicinal Cannabis held on the 22nd and 23rd November 2001 in the Hague.

Participating countries

The countries that participated at this conference were Austria, Belgium, Canada, France, Germany, The Netherlands, Norway, Slovenia, Switzerland and the United Kingdom. Before the meeting, participants had provided a summary of their political, public opinion, legislative and organisational situation regarding the medicinal use of cannabis in their respective country. These summaries are provided in a separate document as an attachment to this report.

Conference program

First day (Steigenberger Kurhaus Hotel)

1. Opening by the director of the Pharmaceutical Affairs Department on behalf of the Minister of Health, Welfare and Sport
2. Introduction by chairman, adoption of agenda and conference arrangements
3. Introduction of participants
4. Country presentations (Political situation, Public opinion, Legislative and organisational situation)
5. Single Convention on Narcotic Drugs
 - Interpretation and consequences of article 28 annex article 23
 - National Agency and the consequences
6. Product development
 - Standardisation
 - Development of different strains, placebo and preparations

Second day (Ministry of Health, Welfare and Sport)

7. Clinical trials
 - Overview of trials
 - Priorities for indications
 - Co-operation between countries concerning standardised product
8. Short round-tour to the buildings of the Ministry of Health, Welfare and Sport (architects: Michael Graves and Sjoerd Soeters) <http://www.minvws.nl/normaal.html?folder=11>
9. Conclusions and ending
 - Conclusions
 - Reporting
 - Co-operation
 - Follow-up

First day of the conference

Opening

The opening of the conference was held by Mr. Léon Wever, Director of the Department of Pharmaceutical Affairs and Medical Technology on behalf of the Minister of Health, Welfare and Sport of the Netherlands.

Mr. Wever welcomed all participants for attending this conference. For this specific conference concerning the medicinal use of cannabis the representatives of those countries were invited that would be interested in the subject.

Mr. Wever stated that The Hague is a very special place for the first conference on medicinal cannabis, because the first opium treaties were also negotiated in this city about one hundred years ago.

Cannabis has been used as a medicine for ages. The old Chinese already found out some 4500 years ago that this plant could ease pain and relieve all kinds of diseases. Through Asia the hemp came to Europe and America and was welcomed by many for its multipurpose use; for example, cannabis has been used as a fibre in agriculture and industry, as a recreational drug and as a medicine. In the 19th century hundreds of scholarly articles have been written on cannabis as a medicinal drug. It was even listed in the official United States Pharmacopoeia in the first half of the last century and it was sold in fluid extracts by respectable companies. However, western medical establishments lost their enthusiasm on the medical properties of cannabis, because research generated other drugs, such as synthesised morphine. Those drugs were more easily to administer and also they permitted closer dosage control. In addition the world realised that the abuse of narcotic substances should be cut back and international control came up: the Single Convention on narcotic drugs and national legislation came into effect, and the use of cannabis as a recreational drug and as a medicine was forbidden.

Regarding cannabis for recreational use, the Netherlands has had already since the 70's a unique approach. Because of this policy we were in the spotlight of international discussion and many other countries criticised our approach. That makes the Netherlands a bit reluctant to pursue a policy upon the medical and pharmaceutical aspects of cannabis. That is one important reason why the Netherlands want to do this in close co-operation with other countries, and that is perhaps the most important reason to organise the conference with the other interested parties.

In addition Mr. Wever gives an elaboration on the philosophy behind the tolerant attitude of the Netherlands in regard to the recreational use of cannabis. Our drug policy is based on the concepts of harm reduction. The main aim of our cannabis policy is to separate the markets and user groups between cannabis and the other (more harmful) drugs. This way, we want to avoid the situation that cannabis users, especially youngsters, are exposed to hard drugs and their criminal environment. To minimise these risks, and therefore to reduce the potential harm, the policy of the Netherlands towards cannabis has been somewhat tolerant compared to other countries.

This conference has the goal to discuss cannabis for medical use, not recreational use. Despite of the illegality of the supply of cannabis, the use of the drug as a medicine is increasing. Patients world wide found the use of cannabis a relief of their complaints. In the Netherlands and elsewhere there was an increasing demand for cannabis as a medicine. In a few countries this led to the conclusion that the possibility of a registered medicine made out of cannabis needs to be investigated (this is the "first track"). According to the European

and national regulations a medicine can only be registered when safety and efficacy have been proven in clinical trials.

In recent years some of those trials have been started. However, the road to a registered medicine is a very long one: it takes from 5 to 10 years, so patience is required. But the patients do not want to be patient.

For this reason the Dutch government decided to follow a second track very recently, by allowing the distribution of medicinal cannabis through pharmacies on doctors prescription. This does not mean that the first track, the development of a registered medicine (i.e. the investigation of the use of cannabis for medical purposes and to acquire more in depth knowledge about the various varieties and components) will be abandoned. The second track is just a shorter, *temporary* way, to bridge the gap until a medicine has been developed. Mr. Scholten, head of the Office of Medicinal Cannabis within the Ministry, will explain this in more detail during the conference. The Dutch government is certainly willing to go on, on this field in developing medicinal cannabis in close co-operation with other countries.

Mr. Wever closes his opening with thanks for the attention and wishes all participants a pleasant and productive meeting.

Introduction by the chairperson

The chairperson of the conference, Mrs. Annemiek van Bolhuis, deputy director of the Department of Mental Health and Addiction Affairs of the Ministry of Health, Welfare and Sport, states several goals of this conference. The committee who prepared this conference thought it would be important that the countries inform each other on the state of affairs of the medicinal cannabis policy within each country here. Other important goals that are intended to be realised are:

- Sharing knowledge, for example concerning the Single Convention or clinical trials;
- Coming to agreements about co-operation in the future and in addition agreements on for example priority and indications;
- Getting to know each other and creating a network.

The chairperson points out that everything said will be recorded for the report. In addition she mentions that it would be nice to reach some general conclusions at the end of the conference, but this is not prerequisite. Clearly being stated is the scope of this day: medical policy and **not** drug policy. And it is about medicinal cannabis *policy*, not about specific trials or specific indications; a somewhat general approach to the subject is desirable. Mrs. Van Bolhuis elaborates on the agenda, on which the participants do not have any comments. The agenda is then adopted as such.

It is the intention that the results of the conference will be transferred to the European scientific conference on cannabis on 25 February 2002 in Brussels. The chairperson requests the participants to speak freely during the entire conference, considering the fact that this conference is not being held on a very official level. Where the matter of confidentiality is concerned, the participants are requested to mention upfront which part should not be included in the report. Then it will be left out of the report of the conference. The report will be the only release of information gathered during this conference. Beside this report, which will be reviewed by each participant, and the final reader no other formal document will be released or published concerning this conference.

Should there exist a need or interest at the end of the second day for a follow up on this conference, the participants should discuss the possibilities for this during the evaluation and conclusions.

Introduction of the participants

All participants gave a brief introduction of themselves. The representatives attending from each country are:

Canada

Mrs. Cindy Cripps-Prawak, Director of the Office of Cannabis Medical Access, Health Canada. She is very interested in the developing, the policies and the practical experience each participant brings to this conference.

Mrs. Suzanne Desjardins Ph.D., Manager, Evaluation and Research Coordination Division, of the Office of Controlled Substances, Health Canada. Started about a year ago on the research programme for medical use of cannabis.

Belgium

Mr. Frans Gosselinckx, counsellor, Office of the minister of health.

Mr. Van den Bosch, pharmaceutical inspector, Ministry of Health.

France

Mr. Bertrand Lebeau, medical doctor and president, French Association for Harm Reduction.

Mr. William Lowenstein, medical doctor and director. Hopital Européen Georges Pompidou (HEGP). Officially in charge within the Ministry of Health of medicinal cannabis.

Norway

Mr. Jorg Morland, trained as a medical doctor, Professor of Pharmacology, MD. Director of the National Institute of Forensic Toxicology, within the Ministry of Health.

The Netherlands

Mrs. Myra Klee, policy advisor at the Office of Medicinal Cannabis.

Mrs. Ingrid Horst, senior Policy advisor at the Office of Medicinal Cannabis.

Mr. Willem Scholten, head of the Office of Medicinal Cannabis, pharmacist.

Mrs. Annemiek Smulders, policy advisor at the Office of Medicinal Cannabis.

The United Kingdom

Mr. J.D. Gerrard, UK, regulatory officer. Polices the licensing of the growing cannabis for medicinal use. Has been involved with GW Pharmaceuticals in the UK for 4 years from the first day they wanted to grow cannabis to the stage they have reached now in the clinical trials.

Switzerland

Mr. Christian Stamm, deputy of the section for control and licenses of the Swiss Federal Office of Public Health. This section is the authority for the illicit control of narcotic drugs, and also for the use of Illicit substances for research.

Austria

Mrs. Birgit Frommer, medical doctor, working at the university hospital at the pain clinic. She does research work with cannabinoids. Representing the ministry.

Germany

Mrs. Carola Lander: pharmacist, works with the Federal Institute for Drugs and Medical Devices. Head of the Federal Opium Agency. The Federal Opium Agency is the competent authority for granting the licenses regarding manufacture of and trade in narcotic drugs. Responsible for issuing import and export authorisation controlling the licence holders and distributing the special prescription forms for narcotics amongst the physicians.

Mr. Horst Möller, pharmacist, works at the Department for Narcotic Drugs, within the Ministry of Public Health in Bonn.

Slovenia

Mr. Matej Kosir, senior counsellor at the government office for drugs in Slovenia. Deals with all aspects of drug policy in Slovenia. The medical use of cannabis is a new issue we are dealing with. He will be hearing a lot of useful information at the conference.

Mr. Tomaž Koran, works at a non-governmental organisation in Slovenia. Works on a website about Hemp and Marihuana and informs the people in Slovenia about the potential use of medicinal cannabis.

Willem Scholten explains that several countries were invited to attend this conference, but not all countries could attend. In specific, Italy did not respond to the invitation and Spain was not interested. Australia and New Zealand were interested but not able to come and the US planned to come but unfortunately they cancelled because of a national holiday. The Scandinavian countries were all invited, but Sweden, Finland and Denmark all could not come for various reasons.

The introduction of the participants will be followed by a presentation of each country.

Country presentations

The United Kingdom

Mr. Gerrard in first instance refers to the information given in the reader; in this presentation he will be focussing on the position of the UK government concerning the development of the medicinal use of cannabis and will update the participants on the first results of the trials by GW Pharmaceuticals.

Position of the UK Government

UK Government endorsed the need for clinical trials on the possible use of cannabis-based medicines for therapeutic purposes. Trials are ongoing to evaluate their safety and efficacy in a number of areas such as spasticity in multiple sclerosis, chronic pain and post-operative pain. However, it separates that debate from the one on the legalisation and decriminalisation of cannabis. At present doctors can prescribe a cannabis-based medicine under licence from the Home Office but only for the purposes of research or other special purposes in the public interest, which includes clinical trials. Public opinion is in favour of the testing of cannabis in a medicinal form to see if it is an effective treatment for certain illnesses.

In the event of cannabis based medicine being shown to be of suitable quality, safety and efficacy a marketing authorisation could be granted and legislative changes could be made to enable it to be prescribed to patients. The Government Agencies involved are the Home Office as the UK's competent authority for regulatory control under the UN Single Convention on Narcotic Drugs and the Medicines Control Agency, which is responsible for the licensing of medicinal products.

First results of the trials by GW Pharmaceuticals

GW pharmaceuticals is leading in the trails, although some other trials have been going on. They have been involved about 4 years from growing their own plants, mainly from seed and then cloning their plants. They have clinical trials going on in a number of places within the UK. GW Pharmaceuticals has reported the following outcomes of its clinical trials using cannabis based medicinal extract:

1. Most patients, whose conditions were previously considered intractable, sustain clinically significant benefit;
2. Over 20 patient-years of treatment show that sublingual cannabis based medicinal extract is safe and generally well tolerated;
3. Self-titration allows most patients to separate thresholds for symptom relief and intoxication; and
4. Analysis of dosage levels over extended period shows no evidence of toleration.

There was recently a television programme in the UK "Panorama" where they dealt with the subject of medicinal use of cannabis. They presented a number of patients from the GW Pharmaceuticals clinical trials; most of them talked about wanting really just to get their life back on track without the pain, rather than to get any intoxication effect from the drugs. They always separated that from what they wanted from the medicinal product.

After the presentation by Mr. Gerrard several questions were asked which will be numbered per question and per answer.

Q1: What is the specific extract used in the trials?

A1: The plant and the leaves are processed into a liquid and then put into a sublingual spray.

Q2: Was there a clinical trial for MS with oral cannabis versus THC versus Placebo? Are there other clinical trials for MS?

A2: Besides the trials by GW Pharmaceuticals there are hospital based trials within the National Health Services (NHS) (see the reader). They are using capsules which come from Germany. All trials are hospital based.

Q3: What will be done with patients after the trial, if the sublingual spray is beneficial? How will you continue with them?

A3: We will continue the trial. The trials are open ended at this moment.

Q4: If you want to export cannabis extracts, what do you export? Have you already exported?

A4: No products used by GW Pharmaceuticals have been exported. All trials and the growing of the crop are in house and we do not allow exports.

Q5: When you use extracts of cannabis, is there a certificate or analysis of what is in these extracts? Can it be reproduced?

A5: Mr. Gerrard points out that he is not a medical expert or a pharmacist, but in his understanding the composition varies (placebo, with CBD, or THC, or 50% CBD + 50% THC). There are however other cannabinoids in these preparations (small percentages), which cannot be excluded at this moment.

General remark: GW Pharmaceuticals was authorised to make products available to the primary investigators in Canada in the context of clinical trials. So there was limited export, for the pharmaceutical context.

Mr. Stamm wants to add an item concerning the export; there is an institute in Switzerland that manufactures those type of extracts and exports to Germany for clinical trials. They had some discussions with the INCB, because the INCB requested to report on the export of cannabis. They decided not to do that, because it is not cannabis anymore, but a THC solution (a cannabis extract). The INCB requested to multiply the amount with seven and report the export as cannabis. It was not clear what sense the factor of seven would make, so Switzerland decided to report in grams of THC.

Slovenia

Mr. Matej Kosir presented the situation in Slovenia. Medical use of cannabis is almost completely unknown in Slovenia. Our office during the preparation of the national strategy and action planned for the area of drugs tries to open new things about themes, on which insufficient information is available for any type of discussion, on political or professional level. These themes include the question of medical use of cannabis. Two years ago a polemic discussion took place in Slovenia about new legislation, especially about new production and trade in the illicit drug act. The debate was mainly focussed on the question of milder sentencing for possession of minor quantities of illicit drugs for single personal use; the adoption of this package of laws in 1999, by which Slovenia added to the production and trade of illicit drugs, regulated additionally the area of prevention of the use of illicit drugs and treatment of users. So the adoption of this package was the best possible political consensus under those given political circumstances within Slovenia.

Slovenia is building a new national strategy now, in which they also wish to include the majority of successful innovations in the area of preventing use and abuse of narcotic drugs: treatments and social rehabilitation of addicts, harm reduction and so on. We also raised the question of the cultivation of industrial cannabis, which had a major polemic effect. We also intend to regulate the area of medicinal use of cannabis. The whole present political conditions are more favourable for tentative measures in the area of illicit drugs: the introduction of the medicinal use of cannabis will be very difficult work for us. Almost nobody has dealt with the medicinal use of cannabis yet. In addition to possible difficulties with politicians, we also anticipate certain resistance in the medical profession.

What are the possibilities of introducing the medical use of cannabis in Slovenia? The production and trade in the illicit drugs act which was adopted in December 1999 classifies illicit drugs into three groups in relation to the seriousness of the risks to the people's health, that could result from the use of a medicine:

Group 1: plants and substances that are very dangerous for the health. They are not used in medicines. Cannabis in all forms and THC are classified in group 1. My opinion is that cannabis does not fit into this group, but politically it is perceived differently. It is also determined in the same act, that the production, trade and possession of illicit drugs from group 1 may only take place for scientific research. So the possibility exists for the start of laboratory or clinical tests in which cannabis or THC would be used. But a change in the law will be needed for the scientific use of cannabis in medicine. This is important, because in the first phase it is unnecessary to reopen the political debate on the amendments and supplements to the legislation. To start with it is necessary on our part to obtain scientific and research institutions in the area on medicine and to present to them the possibilities that cannabis offers in the treatment or alleviation of effects of certain illnesses.

Successful tests could lead to necessary changes of our legislation that would allow the wider medical use of cannabis. For the first phase our office has plans for acquainting medical and other competent professionals mainly from scientific branches of medicine, with the possibilities and changes that the medical use of cannabis offers. For this we intend to organise a professional meeting on this theme in spring next year, with the participation of internationally recognised experts. This meeting will primarily show what the general interest of the experts is in this area. Further action will depend on this.

We anticipate that we will be confronted with several problems along the way, especially from certain political and professional circles that have already shown an extreme position in relation to policies concerning illicit drugs during the debate of the legislation.

One of the major problems that will also appear is that the public opinion is not favourable inclined towards us. People in Slovenia do not see the essential difference between the use of marijuana and medical use of cannabis. This clearly arises yet another problem; the problem of the level of information, which is one of the key problems in the area of illicit drugs in Slovenia. If we succeed in winning to our side the majority of eminent professionals in the medical area and of course the public opinion, then we can count on success, otherwise not.

The conclusion that can be drawn is that a great deal of work awaits. The fact is that we have barely begun, but we count on help from certain international institutions; mainly the international association of medicinal cannabis and countries who have more experience in this field and also have programs which have been running for a number of years, and have achieved good results. We intend to include this area in the national strategy with all seriousness, by organising the international meeting to which competent professional institutions will be invited, to join our efforts. In the coming month we will also prepare an

informative publication on the medical and the political aspects of the use of cannabis. The preparing for this conference and the conference in Berlin will be very useful for us.

Norway

Norway is the only representative of the Scandinavian countries, but speaks only on behalf of Norway. Mr. Morland in first instance is referring to the reader that contains the most information.

The background in Norway is that the use of cannabis is illegal; the possession as well as the use. The practice of the police is with good tolerance. The medicinal use of cannabis has not been to any extent a major topic of interest neither within the medical nor within other professional circles, nor within the society in general. There is no strong opinion against or in favour of the use of medicinal cannabis. So far it is possible for any doctor in Norway to apply to the National Board of Health for an exempt to use the drug in treatment if needed, but it has been done very seldom. It is also required then, to get this permit that you have a rather heavy support from medical experts within the field.

There is also a possibility to apply for an exempt to perform a controlled trial. This has probably been done only once, and not exactly for the medicinal use of cannabis. But in these cases you will have to apply for an exempt at both the National Board of Health (for the use) as well as the Norwegian Medicines Agency (for the allowance to import the cannabis product). This has to be done with again support of medical expertise.

All these institutions that might give you the permit to either use it for a patient or for a trial, are belonging to the Ministry of Health. If there will be good demonstrations of the efficacy and safety with respect to the medicinal use of cannabis, it will probably be accepted very quickly by the Norwegian medical doctors if it can be proven to have a better efficacy/safety ratio than competing treatments. This outcome should probably not arise great resistance, and this would also most likely apply to the society and the authorities in general. Of course depending on the strength of the documentation of evidence behind the claimed success or the claimed effect of the medicinal use of cannabis.

Mr. Morland adds an item that might be interesting concerning the safety of the medicinal use of cannabis. A study based upon case histories shows a risk when people of an older age, than the usual cannabis user, are using cannabis you can see much more important cardiac complications then diagnosed for younger people. Recently there were reported six fatal cases, which however did not concern the medicinal use of cannabis, but could be seen as cannabis misuse. The point is that these people, mostly but not all in their forties, that had some kind of precondition where cardiac complications are concerned, responded in a much more sensitive way to cannabinoids than (younger) people usually do. Mr. Morland has more information about this study and can provide this to those interested. A paper on this topic will be published in January 2002 in *Forensic Science International* Vol 124/2, pp 200-203.

Q1: Could you elaborate on the hypothesis you were using in the study with the older people?

A1: First, the people were not objectively seen old, they were mostly in their forties (it should be seen in relation to the younger people that usually use cannabis). It is well known from physiological and pharmacological studies that you increase the heart rate and lower the blood pressure at certain levels of THC. The hypothesis is that in these cases the cause of these heart conditions, already being there some of in the patients, made

this combination of drug and the already existing condition a fatal one. In other fatal cases no clear precondition was present. In summary the serious effect of cannabis is not a very frequent complication, but it can occur.

Germany

Mrs. Lander will summarise the German policy regarding cannabis, and its suitability as a medicine. Because of the pharmacological effects which cannabis unquestionably possesses the German government supports every serious effort towards making cannabis available for medicinal purposes. This support applies to substances isolated from cannabis, as well as to extracts or fractions of extracts of cannabis. But cannabis and its application and marketing have to be in accordance with the German medicines act just like any other medicinal product. Without any doubt approved cannabis medications prepared under industrial conditions, will have to be given first priority.

However so far there are no such medications on the market, or even in the approval procedure. And from our point of view it is very unlikely that there will be an application for approval in the near future since there are still extensive clinical trials to be made.

As long as marketing authorisations for finished products cannot be granted, it is essential that pharmacies are put into the position of preparing cannabis preparations on an individual bases. This is well justified because good results have been reported in a number of individual cases of serious diseases as for example multiple sclerosis (MS) and cancer. According to the German medicines act pharmacies are allowed to prepare and dispense pharmaceutical products on a physicians individual prescription. The only restriction they have is that they will have to use standardised starting materials of defined quality and in the case of narcotics or psychotropic substances the prescribed drug has to be scheduled as a prescribable substance. That is why recently the commission of the German Drug Code has published a dronabinol monograph and it seems that a monograph of cannabis extracts will be available in the near future. Dronabinol, the primary active ingredient of cannabis is prescribable in Germany and is procurable on the market at defined quality. Up to now about 200 pharmacies procured dronabinol for preparations individually prescribed by physicians.

That is why in the next few days specifications for dronabinol capsules and for an oily dronabinol solution will be published by the mentioned commission of the German Drug Code. We hope this will lead to standardisation of prescriptions, and improve the efficacy of the treatment. As soon as we have a cannabis extract at hand, which is of repeatable quality as described in the earlier mentioned monograph the German government will make it prescribable by listing cannabis extracts in Schedule III of the Narcotics Act, but naturally only if our expert group recommends the scheduling.

On the other hand we would like to point out our strong belief that allowing self-medication with untested cannabis products such as hashish and marihuana is irresponsible and it does not help our suffering patient population.

Q1: Can you tell something about the source of the dronabinol? Where and how is it manufactured?

A1: Dronabinol is manufactured by a manufacturing company and this company has a licence to manufacture dronabinol from hemp which contains less than 0,3 % THC. From this CBD is produced, and from that dronabinol.

Q2: There is also cannabis extract on the market?

A2: No, it isn't, this is only allowed to develop the monograph. So it is restricted to scientific purposes. This cannabis extract contains more than 0,3% THC.

Q3: Do these cannabis extracts appear as capsules?

A3: We only have extracts, no capsules. It is a liquid extract. Up until now there is no administration; it is only to develop the monograph and to determine the specifications so we can produce an extract with repeatable and defined quality. Afterwards, when we have these extracts we can do the clinical trials. We hope we will have industrial produced preparations in the future. So, if we have the extracts, and if we have rescheduled perhaps the industry will apply for approval.

Q4: This plan of development is approved by the government? There is no political resistance?

A4: The procedure described is not a plan exactly, but the normal procedure for the development of an medicine.

Ad Q4: In France however, it is very complicated to have normal development of some drug, so the reason for my question is: if you are at the first step of development, the step of control of quality, the second step would be to prepare magistral administration by oral administration and in France this takes three to four years. Is it so easy in Germany to develop your medicine already next year? Are you receiving special help from your government?

Ad A4: Yes and no. The government declared that they wish medicine of Cannabis, but then the government cannot develop this.

Q5: In Canada dronabinol has been available in a synthetic form for a number of years and it can be prescribed for specific indications. Why would you extract dronabinol from plant material, rather than develop it synthetically?

A5: The company chose to extract from the plant extract, they did not choose to develop synthetically. It is also a matter of price when using plant extracts.

Q6: When you referred to marijuana, are you referring to the dried plant material?

A6: Yes, we referred to the dried material that is being smoked.

Switzerland

Mr. Stamm gives a power point presentation starting with the internet address of the Swiss Federal Office of Public Health: <http://www.bag.admin.ch/e/index.htm>

Political and legal situation

Regarding the political and the legal situation in Switzerland Mr. Stamm elaborates by giving a short overview of the results gathered out of two different referendums. First, in view of the increasing drug problem in the eighties, in 1991 the government decided to intensify its commitment considerably in this area, focussing on the following objectives:

- Reduce the number of new users / addicts;
- To increase the number of addicts, that quit addiction;
- To reduce damage to the health and social integration of users and addicts;
- To protect society from harmful effects of the drug problem and to fight against organised crime.

The referendum held in 1993 "Youth without drugs", called for a strict, abstinence-oriented drug policy that contained elements of repression, prevention and therapy. Swiss voters rejected with a majority of 71%. The referendum held in 1994 entitled „For a reasonable Drug Policy“ proposing the opposite, namely the decriminalisation of drug use, cultivation of plants

used to produce drugs, possession of drugs and purchase of drugs for personal use, was also rejected with a majority of 73%.

The Swiss population has in both cases shown its massive support for the government's pragmatic fourfold approach. The outcome of these two referendums show – after many years of discord- a consensus could be reached concerning the drug policy to be followed in Switzerland.

Mr. Stamm furthermore elaborates on the revision of the Swiss Narcotics Act:

- It is the first substantial revision since 1975;
- It represents an adoption to today's situation;
- It focuses no longer exclusively on controlling trade in narcotic drugs or on combating abuse and criminality (orientation towards Public Health);
- It obliges the Swiss cantons to offer a wide range of services relating to prevention, therapy and harm reduction and to implement measures.

Non-medical use of cannabis

A few numbers on the non-medical use of cannabis in Switzerland are shown in the table underneath:

Results of a survey in November 2000 (N = 1600):

Life-time prevalence	15-19: 44%
	20-24: 59%
	25-44: 35%
	45-59: 15%

- 600'000 Swiss are current cannabis users (= 8,6%)
- 87'000 Swiss (age 15-74) smoke every day (= 1,2%)
- 75% use cannabis as a drug or to relieve from stress, only for 25% it is a form of „protest against the society“
- 50-53% favor decriminalisation or legalisation.

Proposal for a new cannabis policy

A partly new orientation is proposed for addressing the various issues concerning cannabis. Personal use of cannabis and its most closely related preparatory acts will no longer be criminal offences. Cultivation, production, manufacture and trade of cannabis will remain prohibited. However, in accordance with Article 3, Paragraph 6 of the 1988 UN Convention against illicit traffic in narcotic drugs and psychotropic substances the revised Swiss law on narcotics will enable the Federal Council to define clear priorities for the prosecution of drug offences. The legislator will restrict discretionary prosecution to the cannabis-related offences mentioned above and to personal use offences for all substances other than cannabis. The law will furthermore stipulate the kind of prerequisites it deems necessary in order to abstain from prosecution.

Concretely this could mean that trade would be tolerated if:

- cannabis were not sold to people younger than 18 years;
- no advertising takes place;
- public order is not disturbed;

- not more than 5 grams of cannabis is sold at a time.
- Cultivation on a small scale would be tolerated if intended for the local market only. Import and export of cannabis remain prohibited.

Medical use of Cannabis and its active ingredients

Today, any traffic in cannabis or in its products is prohibited (import, export, manufacture, consumption, prescription etc.) in Switzerland. Cannabis and its products, and all isomers of tetrahydrocannabinol (THC) are classified as so-called forbidden substances.

The tables underneath give an overview of the current situation and the proposed medical use:

TODAY	Cannabis	Cannabisextract	THC
General Research	YES	YES	YES
Clinical Studies	YES	YES	YES
Limited Medical Use (Compassionate Use)	NO	NO	YES
General Medical Use	NO	NO	NO

PROPOSAL	Cannabis	Cannabisextract	THC
General Research	YES	YES	YES
Clinical Studies	YES	YES	YES
Limited Medical Use (Compassionate Use)	YES	YES	YES
General Medical Use	NO	NO	NO

Until today, the Swiss Federal Office of Public Health authorised the compassionate use of Marinol® (dronabinol) in 50 cases. Clinical studies are authorised for Marinol®, cannabis extracts and herbal cannabis (appetite in cancer patients, spasticity in paraplegics, spasticity in MS patients, analgesia, cancer patients in palliative treatment). Furthermore, a research institute is allowed to grow cannabis plants and to manufacture standardised cannabis extracts.

The prescription and medical use of herbal cannabis or cannabis extracts is not yet allowed. With the revision of the federal law on narcotic drugs and psychotropic substances from 1951, it is envisaged to allow a limited use of herbal cannabis and cannabis extracts under the supervision of the Swiss Federal Office of Public Health.

Should the results of clinical trials with dronabinol be promising, a re-scheduling of delta-9-THC and its stereochemical variations may be possible to allow the medical use, further research and the registration of pharmaceuticals based on cannabis or synthetic dronabinol.

Final Statements

Final statements made by Mr. Stamm are:

- The medical and the recreational use of cannabis should strictly be separated;
- Manufacture, distribution and prescription etc. of medical cannabis/-extracts must be subject to all existing regulations for pharmaceutical products;

- No legalization of recreational cannabis under the cloak of its medical use;
- The United Nations should reconsider the scheduling of cannabis in schedule IV of the Single Convention. In less than a month Swissmedic will be a merger between "Main Unit Medicines of the Swiss Federal Office of Public Health" and „Intercantonal Office for the Control of Medicines“.

Questions asked to Switzerland

Q1: Do you know the part of the anxiety of the side effects?

A1: 41 Treatments stopped, because of the missing effectiveness not for the side effects.

Q2: Concerning the public opinion about the legislation: What type of question was asked in Switzerland? Do you favour decriminalisation or do you favour legalisation?

A2: Mr. Stamm cannot answer this specific question.

In addition to this presentation in the report, the power point presentation given by Mr. Stamm will be distributed to all participants of the conference. This power point presentation elaborates on the specific issues mentioned by Mr. Stamm in more detail; examples of issues discussed in depth are the clinical studies going on in Switzerland and the manufacturing process of cannabis extracts.

France

Since 1970's law which stipulates prohibition of cannabis even for one's personal and private utilisation, the politicians have denied main neuroscientific studies and have been keeping the same understanding and vision of cannabis, more a political than a scientific one.

The legislative aspect

The following overview is given concerning the Law of December 31st, 1970:

- A. *To protect:*
- Individuals (despite themselves);
 - Society and Democracy;
- The context in 1970: - « 1968 » philosophy
- Heroin epidemic (1st overdose);
 - The « French Connection »

B. Usage was condemned in the same way as Possession, Sales, and Trafficking

C. Two aspects of the Law of 1970

- Sanitary (therapeutic innovation);
- Repressive;

Developments from 1970 till 1999

- Repressive arsenal ⇒ « law of exceptions »
- The failure of therapeutic injunctions (1% finish the treatment, CNRS Study 1994)
- AIDS reveals « the sanitary and social catastrophic situation » of drug users (Pr R. Henrion, 1995);
- Spectacular results with Harm Reduction Policy in 5 years (from 1994 to 1999) for individuals and society;
- The law of 1970 was inadequate for the 5 (?) million cannabis users (... and what about other users ?!...) (85 000 infractions in 1999);

- After Pr B. Roques report (98-99), the MILDT and the Health ministry decided to focus tobacco and alcohol use and its harmful effects, as they had for other psychoactive substances;

The Guigou decree of June 17th, 1999

After elaborating on the French law on drug use and the developments since 1970, the main objectives of the Guigou decree of June 17th, 1999 are discussed. These objectives are to:

- reduce drug consumption and decrease the number of new consumers;
- fight against delinquency related to drug use;
- to prevent and reduce the negative social and sanitary effects related to the usage, abuse and dependency of drug.

In consequence, judicial decisions have to take a more diversified approach and consider the healthcare needs of drug users as well as their social integration. Some alternatives to legal action are proposed (therapeutic injunction particularly concerning addicts).

The main proposals within the Guigou decree are:

- To distinguish between usage, abuse and dependency
- To take in account the personality of the person arrested, his/her way of consumption and his/her general life context.
- Stop the judicial process and give a warning
 - recall of the law
 - recommended for occasional users
 - especially for cannabis users
- Stop the judicial process and give a legal directive towards sanitary structures, social structures and professional structures
- Stop the judicial process under certain conditions; the obligation to go to a designated structure in order to take a secondary decision. *Conclusions in regard to the legislative aspect* The conclusions concerning the legislative aspect are as follows:

- The Law of 1970 still enforced:
 - no differences are made between usage, abuse and dependency;
 - is not very protective;
 - is not adapted to the actual situation;
- Many decrees (from 1982 to 1999) that try to modulate (or to not enforce [!]) the law of 1970.
- A Harm Reduction Policy (1993-2001) “not absolutely official” that showed excellent sanitary and socioeconomic results.
- The simple usage of cannabis is still liable to 1 year of jail and FRF 25.000 of fine (= EUR 3.810). Half of the young people 19 and under have used cannabis at least once.

Medicinal cannabis

Concerning the medicinal cannabis the following developments have been discussed:

- The withdrawal of the French Pharmacopoeia in 1953
- The French medical community is not very interested in medicinal cannabis, most of the studies were done in order to:
 - demonstrate cannabis health damage,
 - characterize the CB1 and CB2 receptors,
 - study the interactions with dopamine pathwayPolitical fear (real or supposed) of seeing cannabis categorized as a medical treatment in the future,
 - No clinical trial before 2000 (one Phase I Clinical trial);
 - No demand for a drug approval;
 - Nominative Temporary Authorization of Use (ATU) only since 1999 for dronabinol and nabilone.
- Since 1999 AFSSAPS has authorized:
 - 3 nominative ATU for medical use of dronabinol (Marinol®) in chronic pain syndrome;
 - 6 Nominative ATU for medical use of nabilone (Cesamet®)
 - 1 pain syndrome in AIDS
 - 4 nausea and vomiting syndrome
 - 1 hyperalgia in multiple sclerosis

The current situation

The current situation in France is that the French Health Ministry has shown undeniable interest in promoting clinical trials in anorexia related diseases, glaucoma, MS and other neurodegenerative diseases. The deadline for the deposit of the protocol draft is end November 2001. The clinical trials started in February – March 2001. The most favourite way of use is orally, spray and eye-drop (glaucoma). The smoking form is not considered to be a good way of use.

In 2001 68% of a representative sample of the French population was favorable to a
MEDICINAL USE OF CANNABIS

“French people, as far as public health is concerned, are ahead of their politics”

Pr Claude GOT
Epidemiologist Expert

The Netherlands

Introduction

I will present you the developments in the Netherlands regarding the medicinal use of cannabis. This is additional to the information in the reader. Of course it is not possible to tell all the details in a presentation of 15 minutes. If you are interested you can find several documents on our ministries' web site www.minvws.nl and search for the key word cannabis. Some of these documents are also available in English.

In my presentation I will go shortly into the history of cannabis in the Netherlands. Then I will tell you about the objectives of our policy, which has two separate tracks: one - a long term objective - to develop a registered medicine and the other to make cannabis available through pharmacies on prescription on a somewhat shorter term. Also can I tell you more about the source of the cannabis: the growers and the requirements to them.

Cannabis was formerly used frequently in Western medicine, especially in the 19th century. It fell in disuse in the 20th century and was prohibited in many countries between 1940 and 1950. Since then it came under international control like many other substances with a

psychotropic activity. It got illegal status in the Netherlands and its prescription was not permitted any more.

During the last ten years a discussion has been going on whether prescribing of cannabis should be permitted or not in the Netherlands. The Minister of Health, Welfare and Sport asked the advise of the Health Council, which is a scientific advisory board to the government. The Health Council made a survey of the literature from 1970 to 1995 and reported in 1996 that there is insufficient evidence for the medicinal use of cannabis.¹ This is due to bad study designs and the use of cannabis of often ill-defined quality with an unknown content of active constituents.

After this report the minister decided to propose to the parliament an amendment to the Opium Act to get the power to allow clinical trials with cannabis and its prescription. This amendment came into force in 1999.² Later in 1999, the government laid down a Royal Decree listing controlled substances that may be prescribed.³ Any controlled substance which is not listed may only be used in clinical trials with a special license. Since cannabis is not in the list, its use is only permitted in trials.

The Office of Medicinal Cannabis

The Dutch government decided to enable clinical trials with the aim to learn more about the medicinal potential of cannabis. However, this requires a legal source of medicinal grade cannabis.

Because the Netherlands is a party to the Single Convention on narcotic drugs it must follow the procedures prescribed by that convention if it wants to culture medicinal grade cannabis. These requirements are that a state allowing the horticulture of hemp for medicinal purposes should establish a "government agency", that should be monopolist in importing and exporting, wholesale and stock keeping of cannabis. Also growers should obligatory and exclusively sell to the agency. In agreement with the requirements of the Single Convention on narcotic drugs regarding the horticulture of cannabis, the government decided to establish a national agency on medicinal use of cannabis in November 1998. This agency is called Office of Medicinal Cannabis (in Dutch: Bureau voor Medicinale Cannabis, BMC) and was founded in March 2000. It acts as national agency since 1 January 2000. It holds the monopoly for the Netherlands of importing, exporting, wholesale of cannabis and its preparations on behalf of the Minister of Health, Welfare and Sport. It is also the licensing authority for cannabis and cannabis preparations. The office is notified to the International Narcotics Control Board in Vienna. There is an amendment to the Opium Act under procedure in parliament to embed the monopoly and the powers of OMC in the law. It has an advisory board with as members health care inspectors specialised in clinical trials and in narcotics, a neurologist, a pharmacognosist, a lawyer and representatives of the Multiple Sclerosis Patients Association and the HIV Patients Association.

The Office of Medicinal Cannabis (OMC) is positioned in the Health Ministries' organisation in the Department of Pharmaceutical Affairs and Medical Technology and not in the Department of Addiction Affairs and Mental Health. The reason for this is that patients using cannabis should be regarded as medicine users and not as drug abusers, even if the medicinal use is still illegal, as it still is in the Netherlands. Another reason is that the product to be developed

¹ Gezondheidsraad *Marihuana als medicijn (Marijuana as a medicine)*. Rijswijk, 1996:10. (In Dutch, with an executive summary in English.)

² Wet van 16 december 1998 tot wijziging van de Opiumwet om onderscheid te kunnen maken tussen Opiumwetmiddelen bij het geven van regels voor het voorschrijven van Opiumwetmiddelen op recept (Opium Act Amendment of December 16, 1998, to differentiate between controlled substances when making rules for the prescription of controlled substances), Staatsblad. 1999;10.

³ Besluit voorschrijven en bestellen opiumwetmiddelen (Royal Decree on Prescribing and Ordering Opium Act Related Medicinal Products). Staatsblad. 1999;256.

should meet all pharmaceutical requirements and this can be best promoted from the pharmaceutical department.

Medicinal cannabis policy

The policy of OMC is to promote the development of at least one cannabis based medicinal product. This part of the policy will take several years to have result, upto 5 to 10 years. For this reason recently a second track was added. This will be the distribution of cannabis as a starting material to pharmacies. The pharmacies can use the cannabis for magisterial preparations.

Let me first give some elucidation on the initial track - developing a registered medicine: the primary aim of establishing such an agency is to make cannabis legally available for research purposes. We hope this will lead to a cannabis-based medicine from legally grown cannabis registered at the Medicines Evaluation Board (CBG-MEB) or the European Medicines Evaluation Agency (EMA). OMC will stimulate pharmaceutical companies to develop such a medicine and it will bring interested companies, clinicians, growers and others in contact with each other. OMC will be the supplier of the cannabis needed. The cannabis will be grown by licensed growers.

The final aim is to have a registered medicine available for therapy that meets the same standards as other registered medicines. This means that the product has a constant composition, and has been used in clinical trials to assess the safety and efficacy. It will make that doctors and patients know what they can expect from the medicine, that they know how much to take, that side effects are minimised, and that the effect is always the same thanks to the constant composition.

Then the newly added track: making the herb available as a prescription drug.

Only recently the government decided that for the time that there is no registered medicine available yet, the supply of medicinal cannabis through pharmacies on a doctors prescription will be allowed. The Royal Decree on prescribing and dispensing of opium act substances will be changed in a way that it is no longer prohibited for doctors to prescribe cannabis and for pharmacists to deliver it. This will come into force as soon as the OMC has organised the legal supply of cannabis to pharmacies. This is expected in spring 2003. Because the medicinal use is still not evidence based, the cost will not be reimbursed by the public health insurance. OMC will be the supplier and wholesaler of the cannabis needed. The cannabis will be grown by licensed growers.

One task of the Office of Medicinal Cannabis is the supply of medicinal grade cannabis to manufacturers and clinicians. The Office will order the cannabis from private growers. On doing so preventing leakage of cannabis to illicit markets is important.

The Dutch law requires licenses of those who grow cannabis. These licenses will be given by the Office on behalf of the Minister of Health. Only growers who are contracted by the Office will be licensed. Growers will be screened before they are contracted. Part of the contract will be the condition that contractors sell their complete crop to the Office. A check on this can be built in by comparing the size of the crop and the area in culture. Another condition is that any remainder will be destroyed. Of course growers will be frequently visited by staff members of the Office and by the narcotics specialist of the Health Care Inspectorate.

OMC intends to develop a monograph on cannabis with uniform standardised methods of analysis and criteria for approval, which is applicable to all products from all growers.

Application of the Guidelines for cultivating cannabis for medicinal purposes, which are rules of Good Agriculture Practice (GAP, which can be found in one of the annexes to the reader), will be required from the grower by OMC. These rules are to ensure that the cannabis is of

constant quality and reproducible. They include the standardisation of the culture through means of standardisation of growing conditions.

Standardisation is important for cannabis. It can be compared to wine: wine also has many constituents. Its quality depends on many factors, like the grape breed, a calciferous soil, a good summer with much sun, and with also some rain, and harvesting at the right moment. For cannabis, we require all these variables to be constant. This means that the cannabis will be grown indoors.

As said, the OMC is established to supply the Dutch market with cannabis and cannabis preparations for medicinal and scientific purposes primarily. However, requests for cannabis from other countries for these purposes will be considered, provided that the authorities of the other country agree. Because the office has got several questions about this possibility. More on this topic can be found in the reader.

In addition to this presentation in the report, the power point presentation given by Mr. Scholten will be distributed to all participants of the conference.

Q1: Which variety have you established as the standardised form of Cannabis?

A1: We have not yet selected a specific variety. We are now planning a clinical trial, comparing high dronabinol cannabis with dronabinol and CBD containing cannabis and with placebo. We are selecting the breeds at the moment. For regular use we did not select at this time.

Austria

Mrs. Birgit Frommer elaborates on the legislation within Austria concerning narcotic drugs. In addition to this she explains some practical solutions in regard to the issue of medicinal use of cannabis.

Austrian narcotic drug legislation classifies cannabis (hemp) as a “narcotic drug”. It is defined as “inflorescence or fructification of the plants belonging to the genus cannabis whose resin has been extracted”. Exemptions exist for the inflorescence and fructification of some hemp varieties that are used for industrial purposes and whose THC concentration does not exceed 0.3 % (i.e. these do not fall under narcotic drugs legislation).

Mrs. Frommer explains that medicines containing narcotic drugs may be prescribed, dispensed or applied within the framework of a medical or veterinary therapy only on the basis of the findings and experiences of medical science. Some narcotic drugs however may not be prescribed in accordance with the applied regulations in Austria. This explicitly applies to cannabis and cannabis preparations.

In addition to this, the cultivation of plants for obtaining narcotic drugs is also explicitly prohibited in Austria (though there are some exceptions, for example for certain scientific institutes). Mrs. Frommer states that a differentiation is necessary however in regard to the agents THC or delta-9-THC (=dronabinol) that are extracted from the cannabis plant. Although THC is not used in medicine (so that the prescription of THC and THC-containing medication is prohibited by the Narcotic Drugs Ordinance), the isomer “delta-9-THC” however is. This applies to the agent extracted from cannabis plants as well as the agent produced synthetically.

Delta-9-THC is contained in the drug “Marinol” licensed in the US for the indications of:

- AIDS-related anorexia associated with weight loss,

- Nausea and vomitus linked to cancer chemotherapy in patients showing an inadequate response to conventional anti-emetic treatment.
- This active ingredient may also be prescribed by doctors in Austria.

At this moment no medical drug containing delta-9-THC as an active ingredient has been approved and no application for approval has been submitted in Austria; upon prescription by a doctor, Marinol as well as nabilone – a THC derivative with a similar action pattern as dronabinol – may be imported by a public pharmacy into Austria. The import from Germany and there is only one company in Austria that does this.

In addition, there are Austrian doctors prescribing delta-9-THC (dronabinol) in the form of magisterial preparations in capsules. This is permitted under Austrian narcotic drugs legislation. In this form, the medicine is less costly for the patients than imported Marinol.

Furthermore Mrs. Frommer elaborates on the political circumstances within Austria.

Political circumstances

There are clinical studies going on for further indications (in particular for MS and pain alleviation) but they have not been completed yet. Depending on their results, a decision will have to be made on the issue whether prescription will be permitted for other indications as well.

Mrs. Frommer ends her introduction by emphasising the importance of standardisation of the products.

Standardisation of the product

Concerning plant medicines, such as the agents extracted from cannabis or synthetically produced, the agents' concentration depends, in particular, on climate conditions, type of cultivation, soil properties and many other small factors. The standardisation of a plant product, in this case of THC, mainly offers the advantage of guaranteeing the patient always receives the same amount of the agent. According to the international scientific literature available, the prescription of preparations containing delta-9-THC in a standardised concentration is advisable if administered orally for clearly defined indications.

Canada

Mrs. Cindy Cripps-Prawak gave the power point presentation "Marihuana Medical Access Regulations, Medical Cannabis Policy in action". Marihuana for Medical Purposes is a broader initiative of which the Marihuana Medical Access Regulations is one component.

Mrs. Cripps started explaining the announced point of view of the Health Minister Allan Rock on the compassionate measure taken to improve the quality of life of sick Canadians, particularly those who are terminally ill (announced on July 4th, 2001). This compassionate measure is applicable to individuals that suffer a severe illness that cannot be treated by the medicines available.

The overview of the issues discussed is as follows:

- Origins – Compassion, S.56, Court decision,
- Marihuana for Medical Purposes Initiatives
 - Regulations - July 30, 2001
 - Eligibility: Possession, Cultivation
 - Research Plan
 - Federal Supply, Distribution

- Policy Development
- Related Issues
- Next steps

To elaborate a bit on the background and origins on the medicinal use of marihuana, Mrs. Cripps explains some history. Under the authority of section 56 of the *Controlled Drugs and Substances Act* exemptions can be provided for medical purposes. The development of this process, that enables the providing of exemptions, took place within the following timeframe:

May 1999:

- Guidelines published

June 1999:

- First exemptions granted
- Health Canada Research Plan for Marihuana for medical Purposes (Status Report)

February 2000

- Multi-stakeholder consultation to improve the section 56 exemption process

After this, the court made the following decisions on July 31, 2000:

- Court of Appeal for Ontario ruled that prohibition on possession of marihuana in CDSA was unconstitutional and of no force.
- Decision set aside for one year to allow government to develop regulation to fill the regulatory void.
- Failure to regulate would have made it lawful to possess marihuana, not only for medical purposes, but for any purpose in Ontario.

On July 30, 2001 the Marihuana Medical Access Regulations (MMAR) came into force. Furthermore Mrs. Cripps explains the framework of regulations. Regulations clearly define the circumstances and the manner in which possession and cultivation of marihuana for medical purposes will be permitted. The regulations deal, among other things, with the following two main components:

- Authorisation to Possess;

Holders of an authorisation to possess may possess a maximum 30-day treatment supply of marihuana at any given time. For example, a patient whose daily dosage is 3 grams will be allowed to possess no more than 90 grams (3 grams x 30 day treatment) at a given time.

- License to Cultivate;

Holders of an authorisation to possess can also hold a license to produce and grow their own marihuana, or they can choose to have a designated person grow the marihuana for them. Applicants are asked to indicate their preference on the application form.

- Applicant or designated person;

A designated person, or grower, must be 18 years of age or older, and ordinarily a resident of Canada. A grower will be issued a production license and an identification card. A production license is required to grow marihuana for medical purposes.

Within the regulations the following three categories of applicants are identified:

Category 1: This category is for applicants who have terminal illnesses with prognosis of a life span of less than 12 months. A medical practitioner must provide a medical declaration that states, among other things, that:

- All conventional treatments have been tried or reasonably considered.
- The benefits of using marihuana exceed risks.

Category 2: This category is for applicants who suffer from specific symptoms associated with certain serious medical conditions, namely:

- Multiple Sclerosis

- Spinal Cord Injury
- Spinal Cord Disease
- Cancer
- AIDS / HIV infection
- Severe forms of Arthritis
- Epilepsy

As described for category 1, also for category 2 it is required that specialists provide a medical declaration that states the issues mentioned above. There is an assessment needed from both the general practitioner as well as the specialist (so 2 experts).

Category 3: this category is for applicants who have symptoms associated with a serious medical condition, other than those described in categories 1 and 2, where among other things conventional treatments have failed to relieve symptoms of the medical condition or its treatment. Declarations from two medical specialists must accompany the application.

The physicians' involvement is related to the following issues:

- General practitioner / specialist;
- Medical necessity - Symptoms and medical conditions;
- Benefit / Risk Assessment;
- Tried or reasonably considered other conventional therapies and are not medically appropriate;
- Patient's follow-up;
- Dosage identification.

The physician plays an active role in determining the necessary treatment and must contribute his or her expertise during the entire process of the treatment.

Mrs. Cripps now elaborates on the issue of the licensing for cultivation. In general can be stated that:

- It applies only to cultivation and possession of marihuana;
- ID Cards are used;
- Hashish or other derivatives are not included;
- The cultivating can be done indoor (estimate of 30 grams per plant) or outdoor (estimate of 250 grams per plant), but not concurrently:
 - Cultivation – number of plants based on dosage recommended by medical practitioner;
 - Max three growers in one location;
- If at a rented location, the landlords' consent is required
- The Growing is not allowed nearby schools;
- The Authorisation to Possess must be approved before a License to Cultivate would be issued.

The growing of the cannabis could also be done by designated persons. The requirements that will have to be met for this are the following:

- The designated person should be identified by the applicant;

Licensed users can grow their own marihuana, or can have a third party grow it for them.

Applicants who want to grow their own, or have designated grower provide them with medical marihuana are asked to indicate their preference on their application form.

- It should be a volunteer – no exchange of money or product is allowed;
- No designated drug offence – none in previous 10 years is allowed;
- The person should be 18 years of age or older;

- Reasonable precautions to protect plants and dried marihuana from loss or theft will have to be taken.

The amount of marihuana that can be grown and stored at one time depends on the daily dosage that has been prescribed by a physician, and whether plants are grown indoors or outside. Health Canada has produced a guide for growers, which outlines the Regulations. It also explains the application process for a production license for individuals who want grow their own supply of medical marihuana, or for those who have chosen a designated-person to supply them with marihuana. The guide explains the criteria, which must be adhered in order to comply with the Regulations. It is available at the Health Canada website at www.hc-sc.gc.ca .

The Legal/Policy Concerns at this moment are:

- Status Confirmation – Voluntary Consent;
 - CPIC?
- Inspection provisions;
- Drug Testing – Workplace;
- Prior Substance addiction – Monitoring;
- Licit Source of Seeds;
- Obligation to supply;
- Second hand smoke.

Furthermore Mrs. Cripps provided an overview of the research plan and briefly discussed the development of the research strategy, the different components of the plan and updated on the progress to date. She concluded by explaining what the expected outcomes of this research programme are.

There has been a renewed public interest for the use of marihuana for therapeutic purposes in the last 5-10 years. "Renewed", because there has been several anecdotal reports from the last century and before about the use of the cannabis plant to relieve several symptoms and ailments; the use of cannabis by Queen Victoria for example has been often cited. However, with the development of better drugs and treatments, cannabis was no longer part of the modern pharmacopoeia. Two points are important mentioning:

- Historically, cannabis was not smoked when used for therapeutic purposes, but rather taken orally;
- THC has been developed as a drug and is available in oral form under physician's prescription on the Canadian market (Marinol, Cesamet).

In the last 10 years, there have been claims from the public, not only in Canada, but also in the US, in Europe and Australia that smoked cannabis is effective in relieving a whole variety of symptoms. However, the evidence for this is only anecdotal and has not yet been supported by solid controlled clinical trials.

In 1999, a strategy was developed to address public concerns and interest.

- Compassionate programme: section 56;
- Research programme: with the advice of the Expert Advisory Committee on New Active Substances of the Therapeutic Products Programme;
- Domestic source of material.

In addition to this, Mrs. Cripps elaborates on the specific research programmes:

- Contribution Agreement with the Community Research Initiative of Toronto (CRIT)
 - Pilot study will start early 2002 in Toronto;
 - Multi-centre trials in 2002-2003
 - About 30 patients on smoked cannabis; for appetite in patients with HIV AIDS.
- Partnership Programme Health Canada/Canadian Institutes for Health Research (CIHR)
 - Pilot study to start in early 2002 in Montreal

HC/CIHR is a partnership programme with the granting agency to ensure scientific validity of the studies. The initial focus of the plan is to look at the smoked form of marihuana. If benefits are shown then, comparisons with other routes of administration (e.g. oral extracts, suppositories etc...) as well as the effects of individual components of marihuana could be examined. The first approved study is a 4-week study with 32 patients with chronic pain.

- Monitoring of authorised individuals who will receive marihuana from Canadian Source;
 - Approach and details to be developed.

The Minister has said that marihuana will be provided to individuals who will agree to provide information to HC for monitoring and research purposes. HC has to develop an approach to collect and analyse valuable information.

- Supply;
 - Prairie Plants System, Saskatoon (growing operation in Flin Flon, Manitoba);
 - Seeds: NIDA; seized; others;
 - First crop due January 2002.

The outcome of the research programme can only be positive. Positive, because knowledge will be acquired about the safety and efficacy of marihuana for medical purposes. The expected outcomes are:

- Increased knowledge on the efficacy and safety of marihuana
- If studies show potential therapeutic benefits of smoked marihuana
 - Pharmaceutical interest for new drug/ routes development risk/benefit assessment and regulatory approval

Everyone agrees that the smoked route of marihuana does not have a future in terms of becoming an approved product. If studies show that smoked marihuana has some benefits in some particular medical conditions, the pharmaceutical industry will then likely be interested in developing products, other formulations or routes of administration. Health Canada is not in the business of developing drugs. The risk/benefit analysis will then be done as for other drugs approved for use in human i.e. through regulatory approval

- Regulatory amendments to the Marihuana Medical Access Regulations
 - Categories of symptoms;
 - Dosages.

Based on the new knowledge, regulatory amendments may have to be made to the Marihuana Medical Access Regulations, for example, a category 2 symptom may have to be removed from the list or daily doses may need to be more precisely determined. If studies are showing no benefits from the use of smoked marihuana, the continued need for the Marihuana Medical Access Regulations may be questioned.

In addition, a decision in regard to the continuing with the MMRP or not will also have to be made, as well as a decision on the source of supply.

Mrs. Cripps explains the cultivating aspect from a federal point of view. Concerning the contractor - selected through competitive process in December 2000 the following issues have been discussed:

- To provide a reliable source of affordable, quality, standardised marihuana for medical and research needs;
- Prairie Plants System, Saskatoon (growing operation in Flin Flon, Manitoba);
- First crop due January 2002;
- PPS also responsible for fabrication and storage, laboratory testing, packaging, labelling and distribution of product;

- Seeds: NIDA; seized; others.

Mrs. Cripps ends her presentation with the next steps that have been summarised as follows:

- Further outreach on implementation;
- Identify and resolve issues on cultivation, production and supply of marihuana by third party sources;
- Minister's commitment to an ongoing review process;
- Resolve key policy issues:
 - One or more licit sources?
 - Involve pharmacies in distribution?
 - Should marihuana be prescribed?
 - Charge patients?
 - Should provincial drug plans pay for marihuana?
 - Relationship with anti-smoking initiatives
 - Impact on Law Enforcement
 - Destruction of Surplus Material (Diversion).

An additional remark has been made to inform the participants on some statistics:

- Exemptions granted 521
- Authorisations issued 38

Belgium

Mr. Frans Gosselinckx from Belgium elaborated on the federal government's drug policy that was presented to parliament. The decision was made to establish a working group that would examine drug problems from a wider perspective (Council of Ministers, January 27th, 2000). The federal Security and Detention plan stated some requirements for this working group. They would have to submit a policy note at the federal level that would cover an evaluation of the situation and a round up of the situation in neighbouring countries. In addition to this recommendations would have to be made by the federal government.

The goal of this drug policy note is to solve the major problems in regard to drug consumption and addiction. Within the context of a standardisation policy focussing on rational risk management, the policy note confirms that drug abuse is a public health problem.

The note contains several action points, divided into five chapters:

- An integrated and comprehensive approach;
- Evaluation, epidemiology and research;
- Prevention;
- Assistance, risk reduction and rehabilitation and reintegration;
- Control.

The federal government is in favour of drug prevention in a way that reduces harm; Belgium prefers to focus their attention on the assistance and reintegration of the drug user, instead of punishing. Instituting criminal proceedings against drug users remains the last resort. Only when the drug user has committed a crime against law and order, is this considered to be appropriate. Only in some specific high-risk situations, such as driving under influence of illicit drugs, should drug use be (considered to be) punished.

This is gist of the Belgian policy on drugs. In fact, the regulations concerning narcotic drugs and psychotropic substances have not fundamentally changed yet.

After explaining the federal government's drug policy Belgium concentrates on the initiating of clinical trials with medicines containing one or more THC.

These trials should have been conducted for a limited number of indications:

- Nausea and vomiting during chemotherapy and radiotherapy;
- Glaucoma;
- MS (spasticity);
- AIDS-related syndrome;
- Chronic pain when all other pain management therapies have failed.

In addition, the opinion of the Ethics Committee is required before any trial can be started.

Following the publication of the Royal Decree, Belgium was faced with the problem of acquiring the active principles without violating the provisions of the International Conventions. Belgium contacted the Netherlands to find practical solutions to this problem. That is also the reason for Belgium to attend the conference. They hope to be able to open up a new supply line of standardised THC-containing medicines that comply with the requirements of the international conventions.

Summary

Countries are in very different stages of the discussion. All countries allow or will allow clinical trials. In Slovenia there is almost no discussion yet. In France there seems to be discrepancy in supporting the medical use, because they believe it will be used for legalising the recreational use.

Concerning the public opinion: in some countries the discussions on medical use and on legalising the recreational use are intermixed one another. In other countries there are two separate debates.

Dronabinol is available as a pharmaceutical product in Germany and in Canada. The use of cannabis will not be authorised in Germany, only substances of cannabis.

Merck & Co Germany has in Germany the licence to develop extracts of cannabis for the monograph. Merck & Co does not have a licence for the marketing of the extracts; they would need a new one for that.

In France there is temporary use of compassionate programmes, but medical experts do not make use of it.

In Slovenia it is possible to use cannabis for research purposes.

The UK stated that the long-term objective should be to produce a medicinal product that meets the normal requirements and standards for pharmaceutical medicinal products in relation to quality, safety and efficacy.

In Belgium there is very restricted use for cannabis for clinical trials, dronabinol has less restrictions.

Single Convention on narcotic drugs

Mrs. Ingrid Horst elaborates on the Single Convention on narcotic drugs of 1961. This Convention of the U.N., says in art 28 that if a party allows the production of cannabis it should establish a national agency.

The national agency is a monopolist on dealings with respect to cannabis, such as importing and exporting, wholesale and stock keeping. This means that the agency acts as an intermediary between growers of cannabis and those who need cannabis. Growers are obliged to sell their whole crop to the agency. The national agency supplies the licenses for growing cannabis. These licenses indicate the conditions such as where and how much cannabis can be grown.

The countries that have established a national agency are:

- The USA: the National Institute of Drug Abuse. This agency concentrates on the abuse of drugs and its research focuses on the drug abuse with cannabis and other drugs.
- The Netherlands: Office of Medicinal Cannabis, OMC (2001) of the Ministry of Health, Welfare and Sport.

These two are the only national agencies in the world that are allowed to import, export, and wholesale and keep stock of cannabis.

In Canada, Health Canada, through its Office of Controlled Substances, is also in a position to control all the activities related to the cultivation of cannabis. Since this governmental unit owns the entire crop which is produced under contract by Prairie Plant Systems Inc., the creation of a separate agency was found to be redundant.

In the Netherlands an amendment to the Opium Act has been presented to the parliament. This amendment, article 8h, is the legal basis for the production of cannabis. It also should guarantee that no cannabis leaks to illicit markets.

The amendment reads as follows:

The Minister of Health, Welfare and Sport will take care that:

- enough hemp is cultivated in the Netherlands for research with respect to the medical application of hemp, hashish and hemp oil or for the production of medicines;
- the above-mentioned cultivated hemp is used for the purpose described.

Another amendment, article 8i, reads:

With respect to hemp, hashish and hemp oil our Minister is, to the exclusion of others, authorised to:

- bring it inside or outside the territory of the Netherlands;
- sell and deliver it;
- have it available, with the exception of stocks maintained by those who have a license to cultivate, work up and convert.

This article is the implementation of article 28 of the Single Convention. The Dutch minister has the monopoly on the dealings mentioned, and she has given a mandate to our office with respect to this monopoly.

Discussion

The participants discuss the need of establishing a national agency when a country permits the growing of cannabis.

On some aspects the Single Convention can be interpreted in several ways; the text is of course the result of negotiations.

The Cannabis in Multiple Sclerosis Study (CAMS) imports its cannabis products and only the GW Pharmaceuticals (GWP) grows cannabis for use in its trials. At present this is restricted to very minor cultivation under laboratory conditions solely for the purposes of clinical research and is licensed as such. The UK's interpretation of Articles 23 and 28 is that they relate to trade in opium and/or cannabis and, on that basis, require signatories to establish appropriate agencies. In our situation the cultivation at present is not for any purpose connected to trade but, as explained above, is exclusively for medical research. Our view, therefore, is that an agency is not required. We do, however, recognise that this position will change should the medical research result in a product, which is then traded either domestically or internationally. In response to an enquiry from INCB the UK has put this interpretation to them. The UK undertook to discuss the possibility of sharing any response from the INCB with participants of this Conference.

France would prefer the agency not to be obligatory for growing cannabis, because it would take a lot of time to establish such an agency. In addition France asks the Netherlands to elaborate on their point of view concerning this matter. The Netherlands respond that in their perception the Single Convention does oblige to the establishing of a national agency, also in the case a country restricts the growing of cannabis to clinical trials.

France proposes to put the question concerning the interpretation of article 23 of the Single Convention together to the INCB. In addition to this, the question is raised if the establishing of a joint EU-agency is considered a possibility. Both suggestions are not supported by the other countries, so the chairperson suggests that each country should separately ask the INCB to clarify the articles 23 and 28 of the Single Convention.

In the context of whether "trade" was the triggering factor for the establishment of an agency, Canada's point of view was that "cultivation" was sufficient. Canada did not create new jobs or new organizations; however, the responsibilities related to the cultivation, importation, exportation etc... of cannabis are clearly those of Health Canada. In that sense, the creation of a separate entity (agency) was found to be redundant. In Canada the patients who grow themselves do this strictly for personal use. The crop out of the mines is government property, so Health Canada does not have to claim it from the growers.

In the Netherlands there is a separate office, but it is within the Department of Pharmaceutical Affairs, which is a part of the ministry of Health, Welfare and Sport. The Netherlands is of the opinion that a national agency is in all cases obligatory.

Switzerland raises the question if clinical studies would have been possible without establishing a national agency. What if further trials do not give us the effect we expect?

Canada answers that should the cultivation of cannabis no longer be required, the agency, as a virtual entity, will no longer be active.

In Austria cannabis is not allowed, therefore the need of an agency to control any growing of cannabis is not supported.

Belgium does not wish to establish an agency in the near future.

Switzerland uses the cannabis extracts only for research purposes. Switzerland does not interpret the convention in the restrictive manner that limits production or extraction of cannabis. Switzerland prefers to continue on the same track as they are doing now, which

means that they wish to continue the research. Only when medicinal cannabis is put on the agenda, the establishing of a national agency will be an issue for consideration.

Slovenia has a shortage of personnel, so they are not able to establish an agency.

The question is raised why cannabis and opium have been singled out in the need for an agency. The Netherlands respond that they have not been singled out, because this rule applies to all substances that can be cropped (see the Single convention articles 23 and 26), e.g. cannabis, opium and coca leaf.

The question is raised if it is allowed for countries with a national agency to export or import cannabis to other countries that signed the Single Convention. The answer is yes. The Netherlands state that if there are countries that wish to use cannabis for different purposes, but do not have the resources, the Netherlands will be able to deliver within a short timeframe.

Product Development

The product development aspects discussed at the conference concern the aspect of standardisation and the development of different strains, placebo and preparations.

Standardisation

Canada starts explaining its approach in regard to standardisation; Canada is treating this product exactly as any other pharmaceutical product. The product needs to meet the standards of an approved product. They do not differ between purposes of use. In that context they follow good manufacture practice and they are establishing a list of these requirements. After review by the regulatory office they will be able to distribute the list of requirements, but not at the moment.

The Netherlands states that they have asked offers from growers for a trial; more in specific laboratory figures were requested and they would welcome a method of analyses that makes the figures comparable.

Canada expects that the accepted method will not be restricted to one. They will be looking at the validity of the method, instead of restricting to one method.

The Netherlands point out that some standardisation however is required for the development of a monograph. It seems it would be best if the monograph would be developed and/or approved by the European Pharmacopoeia.

Belgium mentions that GW Pharmaceuticals should be involved in this standardisation, because of their extensive knowledge. The UK agreed with this, but added that it would be a matter for GW Pharmaceuticals to what extent they wished to be involved.

Health Canada does not only own the plants that are being grown by the earlier mentioned company, but they also own the method of manufacturing. Canada is still in research before they can make all used methods public. Canada needs highly detailed chemical dossiers for releasing standardisation of the plant material. The standardisation is not restricted to the extract, but also applies to the plant material.

Germany explains that a monograph contains a description in which the:

- Plant can be identified;
- The content of the most important substances can be determined;
- The impurities can be determined.

In addition the monograph contains limits in the percentages of the content and describes the method, which has to be used.

Canada asked if a difference is made between the varieties of cannabis that are alleged to exist in the world. Mrs. Lander (Germany) does not have the exact answer to this question concerning this special monograph, but in principle it is possible that the leaves from several varieties are used if they meet the specification. . Canada explains that concerning the concrete specifications described in monographs the framing should not only be intelligible to the research and the science community but also to the consumers of the end product.

There is a difference between Canada and Germany in regard to the end product, where in Canada this is the plant. Mr. Möller (Germany) adds to this that the monographs for plants are being used to facilitate the extraction of substances from this plant. The Netherlands explains that there is a need for a monograph that describes all different varieties.

The UK requests an elaboration on the plant breeder's rights; Mr. Scholten (Neth.) explains that there are indeed plant breeder's rights for cannabis and he referred to the harmonised system in Europe concerning this matter.

Mr. Stamm (Switz.) asked to the pharmacists present a confirmation on the issue of extraction, cultivation and standardisation of cannabis; is the standardisation of cannabis just like any other herbal development? Most present pharmacists confirm this. However, Mr. Scholten disagrees on this matter, because in practice no herbal medicine is made from standardised starting materials. They are never grown under standardised conditions and originate very often from an unknown source somewhere in the world. The standardisation applied now on cannabis is quite unique. For the development of a medicine from cannabis this is desirable, because the quality and the composition varies a lot at this moment.

France stated that it seems unclear if there is any *scientific* base for the determination of the various cannabis (extracts) specified in regard to the efficacy for treatment of certain indications. It seems interesting to determine scientifically which type of cannabis fits with a specific indication, to reduce the indication.

Canada points out the problem concerning the gathering and validation of the expertise knowledge already existing in the illicit market. How do we do this ethically? Mrs. Cripps-Prawak asked the participants if they have any experience in making use of this existing knowledge in the illicit market. The Netherlands respond that they will legalise a grower, which exclusively grows for medicinal use; this grower has built a database that contains several types of plants and compares the characteristics of the various plants and their efficacy as assessed by users of the plants. Mrs. Desjardins stresses the importance of the comparability of results derived from clinical studies. To be able to compare the results, it is important to have the same profile describing (starting) products used.

France is interested in the criteria Canada used when choosing the company for the growing of the marihuana. Canada responds that they were looking for capacity to deliver, experience in the horticulture; they were not looking for the legalisation of an existing grower. They would accept a learning curve in the production of the marihuana by the grower of choice. Canada was criticised for not choosing the already existing experts in the field (on the illicit market).

In respond to a question asked concerning the evidence found to prove the efficacy of cannabis (extracts), Canada elaborates on results found of efficacy of dronabinol for some indications. The field is very dynamic and new data is gathered every day, but it is not possible to support efficacy based only on preliminary results. It would be useful to use the knowledge of the compassionate groups for identifying differing types of cannabis, as a starting point; this could reduce the required time for research.

Austria states that it is very useful to do clinical, evidence-based studies with single agents or compounds too, because of their interesting profiles. A problem right now is that most of the studies are animal studies and not clinical trials, so it necessary to gather proof step-by-step through clinical studies.

Mr. Stamm raises the question why national agencies are being established and export and import is taking place, if there is so little prove out of clinical studies. "Why are we so flexible in regard to cannabis?"

Austria responds to this by pointing out the very specific characteristics of cannabis, which cannot be found easily within other plants. Cannabis contains own receptors, which is interesting to research. France responds by taking another perspective: it could be stated

that the medical science is very late in starting the research in this area. This has been delayed by several factors for example the difficulty in working in this area, the difficulty in accessing the substance, and the difficulty in funding the clinical trials.

Mrs. Desjardins explains that the renewed interest in cannabis is also a political issue; patients are pressuring, that they do not want to use the chemicals, but the natural product.

The Netherlands makes the final comment on this issue by explaining that the national agencies only enable research on the topic, for all the other herbals an agency is not necessary.

Placebo

Mr. Scholten elaborates on the placebo subject. There is a pilot study with oral cannabis extract in gel capsules finished in Amsterdam last year. A comparable study by inhalation will start now. The Netherlands are now searching for a type of cannabis that can be used as placebo. Many people say if you take the cannabinoids out you take out the smell as well, but that does not seem to be true. The percentage of the cannabinoid may not be 0%, but low enough to be a "real" placebo. Theoretically however, there will always remain some doubt concerning the risk that unknown pharmacologically active constituents are still present in such a placebo.

Conclusions

It is very difficult to standardise, concerning several aspects. It is clear that it is important to share as much as possible and to find out what the best practices are in these issues.

The need for monographs was discussed in depth. Germany has already developed 2, and a third one will come. Maybe it is possible to do more on a European level or even in a larger sense. The Netherlands also indicated that they are planning to develop monographs.

Another issue that was discussed was the gathering and combining of knowledge out of the illegal sources. The question was raised in what way this could be done without compromising the research.

Furthermore, the development of strains was discussed and the difficulties in this arising from the fact that it concerns controlled substances.

Also the question came up why we are even trying to deal with cannabis at all, if there is so little evidence. There seems however to be enough indications to go on with the research.

The chairperson now closes the first day of the conference.

Second day of the conference

The chairperson opens the second day of the conference. She elaborates on the agenda and leaves the floor open for any questions or remarks concerning the first day. There are no comments being made by the participants.

Clinical trials

Mrs. Myra Klee gives a power point presentation on the subject of clinical trials.

She elaborates on the following issues:

- Requirements
- Surveys
- Questions to be answered
- Standardised trials
- Conclusions.

The requirements for clinical trials are quality, efficacy and safety. The quality means that a dosage form of constant and known composition is available for the products used in the clinical trials. The efficacy is established when the effectiveness of a medicine is proven by statistics. The safety means that the side effects of a medicine or treatment are in proportion with the therapeutic effect. The use of cannabis must meet these requirements the same way as other medicines do.

Concerning the surveys Myra elaborates on:

- British Medical Association report
- British Medical Journal (volume 323)
- Dutch Health Council report
- Journal of Cannabis Therapeutics

For more in depth information upon these surveys Myra referred to the proposed chapter 10 of the reader.

It is stated that there are still questions to be answered in regard to the medicinal use of cannabis. Three questions that Myra discusses are:

- Which cannabis for which indication?
- Difference between dronabinol and cannabis (extracts)?
- Which dosage form for which indication?

At this moment there are two large trials:

- A Phase III trial by GW Pharmaceuticals concerning the indication MS;
- Institute for Oncology and Immunology concerning the indication cancer.

Mr. Möller points out that there is a problem in finding patients for the clinical trials.

The conclusions:

- many surveys but no good clinical studies showing efficacy, safety and quality
- a lot of questions to be answered by clinical trials
- co-operation important to combine trials into international partnership. This especially applies for those clinical trials, where it is difficult to find patients.

An example of an indication where this is the case, is the Tourette's Syndrome: a small trial is being done in Germany for this indication, but there is only a small group of patients for this trial. It would seem useful to combine efforts of the countries, to enlarge the knowledge and enhance the results, which are already very promising.

The chairperson summarises that there are now 2 studies going on, the rest is anecdotal. We are at the beginning of the road concerning research on this subject.

She asked the participants if there are any countries with plans for clinical trials. Another subject of interest mentioned is the prioritising of indication; it requested to discuss a bit on this item. It could help, if the knowledge is shared and the efforts are combined. Furthermore the practical co-operation is an issue to discuss.

Canada responds to the request as follows: 2 clinical trials that are being funded by Health Canada, they have not yet begun. The first one is being run by the Community Research Initiatives of Toronto. Their objective is to assess the impact of smoked cannabis on the appetite of the HIV patients. The second trial is going to be funded by Health Canada and the objective is to investigate smoked cannabis in relation to neuropathic pain.

The third clinical trial is the GW clinical trial: a small pilot in relation to MS. Details can not be shared as this is proprietary information. Health Canada, in partnership with its national granting agency, is funding clinical trials on the efficacy and safety of marijuana up to a maximum of CAN \$ 1,5 million per year. This program is funded for the next two years, and it might be extended to an additional three years. This is however still under discussion.

Canada expects to have more successful trials in the future, which would also make it easier to get funding.

The priorities are smoked marijuana in the first phase, and then to develop alternative delivery systems (also for cannabis extracts). The approval for the funds has been given; at this moment approval for the studies is required.

Norway asked in what manner is being dealt with the impairment of the risk for patients participating in a trial. How is the degree of impairment monitored? Canada responds that it is handled in the same way as with other clinical trials. It is considered to be the responsibility of the investigator. The effects are not well known, but well enough to conduct trials taking into account the impairment risk and take measures to minimise risk.

Germany comments that in Germany the pharmaceutical industry pays the clinical trials. The government pays as an exception only one clinical trial for heroin, but not for cannabis.

In The Netherlands it is the same as in Germany; the budget is small enough for 1 or 2 small clinical trials, but not for all the trials needed for the development of a medicine. It is possible that the European Parliament decides that there should be funding for clinical trials for cannabis in the future.

Mr. Scholten elaborates on the European issues: the European Parliament amended the proposals for the 6th Framework Programme (which is on all healthcare issues, and involves billions of Euros) with the issue of medicinal cannabis.⁴ It has been adopted last week, and now has to be approved by the European Commission. Organisations can apply for subsidy in this field; they have to organise in consort with companies of at least three different

⁴ Remark of Willem Scholten: After the conference it got out that the amendment was not supported by the European Commission nor the Board of Ministers. There remains a chance that medicinal cannabis will be included in one of the subprogrammes, for instance that on cancer. This will depend also on the support of the Member States.

countries and together they can make an application. For the developments of product the subsidies can go up to 50%.

There is proposal being written by a University in the Netherlands and they are looking for participants within industries in other countries. This concerns the a Eureka project programme. That is another source of funding for the EU countries. Mr. Scholten explicitly requests that if the participants know of an industry or university group in the European countries interested, they should let this know so this organisation can be brought into contact with this university.

France asked the question if specific information on clinical trials is available; especially where registered medicine like Marinol is concerned. Canada responds to this by stating that the availability of detailed information (publishing of data) depends on the wish of companies to make it public or not.⁵

Furthermore France requests to elaborate on the reason for Canada to focus on research on *smoked* marihuana instead of comparing several forms.

Canada responds that the first phase on smoked marihuana is more a political issue than a scientific one; several patients are saying that the oral form does not work for them. Therefore it was decided to determine in the first phase whether positive results can be shown. Should this be the case, the second phase would then prioritize the development of more acceptable routes of administration.

Mrs. Klee requests to receive more information on the Canadian trials, so she can update the list.

Belgium mentions that it is also possible to mix the cannabis with herbs instead of tobacco, so you don't need to smoke it. Canada responds to this that the marihuana is now smoked pure, and they do not want the tobacco in it. The leaves are also not included. It is an unacceptable composition of the products in the perception of the consumers.

Concerning the request of the chairperson to elaborate on the running of clinical trials France responds as follows: there will be clinical trials with dronabinol in the next month in France. The specific indications involved are:

- 1) Appetite disturbance, anorexia for example HIV patients;
- 2) MS, neurological pain (Tourette's syndrome)
- 3) Chronic pain where the patients have a resistance to traditional treatments. The clinical trial will start at the beginning of February 2002. The Ministry of Health in France will be conducting the clinical trials with support of academic institutions.

Slovenia asked if vaporisers are used in clinical trials. Canada responds that this is not the case at this moment. It is hard to quantify the doses with a vaporiser, so it is even harder to compare between the several forms. In the Netherlands vaporisers are being used, but not yet in the clinical trials. It is planned for the trials to use little stainless steel pipes.

A question is asked concerning the preparations used in the clinical trials that will be done in France. At this moment the protocol has to be read and then they will look further into the several preparations and forms of administration.

⁵ Remark of Mrs. Desjardins: A summary of information derived from clinical trials is however available in the Product Monograph (PM) at the time a product is approved for marketing. The PM may be obtained from the manufacturer and is a public document. Most of the content of the PM is also available to physicians in the Canadian Compendium of Pharmaceuticals and Specialties.

In the UK 4 types of sprays are used containing:

(1) water, (2) THC, (3) 50% CBD + 50% THC, (4) only CBD.

Concerning the clinical trials, the chairperson is interested in the possibilities for contacting the several countries. In France Mr. Lowenstein can be contacted. In the UK GW pharmaceuticals would have problems giving information about their trials, because it is proprietary.

The Netherlands is planning a trial with 16 patients in regard to MS, comparing two inhaled active types of cannabis and an inhaled placebo cannabis. This will be done in a similar way as the previous oral pilot with Marinol, Cannador and placebo capsules. They hope this will give a comparison between oral administration and inhalation. The ministry of Health, Welfare and Sport will subsidize this trial.

Mr. Scholten adds a general remark concerning the sharing of information: the International Association for the use of Cannabis as a Medicine has a newsletter being distributed frequently. Should any of the participants be interested in this newsletter, Mr. Scholten can be contacted for more details. (note afterward: for the IACM-Bulletin archives and free subscriptions see: <http://www.cannabis-med.org>)

The chairperson now closes the inventory concerning the ongoing and planned clinical trials, the funding of these trials and the possibilities of contact to obtain information about the trials in the countries.

Comments on the proposed chapter 10 of the reader

The chairperson requests the participants to comment on the proposed chapter 10 of the reader. This paper was initially prepared for the EU conference in February 2002. It may however be necessary to adjust the paper, should there be disagreement on the content.

Germany states that they cannot decide about the content of chapter 10 right now; they would need time to read it. The UK (Mr. Gerrard) said that as he is neither a medical practitioner nor a pharmacist, he is not competent to comment on the contents of the document.

Mrs. Klee gives a summary of chapter 10. At the end of the reader there is large list of indications found. Canada states that they do not endorse this annex. They would prefer this list not to be added as an annex.

Mrs. Lander would prefer to adjust the term "safe" in the first paragraph to "relatively safe".

Mrs. Klee mentions that the document prioritises the four indications; these indications have the most relevance within the Office of Medicinal Cannabis.

Concerning the list of the prioritised indications in chapter 10 France makes the remark that this list is probably too short. Mr. Scholten adds to this that Germany also provides a list of indications in their contribution to the reader; when rewriting the introduction of the paper it will be useful to take into account the input of Germany as well.

Canada would like more elaboration on the prioritising of the indications. They wish to make it as easy as possible to access the researchers and their studies within other countries, because there is a very small group of researchers. The chairperson responded that the issue of collaboration is a specific item on the agenda of the afternoon; this will be discussed in more depth later on.

The Netherlands state that it is not possible to research everything; in first instance they looked at those indications, what seemed the most promising. Canada points out that they have no data of the indication Epilepsy in relation to cannabis. Mrs. Klee responds that the report from Berlin gives some information about epilepsy. The final remark made by France in regard to epilepsy, is that it is a very popular indication but very difficult to investigate.

It is suggested that placebo-controlled trials should not be stated as a prerequisite for validation of results derived from research. The appropriate term should be "controlled" or "randomised", instead of placebo-controlled trials.

The chairperson asked if the participants agree on the questions given in the chapter on page 30. Concerning the third question, where it is asked if there is any difference between oral administration, with which the first pass effect can occur, and other dosage forms Canada suggests to leave out the issue of "the first pass effect".

Belgium mentions that the chapter does not compare THC with cannabis. The chapter maybe should make this difference more explicitly. Mr. Stamm mentions that maybe it is suitable to speak about dronabinol, so there will be no confusion.

It is suggested to the Netherlands that they should rewrite the introduction of Chapter 10, because it is too controversial. Annex 4 should also be skipped.

Mr. Stamm is interested in the connection between the results of this conference and the conference in February 2002. The organising committee of the February conference requested input for their conference, because of the fact that the participants of today's conference are considered to be the experts.

In addition, with regard to the paper and the report, the Netherlands responds that these documents will be presented as a contribution of the Netherlands instead of presenting it on behalf of all participating countries in this conference.

Mr. Gerrard requests that it not be shown that the paper or report is endorsed by the Conference. Mr. Scholten explains that the final report will not be a formal endorsement. The chairperson suggests that if there is a need to plan a second meeting (the earlier mentioned follow up of this conference) this could be an opportunity to rectify or add all information gathered. Chapter 10 will be presented by the Netherlands in an amended form on its own responsibility. If the participants agree, it can be mentioned that the paper and the report has been discussed at this conference but not formally endorsed by the participating countries. Canada points out that the conclusions made out of the conference should be considered as conclusions made by the Netherlands.

Myra suggests it is possible to add the input from the participating countries; she requests that the information can be sent to her if the participants wish to add their information.

Conclusions

The text of the proposed chapter 10 will be presented by the Netherlands on its own responsibility. It will be in an amended form, and as a document that is not related to this conference.

Furthermore, it may be useful to:

- create a type of network, where we can easily follow the process of the clinical trials of the participating countries;
- have collaboration with several countries for sharing patients for difficult indications (for example Tourette's Syndrome) .

Conclusions and ending

Canada wants to know what is possible for contacting other countries concerning research and clinical trials in particular trials related to the areas that interest them. They add to this that from policy perspective it is sometimes difficult to make the linkages with the primary investigators in the different countries. Canada offers to facilitate this process as much as possible.

The UK responds that it would be necessary to contact GW, for information of the trials. They can look for possibilities. The Swiss Federal Office of Public Health could serve as a point of contact if researches wish to gather information concerning the clinical studies done in Switzerland. If there is an official way from Health Canada to the Swiss Government, the information can be shared; this is a prerequisite because of the confidential nature of the information.

France points out that it is well positioned to create a national agency but it needs some adjustments in the organising. This is explicitly mentioned, because on the first day of the conference the position of France concerning the establishing of a national agency might have been unclear.

In general, it can be stated that the point of contacts in the other countries are the Ministries of Health. In Norway this would be the National Medicines Agency.

Concerning the funding aspect, Canada mentions that they are searching for collaboration with parties that bring their own funding.

The Netherlands is willing and able to export the dried herb to countries for clinical trials and compassionate use, if they do not have their own resources. Canada would explore possibilities for this, if there is an interest but this should be communicated explicitly.

France points out that *after agreement* on the report the distribution of the report in the several countries should be up to the countries themselves. The participants do not object to this. The chairperson suggests that the concept report can be recognised by the grey word "Concept" on each page. This grey word will be removed, when the final report is distributed to the participants. That document can then be perceived as an non-formally endorsed report of this conference. The report shows what we have been doing, if it is shown to other countries that have not been attending this informal meeting. It could be used to create understanding.

The chairperson asked the participants if they feel a need for a follow up meeting. Canada sees a momentum being build. It is important to maintain that momentum; so we don't miss any opportunity for collaboration. It is concluded that there is a need for a follow up meeting.

Canada would like to look at the possibilities for sponsoring the follow up conference. This second meeting could be planned in September 2002.

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