Legislative text

The government proposes the following legislative text.

Draft Act amending the Act (2009:366) on trade in medicinal products

It is hereby laid down in respect of the Act (2009:366) on trade in medicinal products

that Chapter 2, Sections 6 and 11, Chapter 2a, Section 5 and Chapter 9, Section 4 shall read as follows;

that three new sections shall be inserted, namely Chapter 2, Sections 6d to 6f, and a new heading shall be inserted immediately before Chapter 2, Section 6d, worded as follows.

Current wording *Proposed wording*

Chapter 2

Section 6[1]

Anyone who has a licence under Section 1 to engage in retail trade in medicinal products to consumers shall:

1. have the premises staffed by one or more pharmacists during opening hours;
2. conduct their activities in premises that are suitable for their purpose and ensure that those parts of the premises where information and advice on medicines, the exchange of medicines, the use of medicines and self-care are provided are designed in such a way that the consumer's privacy is protected;
3. provide all prescribed medicinal products, and all prescribed goods covered by the Act (2002:160) on Pharmaceutical Benefits, etc., as soon as possible;
4. have a person responsible for medicines at the pharmacy who shall have the influence over the business necessary to enable him or her to perform his or her duties;
5. when dispensing a prescription, provide the Swedish eHealth Agency with the information specified in Chapter 3, Sections 8 and 8a of the Act (2018:1212) on the National Medicines List;
6. have an electronic system that enables direct access to data held by the Swedish eHealth Agency;
7. provide the Swedish eHealth Agency with the information necessary for the Agency to compile statistics on retail trade;
8. exercise special control (self-monitoring) over retail trade and other handling and ensure that there is a self-monitoring programme appropriate to the business;

[1] Most recent version 2025:922.

9. issue certificates upon request in accordance with Section 3a of the Act (1992:860) on the Control of Narcotics;

10. upon request, offer consumers partial payment for medicines and goods covered by the Act on Pharmaceutical Benefits, etc.;

11. provide individual and producer-independent information and advice on medicinal products, the exchange of medicinal products, the use of medicinal products and self-care to consumers and ensure that such information and advice is provided only by suitably qualified staff;

12. have a trademark registered by the Medical Products Agency for outpatient pharmacies clearly visible in the pharmacy;

13. in cases where the licence holder cannot directly supply a medicinal product or product referred to in 3, inform the consumer of the retail pharmacy or pharmacies where the medicinal product or product is available for sale;

14. comply with the requirements related to safety features laid down in Commission Delegated Regulation (EU) 2016/161, and

15. when dispensing a prescription for medicinal products for the treatment of animals, provide information to the Swedish eHealth Agency;

14. comply with the requirements related to safety features laid down in Commission Delegated Regulation (EU) 2016/161;

15. when dispensing a prescription for medicinal products for the treatment of animals, provide information to the Swedish eHealth Agency; *and*

16. provide advice by pharmacists in the sale of non-prescription medicinal products requiring specific advice.

Over-the-counter medicinal products requiring specific advice

Section 6d

The system of over-the-counter medicines requiring special advice aims to promote access to medicines while ensuring good, safe and effective use of medicines.

Section 6e

An over-the-counter product which has not been prescribed may be sold to a consumer only after specific advice from a pharmacist, if such advice is necessary to ensure, as far as possible:

1. the safety of the patient or the animal to be treated with the

medicinal product, or the safety of the person administering the medicinal product; or

2. reduction of the risk of adverse effects of the medicinal product on public or animal health, in particular as regards the development of resistance to medicinal products.

Section 6f

Upon application, the Medical Products Agency may decide that a medicinal product shall be subject to the requirement for special advice in accordance with Section 6e.

A decision as referred to in the first paragraph may be subject to conditions.

Section 11[2]

The government or the authority designated by the government may issue regulations on:

1. the design of premises referred to in Section 6(2);
2. the period within which the supply referred to in Section 6(3) is to take place;
3. the competence and experience of a person responsible for medicinal products under Section 6(4);
4. self-monitoring in accordance with Section 6(8);
5. information, advice and staff competence in accordance with Section 6(11);

6. specific advice by a pharmacist pursuant to Section 6(16) and requirements for specific advice pursuant to Section 6(f);

6. use of the trademark referred to in Section 6(12);

7. dispensing prescriptions and exemptions from the requirement of pharmaceutical competence under Section 9a; and

8. design and control of the EU logo referred to in Section 10a(2);

7. use of the trademark referred to in Section 6(12);

8. dispensing prescriptions and exemptions from the requirement of pharmaceutical competence under Section 9a; and

9. design and control of the EU logo referred to in Section 10a(2);

[2] Most recent version 2018:1108.

Chapter 2a

Section 5[3]

The pharmacy agent may, on behalf of the licence holder, sell the non-prescription medicines determined by the licence holder, but not medicines that, in view of patient safety and the protection of public health, are unsuitable for sale through pharmacy agents.

Over-the-counter medicinal products requiring special advice may not be sold through pharmacy agents.

Chapter 9

Section 4

Decisions made by the Swedish Medical Products Agency under this Act may be appealed to a general administrative court if the decision concerns:

1. authorisation pursuant to Chapter 2, Section 1, Chapter 3, Section 1 or Chapter 6, Section 1;

2. whether a medicinal product is to be accompanied by a requirement for special advice in accordance with Chapter 2, Section 6 f;

2. whether a person responsible for medicinal products should be allowed to be responsible for more than three out-patient pharmacies in accordance with Chapter 2, Section 8;

3. whether a person responsible for medicinal products should be allowed to be responsible for more than three out-patient pharmacies in accordance with Chapter 2, Section 8;

3. orders or prohibitions pursuant to Chapter 7, Section 3; or

4. orders or prohibitions pursuant to Chapter 7, Section 3; or

4. revocation of a licence under Chapter 8, Sections 3, 4 or 5;

5. revocation of a licence under Chapter 8, Sections 3, 4 or 5;

Leave to appeal is required when appealing to the Administrative Court of Appeal.

Decisions issued by the Swedish Medical Products Agency or a general administrative court under this Act shall apply immediately, unless otherwise stated in the decision.

This Act comes into force on 1 January 2027.

[3] Most recent version 2018:1107.