

**HSLF-FS  
2025:10**

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**Regulations**

**amending the Swedish Medical Products Agency's Regulations  
(LVFS 2011:9) on the control of narcotic drugs;**

adopted on 14 April 2025.

The Swedish Medical Products Agency prescribes<sup>1</sup>, 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.

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These regulations shall enter into force on 15 September 2025.

NILS GUNNAR BILLINGER

Kenneth Nordback

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<sup>1</sup> 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.
- **Cocaine** preparations containing in a mixture not more than 0.1 % cocaine, calculated as cocaine base, mixed with one or more non-narcotic substances in such a way that the constituent narcotic drug cannot be extracted by simple methods.

<sup>2</sup> 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.