99110008005000, 99110008005000

# Production of veterinary vaccines Permission



| Modul | Sachverhalt |
|---|---|
| **Leistungsschlüssel** | 99110008005000, 99110008005000 |
| **Leistungsbezeichnung I** | Production of veterinary vaccines Permission |
| **Leistungsbezeichnung II** | |
| **Typisierung** | 2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug |
| **Quellredaktion** | Brandenburg |
| **Freigabestatus Katalog** | unbestimmter Freigabestatus |
| **Freigabestatus Bibliothek** | unbestimmter Freigabestatus |
| **Begriffe im Kontext** | |
| **Leistungstyp** | Leistungsobjekt mit Verrichtung |
| **Leistungsgruppierung** | Tierhaltung und Tierschutz (110) |
| **Verrichtungskennung** | Erlaubnis (005) |
| **SDG-Informationsbereich** | |
| **Lagen Portalverbund** | Tierhaltung (1110300) |
| **Einheitlicher** | |

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| **Ansprechpartner** | Nein |
| **Fachlich freigegeben am** | 29.04.2020 |
| **Fachlich freigegen durch** | Ministry of Social Affairs, Health, Integration and Consumer Protection |
| **Handlungsgrundlage** | https://www.gesetze-im-internet.de/viehseuchg/__4.html<br>https://www.gesetze-im-internet.de/viehseuchg/__4.html |
| **Teaser** | You can apply informally to the State Office for Occupational Safety, Consumer Protection and Health (LAVG) for a permit to manufacture animal vaccines. |
| **Volltext** | If you wish to manufacture immunological veterinary medicinal products within the meaning of Section 11 para. 1 sentence 1 TierGesG or in vitro diagnostics within the meaning of Section 11 para. 2 sentence 1 TierGesG for the purpose of placing them on the market, you require a license for the respective product in accordance with Section 12 para. 1 TierGesG.<br><br>If you wish to manufacture immunological veterinary medicinal products within the meaning of Section 11 para. 1 sentence 2 TierGesG ("herd-specific vaccines") and in vitro diagnostic medical devices within the meaning of Section 11 para. 5 sentence 1 no. 1 TierGesG for the purpose of placing them on the market, you require a general authorization pursuant to Section 12 para. 2 that is not related to a specific immunological veterinary medicinal product or in vitro diagnostic medical device.<br><br>The regulations on immunological veterinary medicinal products are excluded from the scope of the German Medicinal Products Act (AMG) in accordance with Section 4a and are regulated in Sections 11 and 12 of the Animal Health Act and in the Animal Vaccine Ordinance.<br><br>The most important provisions on the manufacture, authorization, dispensing, use or import of |

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| | immunological veterinary medicinal products are regulated here. In addition, special requirements apply to animals used for food production (including meat, milk and eggs). Regulation (EU) No. 37/2010 is of particular importance here. |
| **Erforderliche Unterlagen** | • Extract from the commercial register, if applicable<br>• Designation of the business premises (name, street, town)<br><br>• Site plans of the company buildings and premises for production, testing and storage<br>• If available, details of external operating sites (also addresses and site plans)<br>• Proof of availability of the rooms<br>• Appointment of a competent person as well as a competent production and quality control manager in accordance with Section 5 TierimpfStV, stating personal details of the production manager, competent person, control manager and/or sales manager with date of birth, place of birth and address of current residence as well as telephone availability, fax number and e-mail address<br>• Proof of the expertise required in accordance with Section 12 (4) TierGesG in conjunction with Section 5 TierImpfStV (original or certified copy) and proof of the required reliability of the persons by means of certificates of good conduct (original, not older than 3 months)<br>• Designation of the sales management, stating the name, telephone and fax number as well as email address and proof of identity<br>• Proof from the persons responsible that the obligations incumbent upon them can be fulfilled at all times<br>• Details of the planned manufacturing activities (products, processes, scope per year) or testing activities including the manufacturing or testing processes<br>• Designation of the pharmaceutical and dosage forms, scope of manufacture and, if applicable, procedures<br>• If applicable, details of the external companies commissioned with testing<br>• current "Site Master File" or description of the facility, quality assurance manual |

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| **Voraussetzungen** | |
| **Kosten** | Fee for issuing the manufacturing authorization: EUR 150.00 - 5,000 |
| **Verfahrensablauf** | You apply for a license to manufacture animal vaccines in writing (informal):<br><br>• Submit the informal application to the LAVG with your exact name and address and details of your legal form, together with the necessary supporting documents.<br>• The LAVG will then check that the documents are complete and that you are eligible to apply.<br>• An acceptance inspection of the business premises will be carried out.<br>• You must rectify any defects that are discovered.<br>• The LAVG will then issue you with the manufacturing permit. You will receive a fee notice from the LAVG for payment of the fee for issuing the manufacturing permit. |
| **Bearbeitungsdauer** | with complete documents: maximum 3 months |
| **Frist** | Application deadline: complete submission to the LAVG at least 3 months before the planned start of production operations |
| **weiterführende Informationen** | https://www.zlg.de/<br>https://www.zlg.de/ |
| **Hinweise** | On January 28, 2022, Regulation (EU) 2019/6 on veterinary medicinal products will enter into force, repealing Directive 2001/82/EC. This will also change the current legal basis. |
| **Rechtsbehelf** | |
| **Kurztext** | • Production of veterinary vaccines Authorization<br>• Manufacturing authorization is a prerequisite for veterinary vaccines subject to authorization, stock-specific vaccines and in-vitro diagnostics subject to authorization<br>• Explanation of the application requirement<br>• Application required<br>• Responsible: State Office for Occupational Safety, Consumer Protection and Health (LAVG) |

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| **Ansprechpunkt** | State Office for Occupational Safety, Consumer Protection and Health (LAVG)<br><br>Department "Consumer Protection", Division V2<br><br>Von-Schön-Str. 7<br><br>03050 Cottbus<br><br>Tel. 0331-8683540<br><br>Fax. 0331-275484257<br><br>Service hours:<br><br>Mon. 09:00 - 15:00<br><br>Tue. 09:00 - 15:00<br><br>Wed. 09:00 - 15:00<br><br>Thurs. 09:00 - 15:00<br><br>Fri. 09:00 - 15:00 |
| **Zuständige Stelle** | State Office for Occupational Safety, Consumer Protection and Health (LAVG) |
| **Formulare** | |
| **Ursprungsportal** | Herstellung von Tierimpfstoffen Erlaubnis, Production of veterinary vaccines Permission |