

Unofficial translation

Ministry of Social Affairs and Health, Finland

No. 33/2008

Decree of the Ministry of Social Affairs and Health on the detoxification and substitution treatment of opioid addicts with certain medicinal products

Issued in Helsinki on 17 January 2008

Section 1

Scope of application

(1) This Decree is applied to the use of medicinal products containing buprenorphine or methadone in the detoxification and substitution treatment of opioid addicts.

(2) The Decree shall not apply to the use of medicinal products containing buprenorphine or methadone as supportive therapy during an opioid addict's somatic disease in a situation in which detoxification symptoms worsen the patient's clinical condition or hamper the patient's treatment.

(3) In addition, the Act on Welfare for Substance Abusers (41/1986), the Act on the Status and Rights of Patients (785/1992), sections 14 and 15b of the Primary Health Care Act (66/1972) and sections 3 and 31 of the Act on Specialized Medical Care (1061/1989) are applied to the treatment referred to in this Decree. The provisions of the Decision of the Ministry of Social Affairs and Health on the obligation to keep a record and submit information of narcotics and substances used in the manufacture of narcotics and on handling and disposal of narcotics (1708/1993) apply to the handling, disposal, keeping of a record and notification of the medicinal products referred to in this Decree.

Section 2

Definitions

For the purposes of this Decree:

1) *opioid addiction* means that the diagnostic criteria for F11.2x in the Classification of Diseases ICD-10 are met;

2) *detoxification* means treatment aiming at making an opioid addict drug-free by using medicinal products containing buprenorphine or methadone;

3) *substitution treatment* means treatment of an opioid addict by using medicinal products containing buprenorphine or methadone in which the objective is either rehabilitation and a lifestyle free of illegal drugs, or harm reduction and improved quality of life of the patient; and

4) *pharmacy agreement* means an agreement by which a patient promises to collect the medicines according to the agreement from one pharmacy and allows the pharmacy to convey information regarding the treatment to the attending physician and to inform other pharmacies of the pharmacy agreement. Medicinal products according to the agreement may only be prescribed by the physician in charge of the operation of the care place defined in section 4 of this Decree or by the physicians assigned by him or her to attend to the task when they are employed for that task. The physician shall record on the prescription form, in addition to the information required in section 10 of the Decree of the Ministry of Social Affairs and Health on Prescription of Medicines (726/2003), also the office or post he or she is holding.

Section 3

Preconditions for substitution treatment

(1) Substitution treatment with medicinal products referred to in this Decree can be started for a patient who suffers from opioid addiction and who has not been detoxified from opioids.

(2) The objective of substitution treatment must be specified when starting the treatment, and the objective must be adjusted as necessary. Harm reduction must be the objective in particular for persons who probably cannot be made to completely quit illegal drug use but in regard to whom it is probable that the spread of infectious diseases and other health harms can be prevented. These patients' quality of life can thus be improved and they can be prepared for taking part in rehabilitative substitution treatment that is a more demanding form of treatment.

Section 4

Arrangement and provision of treatment

(1) The need for treatment for an opioid addict must be assessed and treatment provided at a municipal health centre, a substance abuse treatment unit or a prison health care unit that has a physician in charge who is acquainted with the treatment and the necessary other staff as well as other prerequisites for provision of treatment.

(2) If the treatment is of a demanding nature, a care needs assessment must be made and treatment started and provided at a care unit of the joint municipal board for a hospital district, the Järvenpää Addiction Hospital or a state psychiatric hospital. The treatment can be continued in cooperation with the unit that started it at a health centre, substance abuse treatment unit or prison health care unit which according to the information available to the care unit that started the treatment has sufficient resources for it. Since substitution treatment is provided on a long-term basis it ought to be provided as close as possible to the patient's place of residence.

(3) The need for treatment must be assessed and treatment started in outpatient settings unless there are particular reasons for assessing the need and starting treatment at an institution.

(4) The State Provincial Office and the National Authority for Medicolegal Affairs must be informed of the name and contact information of the physician in charge of the care provision at the unit as well as of any change of the physician in charge.

Section 5

Treatment plan

The treatment of opioid addicts referred to in this Decree must be based on a treatment plan that specifies, besides pharmacotherapy, also the objective of the patient's treatment, other medical and psychosocial treatment of the patient, rehabilitation and follow-up of the treatment.

Section 6

Pharmacotherapy

(1) The medicinal products referred to in this Decree may be prescribed for detoxification and substitution treatment of opioid addicts only by a physician employed at a care unit referred to in section 4 who is in charge of the operation of the unit or by a physician assigned by him or her for the task. Pharmacotherapy may be provided and the medicine administered to the patient to be taken only under the control of the care unit.

(2) If the patient's adherence to treatment is good, the care unit can administer to the patient an amount of the medicine corresponding to at most eight daily doses. For particular reasons a care unit may exceptionally give such a patient an amount corresponding to 15 daily doses of the medicine.

(3) Medicines may not be prescribed for the detoxification or substitution treatment referred to in this Decree to be dispensed by a pharmacy on the basis of a prescription.

Section 7

Provision of pharmacotherapy in certain cases

Notwithstanding what is provided in section 6, a combination product containing buprenorphine and naxolone may be prescribed to be dispensed at a pharmacy on the basis of a pharmacy agreement signed by the patient as referred to in section 2 (4), as long as the agreement is in force.

Section 8

Monitoring

(1) The care units referred to in section 4 shall submit to the State Provincial Office and the Ministry of Social Affairs and Health the information requested by them about the provision and arrangement of the detoxification and substitution treatment that the units have started.

(2) The care units must monitor how long it takes to obtain access to treatment at their unit. The care unit that started the treatment shall also monitor the appropriateness of the service in cooperation with the care unit continuing the treatment.

(3) Information on a patient's treatment may be exchanged by the patient's consent between the care units engaged in the treatment as referred to in section 13 of the Act on the Status and Rights of Patients.

Section 9

Entry into force

- (1) This Decree enters into force on 1 February 2008.
- (2) This Decree repeals the Decree of the Ministry of Social Affairs and Health on the detoxification, substitution and maintenance treatment of opioid addicts with certain medicinal products (289/2002) of 15 April 2002.
- (3) Measures necessary for the implementation of the Decree may be undertaken before the Decree's entry into force.