

Common Code of Statutes concerning healthcare, medical care, social services, medicinal products, public health, etc.

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Regulations amending the Swedish Medical Products Agency’s Regulations (LVFS 2011:9) on the control of nar- cotic drugs;

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decided on XX 2025.

The Swedish Medical Products Agency prescribes¹, pursuant to Sec-
tion 11 of the Ordinance (1992:1554) on the control of narcotic
drugs, with regard to the Agency’s Regulations (LVFS 2011:9) on
the control of narcotic drugs, that the Annex shall read as follows.

These regulations enter into force on 1 July 2025.

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¹ See Directive (EU) 2015/1535 of the European Parliament and of the
Council of 9 September 2015 laying down a procedure for the provision
of information in the field of technical regulations and of rules on Infor-
mation Society services.

Preparations exempted from certain requirements when they are to be used exclusively for medical purposes

- Preparations containing, in a mixture with one or more other ingredients, one of the substances: **acetyldihydrocodeine**, **dihydrocodeine**, **ethylmorphine**, **pholcodine**, **codeine**, **nicodicodine**, **nicocodine** or **norcodeine** to a quantity of no more than 100 milligrams in each measured dose or to a concentration of not more than 2.5 % if the preparations are not in measured doses.
- Preparations of **propiram** which, in each measured dose, do not contain more than 100 milligrams of propiram in a mixture with at least the same amount of methylcellulose.
- Preparations for oral use containing only **dextropropoxyphene** as a narcotic substance in a quantity of no more than 135 milligrams in each measured dose or to a concentration of not more than 2.5 % if the preparations are not in measured doses.
- Preparations of **opium** or **morphine**, containing in a mixture no more than 0.2 % morphine, calculated as an anhydrous morphine base, mixed with one or more other therapeutically active non-narcotic substances.
- Preparations of **difenoxin** which, in each measured dose, do not contain more than 0.5 milligrams of difenoxin and an amount of atropine sulphate corresponding to at least 5 % of the difenoxin dose.
- Preparations of **diphenoxylate** which, in each measured dose, do not contain more than 2.5 milligrams of diphenoxylate calculated as a base and an amount of atropine sulphate corresponding to at least 1 % of the diphenoxylate dose.
- Preparations of **cocaine** which, in a mixture, do not contain more than 0.1 % of cocaine, calculated as a cocaine base, mixed

² Most recent wording LVFS 2012:2. The amendment removes from the Annex, inter alia, preparations of tramadol containing not more than 400 mg of tramadol per dose in a mixture with one or more other ingredients or containing not more than 10 % tramadol if the preparations are not in measured doses.

with one or more non-narcotic substances in such a way that the narcotic drug contained cannot be extracted by simple means.

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