

99003007001000

# Permission to traffic in narcotics Issuance

Heruntergeladen am 05.06.2025

<https://fimportal.de/xzufi-services/577611/B100019>

| Modul                     | Sachverhalt  |
|---------------------------|--|
| Leistungsschlüssel        | 99003007001000   |
| Leistungsbezeichnung I    | Permission to traffic in narcotics Issuance  |
| Leistungsbezeichnung II   | Apply for a permit to participate in the narcotics trade   |
| Typisierung               | 1 - Bund: Regelung und Vollzug   |
| Quellredaktion            | Bund   |
| Freigabestatus Katalog    | unbestimmter Freigabestatus  |
| Freigabestatus Bibliothek | unbestimmter Freigabestatus  |
| Begriffe im Kontext       |  |
| Leistungstyp              | Leistungsobjekt mit Verrichtung  |
| Leistungsgruppierung      |  |
| Verrichtungskennung       | Erteilung (1)  |
| SDG-Informationsbereich   | nicht SDG-relevant   |
| Lagen Portalverbund       | Erlaubnisse und Genehmigungen (2010400), Produkt- und Stoffzulassung (2120200), Berufszulassungen und Berechtigungen (1040500) |

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| Einheitlicher Ansprechpartner | Nein  |
| Fachlich freigegeben am       | 09.04.2025  |
| Fachlich freigegeben durch    | Federal Ministry of Health (BMG)  |
| Handlungsgrundlage            | <a href="https://www.gesetze-im-internet.de/btmg_1981/index.html#BJNR106810981BJNE001107116">https://www.gesetze-im-internet.de/btmg_1981/index.html#BJNR106810981BJNE001107116</a><br><a href="https://www.gesetze-im-internet.de/btmg_1981/_15.html">https://www.gesetze-im-internet.de/btmg_1981/_15.html</a>  |
| Teaser                        | If you wish to participate in the narcotics trade, you must apply for a permit.   |
| Volltext                      | <p>You require a permit if you wish to participate in the narcotics trade.</p> <p>This applies, for example, to</p> <ul style="list-style-type: none"> <li>• cultivation</li> <li>• Production of narcotics and exempt preparations</li> <li>• Trade including import and export</li> <li>• scientific purposes</li> <li>• clinical trials</li> <li>• other placing on the market</li> </ul> <p>The license is issued by the Federal Institute for Drugs and Medical Devices (BfArM). You will only ever receive the permit for the establishment you have applied for and the volume of narcotics you require. You will generally receive a temporary permit for scientific projects.</p> <p>There are separate requirements and application options for each form of handling narcotics, depending on the function in which you wish to participate in the narcotics trade, for example as a:</p> <ul style="list-style-type: none"> <li>• Grower</li> <li>• Trading company</li> <li>• manufacturer</li> <li>• investigator</li> </ul> |

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- university institution
- Non-university scientific institution
- public authority

You must take suitable security measures to ensure that the narcotics cannot be stolen or diverted without authorization. The respective security level depends on the type and quantity of narcotics you wish to handle. You agree the necessary security measures with the BfArM during the project planning phase.

**Erforderliche Unterlagen**

Depending on the permit applied for, you must submit different documents and evidence.

You must always provide the following information with every application for a permit:

- Your surname, first name or company name and address
  - for legal entities: usually a current extract from the commercial register and the names of the responsible persons
- Proof of the required expertise of the persons responsible
  - Declaration that the persons responsible can fulfill their obligations at all times
  - Description of the location of the business premises with:
    - Place and, if applicable, parcel name
    - Street and house number
    - Building and building section
    - Construction of the building
  - Description of the existing safeguards against the removal of narcotics by unauthorized persons
    - Information on the type of legal narcotics traffic, e.g. trade, production or cultivation
    - Type and expected annual quantity of narcotics to be produced or required

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If you wish to manufacture narcotics or exempt preparations, you must also provide the following information:

- a brief description of the manufacturing process, stating the type and quantity:
  - the starting substances or preparations, even if these are not narcotics
  - the intermediate and end products, even if these are not narcotics
  - in the case of non-divided preparations, also the percentages by weight
  - in the case of divided preparations, the quantities by weight of narcotics contained in each divided form
  - in the case of use for scientific or other purposes in the public interest, e.g. domestic acquisition or cross-border import:
    - Explanation of the purpose pursued with reference to relevant scientific literature

**Voraussetzungen**

- Your company is based in Germany. If you submit the application as a private individual, your place of residence is in Germany.
- You have appointed a responsible person with the necessary expertise.
- You have suitable premises, facilities and security measures for participating in narcotics traffic.
- You and the responsible person are reliable.
- The type and purpose of the narcotics traffic applied for must be compatible with the Narcotics Act.

**Kosten**

Gebühr: 590€  
<https://www.gesetze-im-internet.de/bmgbgebv/anlage.html>  
 Gebühr: 1.040€  
<https://www.gesetze-im-internet.de/bmgbgebv/anlage.html>  
 Gebühr: 500€  
<https://www.gesetze-im-internet.de/bmgbgebv/anlage.html>  
 Gebühr: 240€  
<https://www.gesetze-im-internet.de/bmgbgebv/anlage.html>  
 Gebühr: 480€  
<https://www.gesetze-im-internet.de/bmgbgebv/anlage.html>

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html  
Gebühr: 190€  
<https://www.gesetze-im-internet.de/bmggbgebv/anlage.html>

## Verfahrensablauf

You can apply for permission to participate in the narcotics trade online, informally in writing or in part using an application form at the Federal Institute for Drugs and Medical Devices (BfArM).

If you apply for the permit online:

- Go to the website of the federal portal and call up the online application. This will guide you step by step through the necessary information.
- If you are applying as an organization, you will need an ELSTER company account and an ELSTER organization certificate.
- If you are applying as a private individual, you will need a BundID account and
  - an electronic ID document, for example the online ID function of your ID card or the eID of your European home country
  - or an ELSTER certificate
- Upload the required documents as a file. The following formats are permitted: PDF, DOC, JPEG, PNG, XLS, ZIP with a maximum of 10 megabytes per file.
- The BfArM will check your information and documents.
- The BfArM will contact you if your information or documents are incomplete and will give you a deadline for subsequent submission.
- The BfArM will send you a certificate of authorization or a notice of refusal as well as a notice of costs.

If you apply for a license using an application form or in writing:

- Compose a cover letter with all the required information or complete the relevant application form on the BfArM website.
- Print it out and sign it.
- Send your informal application or the application

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|                              | <p>form by post to the BfArM.</p> <ul style="list-style-type: none"> <li>• The BfArM will check your details.</li> <li>• The BfArM will contact you if your information or documents are incomplete and give you a deadline for submitting them.</li> </ul> <p>The BfArM will send you a certificate of authorization or a notice of rejection and a notification of costs by post.</p>  |
| Bearbeitungsdauer            | 3 Monat(e)   |
| Frist                        | There is no deadline.  |
| weiterführende Informationen | <a href="https://www.bfarm.de/DE/Bundesopiumstelle/Betaeubungsmittel/Erlaubnis/_node.html">https://www.bfarm.de/DE/Bundesopiumstelle/Betaeubungsmittel/Erlaubnis/_node.html</a><br><a href="https://www.bfarm.de/DE/Bundesopiumstelle/Betaeubungsmittel/Sicherungsrichtlinien/_artikel.html">https://www.bfarm.de/DE/Bundesopiumstelle/Betaeubungsmittel/Sicherungsrichtlinien/_artikel.html</a>   |
| Hinweise                     |  |
| Rechtsbehelf                 | <ul style="list-style-type: none"> <li>• Objection               <ul style="list-style-type: none"> <li>• Detailed information on how to lodge an objection can be found in the notification.</li> </ul> </li> <li>• Appeal to the administrative court</li> </ul>   |
| Kurztext                     | <ul style="list-style-type: none"> <li>• Permit required for participation in narcotics traffic</li> <li>• Appointment of narcotics (BtM) manager required for legal entities</li> <li>• BfArM only ever issues permits for the respective business premises and the respective required volume of narcotics</li> <li>• Requirements for proof and prerequisites vary depending on the type of narcotics traffic, for example               <ul style="list-style-type: none"> <li>• cultivation</li> <li>• trade</li> <li>• manufacture of BtM and exempt preparations</li> <li>• clinical trials</li> <li>• Import and export</li> </ul> </li> <li>• Applications online, informally in writing or with application form               <ul style="list-style-type: none"> <li>• Application forms are available for:                   <ul style="list-style-type: none"> <li>• cultivation</li> <li>• clinical trial</li> </ul> </li> </ul> </li> </ul> |

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|                   | <ul style="list-style-type: none"> <li>• Use as a non-university institution</li> <li>• Use as a public authority</li> <li>• Applications and applications for amendments are subject to a fee, the fee varies depending on the type and scope of narcotics traffic</li> <li>• Processing time: statutory processing period of 3 months, actual average of around 4 to 6 weeks, possibly shorter or longer depending on the volume of applications and the completeness of the application</li> <li>• Information from the Federal Institute for Drugs and Medical Devices (BfArM)</li> </ul> |
| Ansprechpunkt     |   |
| Zuständige Stelle |   |
| Formulare         |   |
| Ursprungsportal   | Permission to traffic in narcotics Issuance, Erlaubnis zum Verkehr mit Betäubungsmitteln Erteilung  |