



## LAWS AND REGULATIONS

### PROMULGATED TO GIVE EFFECT TO THE PROVISIONS OF THE INTERNATIONAL TREATIES ON NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES

*In accordance with the relevant articles of the international treaties on narcotic drugs and psychotropic substances,  
the Secretary-General has the honour to communicate the following legislative texts*

#### NETHERLANDS

Communicated by the Government of Netherlands

##### NOTE BY THE SECRETARIAT

- (a) Some editing of texts may be done by the Secretariat in the interest of clarity. In this connection, words in square brackets [ ] have been added or changed by the Secretariat.
- (b) Only passages directly relevant to the control of narcotic drugs or psychotropic substances have been reproduced in this document. Non-relevant parts of laws and regulations have been deleted by the Secretariat; such deletions are indicated by [...].

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**E/NL.2003/31**

**Compulsory Incarceration of Criminal Addicts by Order of the Judge under Criminal Law**<sup>1</sup>  
Act Of 21 December 2000 amending the Penal Code, the Code of Criminal Procedure,  
the Judiciary Organization Act and the Prisons Act

**Article I**

*The Penal Code shall be amended as follows:*

A third section shall be added to the First Book, Title II A, after the second section, reading:

**“THIRD SECTION**

*Compulsory Incarceration Of Criminal Addicts*

**“ARTICLE 38m**

1. On application by the public prosecutor, the court may issue the order of compulsory incarceration of criminal addicts only:

- 1°. Where it concerns a serious offence for which pre-trial custody is allowed;
- 2°. Where the accused in the five years preceding to the offence committed by him has been sentenced at least three times on account of a serious offence to an irrevocable prison sentence or order, a freedom-restricting order or to community service, where the offence is committed following the enforcement of these sentences or orders and where it must furthermore be taken into account that the accused shall repeat to commit a serious offence;
- 3°. Where the accused is an addict, and the serious offence referred to under 2°, the offence committed by him and the circumstance that it must be taken into account that it is likely that he shall repeat to commit a serious offence related to his addiction, and
- 4°. Where the safety of persons or property demand the issue of the order.

2. The order also intends to make a contribution to solving the addiction problems of the accused for the benefit of his return to society and the termination of his recidivism.

3. An addict referred to in the first paragraph must be taken to mean a person regarding whom facts and circumstances have demonstrated that he has a physical or psychological dependence on one or more of the substances referred to in list I pertaining to the Opium Act<sup>2</sup>.

4. The court shall only issue the order after submission of a reasoned, dated and signed opinion by a behavioural scientist. Where the date of this opinion precedes the commencement of the trial by more than one year, the court may only rely upon it with the consent of the public prosecutor and the accused.

5. The fourth paragraph is not applicable where the accused refuses to co-operate with the examination required for submission of the opinion. Where possible, the behavioural scientist shall draw up a report on the reason for the refusal. Where the person in question is willing to cooperate with the completion of another opinion or report to advise the court on the desirability or necessity of the order, the court shall make every effort to secure its submission.

6. As regards the issue of the order, the court shall take into account the content of the other advice and reports issued on the accused, as well as the frequency of serious offences for which the accused has previously convicted.

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<sup>1</sup> Note by the Secretariat: Entered into force on 1 April 2001.

<sup>2</sup> Note by the Secretariat: E/NL.2001/44

## “ARTICLE 38n

1. The order shall apply for a maximum period of two years, counting from the date on which the decision of the court imposed became final.
2. In determining the duration of the order, the court may take account of the period spent in police custody, pre-trial custody, in a psychiatric hospital or an institution for clinical observation under an observation order by the accused prior to the enforcement of the judgment.

## “ARTICLE 38o

1. The treatment shall take place in an institution designated by our Minister of Justice for the treatment of addicts.
2. Regulations shall be laid down under or by virtue of the law with respect to the enforcement of the order in and outside the institution and the legal position of the person to whom the order is issued.
3. The costs of the enforcement of the order shall be borne by the State. The costs of the enforcement of the final stage of the order shall be borne by the municipalities that participate in its enforcement in conformity with regulations to be laid down by General Administrative Order.

## “ARTICLE 38p

1. The court may determine that the order shall not be enforced.
2. The court that determines that the order issued by it shall not be enforced shall determine a period of probation of a maximum period of three years.
3. The application of the first paragraph is subject to the general condition that the person convicted does not commit any offence before the end of the period of probation.
4. The court shall lay down conditions with respect to the conduct of the person convicted for the protection of persons or property. The court may order a[n] institution of probation and after-care service designated by virtue of a General Administrative Order to provide assistance and support to the person convicted in the performance of the conditions.
5. A condition as referred to in the fourth paragraph may mean that the person convicted receive ambulatory or intramural treatment. Incarceration in an institution in this regard shall only take place by order of the court for a maximum period of two years. This condition shall only be laid down where the person convicted has declared his willingness to be treated.
6. Regulations may be laid down in conformity of a General Administrative Order with regard to requirements that an institution and a treatment referred to in the fifth paragraph must satisfy.
7. The conditions referred to in the fourth paragraph may neither restrict the freedom of the person convicted to practise his religion or beliefs nor his constitutional freedom.
8. The Public Prosecutions Department shall supervise the compliance with the conditions laid down.

“ARTICLE 38q

The court may, on its own motion, on application by the public prosecutor, at the request of the person convicted or his counsel, with due regard to Articles 38m – 38p:

- 1°. Supplement, amend or withdraw the conditions;
- 2°. Order a probation and after-care institution other than the institution previously entrusted with this to provide assistance and support in the compliance with the conditions.

“ARTICLE 38r

If a condition is not complied with, the court may, on application by the public prosecutor, proceed to order the enforcement of the order.

“ARTICLE 38s

1. The court may, either on its own motion, on application by the public prosecutor, at the request of the accused or his counsel, upon the imposition of the order, and after that once more on its own motion, on application by the public prosecutor, at the request of the person convicted or his counsel, determine that the public prosecutor must submit to the court a report, within a certain period, on the desirability or necessity of the progress of the enforcement of the order. The report must include a statement by the head of the institution with respect to the progress of the treatment plan of the person convicted.

2. If the court is of the opinion, further to the information provided under the first paragraph, that the further enforcement of the order is no longer required, it shall terminate this.

“ARTICLE 38t

The period of the order shall not run:

- a. During the time that the person on whom it is imposed is deprived of his liberty for another reason and during the time that he has evaded such deprivation of liberty;
- b. In the event that he remains unlawfully outside the institution where he has been placed for more than one day.

“ARTICLE 38u

Our Minister of Justice may terminate the order at any time.”

**ARTICLE II**

*The Code of Criminal Procedure shall be amended as follows:*

**A**

In Article 369, second paragraph, the following shall be inserted after “Article 37a first paragraph”: *or Article 38m.*

**B**

Article 509m shall be amended as follows:

- a. The second paragraph shall read:

“2. Articles 269 – 272, 273 first and third paragraphs, 274 – 277, 278 second paragraph, 281, 284 first paragraph, 286 – 297, 299 – 301, 309 – 311, 315, 318 – 322, 324, 328 – 331, 345 first and third paragraphs and 346 apply mutatis mutandis to the investigation conducted.”

- b. The third paragraph is repealed.
- c. The fourth and fifth paragraphs shall be renumbered as third and fourth paragraphs.

## C

A new title II c shall be inserted in the Fourth Book after title II B, which shall read:

### “TITLE II c

#### *Procedures Concerning The Order Of Compulsory Incarceration Of Criminal Addicts*

#### “ARTICLE 509y

In this title, the following shall be taken to mean:

The person convicted: the person incarcerated in an institution for criminal addicts;

Order: compulsory incarceration of criminal addicts;

Probation officer: the person entrusted under Article 38p fourth paragraph of the Penal Code with maintaining contact with the person convicted.

#### “ARTICLE 509z

1. If the public prosecutor is of the opinion that one of the provisions of Articles 38q or 38r of the Penal Code must be applied, he must submit a reasoned application to that effect. If the person to whom the suspended order has been issued has submitted a request referred to in Article 38q of the Penal Code, the court registry shall inform the public prosecutor of this upon which the latter shall without delay deliver a statement.
2. The court that has issued the order in the first instance has exclusive jurisdiction to hear the application or request.
3. If the court is of the opinion that it lacks jurisdiction, it shall refer the matter to the court that must hear the action in its opinion. In such a case, the application shall be deemed to have been submitted by the public prosecutor to the latter court.
4. Immediately after the application or the statement has been submitted, the presiding judge shall appoint a day for the hearing of the case, unless a summary examination of the documents causes him to dismiss the application or the request.
5. The public prosecutor shall, subsequently, without delay have the person convicted and the probation officer notified to attend the hearing, while serving the application or statement on the person convicted.

“ARTICLE 509aa

If the court has applied Article 38s first paragraph of the Penal Code, the presiding judge shall without delay appoint a day for the hearing of the case upon receiving the information referred to in that paragraph. The public prosecutor shall, subsequently, cause to notify the person convicted in timely fashion to attend the hearing.

“ARTICLE 509bb

1. Where the public prosecutor’s application intends to apply Article 38r of the Penal Code, the presiding judge shall order the Legal Representation Assignment Bureau to assign counsel to the person convicted, in the event that he is not represented by counsel.
2. The counsel is entitled to be present at the hearing and to examine all documents relating to the matter.
3. The Articles 38, 39, 41, second paragraph, 45 [to] 49 and 50 first paragraph apply *mutatis mutandis*.

“ARTICLE 509cc

1. The public prosecutor, the person convicted and his counsel may all cause to summon witnesses and experts or to cause to notify them in writing. The presiding judge may furthermore order the summoning or notification of witnesses and experts in the name of the public prosecutor. He may also order the court registrar to invite other persons to appear at the hearing.
2. Prior to the commencement of the hearing, the person convicted and the probation officer may take cognisance of the documents at the court registry. The provisions under Articles 34 apply.

“ARTICLE 509dd

1. The hearing is held in open court.
2. Articles 269 – 272\*, 273 first and third paragraphs, 274 – 281, 284 first paragraph, 286 – 297, 299 – 301, 309 – 311, 315, 318 – 322, 324, 328 – 331, 345 first and third paragraphs, 346 apply *mutatis mutandis* to the hearing.
3. The public prosecutor and the person convicted may change the application or the statement and/or the request during the hearing.

“ARTICLE 509ee

1. Where Article 38r of the Penal Code is applied, the decision shall state the special reasons for applying this article.
2. The decision on an application or a request to apply Article 38q Penal Code is not open to appeal.
3. The decision is without delay served on the person convicted. The summons of the decision on the application of Articles 38r and 38s second paragraph shall state the legal remedy available against the decision and the term within which it must be lodged.
4. If the decision includes an amendment to the special conditions referred to in Article 38p fourth paragraph, the decision shall be served personally on the person convicted.
5. A decision referred to in Article 38q part 2° shall be communicated in writing to the institution or the expert.

6. If the court terminates the order in conformity with Article 38s second paragraph, the order shall remain in force until the decision is final.

“ARTICLE 509ff

1. The decision by the court concerning the application of Articles 38r and 38s second paragraph is open to appeal to the Arnhem Court of Appeal by the public prosecutor within fourteen days of the date on the decision and by the person convicted within fourteen days of the decision being served on him.

2. Articles 409 first paragraph, 410, 449 first paragraph, 450 – 454, 455 first paragraph and 509z fourth and fifth paragraphs and 509aa [to] 509dd apply *mutatis mutandis*.

“ARTICLE 509gg

1. The Court of Appeal shall render a decision without delay. It upholds the decision by the District Court or quashes this decision and renders the decision that the District Court should have rendered. Article 509ee first paragraph applies *mutatis mutandis*.

2. There is no ordinary legal remedy available against the decision by the Court of Appeal.”

**D**

In Article 558 third paragraph, the following shall be inserted after “by the government”: *compulsory incarceration of criminal addicts*.

**E**

In Article 559a second paragraph, “prison sentence or” shall be replaced by “prison sentence,” and the following shall be inserted after “by the government”: or the order of compulsory incarceration of criminal addicts.

**ARTICLE III**

In Article 73 first paragraph of the Judiciary Organization Act, “and 509v” shall be replaced by; 509v and 509ff.

**ARTICLE IV**

The Prisons Act shall be amended as follows:

**A**

In Article 1 part t, the following shall be inserted after “treatment”: *compulsory incarceration of criminal addicts*.

**B**

A sixth paragraph shall be added to Article 4, reading:

“1. The second paragraph does not apply to the order of compulsory incarceration of criminal addicts as referred to in Article 38m of the Penal Code.”

**C**

Article 9 shall be amended as follows:

“1. The first paragraph, first sentence, shall read as follows:

Institutions may be divided into detention centres, prisons and penal facilities for addicts.

“2. In the second paragraph, after the re-lettering of part g [to] part h, a new part g shall be inserted, reading:

- g. Persons to whom the order of compulsory incarceration of criminal addicts has been issued if incarceration in the institution meant for them is not possible.”

**D**

A new Article 10a shall be inserted after Article 10, reading:

“ARTICLE 10a

- 1. Institutions for criminal addicts are meant for the committal of persons to whom an order as referred to in Article 38m of the Penal Code has been issued.
- 2. Our Minister may assign an institution for criminal addicts as a detention centre. He may also assign a detention centre as an institution for criminal addicts.”

**E**

A new Chapter IV A shall be inserted after Chapter IV, reading:

“**CHAPTER IV A**  
*Compulsory Incarceration of Criminal Addicts*

“ARTICLE 18a

- 1. The head of the institution ensures that a treatment plan is drawn up, as much as possible in consultation with the criminal addict, without delay and at any rate within a month of the arrival of the criminal addict in the institution.
- 2. By General Administrative Order, regulations are laid down for the requirements that a treatment plan must satisfy and the prescriptions that must be observed in the determination of or any amendment to the plan.

“ARTICLE 18b

The head of the institution ensures that the treatment is in accordance with the treatment plan.

“ARTICLE 18c

- 1. The criminal addict is entitled to a periodic evaluation of the progress of the treatment by the head of the institution. This evaluation is at any rate conducted every six months.
- 2. If the court has determined upon issuing the order that the public prosecutor must inform the court on the desirability or necessity of the progress of its enforcement within a period determined by the court, the first evaluation shall at any rate be conducted prior to the expiry of that period.
- 3. The head of the institution ensures that a report is made of all evaluations and that this report be discussed with the criminal addict in timely fashion.



4. If the criminal addict is of the opinion that the evaluation report is inaccurate or incomplete, he may comment on this report in writing. If the evaluation report is not corrected in accordance with the comments, the head of the institution shall ensure that the comment is appended to the report.
5. By General Administrative Order, regulations are laid down for the procedure that must be followed with respect to the evaluation and the requirements that its report must satisfy.”

#### **ARTICLE V**

If the legislative proposal submitted by Royal Message on 27 July 1998 to amend the Penal Code and the Code of Criminal Procedure and any other Acts with respect to the community service order (Parliamentary Documents II 1997/8, 26 114, no 2) becomes law, this Act shall be amended as follows:

The phrase “community service” in Article I, Article 38m first paragraph under 2° shall be replaced by: *restorative justice*.

#### **ARTICLE VI**

1. Within three years of the entry into force of this Act and every three years after that date, Our Minister of Justice shall send a report to the States General on the effectiveness and the effects of this Act in practice.
2. The municipalities participating in the enforcement of the order of compulsory incarceration of criminal addicts grant their cooperation to the realization of the report referred to in the first paragraph.

#### **ARTICLE VII**

1. This Act shall enter into force at a date to be laid down by Royal Decree.
2. By Royal Decree, it may be determined that this Act shall only apply in the district(s) to be designated by that Royal Decree. Subject to earlier withdrawal, this designation shall lapse three years after the date referred to in the first paragraph.

We order and command that this Act shall be published in the Bulletin of Acts and Decrees, and that all ministerial departments, authorities, bodies and officials whom it may concern shall diligently implement it.

## **Guidelines for Cultivating Cannabis for Medic[al] Purposes<sup>1</sup>**

*Annex to the Regulation of the Minister of Health, Welfare and Sport of 9 January 2003, GMT/BMC 2340685, containing policy guidelines for the decision on applications for Opium Act exemptions (Policy guidelines Opium Act exemptions)*

(Authorised English Translation)

### **1. INTRODUCTION**

Under certain conditions, the Dutch government permits the cultivation of cannabis for medicinal purposes. In the case of herbal drugs, the cultivation method and primary processing of the plant determines the ultimate properties of the active pharmaceutical ingredient. Starting materials of herbal origin have a complex composition and can only be characterised to a limited extent through chemical or biological analysis. Therefore, an effective quality assurance system in the steps leading up to the production of the active pharmaceutical ingredient is needed in order to guarantee reproducible quality. These steps are cultivation, harvesting and primary processing.

The following guidelines for cultivating, harvesting and primary processing of cannabis constitute a quality assurance system that meets these requirements. The Office of Medicinal Cannabis (Bureau voor Medicinale Cannabis) will test on the basis of these requirements.

These guidelines have been derived from the general rules for Good Agricultural Practice of the Working Group on Herbal Medicinal Products of the European Medicines Evaluation Agency (EMA).

This is a non-authorised translation of the official version in Dutch.

### **2. GENERAL**

2.1. These guidelines apply to the cultivation, harvesting and primary processing of cannabis plants intended for medicinal use or the preparation of medicinal drugs. These guidelines must be read in connection with the European Good Manufacturing Practice (GMP) guidelines for active pharmaceutical products. They apply to all methods of production including organic cultivation. These guidelines also provide additional standards for the production and processing of herbal starting materials insofar as they identify the critical production steps that are needed to ensure good, reproducible quality.

2.2. The main objective of these guidelines is to increase the reliability of the medicines prepared from cannabis by establishing an appropriate quality standard for the herbal medicine cannabis. In particular, it is important that the cannabis:

- Is produced hygienically to keep microbiological contamination to a minimum;
- Is produced such that negative effects on the plants during cultivation, processing and storage are kept to a minimum;
- Is produced under conditions that ensure that the therapeutic properties of the end product are constant and reproducible.

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<sup>1</sup> Note by the Secretariat: Entered into force on 17 March 2003.

### **3. PERSONNEL AND TRAINING**

#### 3.1. Training

3.1.1. Personnel must have received adequate botanical/horticultural training before performing the tasks given to them.

3.1.2. Production personnel must be trained in the production techniques used.

3.1.3. Primary processing procedures must comply with the regulations on food hygiene.

#### 3.2. Hygiene

3.2.1. All personnel entrusted with handling the herbal material must maintain proper personal hygiene.

3.2.2. Persons suffering from infectious diseases transmittable via food, including diarrhoea, or carriers of these diseases must be forbidden access to areas where they could come into contact with the herbal material.

3.2.3. Persons with open wounds; inflammations and skin-infections must be suspended from areas where they could come into contact with herbal material, unless they wear protective clothing or gloves until they have recovered completely.

3.2.4. Personnel must be protected from contact with toxic or potentially allergenic herbal material by means of adequate protective clothing.

### **4. BUILDINGS AND FACILITIES**

4.1. Rooms used in the processing of harvested crops must be clean, well ventilated and must never be used for other activities.

4.2. Buildings must be designed in a manner that protects the crops against pests and domestic animals.

4.3. The medicinal cannabis must be stored:

- In a suitable packaging
- In rooms with concrete or similar floors which are easy to clean;
- On pallets;
- At a sufficient distance from walls;
- Well separated from other crops in order to prevent cross-contamination.

Organic products must be stored separately from products not grown organically.

4.4. Buildings where plant processing is carried out must have changing facilities, toilets and hand-washing facilities.

### **5. EQUIPMENT**

5.1. Equipment used in plant cultivation and processing must be easy to clean in order to eliminate the risk of contamination.

5.2. Equipment and machinery should be mounted such that they are easily accessible. Machines used in fertiliser and pesticide application must be calibrated regularly.

5.3. The equipment must be made from materials other than wood. If wooden materials (such as pallets) are used, they must not come into direct contact with chemicals and contaminated materials, in order to prevent contamination of the herbal materials.

5.4. Equipment and machinery used for harvesting must be clean and in very good working condition. Machine parts that come into direct contact with the harvested crop must be cleaned regularly and must be free from oil and contamination, including residual plant matter.

## **6. SEEDS AND PROPAGATION MATERIAL**

6.1. Seeds and propagation material must be botanically identified as to species, variety, chemo type and origin. The materials used must be traceable. Starting material must be free from pests and disease as much as possible in order to guarantee healthy growth.

6.2. Cuttings of female plants must be used as propagation material for the production of cannabis.

6.3. During the entire production process (cultivation, harvest, drying, packaging), the presence of male plants and of different species, different varieties or different plant parts must be monitored. Any impurities must be removed immediately.

## **7. CULTIVATION**

### **7.1. Soil and fertilisation**

7.1.1. Cannabis for medicinal purposes must not be grown on soil contaminated with sludge, heavy metals, pesticide residues or other chemicals. Any chemicals used must therefore be kept to the minimum effective dose.

7.1.2. Manure applied should be thoroughly composted and must be devoid of human faeces. Irrigation should be controlled and according to the needs of the cannabis plant. Fertilisers should be used in such a way that leaching is reduced to a minimum.

### **7.2. Irrigation**

7.2.1. Irrigation must be controlled and only as required by the cannabis plant.

7.2.2. Irrigation water must contain as few as possible contaminants like faeces, heavy metals, pesticides and toxicologically hazardous substances.

7.3. All tillage must be adapted to plant growth and requirements. Using herbicides and pesticides must be avoided as far as possible. Use and storage of pesticides must be in accordance with the recommendations of the manufacturer and the relevant approval authorities. Only qualified personnel are allowed to use such substances using only approved material but not in a period preceding the harvest, as indicated by the buyer or producer.

## **8. HARVESTING**

8.1. Harvesting must be done when the plants have reached the best quality for the intended use.

8.2. Damaged, and dead plants must be removed.

8.3. Harvesting must take place under the best possible conditions, avoiding wet soil or extremely high air humidity. If harvesting occurs in wet conditions, additional care needs to be taken to avoid the adverse effects of moisture.

8.4. During harvesting, care must be taken that no other species or cannabis variety gets mixed with the crop.

8.5. The harvested crop must not come into direct contact with the soil. Directly after harvesting, it must be prepared for transport in clean, dry conditions (e.g. sacks, baskets, boxes).

8.6. All containers must be clean and free from any residues from previous harvests; containers that are not in use must be kept in dry conditions, free of pests and inaccessible to domestic animals.

8.7. Mechanical damage and compacting of the herbal drug that could result in undesirable quality changes must be avoided. In this respect, take care to avoid:

- Overfilling sacks/containers;
- Stacking sacks/containers too high.

8.8. Freshly harvested herbal material must be delivered to the processing facility as quickly as possible in order to prevent thermal degradation.

8.9. The harvested crop must be protected from pests and domestic animals.

## **9. PRIMARY PROCESSING**

9.1. Primary processing includes washing, cutting before drying, freezing, distillation, drying, etc.

9.2. On arrival at the processing facility, the harvested crop must be directly unloaded and unpacked. Prior to processing, the material must not be exposed to direct sunlight (except in cases that specifically require this) and must be protected from rain.

9.3. Drying

9.3.1. Drying crops directly on the ground or under direct sunlight must be avoided.

9.3.2. Uniform drying speed and prevention of mould growth must be assured.

9.3.3. In the case that plant material is dried in the open air, it must be spread in a thin layer. To ensure good air circulation the drying racks must be placed at sufficient distance to the floor.

9.3.4. In the case plant material is not dried in the open air optimal drying circumstances like temperature and drying time must be chosen.

9.4. Waste bins must be available and must be emptied and cleaned daily. Waste must be collected in bags and/or in closable containers.

## **10. PACKAGING**

10.1. Following repeated controls and removal of any material not meeting its requirements or of undesired objects, the product must be packaged in clean, dry and preferably new packaging. The label must be clear, firmly fixed and made from non-toxic material.

10.2. Reusable packaging material must be well cleaned and dried prior to use.

10.3. Packaging material must be stored in a clean, dry place that is free of pests and inaccessible to domestic animals. The packaging material must not contaminate the product.

## 11. STORAGE AND DISTRIBUTION

11.1. Dried, packaged products and extracts must be stored in a dry, well-ventilated room in which daily temperature fluctuations are limited and good ventilation is ensured. Fresh products must be stored between 1°C and 5°C; frozen products must be kept at temperatures below -18°C (or below -20°C for long-term storage).

11.2. In the event of bulk transport, it is important to ensure dry conditions. To prevent mould formation or fermentation, it is advisable to use ventilated containers, transport vehicles and other ventilated facilities.

11.3. Decontamination of the storage area to combat pests must be carried out only where necessary and by authorised personnel only.

11.4. When frozen storage or saturated steam is used for pest control, the moisture content of the product must be controlled after treatment.

## 12. SPECIAL PROVISIONS FOR THE PRODUCTION OF CANNABIS INTENDED FOR PROCESSING INTO A STANDARDISED HERBAL DRUG

### 12.1. Herbs

- a. In these guidelines an herbal medicine is understood to mean any medicine that contains exclusively herbal drugs or herbal preparations as active ingredients.
- b. Herbal drugs are plants or parts of plants in an unprocessed state which are used for medicinal or pharmaceutical purposes. An herbal drug or a preparation is regarded as one active substance in its entirety whether or not the constituents with therapeutic activity are known.
- c. Herbal drug preparations are comminute or powdered herbal drugs, extracts, tinctures, fatty or essential oils, expressed juices, processed resins or gums, etc. prepared from herbal drugs, and preparations that are produced through fractionation, purification or concentration.
- d. In departure from the above, chemically defined isolated constituents or their mixtures are not considered herbal drug preparations.
- e. Herbal drug preparations may contain other components such as solvents, diluents and preservatives.

12.2. If the cannabis is intended for processing into a standardised herbal medicine, the cannabis must be cultivated under such standardised conditions that the content of the constituents is constant. Protocols of the operations committed during the cultivation must be kept available.

12.3. The content of the main constituents, which includes D-9-tetrahydrocannabinol (D-9-THC) and cannabidiol (CBD), is determined quantitatively. For a selection of the other constituents, fingerprinting with a suitable technique, such as GC-MS, GC, HPLC or TLC will suffice.

12.4. Unless it is proven that omitting the standardisation of one of the following elements results in a constant and reproducible product, at least the following must be standardised during cultivation:

- a. Cultivars of the cannabis plant;
- b. Cultivation substrate;
- c. Day length;
- d. Light intensity;
- e. Colour temperature of the lighting;
- f. Atmospheric humidity;
- g. Temperature;
- h. Irrigation
- i. Ventilation;
- j. Plant age at the time of harvesting;
- k. Time of day of harvesting.

12.5. Unless it is proven that omitting the standardisation of one of the following elements results in a constant and reproducible product, at least the following must be standardised during drying:

- a. Atmospheric humidity;
- b. Temperature;
- c. Ventilation;
- d. Drying time.

### **13. DOCUMENTATION**

13.1. All processes and procedures which may affect the quality of the product must be recorded in the documentation for each batch. The following in particular must be documented:

- a. The location of cultivation and the name of the cultivator in charge;
- b. Details on crops previously grown at that location;
- c. Nature, origin and quantity of the herbal starting materials;
- d. The chemicals and other substances used during cultivation, such as fertilisers, pesticides and herbicides;
- e. Standard cultivation conditions, if applicable;
- f. Particular circumstances which occurred during cultivation, harvesting and production which may affect the chemical composition, such as plant diseases or temporary departure from standard cultivation conditions, particularly during the harvesting period;
- g. Nature and quantity of the yield;
- h. Date or dates, and time or times of day when harvesting occurred;
- i. Drying conditions;
- j. Measures for pest control.

13.2. Analysis reports of soil analysis must be kept available in the dossier

13.3. Location

13.3.1. All batches originating from one location must be clearly labelled (e.g. with a batch number). This must be done as early on in the process as possible.

13.3.2. Batches originating from different geographic locations may only be combined if guaranteed to be the same, and that the mixture is homogenous. Mixing of batches must be documented.

13.3. It must be recorded in the documentation for each batch that the cultivation, harvest and primary processing procedures were in accordance with these requirements.

13.4. All parties involved in the production process must demand that their suppliers document all relevant stages and elements of the production process for each batch.

13.5. Audit results must be recorded in an audit report. The audit report and concomitant analysis reports and other documents must be kept for at least ten years.

### **14. SAFEGUARDING THE MATERIAL**

14.1. The buildings in which the cannabis is cultivated, processed, packaged and stored must be sufficiently secured. This means that there must be security in force and that only authorised personnel is allowed access to the buildings.

14.2. The personnel involved in the production process of cannabis must be authorised for that purpose by the employer. When concluding the supply contract, the supplier designates authorised persons and indicates how this will be verified.

14.3. There must be a balanced administration of the cannabis.

14.4. Waste must be stored in such a way that theft is impossible. If waste is collected in bags it must be stored in a lockable container (for instance a pressing container) immediately.