99005068006000

Schulungsmaterial (Educational Material) als Teil des Risikomanagement-Plans Genehmigung

Modul	Sachverhalt
Leistungsschlüssel	99005068006000
Leistungsbezeichnung I	Schulungsmaterial (Educational Material) als Teil des Risikomanagement-Plans Genehmigung
Leistungsbezeichnung II	Submit educational material for medicinal products for approval
Typisierung	1 - Bund: Regelung und Vollzug
Quellredaktion	Bund
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	

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Verrichtungskennung	Genehmigung (6)
SDG-Informationsbereich	Erlangung von Lizenzen, Genehmigungen oder Zulassungen im Hinblick auf die Gründung und Führung eines Unternehmens
Lagen Portalverbund	Krankheit (1130200), Produkt- und Stoffzulassung (2120200)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	28.10.2024
Fachlich freigegen durch	Federal Ministry of Health (BMG)
Handlungsgrundlage	https://www.gesetze-im-internet.de/amg_1976/__4.html https://www.gesetze-im-internet.de/amg_1976/__34.html
Teaser	If you, as the marketing authorization holder of medicinal products, are obliged to create additional educational material for your product, you must submit this for national approval.
Volltext	As a manufacturer of medicinal products, you must provide educational material in addition to the information for healthcare professionals and instructions for use if this has been requested as part of the approval procedure. The educational material must be reviewed and approved by the competent national authority, in this case the Paul-Ehrlich-Institut (PEI), before the product is marketed in Germany. Paul-Ehrlich-Institut is responsible for • Sera • vaccines • Monoclonal antibodies • Immunoglobulins • Blood preparations • Tissues and tissue preparations • Allergens • Advanced therapy medicinal products • xenogeneic medicinal products

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	• Genetically engineered blood components • in vitro diagnostics The Federal Institute for Drugs and Medical Devices (BfArM) is responsible for all other medicinal products. Whether training materials have been ordered for a medicinal product can be found in the product information of the corresponding medicinal product. The package leaflets and information for healthcare professionals provide information on how a medicine is used as intended and what side effects may occur. For some medicinal products for which certain and potentially very serious side effects are known, it is considered necessary to refer specifically to these possible side effects in addition to the information contained in the package leaflet and the information for healthcare professionals. This serves the purpose of early identification and/or correct treatment of the reaction that may occur. In addition to the information on specific side effects, educational material may be used to support correct use where safety concerns may arise. The information contained in the educational material goes beyond that provided in the package leaflet and the information for healthcare professionals. This can be, for example, a patient passport or a patient brochure. For some medicinal products, educational material is a prerequisite for the benefit-risk ratio for the medicinal product to be assessed as positive and for the marketing authorization holder to be allowed to place the medicinal product on the market. The educational material must be made available to your company's target groups in the manner specified by the BfArM/PEI. You must also comply with certain content requirements when creating the material. Training material includes, for example • Patient card / patient passport • Brochure for doctors, pharmacists and nursing staff

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	• Brochure for patients, parents and caregivers • Checklists for doctors, pharmacists, nursing staff and patients • Videos or spoken audio versions of patient brochures • for training and instructions on correct application: e.g. images, information on the website If training material is ordered for a medicinal product, it is created on the basis of the commissioned pharmacovigilance activities and Annex VI from the risk management plan, as well as the product information for your product, and submitted to the PEI for approval. To ensure that the officially approved training material can be distinguished at first glance from other information material issued by pharmaceutical companies, the labeling of newly approved training material with the "Blue Hand logo" has been mandatory since 01.12.2016. For training material that has already been approved and is in circulation, the "Blue Hand logo" will be affixed from 01.12.2016 with every new or renewed approval. The current formal requirements from the available guidance documents must then also be complied with. The logo is intended to prevent training material approved by the authority from being mistaken for advertising and thrown away by the recipient. This could, for example, lead to doctors and patients not being sufficiently informed about certain side effects or the treatment of certain reactions, or to incorrect dosages or applications of a medicine. The production of educational material can be reordered at any time during an existing marketing authorization as part of a variation to the marketing authorization dossier.
Erforderliche Unterlagen	• Cover letter naming the product and specifying the active substance for which the training material is to apply Indication of the authorization number and, if applicable, the EU procedure number Description of the background to the application, e.g. the underlying procedure and other reasons

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	• Editable Word files of the proposed training material, in the case of amendments also amendment versions • Layout versions of the training material or mock-ups (PDF files) • Cover letter to addressees, if applicable • Communication plan with details of a defined distribution group using the published template; in the case of updates, additional amendment version • Document on the core elements of the medicinal product for new submissions or changes to the core elements: relevant parts of the current risk management plan (usually Annex 6) and Annex II D of the current implementing decision of the EU Commission If there is no change to the core elements: Confirmation that these are unchanged from the last submission More detailed information on the formalities can be found in the checklist and the technical submission instructions for the training material.
Voraussetzungen	• The preparation of training materials was ordered for the product as part of the approval or when the approval documents were amended, or this was ordered as part of the risk management plan (RMP).
Kosten	Gebühr: Es fallen keine Kosten an There are no costs.
Verfahrensablauf	You can submit the training material for your product by e-mail, EudraLink or via the Common European Submission Portal (CESP). Submission by e-mail or EudraLink: • Follow the guidelines required by the BfArM/PEI when creating the training material. Standard layouts, a checklist, a template for the communication plan and technical submission instructions can be found on the BfArM/PEI website. • Send the completed training material by e-mail or EudraLink to the pharmacovigilance function mailbox. • After review by the BfArM/PEI, you will receive approval of the training materials or correction notes. • After final approval, you can publish the training

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	material. • The training material will also be published on the PEI website. Submission via CESP: • Upload the completed training material via CESP for review by the BfArM/PEI. • You will need an account on the CESP platform to register. If your organization is not yet registered on CESP, you must first apply for an account. • After verification by the BfArM/PEI, you will receive approval of the training materials or correction notes. • After final approval, you can publish the training material. • The training material will also be published on the PEI website.
Bearbeitungsdauer	The duration of the review depends on the scope of the requested materials, the completeness of the submission, the preparation by the marketing authorization holder, as well as the speed of adaptation and consideration of the comments by the marketing authorization holder in the event of comments. As a rule, initial feedback is given within a few weeks.
Frist	There is no explicit deadline. However, educational material must be reviewed and approved by the BfArM/PEI before medicinal products can be marketed in Germany.
weiterführende Informationen	https://www.pei.de/DE/arzneimittelsicherheit/schulungsmaterial/schulungsmaterial-inhalt.html https://www.pei.de/DE/regulation/zulassung-human/schulungsmaterial/schulungsmaterial-node.html https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Pharmakovigilanz/Risikoinformationen/EducationMaterial/flyer_blaue-hand.html https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Pharmakovigilanz/Risikoinformationen/EducationMaterial/weitere-informationen/tabelle-educatmaterial.html https://www.bfarm.de/DE/Arzneimittel/Pharmakovigilanz/Risikoinformationen/Schulungsmaterial/Zusatzinfor

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Hinweise	
Rechtsbehelf	• Appeal to BfArM/PEI
Kurztext	• Educational material as part of the risk management plan Approval • Preparation of supplementary educational material by manufacturers for certain medicinal products for which educational material is requested as part of the approval procedure • Preparation of educational material based on the so-called core elements of the risk management plan and the product information of the medicinal product under the responsibility of the Paul-Ehrlich-Institut (PEI) • Training material is for example Patient passport / patient card Brochure for doctors, pharmacists and nursing staff Brochure for patients, parents and

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	caregivers Checklists for doctors, pharmacists, nursing staff and patients Videos or spoken audio versions of patient brochures • Submission primarily by e-mail, but also via EudraLink or online via the Common European Submission Portal (CESP) • Paul-Ehrlich-Institut is responsible for Sera vaccines Monoclonal antibodies Immunoglobulins Blood preparations Tissues and tissue preparations Allergens Advanced therapy medicinal products xenogeneic medicinal products Genetically engineered blood components in vitro diagnostics • the Federal Institute for Drugs and Medical Devices (BfArM) is responsible for all other medicinal products
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	Schulungsmaterial (Educational Material) als Teil des Risikomanagement-Plans Genehmigung, Schulungsmaterial (Educational Material) als Teil des Risikomanagement-Plans Genehmigung