

Brief instructions for the special application "Product Information Texts" (PIT)



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1 Introduction

In accordance with Sections 11 (1a), 11a (3) AMG, the submission of current text versions is required. These current text versions are made available to the public in electronic form in accordance with Section 34 AMG. The texts to be submitted via the "PIT" special application are the final texts of the Package Leaflets (PIL) and the Summary of Product Characteristics (SmPC) after completion of the procedure. The "PIT" special application has replaced the previous procedure of submission by e-mail according to the so-called "AMG-EV procedure".

In addition to the German language versions there is also the possibility of uploading English texts. A submission is always required if the texts of the Package Leaflets or the Summary of Product Characteristics have been modified within the procedure.

2 Registration

The new application is integrated into the PharmNet.Bund project. The registration is done centrally via DIMDI and the application RuBen. This allows several employees of one company to receive their own access authorisations. Information on both the central registration procedure and the registration requirements can be requested from DIMDI (www.dimdi.de).

3 Submission of final text versions

3.1 Terms of use

In order to be able to submit the final text versions, you must first confirm that you accept the current terms of use.

Nutzungsbedingungen (PIT-01)

Terms of use

Terms of use

This confirms that the product information texts have been prepared correctly and uploaded in the version approved by the responsible federal authority. It also confirms that the submission is made by a person authorised by the marketing authorisation holder. It also confirms that the current submission contains all the information to be published in full.

I hereby confirm that I accept these conditions!

3.2 Further navigation steps and functionalities

After the terms of use have been accepted, the user receives the rights assigned to him by the main user of the entrepreneur to make submissions for one or, if applicable, several companies (field: Select PNR). The responsibility for assigning the rights lies with the main user of the company.

There are three categories:

1. New submissions: the federal higher authorities using the system will issue specific instructions as to the procedures for which texts are to be submitted. These are displayed in this category
2. In progress: here are the procedures that the entrepreneur has already started
3. Released: here the procedures are listed which have been released by the entrepreneur

?	ENR	Ver.	ZNR	AM-Bezeichnung	Stärke	Darreichungsform	FI/GI	Verfahrensnr.	Regulatorische Aktivität	Bescheid / Abschlussdatum
<input type="checkbox"/>	1998868	11.0.0	6998816.48.71	Test-Arzneimittel dezentralisiert DE=RMS		Filmtablette	+ / +		Verlängerung/Renewal	30.03.2020
<input type="checkbox"/>	1998868	14.0.0	6998816.48.71	Test-Arzneimittel dezentralisiert DE=RMS		Filmtablette	- / +		Verlängerung/Renewal	31.03.2020
<input type="checkbox"/>	1998868	12.0.0	6998816.48.71	Test-Arzneimittel dezentralisiert DE=RMS		Filmtablette	- / +		Verlängerung/Renewal	31.03.2020

3.3 Category "New submission"

The category "New submission" is preset, i.e. the user will see these procedures when the page opens.

?	ENR	Ver.	ZNR	AM-Bezeichnung	Stärke	Darreichungsform	FI/GI	Verfahrensnr.	Regulatorische Aktivität	Bescheid / Abschlussdatum
<input type="checkbox"/>	1998868	11.0.0	6998816.48.71	Test-Arzneimittel dezentralisiert DE=RMS		Filmtablette	+ / +		Verlängerung/Renewal	30.03.2020
<input type="checkbox"/>	1998868	14.0.0	6998816.48.71	Test-Arzneimittel dezentralisiert DE=RMS		Filmtablette	- / +		Verlängerung/Renewal	31.03.2020
<input type="checkbox"/>	1998868	12.0.0	6998816.48.71	Test-Arzneimittel dezentralisiert DE=RMS		Filmtablette	- / +		Verlängerung/Renewal	31.03.2020

One or more procedures may be selected for which identical texts must be submitted. This means that, for example, if several text-relevant procedures have been completed in a short time, identical texts for several procedures can be submitted in one step.

After selecting one or more procedures and clicking on "edit", the actual input screen is displayed. Here, it is mandatory to upload the Package Leaflet and the Summary of Product Characteristics (if the obligation to create a summary of product characteristics exists). English texts can also be uploaded additionally.

The texts are selected by clicking on "Browse" and choosing the file in your own file system.

Einreichung ProdInfo-Texte (PII-11) Meldedatum: 30.03.2020

Pharmazeutische Unternehmer Nummer (PNR): 4100017

Fach- und Gebrauchsinformationen

ENR: 1998868
 AM-Bezeichnung: Test-Arzneimittel dezentralisiert DE=RMS
 Stärke:
 Darreichungsform: Filmtablette
 VNR:
 Regulatorische Aktivität: Verlängerung/Renewal
 Bescheid / Abschlussdatum: 30.03.2020
 Fachinfo / Gebrauchsinfo: + / +
 Status: offen

Pflichttexte und -Angaben

Fachinformation zur Freigabe in Deutsch

Gebrauchsinformation zur Freigabe in Deutsch

Optionale Texte

Fachinformation zur Freigabe in Englisch

Gebrauchsinformation zur Freigabe in Englisch

Timeout: 00:08:14

Important: Only pdf documents can be uploaded.

The data set can then be

- saved. This can then be called up again under "In process".
- saved and released: The documents are then transmitted directly to the medicinal product database of the federal higher authorities and are assigned to the procedures.

3.4 Category "In progress"

In the category "In progress" the procedures are shown that have been processed and saved but not yet released. The editing process is identical to the procedure described under point 3.3.

PII-Meldungen in Bearbeitung (PII-20)

?	ENR	Ver.	Zulassungsnummer	AM-Bezeichnung	Stärke	Darreichungsform	FI/GI	Verfahrensnr.	Regulatorische Aktivität	Bescheid / Abschlussdatum	Status
<input type="checkbox"/>	1998868	14.0.0	6998816.48.71	Test-Arzneimittel dezentralisiert DE=RMS		Filmtablette	- / +		Verlängerung/Renewal	31.03.2020	in Bearbeitung

3.5 Category "Released"

The "Released" category shows the procedures that have been transferred by the company to the federal higher authorities.

PIT-Meldungen freigeben (PIT-30)

?	ENR	Ver.	ZNR	AM-Bezeichnung	Stärke	Darreichungsform	FI/GI	Verfahrensnr.	Regulatorische Aktivität	Bescheid / Abschlussdatum	Status	Hochgeladen am
<input type="checkbox"/>	1998868	10.0.0	6998816.48.71	Test-Arzneimittel dezentralisiert DE=RMS		Filmtablette	- / +		Verlängerung/Renewal	27.03.2020	freigegeben	27.03.2020
<input type="checkbox"/>	1998868	11.0.0	6998816.48.71	Test-Arzneimittel dezentralisiert DE=RMS		Filmtablette	+ / +		Verlängerung/Renewal	30.03.2020	freigegeben	14.04.2020
<input type="checkbox"/>	1998868	13.0.0	6998816.48.71	Test-Arzneimittel dezentralisiert DE=RMS		Filmtablette	- / +		Verlängerung/Renewal	31.03.2020	freigegeben	14.04.2020

Anzeigen Suche Ansicht exportieren

Again, one or more procedures can be selected. If several procedures are selected, you can navigate between them by clicking on the hyperlink. The view offers the possibility to call up the transferred documents again.

Anzeige ProdInfo-Texte (PIT-31)

ENR: 1998868 Pharmazeutische Unternehmer Nummer (PNR): 4100017 Meldedatum: 27.03.2020

1998868
1998868
1998868

Details

ENR: 1998868
AM-Bezeichnung: Test-Arzneimittel dezentralisiert DE=RMS
Stärke:
Darreichungsform: Filmtablette
VNR:
Regulatorische Aktivität: Verlängerung/Renewal
Bescheid / Abschlussdatum: 27.03.2020
Fachinfo / Gebrauchsinfo: - / +
Status: freigegeben
Bearbeitungsnr.: 20200000003

Pflichttexte und -Angaben

Fachinformation zur Freigabe in Deutsch

Gebrauchsinformation zur Freigabe in Deutsch
[GI_de_1998868_20200000003.pdf \(GI-DE.pdf\)](#)

Optionale Texte

Fachinformation zur Freigabe in Englisch

Gebrauchsinformation zur Freigabe in Englisch
[GI_en_1998868_20200000003.pdf \(GI-EN.pdf\)](#)

Abbrechen

4. Further functionalities

4.1 Export view

With the function "Export view" the hit lists that are currently displayed on the screen can be downloaded into an excel file.

4.1 Search

You can use the search function to look for medicinal products in various categories:

- ENR
- Marketing authorisation number
- Name of medicinal product
- Procedure number
- Regulatory activity

X
Suche

Tipp: Geben Sie mindestens ein Zeichen in das Suchfeld ein, um die Suche auszulösen.
 Grundsätzlich gilt: Gross- und Kleinschreibung wird nicht beachtet,
 ? als Maskierung für ein beliebiges Zeichen und * für eine beliebige Zeichenfolge benutzt werden.

suche nach in ENR ▼ suchen zurücksetzen

The application is continuously being developed.

5 Support

5.1 Helpdesk

Questions about the application can be sent to the e-mail address: PIT@bfarm.de.

In order for the helpdesk team to be able to provide optimal assistance, the following information should be provided:

1. name of the person inquiring, including relevant contact details (e.g. telephone number)
2. ENR (processing number) of the medicinal product(s) concerned
3. precise description of the problem, e.g.,
 - a. in which order was the procedure followed?
 - b. screenshots of the screens, error messages etc.
4. in case of technical problems e.g. which browser (including the version) is being used

5.2 FAQ

We intend to publish answers to frequently asked questions on the PharmNet. Bund homepage under "Product Information Texts (PIT)". These FAQ will supplement information in this manual and will be included in future versions.