COOPERATION IN THE BUSINESS AREA OF THE

PharmNet.Bund

Bundesministerium für Gesundheit

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

Contact person 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.

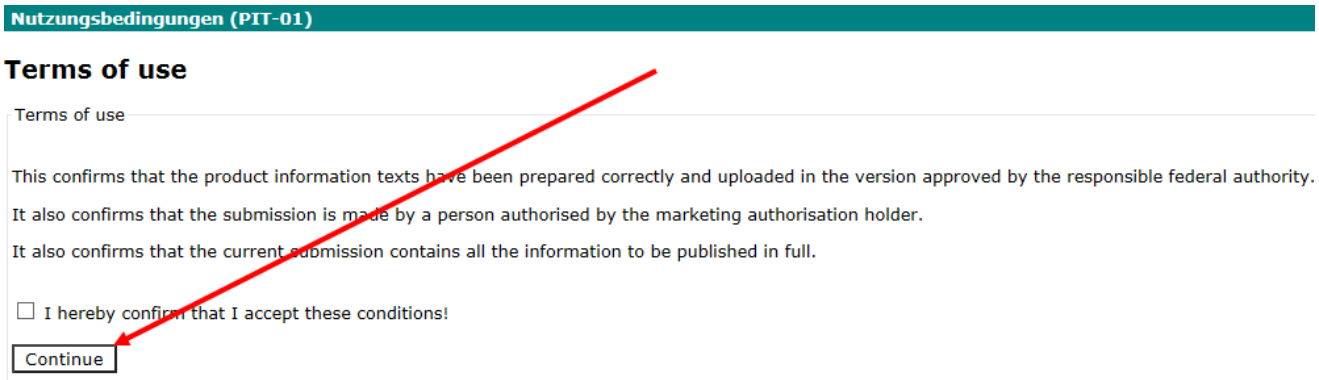
2 Registration

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.



3.2 Further navigation steps and functionalities

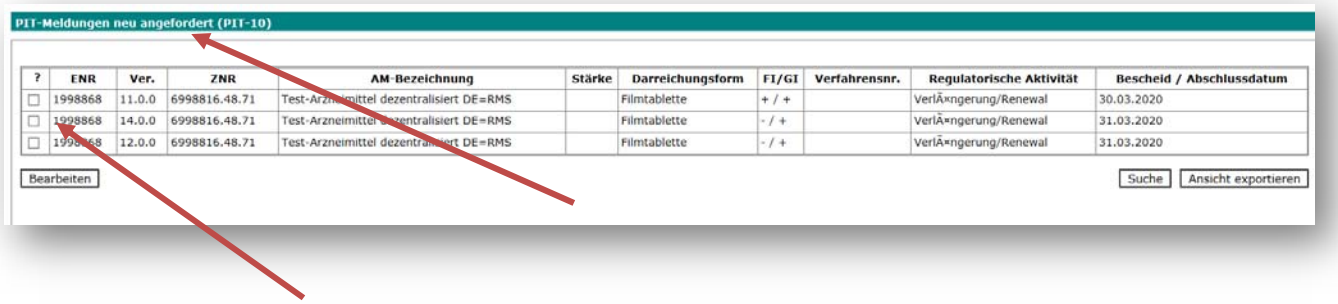
After the terms of use have been accepted, the user receives the rights assigned to him by the main user of the entrepreneur to make submissions for one or, if applicable, several companies (field: Select PNR). The responsibility for assigning the rights lies with the main user of the company.

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

3.3 Category "New submission"

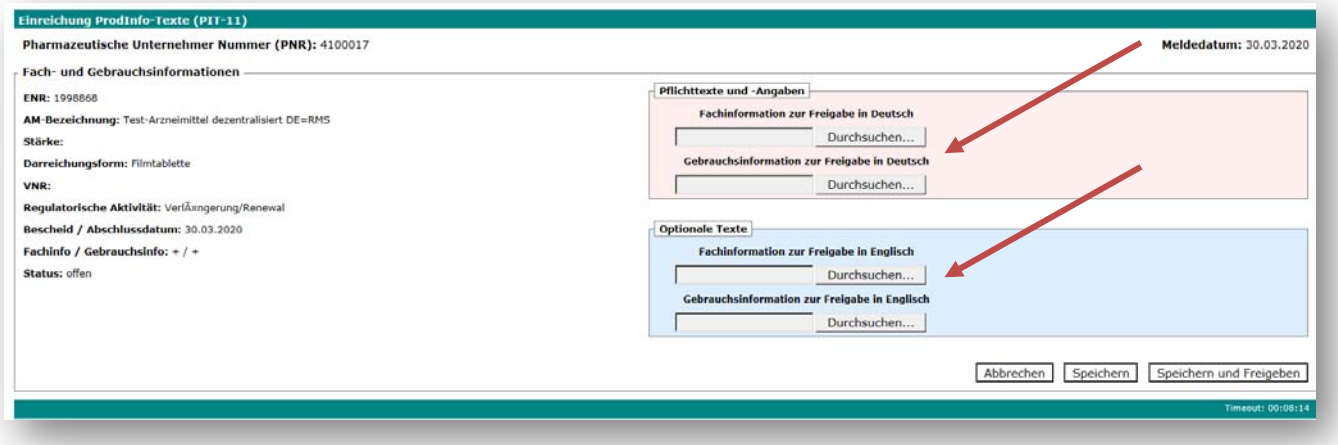
The category "New submission" is preset, i.e. the user will see these procedures when the page opens.



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.



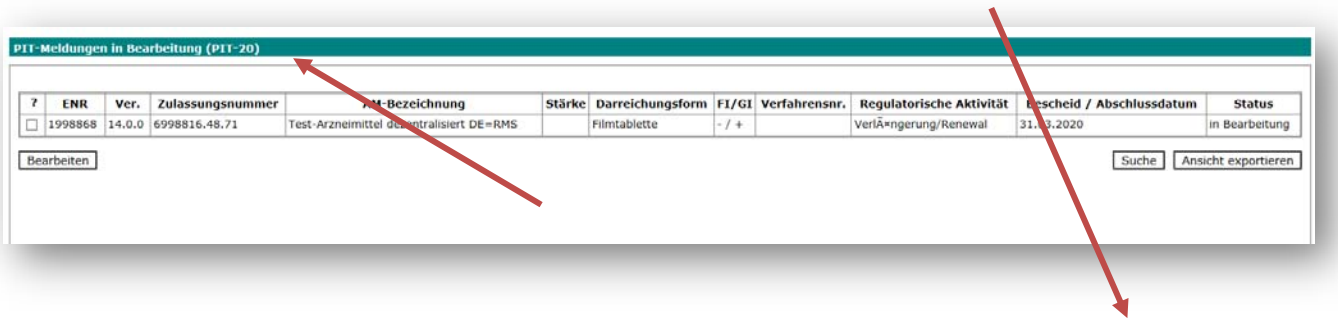
Important: Only pdf documents can be uploaded.

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"

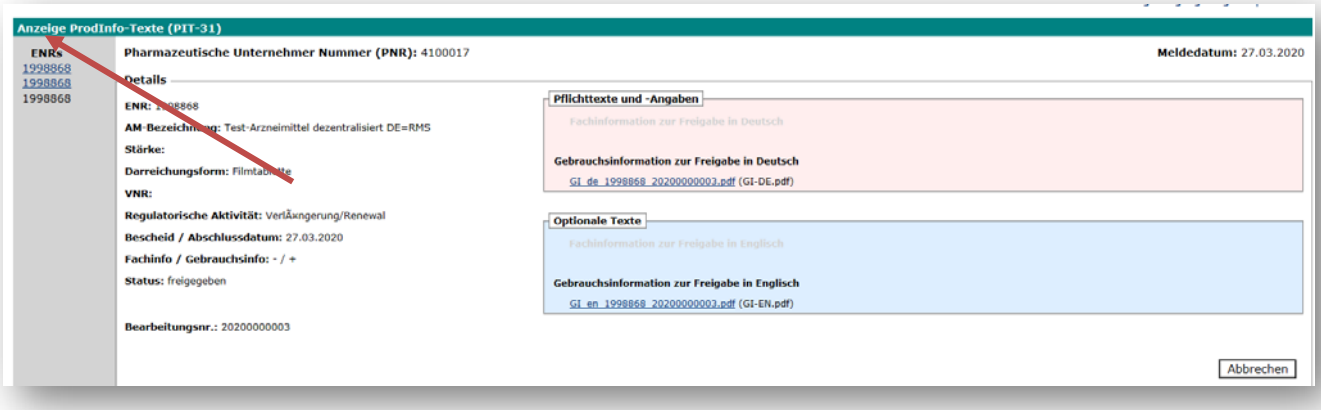
In the category "In progress" the procedures are shown that have been processed and saved but not yet released. The editing process is identical to the procedure described under point 3.3.



3.5 Category "Released"

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

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.



4. Further functionalities

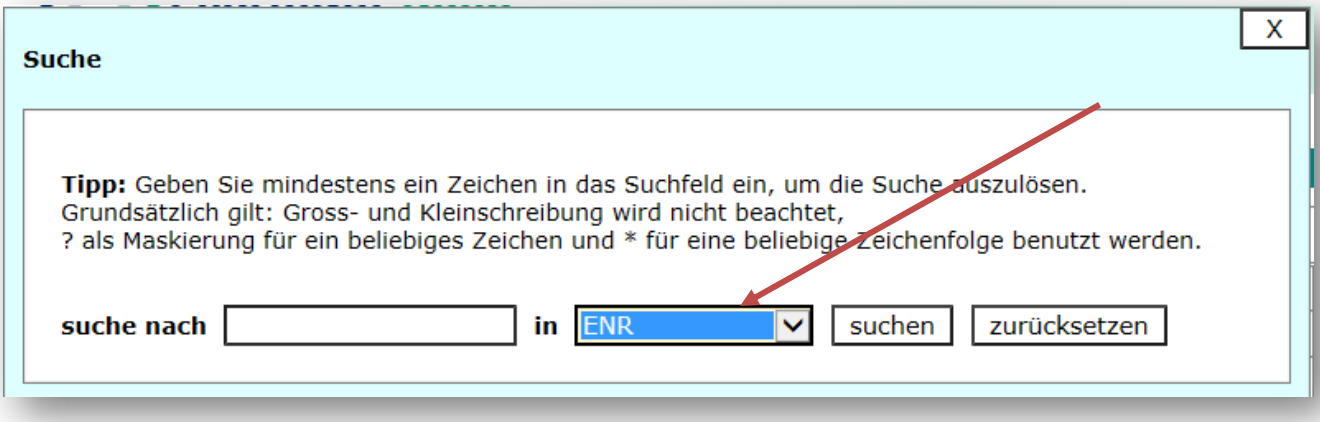
4.1 Export view

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



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.