

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 Section 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 Information 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 no 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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