

Production of medicinal products without permission

In certain cases, physicians, dentists and non-medical practitioners may manufacture medicinal products without a license, i.e. without having a manufacturing authorization. There are certain regulations for this, and the competent authority must be notified before the activity is commenced.

Competent Department

- [Die Senatorin für Gesundheit, Frauen und Verbraucherschutz | Referat 23 Pharmazie, Medizinprodukte und Umwelthygiene](#)

Basic information

Anyone who intends to manufacture medicinal products generally requires a manufacturing license in accordance with Section 13 (1) of the German Medicines Act (AMG). For physicians, dentists and non-medical practitioners, the law describes an exception under certain conditions under § 13 para. 2b or § 20d.

Anyone wishing to make use of this exemption must notify the competent authority in accordance with Section 67 (1) and (2) AMG.

Requirements

You have a license as a (dental) physician or a license as a non-medical practitioner and the production of the medicinal product takes place

- under your direct professional responsibility and
- for the purpose of personal use by you on a specific patient.

The notification to the competent authority must be made before the start of the activity.

Procedure

After you have completed the online form, the competent authority will be informed about the notification. The authority checks the notification and contacts you with queries in the event of ambiguities or discrepancies. You will receive a notification from the competent authority that the notification has been received.

Legal bases

- [§ 13 Abs. 2b Arzneimittelgesetz \(AMG\)](#)
- [§ 20d Arzneimittelgesetz \(AMG\)](#)
- [§ 67 Abs. 1 und 2 Arzneimittelgesetz \(AMG\)](#)

How long does it take to process

3 weeks

What are the costs?

The notification is usually free of charge. In the case of more complex tests and monitoring measures, costs may be incurred in accordance with the Bremen Health Costs Ordinance.