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Contact person**Online Variation****Submission**

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1 Introduction

We are very pleased to present the *Online Variation Submission* application, the first phase of the Pharmnet.Bund.de *Electronic Application Filing Module*. The *Online Variation Submission* application provides both the pharmaceutical industry and the CAs with a highly modern, safe, and reliable method for the electronic submission of national variations pursuant to § 29 German Drugs Law (AMG) and European variations according to Regulation 1084/2003/EC to www.pharmnet.bund.de. Please take the time to familiarise yourself with the various functions described in this manual.

The *Online Variation Submission* application enables pharmaceutical companies both to create national variations in accordance with § 29 German Drugs Law (AMG) and European variations (pursuant to Commission Regulation (EC) 1084/2003) using the data stored with the Competent Authorities (CAs), and also to submit these generated variations directly to the CAs.

As with any software, the *Online Variation Submission* application is undergoing continual development. The version that is presented here supports the functions described in this manual. This development phase, moreover, has seen the adoption in the planning process of other functions for future extension of the application. These other upgrades of the *Online Variation Submission* application and the extension to cover other types of applications, such as Marketing Authorisation Applications, are planned for the time immediately after the application is launched.

2 Basic Principles

2.1 Legal basis

Variations for national approvals are to be submitted to the national licensing authorities.

- ◆ For approval on a purely national level, the applicant must notify the CA without delay pursuant to § 29 Abs. 1 AMG by providing the appropriate documentation where there are changes to the product information and documentation as defined by § 22 to § 24a and § 25b. Following the issue of the Marketing Authorisation, the Marketing Authorisation Holder (MAH) must comply with this obligation.
- ◆ In regard to changes of national authorisations which are issued by means of the mutual recognition procedure (MRP), or the decentralised procedure (DCP), the provisions of the Commission Regulation (EC) 1084/2003 apply.

Use of the *Online Variation Submission* application is currently voluntary because the submission of an electronic application is not required by either the AMG or the AMG e-Submission Ordinance (AMG-EV). Since the current registration procedure does not yet satisfy the requirements of the German Signature Law, the following documentation must also be submitted to the CAs in paper along with the electronic submission when using the online application:

- ◆ Variation form (generated automatically by the application);
- ◆ Expert reports (regulation from the AMG eSubmission ordinance);
- ◆ Product information, where the variation content is not adequately described in the variation form.

Users of the *Online Variation Submission* application must accept the currently valid German Terms and Conditions of Use (GTC Use). The GTC of Use can be accessed on the Submit page.

Use of the PharmNet.Bund portal is subject to the “Declaration and Notice on Liability, Links and Linking, Copyright, Data protection” found under the “Legal Notice” (“Impressum”).

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.



2.2 Technical principles

The *Online Variation Submission* application is a web-based application enabling the generation of online variation forms. All entries and attached documentation are stored directly on the target computer at PharmNet.Bund. It is **not** possible to generate variation forms when offline.

The application is available from Monday to Friday between 8 am and 6 pm. An information notice will be displayed outside of these hours.

Vielen Dank für Ihr Interesse an den Elektronischen Änderungsanzeigen.
Bitte besuchen Sie uns innerhalb der unten angegebenen Servicezeiten wieder.

Mo. - Fr. von 8:00 Uhr bis 18:00 Uhr

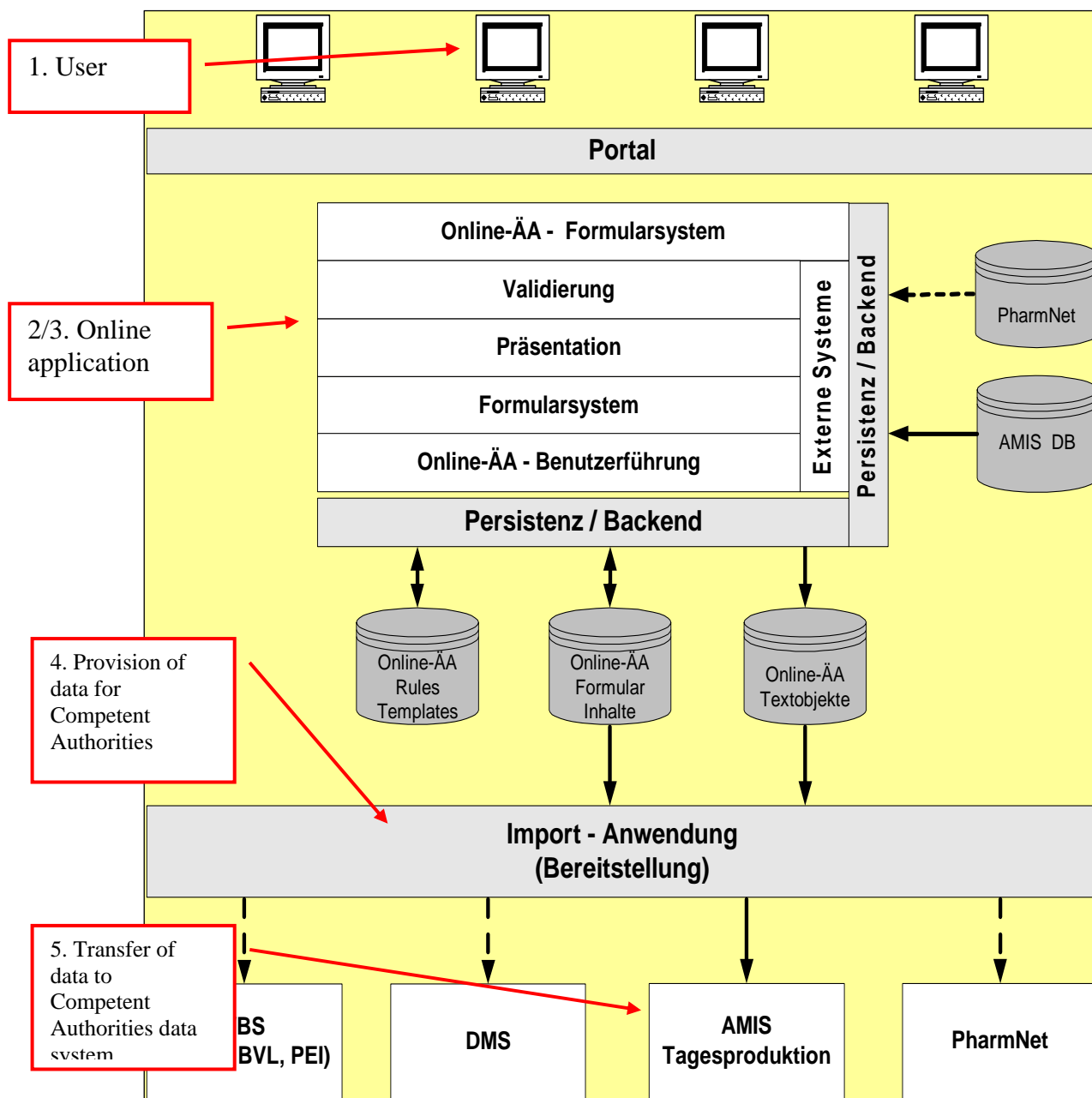
It is strongly recommended that users of the application have a high-speed internet connection (broad band). The following system requirements and recommendation also apply:

In order to render a paper version of variations pursuant to (EC) 1084/2003, users are required to use the Word 2003 Viewer. This is available as a [Download](#) free of charge. Where the generated versions are to be modified pursuant to (EC) 1084/2003, e.g. for conventional submission in other Member States, users will require a Microsoft Word-compatible word processing program, version 2003 and later.

The application has been developed and tested using the web browser Internet Explorer Version 6 and Adobe Acrobat Reader Version 6. It is, therefore, recommended not to use earlier versions. The full functionality of the application cannot be guaranteed when using alternative web browsers (e.g. Firefox).

The following figure illustrates the underlying technical structure.

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.



1. Users go to www.pharmnet.bund.de and enter username and password before proceeding to access the *Online Variation Submission* application.
2. The application provides the online forms and contents. Documents uploaded by the user will be stored on the PharmNet server.
3. As long as the variation has not been submitted, the data are available only to the MAH and other persons authorised by it - i.e. the CAs do not have any access to data and documents that have not yet been sent.
4. The "Submit" procedure makes the data available to the CAs by means of the import application.
5. The CAs 'collect' the data and integrate it within their own independent data systems.

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

3 Registration

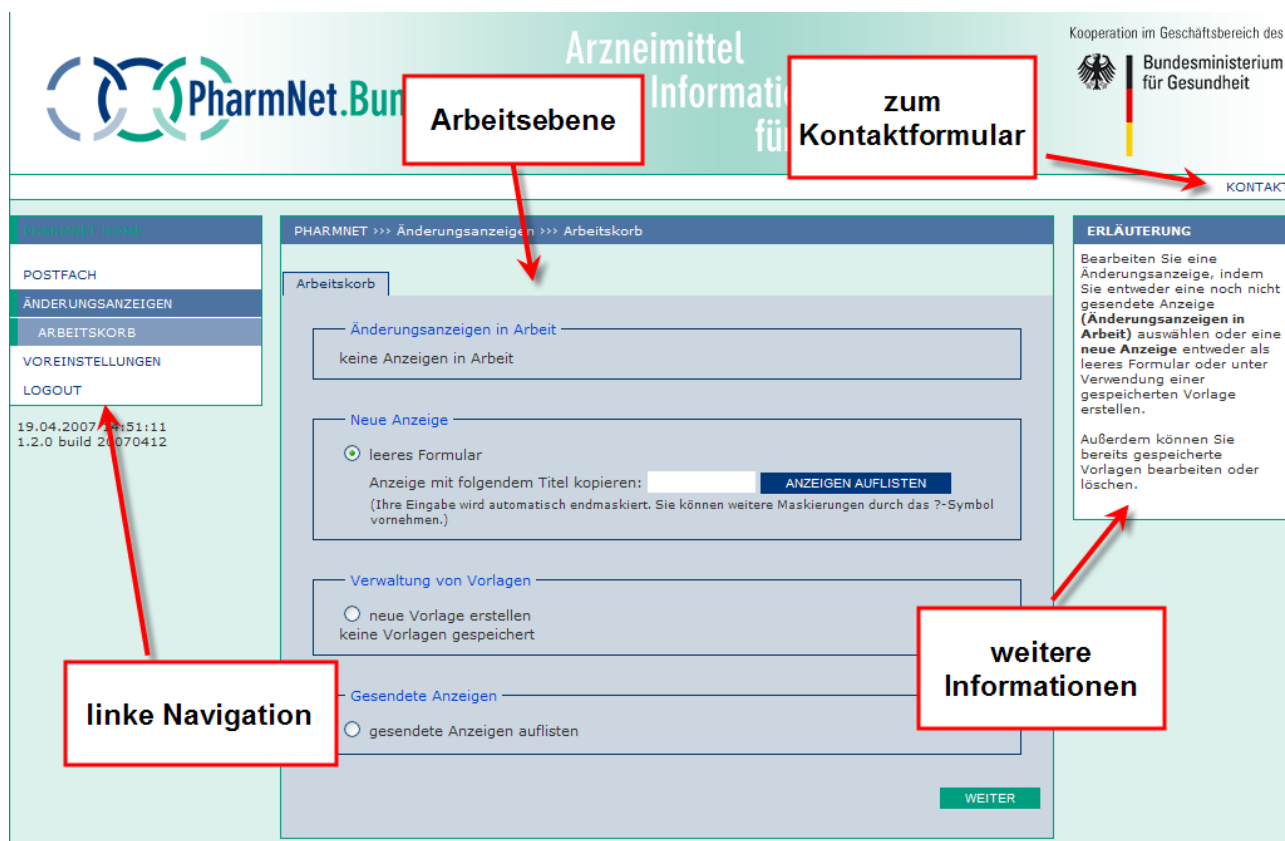
The Registration tool is an independent application and is not part of the *Online Variation Submission* product. [Information on registration](#) is made available on the BfArM homepage for example.

4 Screen Layout

4.1 Start screen

The navigation is arranged with various logical aspects and a repetitive structure so that it can be used intuitively.

The pages have both a header and footer with the logos of PharmNet.Bund and the institutions contributing to PharmNet.Bund. Under the header on the right, there is a link to the contact form which enables users to ask questions to the Helpdesk about applications at PharmNet.Bund. The left margin is where the navigation bar is located. Underneath the navigation bar on the left there is a date stamp, which displays the time of the last activity performed by the user. Below the date stamp there is the version number and the date of the last update of the displayed page (in this case the Task Area page). In the centre is the actual task area frame. On the right hand side, there is the *Explanations* panel. This panel provides users with additional information.



The screenshot shows the PharmNet.Bund start screen. The header includes the PharmNet.Bund logo, the text 'Arzneimittel Information für', and the logo of the Bundesministerium für Gesundheit. A red box labeled 'Arbeitsebene' points to the 'Arbeitskorb' tab. Another red box labeled 'zum Kontaktformular' points to the 'KONTAKT' link. A red box labeled 'linke Navigation' points to the left navigation bar. A red box labeled 'weitere Informationen' points to the 'ERLÄUTERUNG' panel. The main content area shows the 'Arbeitskorb' with options for 'Änderungsanzeigen in Arbeit', 'Neue Anzeige', and 'Verwaltung von Vorlagen'. The 'ERLÄUTERUNG' panel provides instructions on how to use the system.

4.2 Further basics of navigation

The navigation bar changes as the processing progresses; at the same time, the central area is organised into a tab structure. During processing, the navigation can be controlled using either the tabs or the navigation bar on the left. It is not required that users work through the tabs from left to right or the navigation bar from top to bottom. Users can at any time move back to change the entries made previously. A status report can also be generated at any time displaying the current status of the variation.

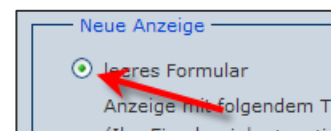
Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.



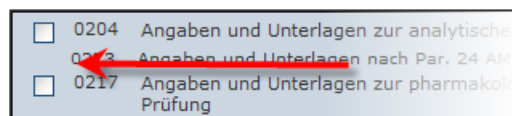
As a rule entries are confirmed at the bottom of the page (fields, such as *Next*, *Accept*, *Submit data*).

Various basic functions are provided:

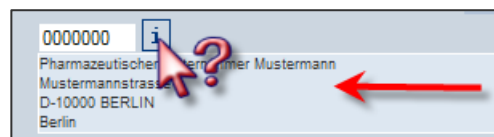
1. Radio buttons: By using a radio button a single choice is selected. The last selected button will normally be marked.



2. Check boxes: Check boxes differ from radio buttons in that several choices can be selected, or, in some cases, no entry needs to be made at all.



3. Information field (i-field): The i-field can be activated to obtain additional information by hovering the mouse pointer over the field (**without** clicking the left or right buttons).



4. Transfer all current data: In various forms the data currently stored in AMIS will be transferred to the "current" and "future" text fields of the forms. If the current data do not correspond with the data held by the company, the data can be changed. When changing these current, but apparently incorrect data, the user should insert an explanation as to why he or she thinks the discrepancy has arisen (e.g. see variation dated xxx) into the remarks field. Before the intended changes are performed, the changed current data should be transferred again.



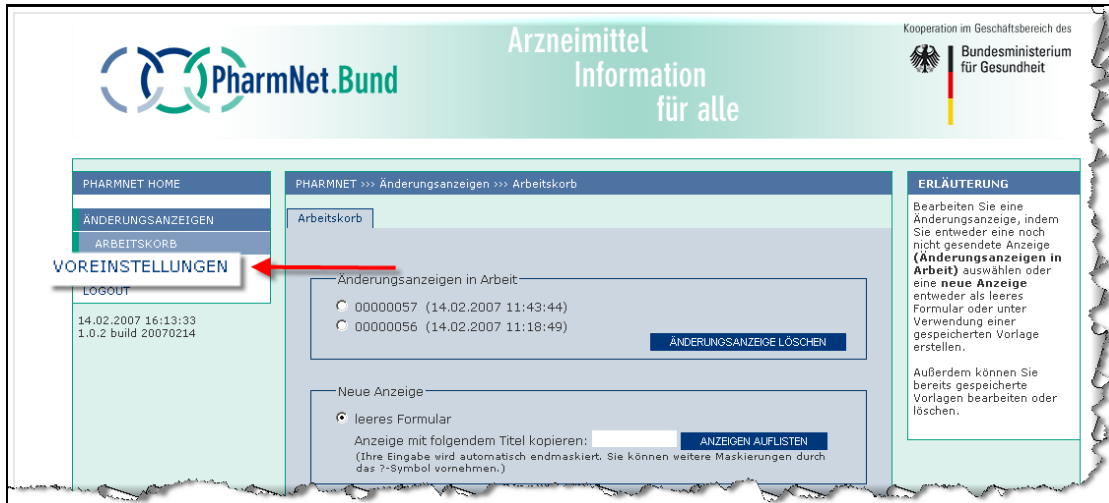
Note:

Correcting the current data does not automatically update the AMIS database. The changed information will be submitted along with the variation, and, during processing at the CA, a check will be performed to see if an error has indeed occurred. Where necessary, the staff of the CA will then correct the data in the AMIS database.

5 Presettings

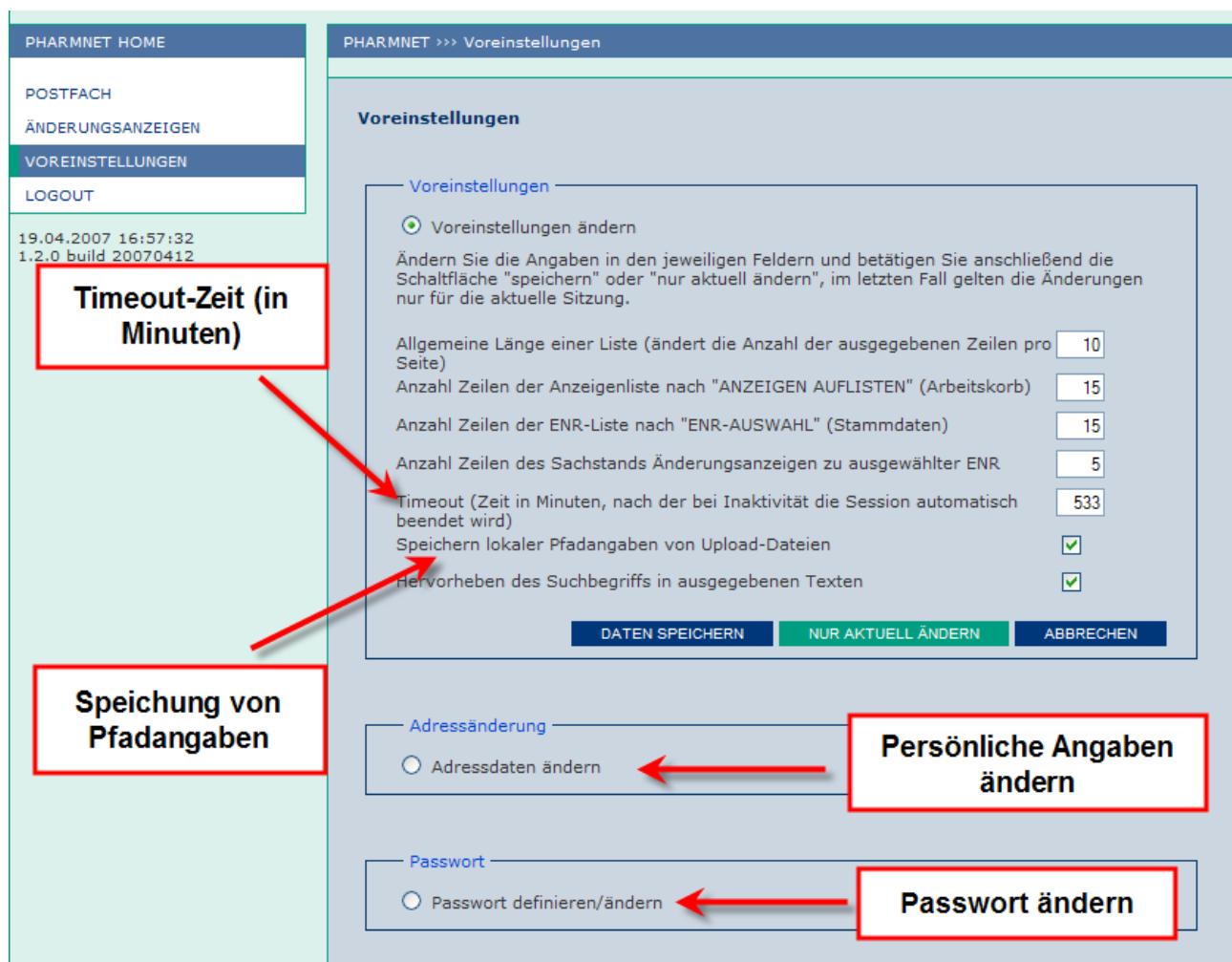
By clicking on *Presettings* (below the task list on the navigation bar on the left) the user can set various preferred settings for the application.

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.



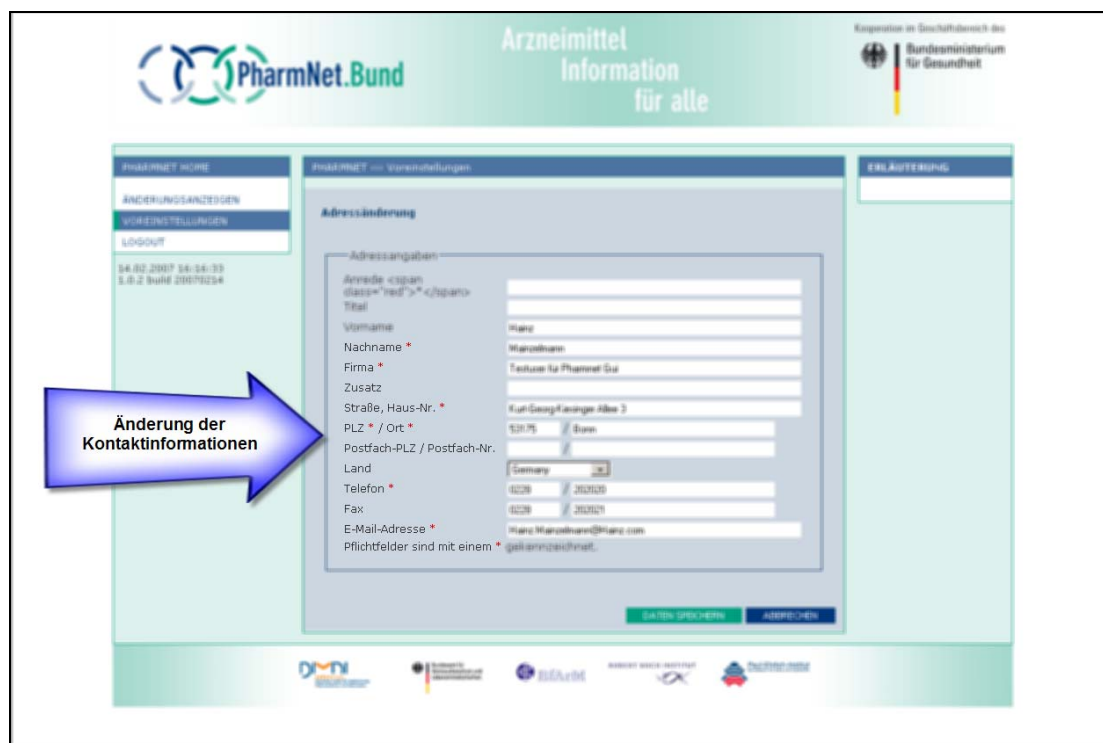
The options available include:

- ◆ The timeout (automatic logout if there is no activity) can be freely selected;
- ◆ Choosing whether to specify the file path of the uploaded document in the form;
- ◆ Changing personal information and the password.

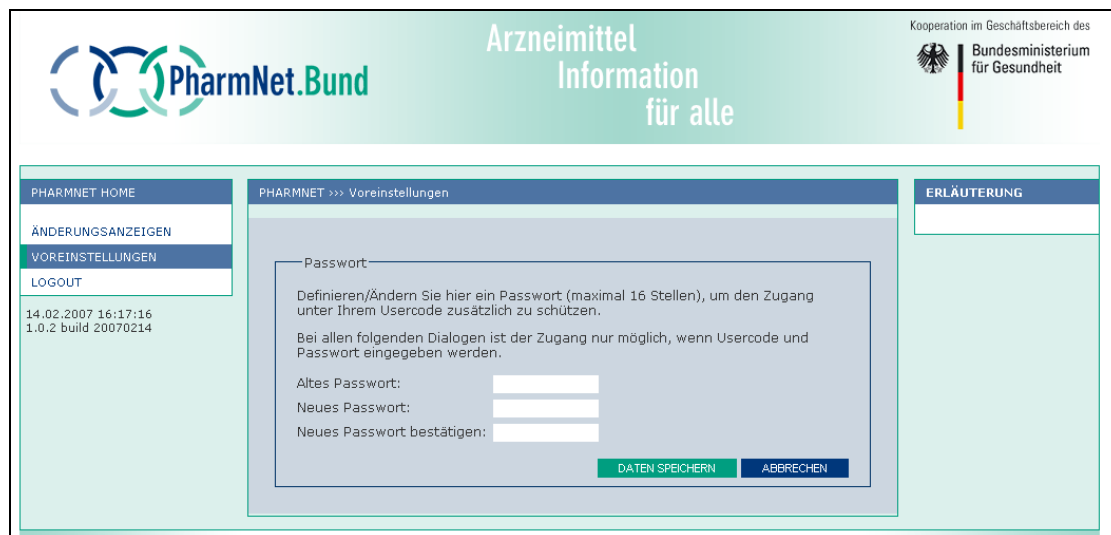


Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

Registration information can be updated in the *Address change* field. Mandatory fields are indicated by an asterisk *. The mail address recorded here will be used for communications via the mailbox (mails automatically dropped when there is a change in status).



In the *Password* field, a new password can be set by entering the current one.



The Task List

The task list gives the user access to all the important functions to begin processing:

- ◆ Variations in process
- ◆ New variation

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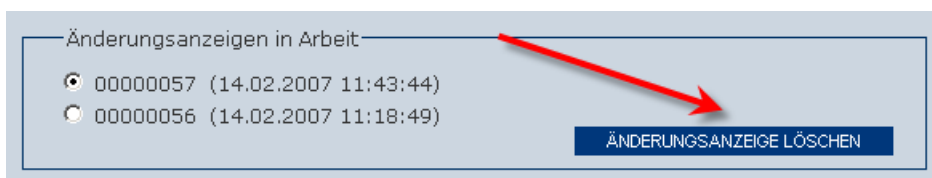
- ◆ Template administration
- ◆ Submitted variations



5.1 Variations in progress

With the *Variations in progress* field, users are given a list of all the variations which have been started but not yet submitted to the CA. Saving of the variations is carried out automatically. Processing can be interrupted at any time. Data loss will not occur. This allows variations to be recommenced at a later time. The task list always displays the last 5 variations. If more than 5 are open, another field is displayed which shows all the variations currently in progress.

In order to continue with the processing of a variation, the required variation is selected followed by a clicking on *Next* located at the bottom of the task list. If a variation already commenced is no longer needed, it can be completely deleted by selecting the *Delete variation* command.



Note:

If several users are working under one ID (one PNR), it is recommended that the variations be labelled with a clear title, e.g. beginning with the initials of the respective user. It may also make sense to incorporate other information into the title because these variations can be used at a later time as master copies for subsequent variations.

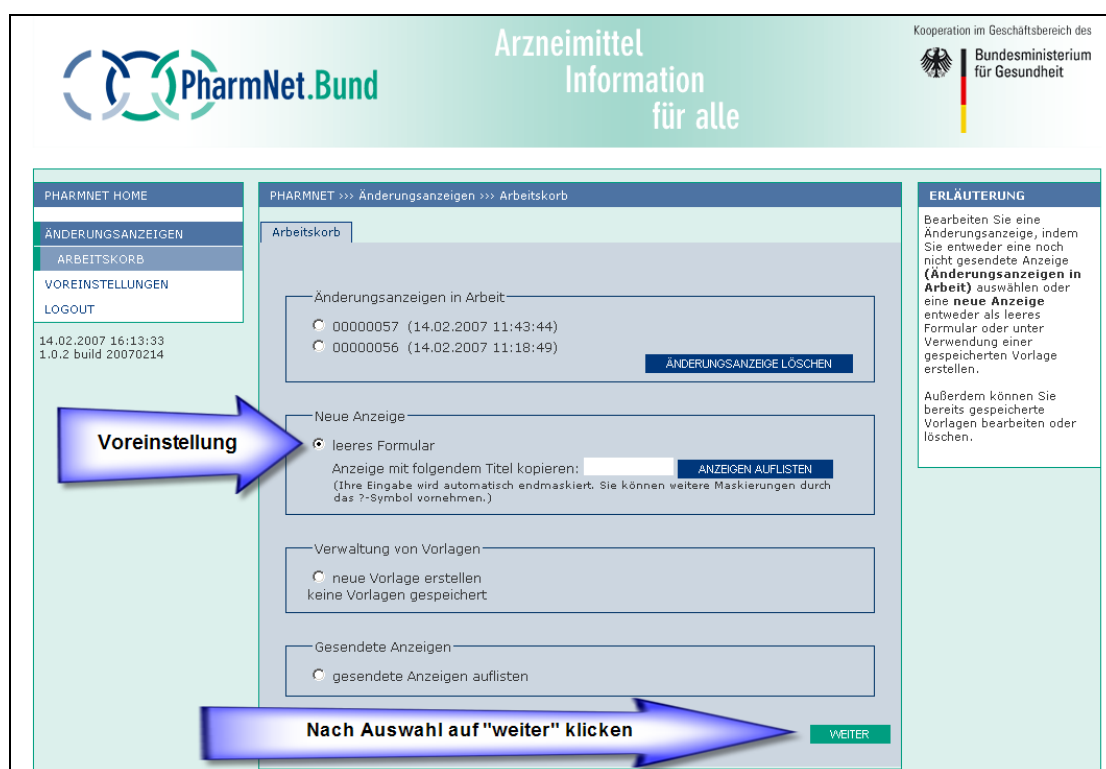
Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

5.2 New variations

When the application is first opened, the user only has the option of selecting an empty form to create a new variation.

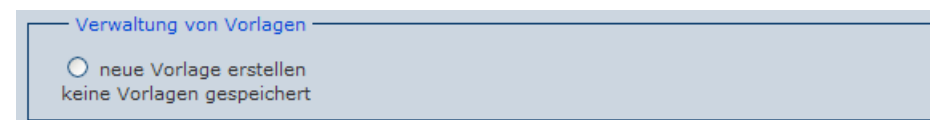


If there are variations in progress or if variations have already been submitted, a new option appears in the *New variations* field, which enables this variation to be used as a master copy. To restrict the selection, the title (if the complete title is known) or a part of the title can be entered. The entry will be automatically end-masked. By using a “?” other maskings can be performed.



5.3 Template administration

Apart from the creation of new variations, the application also offers the option of creating templates.



The creation of templates offers a variety of benefits, e.g.:

- ◆ Where there are several users, each single user can define his or her own standard template with his or her contact data so that every variation form is correctly initialised in advance;

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- ◆ If similar variations are frequently needed, all the relevant elements can be copied into a template and this can be retrieved when required;
- ◆ All master data for variations need only be entered once.

Created templates can also be changed or deleted at any time. Once templates have been created, they can be selected under *New variations* as well.

5.4 Sent variations

By using the *Sent variations* options, all variations sent to the CA will be listed.



6 Generation of Variations

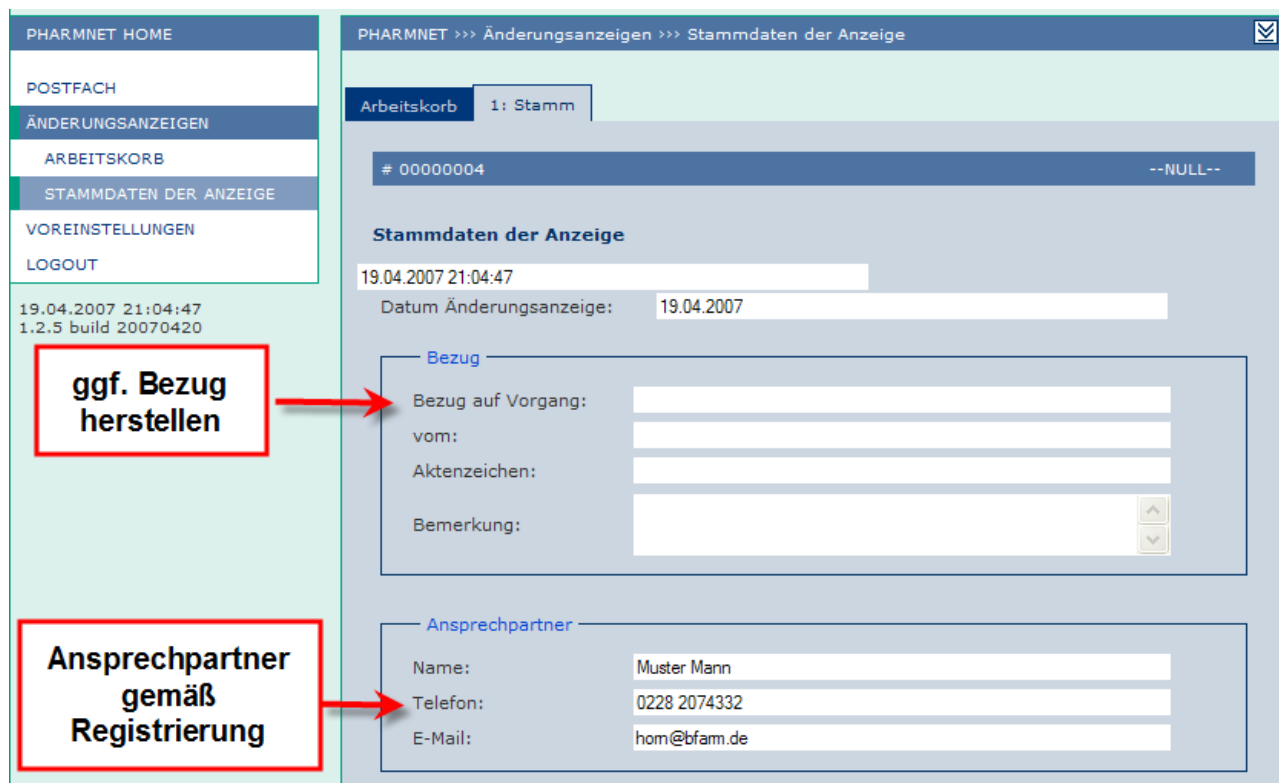
6.1 National variations according to § 29 German Drugs Law

6.1.1 Master data of the variation (1)

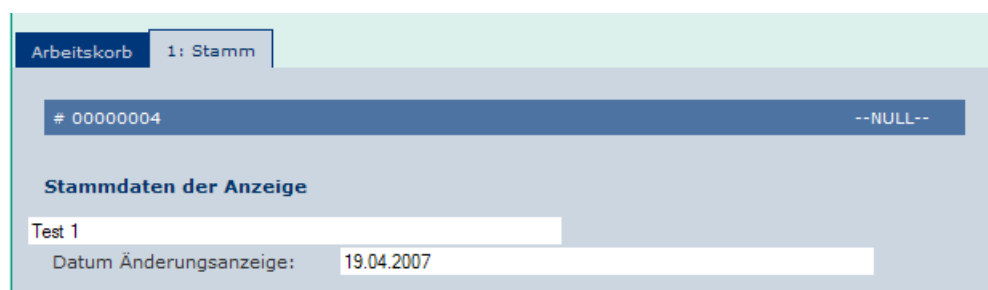
Selecting *New variations* and clicking on *Next* will open the *Master data* window. The line highlighted in colour under the tabs contains the following information:

- ◆ Unique identification number of the variation (in this case: 00000004);
- ◆ Procedure (in this case: --zero--, because this procedure will first be assigned at a later stage).

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Beneath the heading *Master data of the variation* the variation can be assigned to a freely selectable title. Below this, a date of the variation can be freely assigned. However, the date should not be later than the planned submission date.



In this screen a reference can be noted to another concrete procedure. In addition, a contact person must be named for this variation procedure. By default, the fields will be populated with the data stored under the presets, or those from a selected template or master copy.

The name(s), location, and function of the subsequent signatory(ies) are then entered. The entries for the first person are mandatory fields; those for the second person are optional. By selecting the procedure, there is a separation between either a national variation or a variation within MR or DC procedures. The medicinal product is selected for which the variation is to be made. This can be done either by manually entering the ENR or by selecting the correct one from an ENR list (activate the option *ENR Selection*).

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

Unterzeichnung des Anschreibens

1. Unterschrift Name:

1. Unterschrift Ort:

1. Unterschrift Funkt.:

2. Unterschrift Name:

2. Unterschrift Ort:

2. Unterschrift Funkt.:

Daten für Unterschriftenzeile

Bitte bestimmen Sie die Art des Verfahrens und wählen Sie das AM aus, für das Änderungen angezeigt werden sollen.

Auswahl des Verfahrens

Bitte wählen Sie das richtige Verfahren aus:

☐ Anzeige einer Änderung gemäß §29 AMG
 ☐ Anzeige einer Änderung gemäß Variation Regulation

Auswahl des Verfahrens

ENR

Bitte geben Sie die ENR für das Arzneimittel an, für das Änderungen angezeigt werden sollen

ENR:

ENR-AUSWAHL

Eingabe oder Auswahl der ENR

gewählte ENR anzeigen

ZURÜCK

WEITER

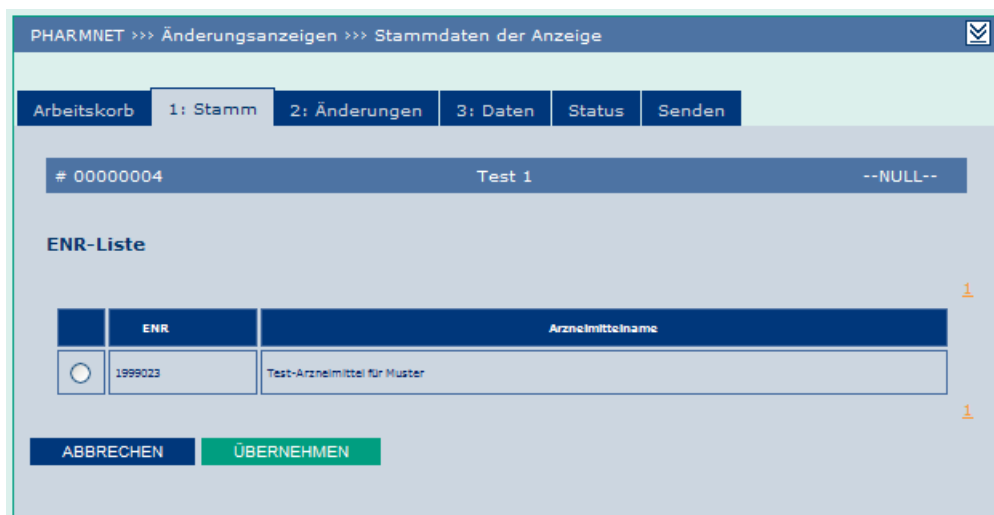
The ENR list shows all medicinal products registered for the pharmaceutical company that is logged on and, which according to the AMIS database, are authorised and/or are marketable. If the user intends to submit a national variation by clicking on *Variation pursuant to § 29 German Drugs Law (AMG)*, the page changes again and the tab structure for national variations will appear after the next page change.

Auswahl des Verfahrens

Bitte wählen Sie das richtige Verfahren aus:

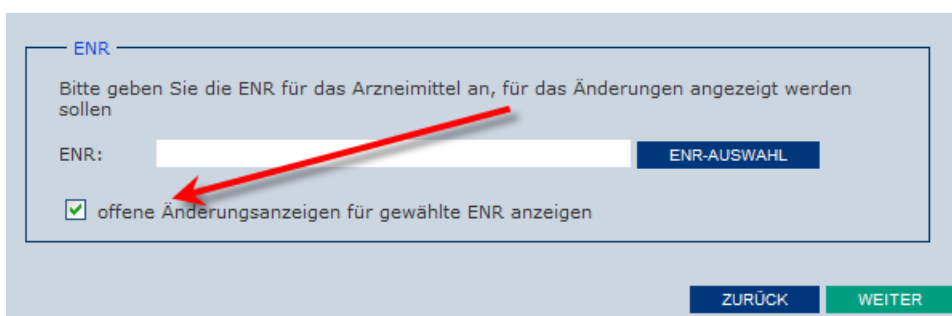
☒ Anzeige einer Änderung gemäß §29 AMG
 ☐ Anzeige einer Änderung gemäß Variation Regulation

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.



The available data of the medicinal product required is transferred to the form by activating the option field and clicking on *Accept*.

For both national variations and variations within MR or DC procedures, there is the option to create a report of the ongoing variations including details of the variation particulars for the ENR in question.



The purpose of the *Variations status* report is primarily to support quality assurance. On the one hand, it is made certain that variations are not submitted repeatedly, on the other hand, a warning is given that due to open variations, the AMIS data does not correspond with the documentation of the MAH. This should be considered prior to correcting the current data (see above).

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

Arbeitskorb
1: Stamm
2: Änderungen
3: Daten
Status
Senden

#00000396
30.04.2007 09:46:54
Anzeige

Sachstand Änderungsanzeigen

Antragsteller

Zulassungsinhaber: Pharmazeutischer Unternehmer Mustermann
Unternehmensnummer: 0000000

Zu der von Ihnen gewählten ENR wurden folgende Änderungsanzeigen gefunden, die bei der Bundesoberbehörde noch nicht abgeschlossen sind:

ENR	Antrags-/Brief-datum	Nr.	SKNR	SKNR Text	Stand
1999023	20070424	01	0299	Vertreiber	gesendet
1999023	20070420	03	2004	Variation Typ IB	gesendet
1999023	20070420	01	0299	Vertreiber	gesendet
1999023	20070419	02	1986	Variation Typ IA	gesendet
1999023	20070419	01	0039	Bezeichnung des Arzneimittels	gesendet
			1002	Angaben der GI gem. § 11 AMG	

ZURÜCK
WEITER

6.1.2 Selecting variation particulars (2)

Following the switch from the master data to the variation particulars, the user assigned title and variation type is shown in the line highlighted in colour.

Arbeitskorb
1: Stamm
2: Änderungen
3: Daten
Status
Senden

00000005
Test 1
Anzeige

Auswahl des Änderungstatbestandes

Direkte Auswahl des Änderungstatbestandes

SKNR*:

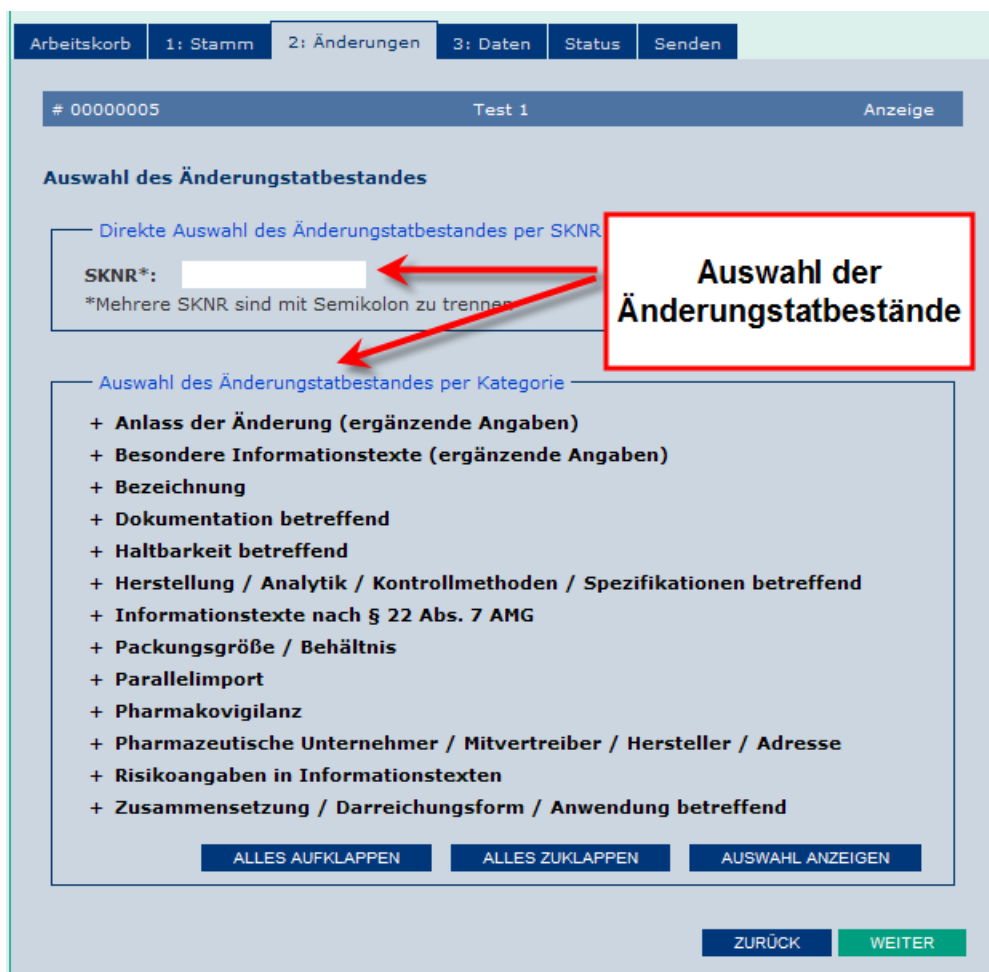
*Mehrere SKNR sind mit Semikolon zu

Angaben der Stamm-
Informationen wurden
übernommen

The variation particulars can be selected in two ways:

1. Manual entry of the structure number (SKNR). The currently [valid SKNR lists](#) are published on the BfArM homepage;
2. Selection of variation particulars according to category.

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.



Arbeitskorb | 1: Stamm | 2: Änderungen | 3: Daten | Status | Senden

00000005 | Test 1 | Anzeige

Auswahl des Änderungstatbestandes

Direkte Auswahl des Änderungstatbestandes per SKNR

SKNR*:

*Mehrere SKNR sind mit Semikolon zu trennen

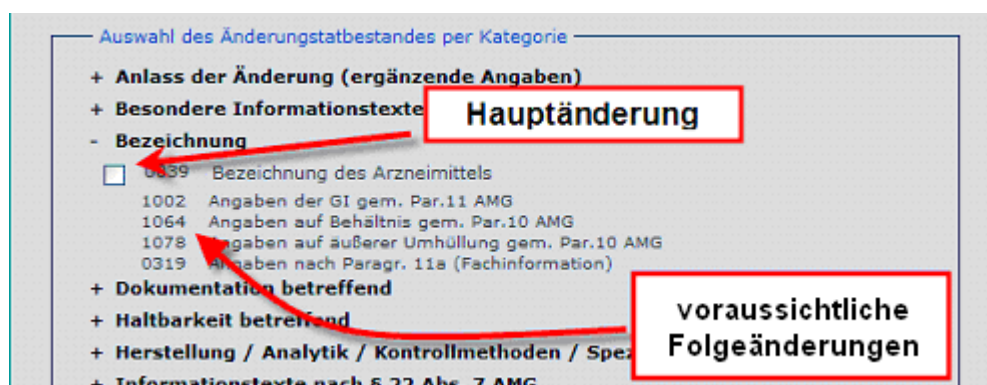
Auswahl des Änderungstatbestandes per Kategorie

- + Anlass der Änderung (ergänzende Angaben)
- + Besondere Informationstexte (ergänzende Angaben)
- + Bezeichnung
- + Dokumentation betreffend
- + Haltbarkeit betreffend
- + Herstellung / Analytik / Kontrollmethoden / Spezifikationen betreffend
- + Informationstexte nach § 22 Abs. 7 AMG
- + Packungsgröße / Behältnis
- + Parallelimport
- + Pharmakovigilanz
- + Pharmazeutische Unternehmer / Mitvertreiber / Hersteller / Adresse
- + Risikoangaben in Informationstexten
- + Zusammensetzung / Darreichungsform / Anwendung betreffend

ALLES AUFKLAPPEN | ALLES ZUKLAPPEN | AUSWAHL ANZEIGEN

ZURÜCK | WEITER

Regardless of whether the variation particulars selected, manually or according to category depending on the main variation, consequential changes will be displayed. These proposed consequential changes will primarily ensure that the variation is complete. This pre-selection of the variation particulars does not relieve the MAH of the responsibility of stating a full description of the planned changes with documentation. The proposed consequential changes are for support purposes only.



Auswahl des Änderungstatbestandes per Kategorie

- + Anlass der Änderung (ergänzende Angaben)
- + Besondere Informationstexte
- Bezeichnung
 - ☐ 1039 Bezeichnung des Arzneimittels
 - 1002 Angaben der GI gem. Par.11 AMG
 - 1064 Angaben auf Behältnis gem. Par.10 AMG
 - 1078 Angaben auf äußerer Umhüllung gem. Par.10 AMG
 - 0319 Angaben nach Paragr. 11a (Fachinformation)
- + Dokumentation betreffend
- + Haltbarkeit betreffend
- + Herstellung / Analytik / Kontrollmethoden / Spezifikationen betreffend
- + Informationstexte nach § 22 Abs. 7 AMG

Hauptänderung

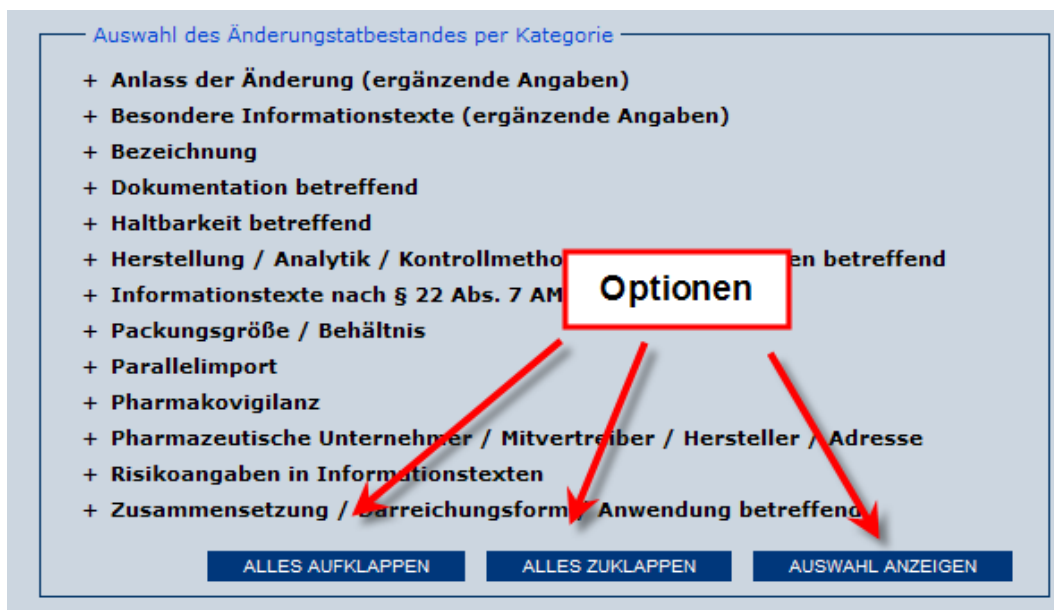
voraussichtliche Folgeänderungen

To improve the overview, the selection of variation particulars on the basis of categories offers three options:

1. Expand everything: All variation particulars are offered.
2. Close completely: No variation particulars are offered.

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

3. Display selection: Those categories remain open in which at least one SKNR was selected.



Following the selection of the required variation particulars, the user moves to the next step – input of the actual variation content – by clicking on *Next*.

6.1.3 Deleting variation particulars

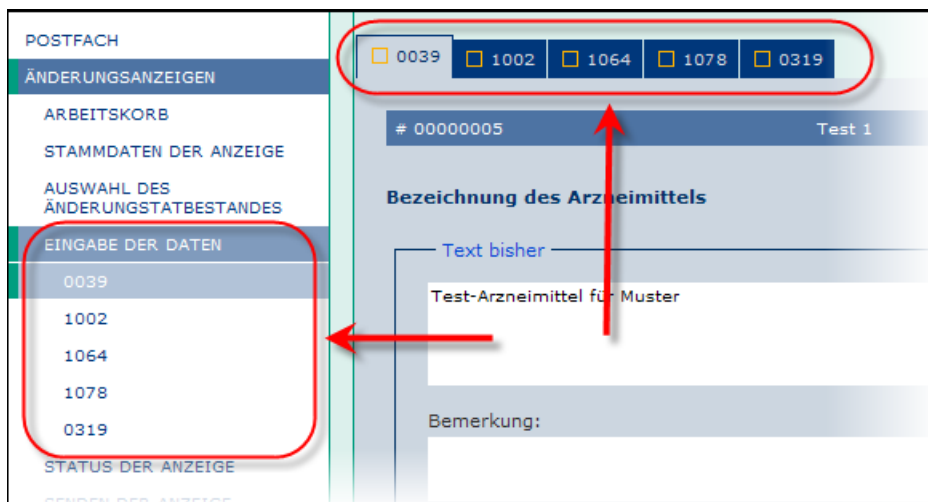
Variation particulars can be deselected in a similar manner as they were selected. Clicking the previously selected check box in the *Variations particulars* tab again will deselect this variation particular. This change of the variation particulars is then accepted by clicking on *Next*. Individual variation particulars may be deleted at any time of the user's choice prior to submission, i.e. the user always has the option of returning to the *Variations particulars* tab.

Structure numbers of consequential changes cannot be deleted as long as the main variation particular remains selected. If the user considers these structure numbers not to be relevant for his or her specific variation, the option exists to notify the CA by marking *SKNR not relevant for the current variation*.

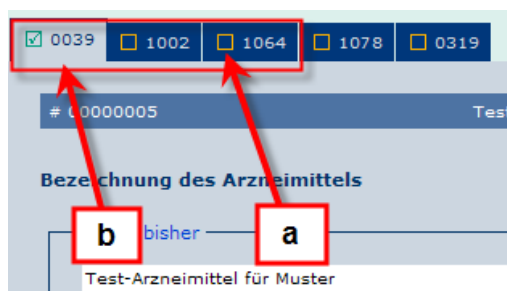
6.1.4 Data input (3)

To enter the contents of the variation the left hand navigation bar is expanded to include the selected structure numbers and placed in tab form in the task area frame.

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.



Variation particulars that have not yet been processed are identified by an empty box (a), variation particulars that have been processed are marked with a green tick in a green box (b). The change is carried out in the usual way by clicking on *Next*, *Accept*, *Submit data* etc buttons at the bottom of the page.



6.1.5 Partial forms

In the *Online Variation Submission* application all the variation particulars are assigned to defined partial forms which are equipped with various functions.


Available partial forms:

1. Free text form
2. Upload form
3. Forms with catalogue support
4. Package size form
5. Shelf-life form

6.1.5.1 Free text form

Unstructured data may be entered in the free text fields. Provided that data are available in AMIS for the selected variation particular (e.g. for the name of the medicinal product), the data will be automatically entered into the forms in the *Current text* and *Text changed to* fields. If no corresponding data are stored in the AMIS database in relation to the variation particular, the form remains empty.

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.



The screenshot shows the 'Bezeichnung des Arzneimittels' section. It has two sub-sections: 'Text bisher' and 'Text geändert in'. Each sub-section has a text input field and a 'Bemerkung:' field below it. Red arrows point to the text input fields with labels: 'aktueller Text' for the 'Text bisher' field and 'künftiger Text' for the 'Text geändert in' field. Another red arrow points to the 'Bemerkung:' field under 'Text bisher' with a label: 'Bemerkungsfeld bei Änderung des bisherigen Textes (z.B. vgl. Änderungsanzeige vom xx.yy.zzzz)'. A third red arrow points to the 'Bemerkung:' field under 'Text geändert in' with a label: 'Bemerkungsfeld für zusätzlich Angaben, z.B. "vgl. identische Änderung für ENR 1234567 vom xx.yy.zzzz". At the bottom are buttons 'ZURÜCKSETZEN' and 'ÜBERNEHMEN'.

In many free text forms the *Text changed to* field includes a document upload function. This can be used two ways:

1. Attaching additional supporting documentation;
2. For empty forms – uploading the contents of the change, e.g. in the format of a tabulated comparison or in case of large amounts of text, such as variations of the side effects.



This screenshot shows a close-up of the 'Text geändert in' section. It features a large text input field. Below it is a checkbox labeled 'Datei(en) hochladen'. A red arrow points to this checkbox. Below the checkbox is a 'Bemerkung:' field. At the bottom are buttons 'ZURÜCKSETZEN' and 'ÜBERNEHMEN'.

6.1.5.2 Upload form

Note:

The obligations of the AMG eSubmission Ordinance are fulfilled for variations submitted via this online procedure by uploading the required documents concomitantly, i.e. an additional submission via the email procedure is not required. The published conditions regarding the document type and format to be submitted (.rtf/pdf), as well as naming convention, apply irrespective of the method of submission (for exceptions in regard to product information, see below).

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

Angaben der GI gem. Par.11 AMG

Datei Upload

Wählen Sie den Dokumenttyp der hochzuladenden Datei aus:

☒ Clean Version
☐ Highlighted Version
☐ Änderungsindex
☐ Bilddatei
☐ 1. weiterer Upload Titel:
☐ 2. weiterer Upload Titel:
☐ 3. weiterer Upload Titel:
☐ 4. weiterer Upload Titel:
☐ 5. weiterer Upload Titel:

Wählen Sie die hochzuladende Datei von Ihrem Rechner aus (*.rtf/*.pdf):

☐ SKNR für die vorliegende Anzeige nicht relevant

Bemerkung:

The upload form is provided for all structure numbers which require a document upload. Several options are displayed:

1. Upload of predefined document types;
2. Upload of documents with user-specified allocation of title;
3. Option to mark *SKNR not relevant for the current variation*;
4. Entering remarks.

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

Angaben der GI gem. Par.11 AMG

Datei Upload

Wählen Sie den Dokumenttyp der hochzuladenden Datei aus:

- ☒ Clean Version
- ☐ Highlighted Version
- ☐ Änderungsindex
- ☐ Bilddatei

1. weiterer Upload
2. weiterer Upload
3. weiterer Upload
4. weiterer Upload
5. weiterer Upload

Titel: _____
Titel: _____
Titel: _____
Titel: _____
Titel: _____

Wählen Sie die hochzuladende Datei von Ihrem Rechner aus:

☐ SKNR für die vorliegende

Bemerkung: _____

1. Basistypen für bekanntes Uploadobjekt

2. "freier" Upload

Titel sofern vorhanden mit AMG-EV kürzel beginnen

3. Abwahl einer SKNR, sofern für die Anzeige nicht erforderlich

In contrast to the previous email procedure, here the option of uploading several documents for one structure number exists (e.g. SKNR 0039 change of the invented name – consequential change SKNR 1002 change of the package leaflet). It is, therefore, highly recommended to upload a clean version (for the later release to the public) and a highlighted version (for the evaluation) of the Package Leaflet, the Summary of Product Characteristics (Fachinformation), and the Labelling.

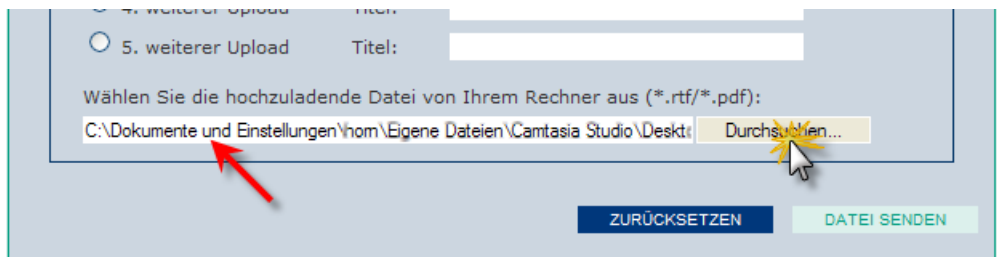
Provided that the document type relating to the selected structure number is defined by default (particularly the Package Leaflet, the Summary of Product Characteristics (Fachinformation), and the Labelling), document file names will be created by the system according the AMG eSubmission Ordinance during the *Submit* procedure. If the document type is not pre-defined (e.g. expert reports), the area *Further upload* is to be used and – where available – the document naming convention from the explanatory notes on the AMG eSubmission Ordinance or from *Table of the element of files names* (see implementation of the AMG eSubmission Ordinance at www.bfarm.de) is to be used at the beginning of the file name.

e.g.: qos-001-[Free text]
qts-[Free text]
qws-[Free text]

In case of Package Leaflet, Summary of Product Characteristics (Fachinformation), and Labelling, the original and the newly created file names will be stated in the form. As described in the *Presettings* section, the sender has the option to include into or omit the original file path from the file name.

Attachment of files is carried out by clicking on the *Browse* button, selecting the respective file from the user's own local file system.

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

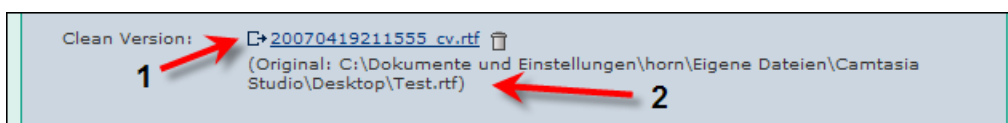


5. weiterer Upload Titel:

Wählen Sie die hochzuladende Datei von Ihrem Rechner aus (*.rtf/*.pdf):

Once a file is selected, in order to allow verification it will be displayed together with the file path. If the correct file has been selected, it will be attached to the variation on the PharmNet.Bund server by choosing *Submit file*. If a file has been chosen by mistake, the selection can be *Cancelled*.

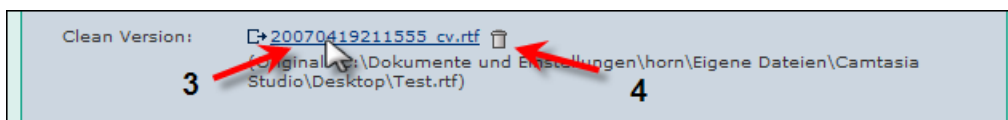
Following completion of the upload, the file will be displayed with the new (system allocated) name (1) and the original name (2), with or without the file path, depending on the presets chosen.



Clean Version: [20070419211555 cv.rtf](#)

(Original: C:\Dokumente und Einstellungen\horn\Eigene Dateien\Camtasia Studio\Desktop\Test.rtf)

By clicking on the hyperlink (3), the file can be opened on the PharmNet.Bund server; by selecting the bin (4), the file can be deleted again from the server.



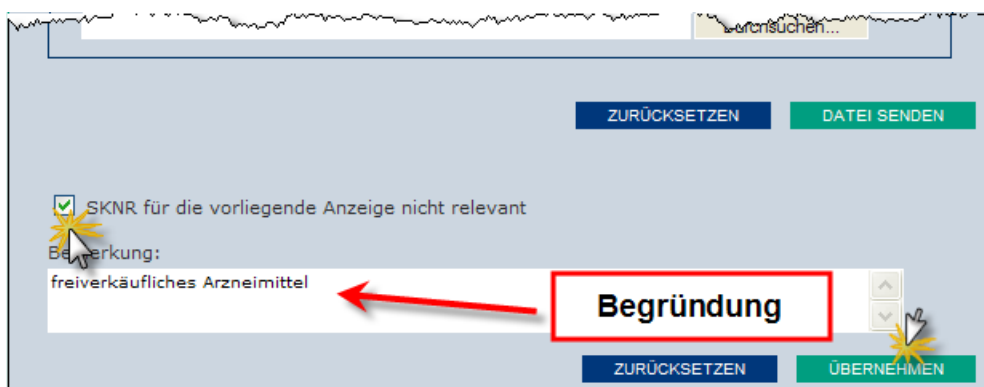
Clean Version: [20070419211555 cv.rtf](#)

(Original: C:\Dokumente und Einstellungen\horn\Eigene Dateien\Camtasia Studio\Desktop\Test.rtf)

Note:

If a structure number is deselected during the generation of a variation where an upload has already been processed, the file will then be deleted automatically from the PharmNet.Bund server.

Upload structure numbers are often consequential changes. There is an option to mark *SKNR not relevant for the current variation* here as well. In the *Remarks* field a plausible reasoning should be inserted. This information will be appended to the variation by clicking on *Accept*.



☒ SKNR für die vorliegende Anzeige nicht relevant

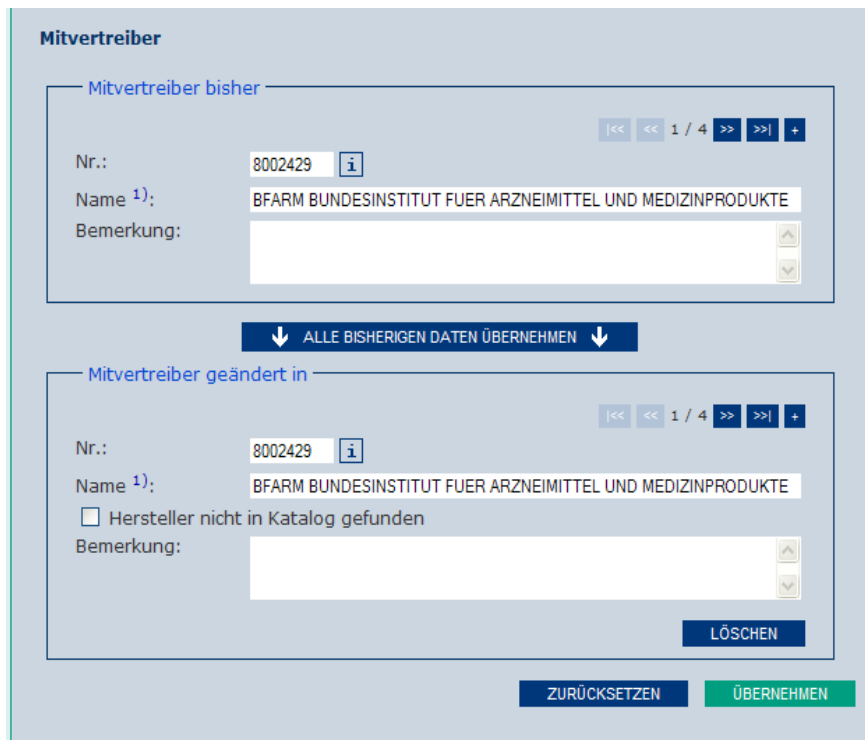
Bemerkung: freiverkäufliches Arzneimittel

Begründung

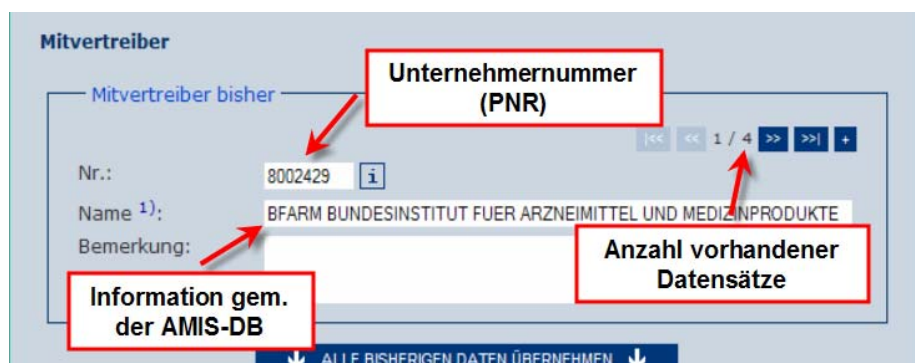
Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

6.1.5.3 Forms with catalogue support: Pharmaceutical companies

This form type is assigned to all structure numbers for which information is stored in catalogues made available by the CAs. For example, this may be information about pharmaceutical companies, pharmaceutical forms and the type of application.

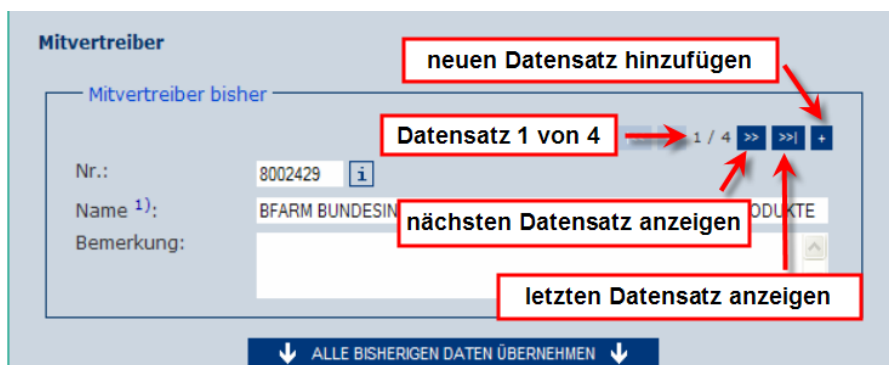


When selecting variation particulars supported by catalogue data, the available data from AMIS database will be inserted into the form. For pharmaceutical companies their assigned number (PNR) will be displayed alongside. Where there are multiple fields, i.e. more than one dataset is available for the selected structure number, the respective datasets will be displayed additionally as exemplified by the co-distributor.



The next dataset is accessed by clicking on the double arrow beside the number of datasets. The last dataset is accessed by clicking on the button next to that (double arrow with vertical line). By clicking the “+” button an empty field is generated in which a new dataset can be entered.

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.



TIP:

Where there are numerous datasets, users are recommended to call up the structure number in the *Entering Data* step and then to generate a status report. Consideration should be taken of the fact that the data for the individual structure numbers will only be inserted following the initial call of the corresponding tab in the status report. In the status report all datasets are displayed together enabling a swift and easy determination to be made as to whether the *Current data* corresponds with the user's own records. Following the check, the user can return to the structure number in order to proceed with processing.

If the *Current data* are correct, the required change can be carried out in the lower part of the form, depending on the individual case either by:

- ◆ Overwriting the dataset with a new one (in the example a co-distributor is cancelled and a new one takes its place);
- ◆ Inserting a new dataset (in the example an additional co-distributor is added);
- ◆ Deleting an existing dataset (in the example a co-distributor is cancelled).

In principle, the respective pharmaceutical company can be selected in two ways:

1. If known, the PNR can be entered directly;
2. Alternatively under *Name*, the first letters (in this case) of the pharmaceutical company can be entered. The catalogue displays all entries with this combination of letters. The required company can be selected by mouse click.

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

↓ ALLE BISHERIGEN DATEN ÜBERNEHMEN ↓

ert in

Eingabe der bekannten PNR

Nr.: 8002429 **Eingabe der ersten Buchstaben des pU**

Name ¹⁾: BFARM BUNDESINSTITUT FUER ARZNEIMITTEL UND MEDIZINPRODUKTE

☐ Hersteller nicht in Katalog gefunden

Bemerkung:

Löschen eines Datensatzes → LÖSCHEN

ZURÜCKSETZEN ÜBERNEHMEN

If entries in the catalogue are very similar, following selection, the mouse can be hovered over the **i**-field to display the complete address in a pop-up.

Deletion of a dataset is carried out by selecting the required dataset and clicking the *Delete* button.

Clicking on *Accept* will add the data to the variation.

If corrections need to be made to the *Current data*, this is carried out in a similar way as above, except current data cannot be deleted directly by using a button. If one or more too many datasets are displayed in *Current data*, the entry must be removed (e.g. with select and cut), transferred to the remarks field, and a brief reasoning must be entered, as per usual.

Note: Where current data are changed, before entering the actual change, the current data must be transferred to the lower part of the form, i.e. the data must be synchronised in advance. This is done by activating the *Transfer all current data* button.

↓ ALLE BISHERIGEN DATEN ÜBERNEHMEN ↓

If the required entry is not available in the catalogue, the user has the option of selecting the *Entry (manufacturer in this case) not found in catalogue* check box and adding a free text entry. Depending on the structure number selected, further documentation may be required (e.g. Certificate of Registration, Certificate of Suitability, etc.).

☐ Hersteller nicht in Katalog gefunden

Bemerkung:

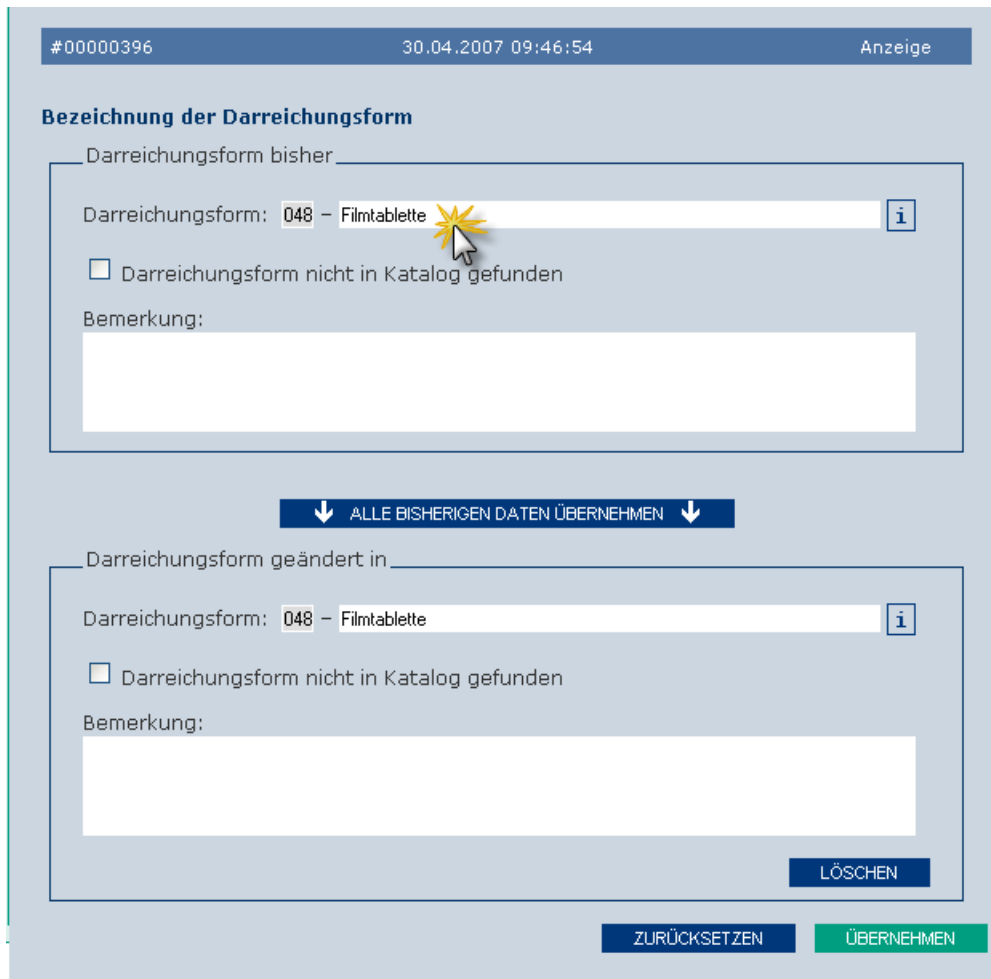
LÖSCHEN

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

Entries made in this way are not automatically added to the respective catalogue, during the processing these will be assessed by the CAs and added to the catalogue as appropriate.

6.1.5.4 Form with catalogue support: Pharmaceutical form

The pharmaceutical form has similar functionalities as that for pharmaceutical companies. As only one pharmaceutical form is permissible in each case, there are no functions for adding further datasets, or for switching between several datasets.



By using the mouse to click on the *pharmaceutical form* field, the catalogue is opened. This displays all entries that contain the term entered as a word. By clicking on one of the terms displayed, a new pharmaceutical form can be selected.

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

Bezeichnung der Darreichungsform

Darreichungsform bisher _____

Darreichungsform: 048 – Filmtablette 


- 048 ... FILMTABLETTE
- 366 ... FILMTABLETTEN UND CREME
- 351 ... FILMTABLETTEN UND INFUSIONSLOESUNG
- 351 ... FILMTABLETTEN UND INFUSIONSLOESUNG
- 370 ... FILMTABLETTEN UND MAGENSAFTRESISTEN ... TABLETTEN
- 335 ... FILMTABLETTEN UND PULVER
- 336 ... FILMTABLETTEN UND VAGINAL-OVULA

☐ Darreichungsform nicht in Katalog gefunden

Bemerkung:

This will be transferred into the upper line.

Darreichungsform bisher _____

Darreichungsform: 351 – FILMTABLETTEN UND INFUSIONSLOESUNG 

If the user wants to enter his or her own term, this is made possible by clicking on the *pharmaceutical form not found in catalogue* field.

#00000396 30.04.2007 09:46:54 Anzeige

Bezeichnung der Darreichungsform

Darreichungsform bisher _____

Darreichungsform: 351 – FILMTABLETTEN UND INFUSIONSLOESUNG 

 Darreichungsform nicht in Katalog gefunden

Katalogtext: _____

Bemerkung:

↓ ALLE BISHERIGEN DATEN ÜBERNEHMEN ↓

6.1.5.5 Form with catalogue support: Parallel import countries

The form for displaying parallel import countries (applies only to parallel imports) has similar functionalities as the type *Form with catalogue support for pharmaceutical companies*, but is adapted to meet the requirements for displaying parallel import countries.

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

#00000395
30.04.2007 09:27:24
Anzeige

Parallelimportländer (zusätzlich)

Parallelimporte bisher

[<<] [<] 1 / 1 [>] [>>] [+]

Staat: - i

Packungsgröße:

Zul.-Datum:

ZNR:

AM-Bezeichnung im Ausland:

☐ Staat nicht in Katalog gefunden

Bemerkung:

↓ ALLE BISHERIGEN DATEN ÜBERNEHMEN ↓

By entering a letter in the *Country* line, the country catalogue is opened from where the user can select the required country.

↓ ALLE BISHERIGEN DATEN ÜBERNEHMEN ↓

Parallelimporte geändert in

[<<] [<] 1 / 1 [>] [>>] [+]

Staat: - d i

GA ... GABUN

GM ... GAMBIA

GE ... GEORGIEN

GH ... GHANA

GI ... GIBRALTAR

GD ... GRENADA

GR ... GRIECHENLAND

GL ... GRÖNLAND

GP ... GUADELOUPE

Packungsgröße:

Zul.-Datum:

ZNR:

AM-Bezeichnung im Ausland:

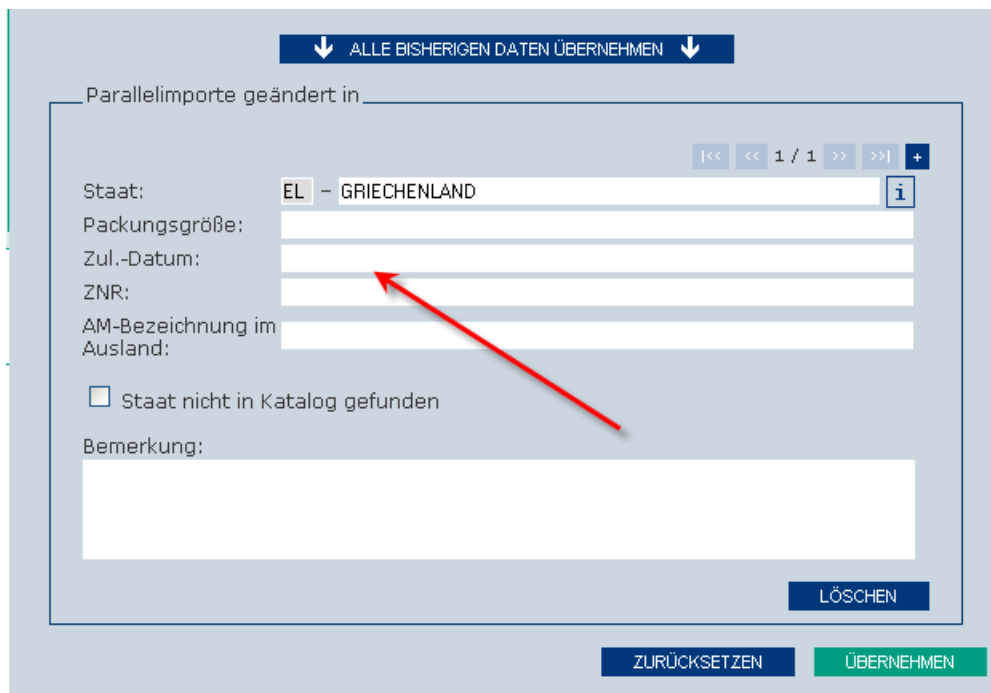
☐ Staat nicht in Katalog gefunden

Bemerkung:

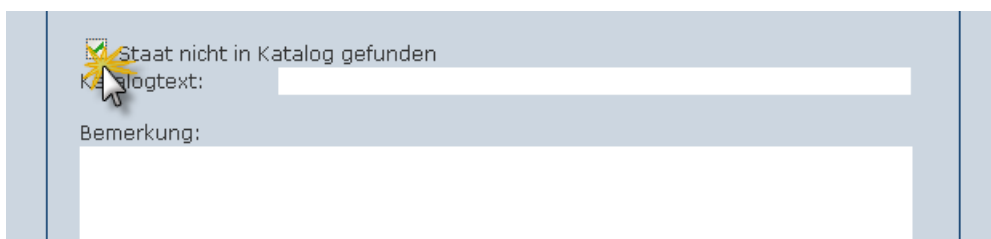
Note:

Even though the catalogue provides a large number of countries, the general rules as to which countries are authorised for parallel imports also apply to Online Variation Submission as well.

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.



This form type also allows a free text entry where the required State is not stored in the catalogue.



6.1.5.6 Package size form

The package size form largely corresponds with the functionalities of the *Form with catalogue support* type. Package sizes do not comprise a catalogue so that entries are performed using free text. In addition, a grading of N1 to N3 can be entered using the appropriate radio button. This entry will not be assessed within the terms of the variation and is added only as additional information.

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

#00000395
30.04.2007 09:27:24
Anzeige

Packungsgröße (Zustimmungspflichtig)

Packungsgröße bisher _____

|<<
<<
1 / 1
>>
|>>
+

Packungsgröße:

Einstufung: ☐ N1 ☐ N2 ☐ N3 ☒ nichts zutreffend

Besonderheiten:

Bemerkung:

↓ ALLE BISHERIGEN DATEN ÜBERNEHMEN ↓

Packungsgröße geändert in _____

|<<
<<
2 / 2
>>
|>>
+

Packungsgröße:

Einstufung: ☐ N1 ☐ N2 ☐ N3 ☒ nichts zutreffend

Besonderheiten:

Bemerkung:

LÖSCHEN

ZURÜCKSETZEN
ÜBERNEHMEN

Clicking on the “+” button allows other package sizes to be displayed.

↓ ALLE BISHERIGEN DATEN ÜBERNEHMEN ↓

Packungsgröße geändert in _____

|<<
<<
2 / 2
>>
|>>
+

Packungsgröße:

Einstufung: ☐ N1 ☒ N2 ☐ N3 ☒ nichts zutreffend

Besonderheiten:

Bemerkung:

LÖSCHEN

ZURÜCKSETZEN
ÜBERNEHMEN

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

The package sizes can be entered as free text and a grading from N1 - N3 can be added. Further information can be added to the *Peculiarities* line and the *Remarks* field. The *Remarks* field is particularly to be used for information on the primary packaging if the medicinal product is authorised with different types of primary packaging (e.g. blister packs and glass bottles).

6.1.5.7 Shelf-life form

In the *shelf-life* form the entry stored in AMIS is represented by means of a logical structure. The value of the shelf life is specified as a 3-digit number and then connected to a unit by means of the appropriate button.

Änderung der Dauer der Haltbarkeit des Arzneimittels (und Ergebnisse von Haltbarkeitsversuchen) [Par.22(1)14]

Dauer der Haltbarkeit bisher _____

Wert der Dauer:

Einheit der Dauer:

- ☐ Tag(e)
- ☐ Woche(n)
- ☐ Monat(e)
- ☒ Jahr(e)
- ☐ Stunde(n)
- ☐ Minute(n)
- ☐ nichts zutreffend

☐ Neue Einheit

Bemerkung:

↓ ALLE BISHERIGEN DATEN ÜBERNEHMEN ↓

Dauer der Haltbarkeit geändert in _____

Wert der Dauer:

Einheit der Dauer:

If the shelf life cannot be represented using the units on offer, this form type enables other units to be entered.

☐ Minute(n)

☐ nichts zutreffend

☒ Neue Einheit

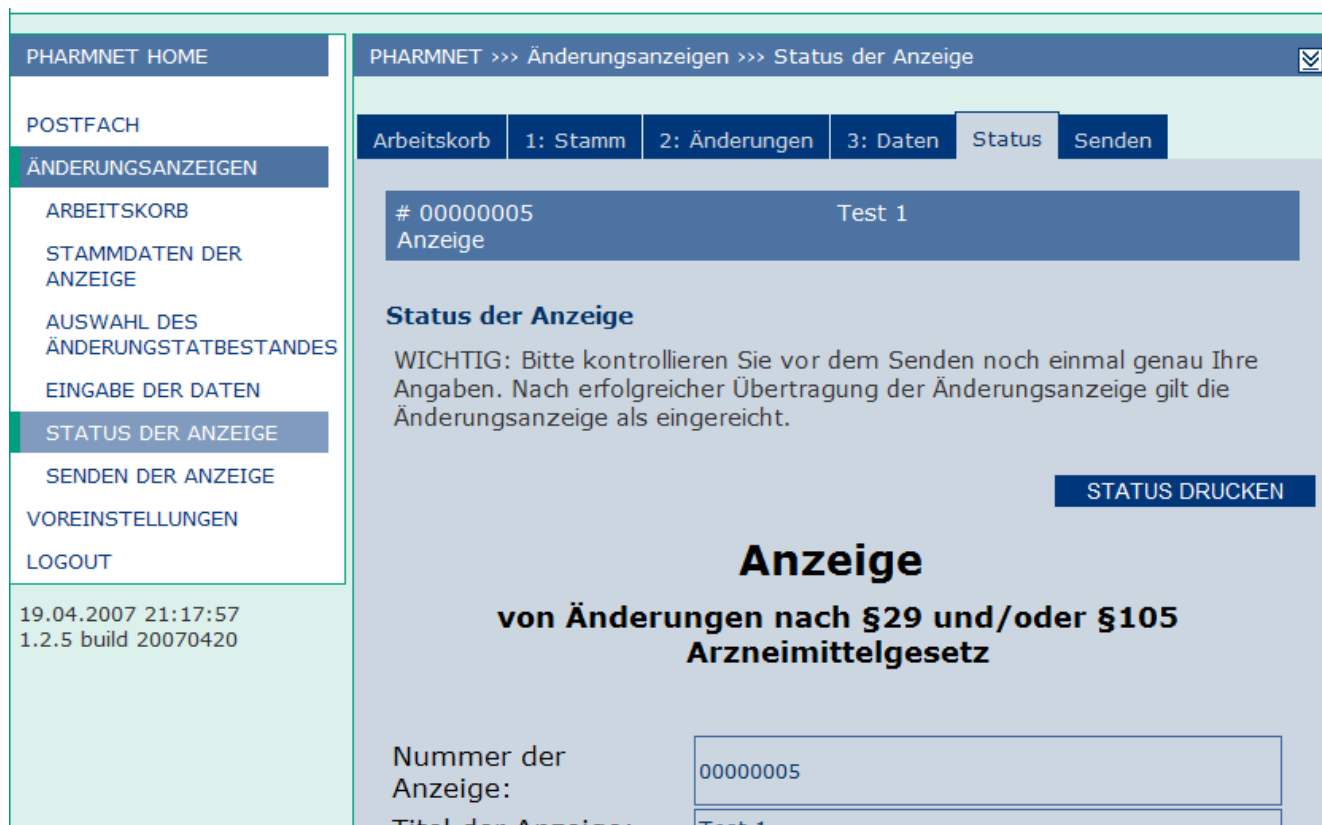
Kein Logtext:

Bemerkung:

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

6.1.6 Status of the variation

Preparing a national variation or a European variation, the user can at any time display a status report. This is generated in real time online in each case and will contain the entries made up until the particular point in time. Variation particulars will be included in the report following the initial click in the *Entering data* step. For national variations the report corresponds to the later form and offers a good overview of the current status.



The screenshot shows the PHARMNET interface for viewing the status of a variation. The left sidebar contains navigation links: PHARMNET HOME, POSTFACH, ÄNDERUNGSANZEIGEN (highlighted), ARBEITSKORB, STAMMDATEN DER ANZEIGE, AUSWAHL DES ÄNDERUNGSTATBESTANDES, EINGABE DER DATEN, STATUS DER ANZEIGE (highlighted), SENDEN DER ANZEIGE, VOREINSTELLUNGEN, and LOGOUT. Below these links is a timestamp: 19.04.2007 21:17:57, 1.2.5 build 20070420.

The main content area has a breadcrumb trail: PHARMNET >>> Änderungsanzeigen >>> Status der Anzeige. Below this is a tabbed interface with tabs: Arbeitskorb, 1: Stamm, 2: Änderungen, 3: Daten, Status (selected), and Senden. A button 'STATUS DRUCKEN' is located to the right of the 'Status' tab.

The 'Status' tab displays the following information:

- Header: # 00000005, Test 1, Anzeige
- Section: **Status der Anzeige**
- Text: WICHTIG: Bitte kontrollieren Sie vor dem Senden noch einmal genau Ihre Angaben. Nach erfolgreicher Übertragung der Änderungsanzeige gilt die Änderungsanzeige als eingereicht.
- Section: **Anzeige**
- Text: **von Änderungen nach §29 und/oder §105 Arzneimittelgesetz**
- Form fields:
 - Nummer der Anzeige: 00000005
 - Titel der Anzeige: Test 1

The user can print out the form at any time in order, for example, to conduct internal company discussions or obtain other contributions, etc. If the status report is generated before submission, some details will be missing which are contained in the clean copy following submission. This is intended to prevent the mistaken submission of drafts as originals.

Drafts do not have

- ◆ a sent date,
- ◆ a signature line,
- ◆ a barcode,
- ◆ the info box, whether other documentation has been submitted with the paper version,
- ◆ or the organisational unit in the address of the CA.

Drafts, moreover, have the watermark "DRAFT".

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

00000396
30.04.2007 09:46:54

Platz für BfArM-Eingangsstempel

An das

Bundesinstitut für
Arzneimittel und Medizinprodukte
Kurt-Georg-Kiesinger-Allee 3
D-53175 Bonn

Anzeige
von Änderungen nach §29 und/oder §105 Arzneimittelgesetz

Nummer der Anzeige:	00000396
Titel der Anzeige:	30.04.2007 09:46:54
Datum Änderungsanzeige:	30.04.2007
Sendedatum der Anzeige:	
Zulassungsinhaber:	Pharmazeutischer Unternehmer Mustermann
Unternehmensnummer:	0000000
Online Usernummer:	PEA00023
Online Username:	Muster Mann

Bezug

Bezug auf Vorgang:

vom:

Aktenzeichen:

Bemerkung:

Ansprechpartner

Name: Muster Mann

Telefon: 0228 2074332

E-Mail: horn@bfarm.de

Angaben zum Arzneimittel

Arzneimittelbezeichnung: Test-Arzneimittel für Muster

Darreichungsform: Filmtablette

6.1.7 Submitting the variation

If all the required changes have been made, the variation can be sent. Activating the last tab *Submit* or *Submit the variation* requires following actions: Prior to submission, the user must specify if documentation other than that submitted electronically will be sent with the paper version.

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

PHARMNET HOME

POSTFACH

ÄNDERUNGSANZEIGEN

ARBEITSKORB

STAMMDATEN DER ANZEIGE

AUSWAHL DES ÄNDERUNGSTATBESTANDES

EINGABE DER DATEN

STATUS DER ANZEIGE

SENDEN DER ANZEIGE

VOREINSTELLUNGEN

LOGOUT

19.04.2007 21:19:42
1.2.5 build 20070420

PHARMNET >>> Änderungsanzeigen >>> Senden der Anzeige

Arbeitskorb 1: Stamm 2: Änderungen 3: Daten Status **Senden**

00000005 Test 1
Anzeige

Senden der Anzeige

Dokumentation

Mit der Papierversion werden weitere Dokumentationen eingereicht:

☐ ja
 ☐ nein

Allgemeine Nutzungsbedingungen

☒ Die [allgemeinen Nutzungsbedingungen](#) des BfArM zum elektronischen Anzeigeverfahren für Anzeigen nach §29 AMG sowie Variations gemäß Commission Regulation (EC) 1084/2003 werden akzeptiert.

Bemerkung

ÜBERNEHMEN

SENDEN

The user must also indicate acceptance of the *General Terms and Conditions of Use*. By clicking on the link, the user can read the current Conditions of Use and print these out, if required. Only once these have been accepted, the *Submit* button is activated and the variation can then be sent.

Allgemeine Nutzungsbedingungen

☒ Die [allgemeinen Nutzungsbedingungen](#) des BfArM zum elektronischen Anzeigeverfahren für Anzeigen nach §29 AMG sowie Variations gemäß Commission Regulation (EC) 1084/2003 werden akzeptiert.

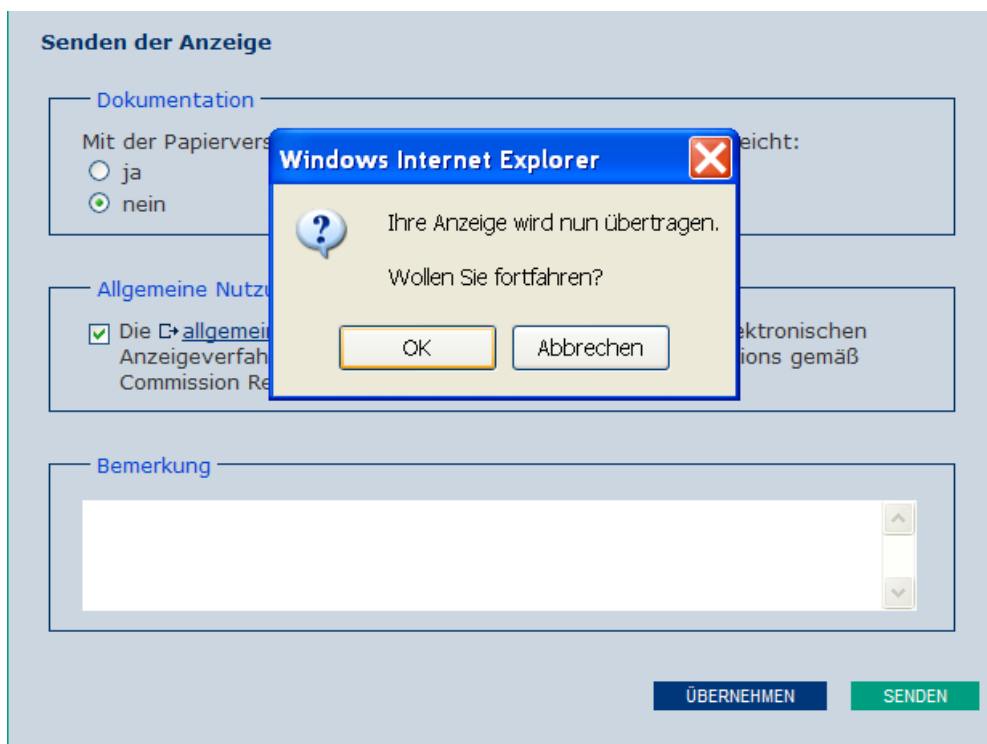
Bemerkung

ÜBERNEHMEN

SENDEN

After clicking on *Submit*, a confirmation dialogue is displayed asking if the user does indeed intend to submit the variation. If this is confirmed, the data are sent definitely.

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.



Senden der Anzeige

Dokumentation

Mit der Papierversion:

☐ ja

☒ nein

Allgemeine Nutzung

☒ Die C-**allgemein**

Anzeigeverfahren

Commission Re

Bemerkung

ÜBERNEHMEN SENDEN

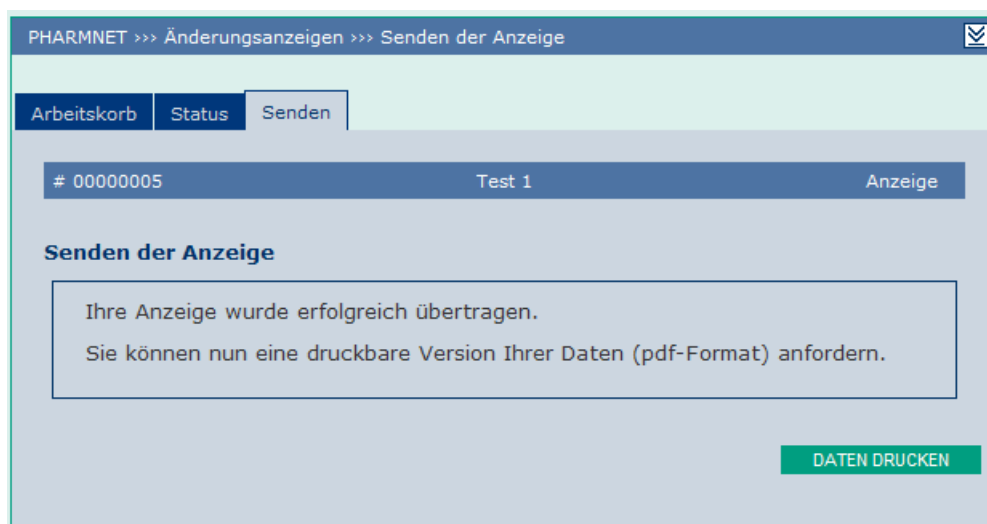
Windows Internet Explorer

Ihre Anzeige wird nun übertragen.

Wollen Sie fortfahren?

OK Abbrechen

If the data have been successfully sent, the user will receive a message confirming the action with the option of printing the message.



PHARMNET >>> Änderungsanzeigen >>> Senden der Anzeige

Arbeitskorb Status **Senden**

00000005 Test 1 Anzeige

Senden der Anzeige

Ihre Anzeige wurde erfolgreich übertragen.

Sie können nun eine druckbare Version Ihrer Daten (pdf-Format) anfordern.

DATEN DRUCKEN

Depending on whether additional documentation is to be submitted with the paper version, the variation is presented differently:

1. If no further documentation is to be submitted, the form will have a green-framed info box with a notice indicating that that data has been successfully submitted.
2. If additional documentation is to be submitted, the info box will be framed in red.

Depending on the particular case, an organisational unit will be included in the address of the CA.

The original variation has the watermark "FINAL".

Notice: The next version of the user manual will contain screenshots and explanations in English.

It will be published soon.

Note:

It is important to state expressly that **no subsequent changes** must be made to the variation, except the handwritten signature. The user has agreed to accept this and the other conditions of using this procedure by his or her confirmation of the *General Terms and Conditions of Use*.



A200704020000537

An das

Bundesinstitut für
Arzneimittel und Medizinprodukte
an Z14
Kurt-Georg-Kiesinger-Allee 3
D-53175 Bonn

Platz für BfArM-Eingangsstempel

Papierversion **ohne** weitere Unterlagen
im Vergleich zu den elektronisch
eingereichten Unterlagen

Anzeige

von Änderungen nach §29 und/oder §105 Arzneimittelgesetz

Nummer der Anzeige:	00000537
Titel der Anzeige:	Hon 1
Datum Änderungsanzeige:	02.04.2007
Sendedatum der Anzeige:	2007-04-02 13:17:12993
Zulassungsinhaber:	Pharmazeutischer Unternehmer Mustermann
Unternehmensnummer:	0000000
Online-Usernummer:	PEA00023



A200704020000538

An das

Bundesinstitut für
Arzneimittel und Medizinprodukte
an FG11
Kurt-Georg-Kiesinger-Allee 3
D-53175 Bonn

Platz für BfArM-Eingangsstempel

Papierversion **enthält zusätzliche**
Unterlagen im Vergleich zu den
elektronisch eingereichten Unterlagen

Anzeige

von Änderungen nach §29 und/oder §105 Arzneimittelgesetz

Nummer der Anzeige:	00000539
Titel der Anzeige:	Hon 2
Datum Änderungsanzeige:	02.04.2007
Sendedatum der Anzeige:	2007-04-02 13:47:02642
Zulassungsinhaber:	Pharmazeutischer Unternehmer Mustermann
Unternehmensnummer:	0000000
Online-Usernummer:	PEA00023
Online-Username:	Muster Mann

Bezug

Bezug auf Vorgang:

von:

Nachschub:

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

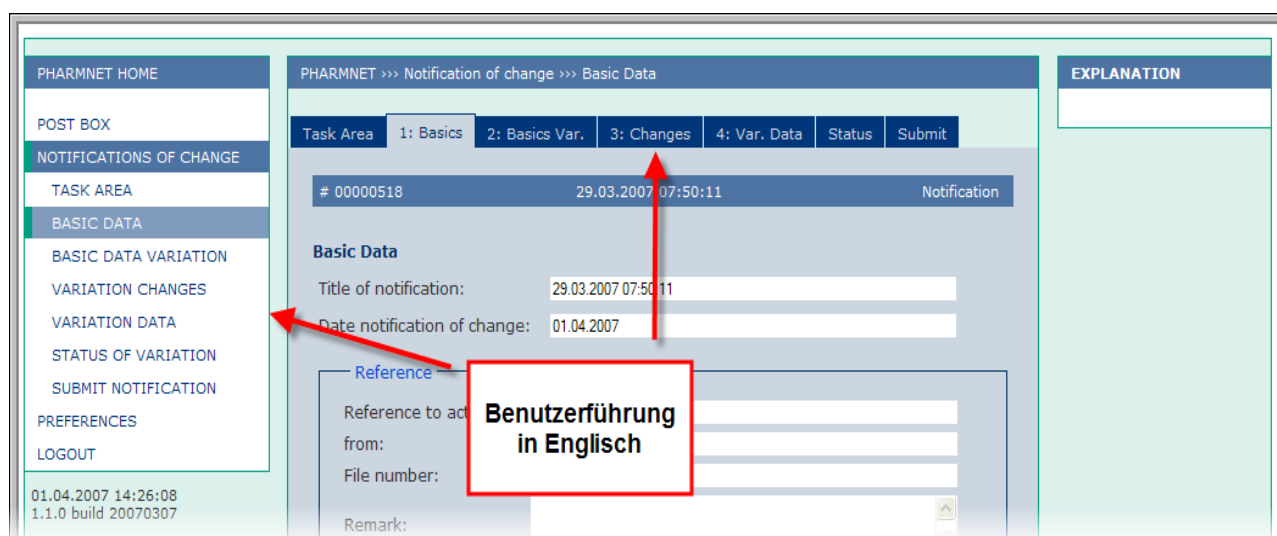
6.2 European variations according to Regulation 1084/2003/EC

The generation of European variations with the *Online Variation Submission* application follows the same principles as purely national variations. By necessity, there are differences due to the different legal basis and the mandatory European form. To comply with published requirements and guidance documents, two types of documents are generated:

1. The fully completed variation form;
2. The cover letter to the CAs with the necessary additional information.

In contrast to the national variations and the cover letter (both of which are generated as a pdf-document), the European variation form is produced in Microsoft Word format, compatible with the 2003 version and later. This enables the user who employs Word for the online application with the BfArM-generated form to use it for other participating countries too. If no further processing is planned, the document can be opened and printed out with the Word 2003 Viewer available free of charge.

The Variations menu is displayed in English only. At present, when the *European Variation* procedure is selected, the navigation switches automatically from German to English. The application will soon be enhanced to permit user language-select from the very outset.



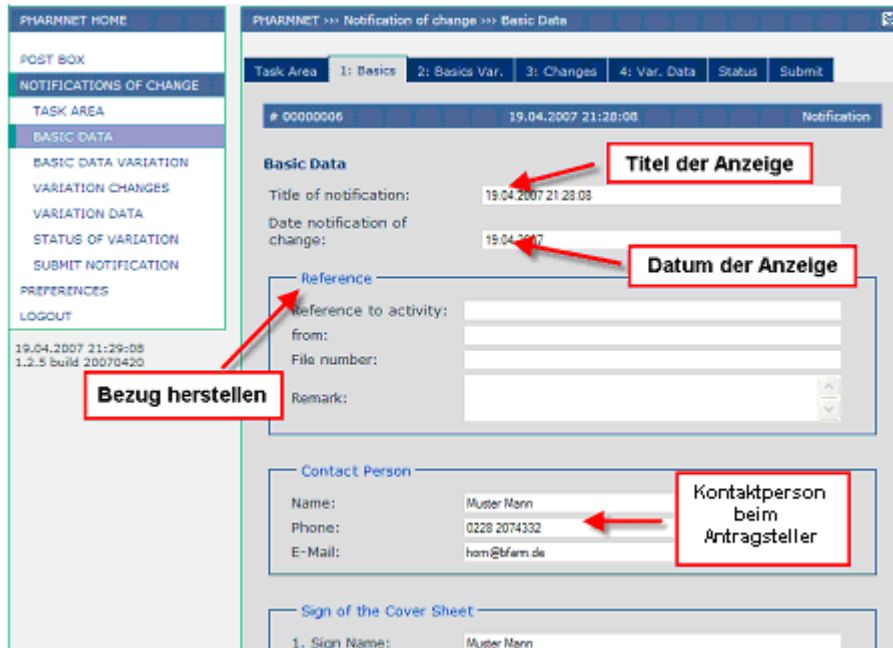
6.2.1 Task Area frame

The Task Area contains the same functions as the national variations that have been described above.

6.2.2 Master data

As with national variations, a European variation can also be assigned a user-defined title and a submission date. This is done by overwriting the default title (title = date stamp, date = current date) with which the variation is generated. There is also the option of referring to a former submission or activity.

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.



As with national variations, the details of the contact person are populated with the data of the presetsings or data from a master copy/template. The details for the first signatory in the *Sign of the Cover Sheet* area are obligatory.

At *Mode of Process*, select the second option for European variations and then select an ENR that is valid for BfArM.

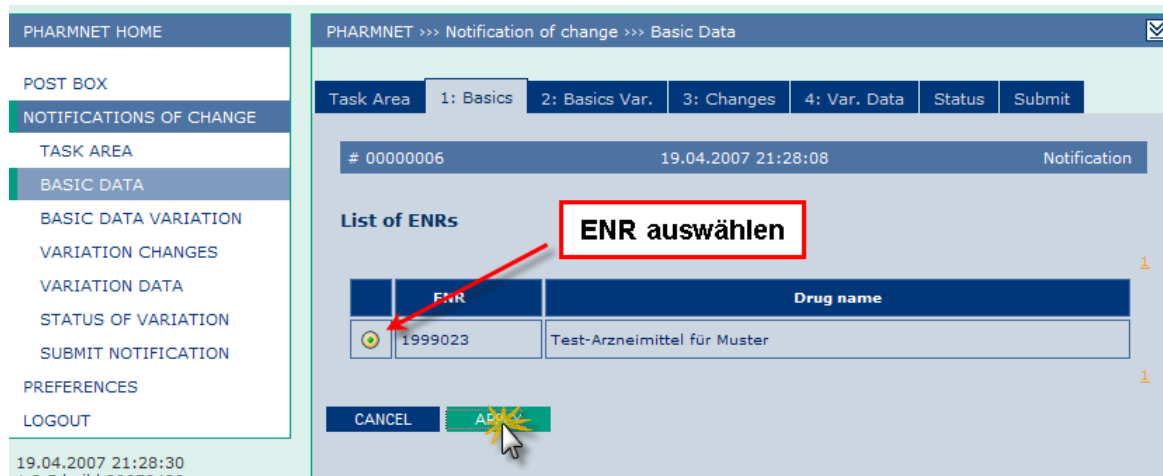


These details are entered into the variation form by clicking on *Next*.

Notice: The next version of the user manual will contain screenshots and explanations in English.

It will be published soon.

As an alternative to direct entry of the ENR, the list of available medicinal products will be displayed by using the *ENR Selection* option enabling a selection then to be made.



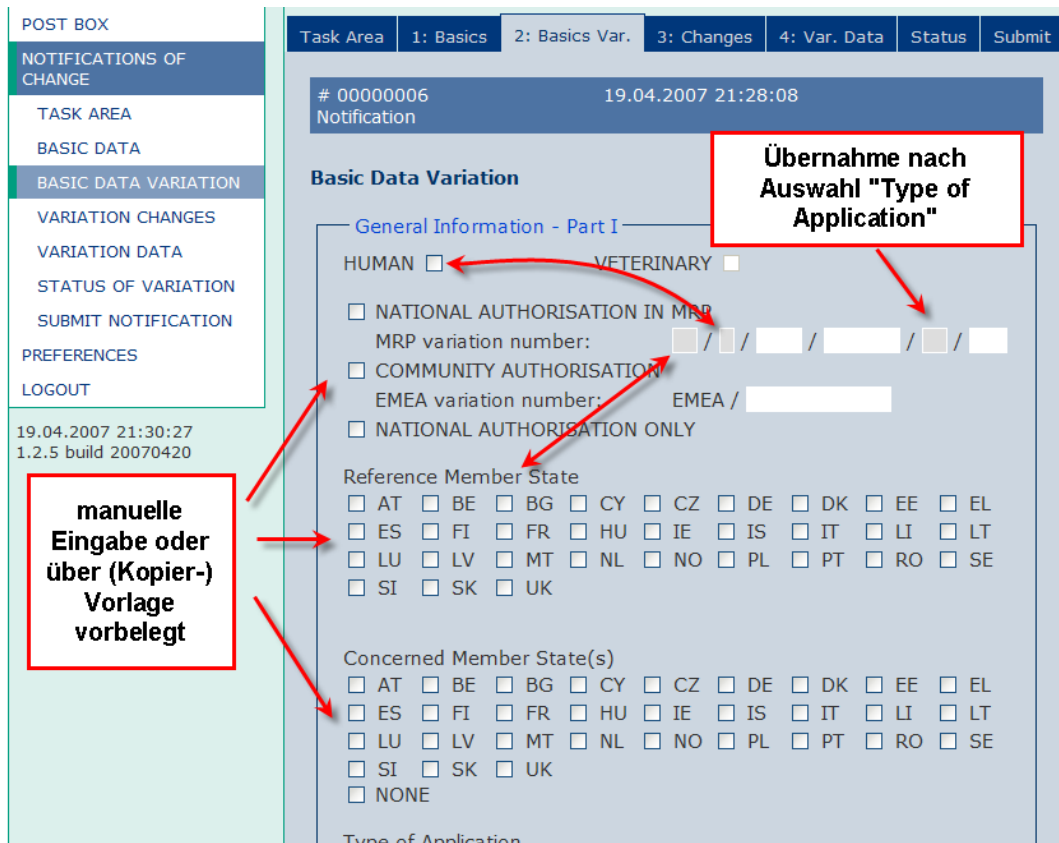
6.2.3 Variation master data

The next step is entry of the master data of the variation.

6.2.3.1 General Information - Part I

In the General Information - Part I area, the variation type, the variation number, and the concerned Member States will be defined. The fields of the MRP/DCP variation number with a grey background automatically contain the selection *Human*, the RMS, and the variation type. The fields with a white background are completed manually. According to the *Best Practice Guide*, the AM number is four-digit, with the number of the strength and the serial number of the variation to be entered in three-digit format.

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.



POST BOX

NOTIFICATIONS OF CHANGE

TASK AREA

BASIC DATA

BASIC DATA VARIATION

VARIATION CHANGES

VARIATION DATA

STATUS OF VARIATION

SUBMIT NOTIFICATION

PREFERENCES

LOGOUT

19.04.2007 21:30:27
1.2.5 build 20070420

Task Area: 1: Basics | 2: Basics Var. | 3: Changes | 4: Var. Data | Status | Submit

00000006 19.04.2007 21:28:08
Notification

Basic Data Variation

General Information - Part I

HUMAN ☐ VETERINARY ☐

☐ NATIONAL AUTHORISATION IN MRP
MRP variation number: / / / / /

☐ COMMUNITY AUTHORISATION
EMA variation number: EMA /

☐ NATIONAL AUTHORISATION ONLY

Reference Member State

☐ AT ☐ BE ☐ BG ☐ CY ☐ CZ ☐ DE ☐ DK ☐ EE ☐ EL
☐ ES ☐ FI ☐ FR ☐ HU ☐ IE ☐ IS ☐ IT ☐ LI ☐ LT
☐ LU ☐ LV ☐ MT ☐ NL ☐ NO ☐ PL ☐ PT ☐ RO ☐ SE
☐ SI ☐ SK ☐ UK

Concerned Member State(s)

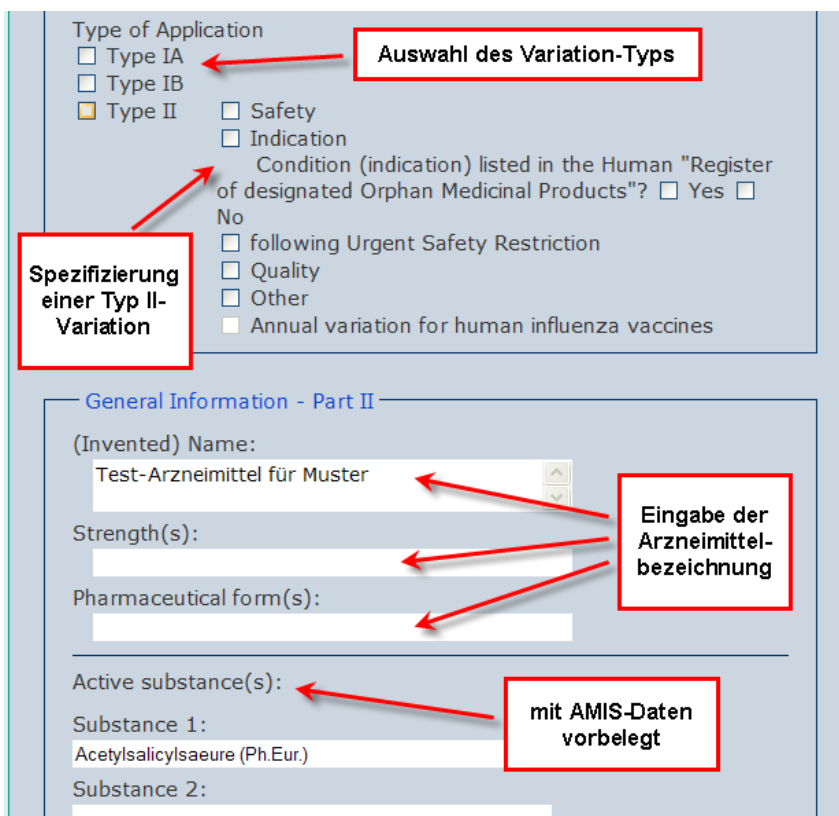
☐ AT ☐ BE ☐ BG ☐ CY ☐ CZ ☐ DE ☐ DK ☐ EE ☐ EL
☐ ES ☐ FI ☐ FR ☐ HU ☐ IE ☐ IS ☐ IT ☐ LI ☐ LT
☐ LU ☐ LV ☐ MT ☐ NL ☐ NO ☐ PL ☐ PT ☐ RO ☐ SE
☐ SI ☐ SK ☐ UK
☐ NONE

Type of Application

manuelle Eingabe oder über (Kopier-) Vorlage vorbelegt

Übernahme nach Auswahl "Type of Application"

For Type II variations the selection must be specified in greater detail.



Type of Application

☐ Type IA

☐ Type IB

☒ Type II

☐ Safety

☐ Indication

Condition (indication) listed in the Human "Register of designated Orphan Medicinal Products"? ☐ Yes ☐ No

☐ following Urgent Safety Restriction

☐ Quality

☐ Other

☐ Annual variation for human influenza vaccines

Auswahl des Variation-Typs

Spezifizierung einer Typ II-Variation

General Information - Part II

(Invented) Name:
Test-Arzneimittel für Muster

Strength(s):

Pharmaceutical form(s):

Active substance(s):

Substance 1:
Acetylsalicylsäure (Ph.Eur.)

Substance 2:

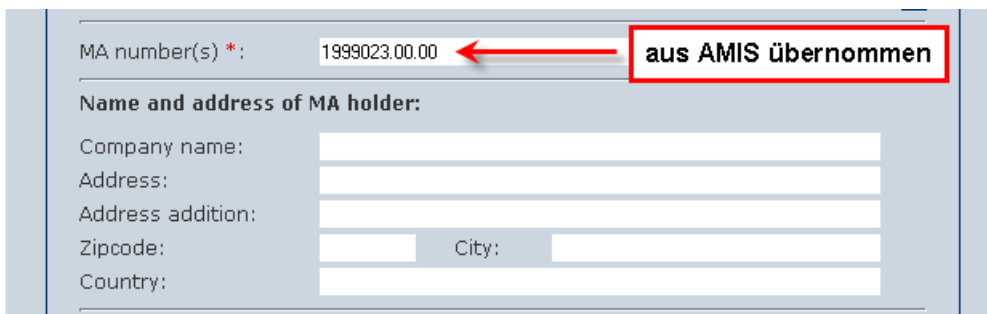
Eingabe der Arzneimittelbezeichnung

mit AMIS-Daten vorbelegt

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

6.2.3.2 General Information - Part II

In the General Information - Part II area, specific details on the company and the medicinal product are entered. The name of the medicinal product and of the active pharmaceutical ingredients are taken from AMIS and added to an empty form. The *Strength* and *Pharmaceutical form(s)* fields are mandatory and must be completed manually. Due to the structuring of the product name into three parts, i.e. *Invented Name*, *Strength*, and *Pharmaceutical form*, the name of the medicinal product cannot currently be displayed directly from AMIS. This information must be distributed among three fields for the complete description to be displayed under the Invented Name. The active pharmaceutical ingredients are taken from AMIS, as is the German marketing authorisation number.



The other data are to be entered appropriately. Where necessary, the telephone number must be amended in accordance with the European Guidelines; (this should thus be carried out in the presettings). The data entry is confirmed by clicking on *NEXT*.

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

Name and address of Contact:
 During variation procedure:
 Company name:
 Contact name:
 Address:
 Address addition:
 Zipcode:
 City:
 Country:
 Telephone number:
 Fax number:
 E-mail:

After completion variation:
 Company name:
 Contact name:
 Address:
 Address addition:
 Zipcode:
 City:
 Country:
 Telephone number:
 Fax number:
 E-mail:
 Applicant's reference:

Nummer gem. europ. Regeln anpassen

BACK

NEXT

TIP:

Due to the large amount of data to be entered manually in the General Information - Part II, it is strongly recommended that company-specific templates are prepared in advance. If a variation has already been generated for a medicinal product by this software tool, this can then be used as a master copy for subsequent variations

6.2.4 Variation changes

Irrespective of whether the variation is a Type IA/IB or a Type II variation, in the next step the user is presented with the catalogue of minor changes or with the form for major changes.

6.2.4.1 Type IA and IB variations

The catalogue for minor changes contains all 46 positions for main changes and consequential changes. If the Type IA is selected, then the IA options are made available, both for the main change and for the consequential changes. For Type IB changes, the IA options are inactivated for the main changes. For the consequential changes, both types are available for selection.

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

Type IA and IB Changes

	Main Change		Consequential change ⁵	
	IA	IB	IA	IB
1 Change in the name and/or address of the marketing authorisation holder	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2 Change in the name of the medicinal product	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
3 Change in name of the active substance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4 Change in the name and/or address of a manufacturer of the active substance where no Ph.Eur.Certificate of Suitability is available	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5 Change in the name and/or address of a manufacturer of the finished product	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6 Change in ATC Code				
a) Medicinal products for human use	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Medicinal products for veterinary use	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Apart from the restrictions just described above, the choice of changes is at the discretion of the user.

6.2.4.2 Type II variations

For Type II variations, the module in which changes are to be made is selected.

Task Area
1: Basics
2: Basics Var.
3: Changes
4: Var. Data
Status
Submit

#00000397
30.04.2007 10:00:27
Notification

Type II Changes

for human medicinal products only

☐ Change to Module 1
☐ Change to Module 2
☒ Change to Module 3
☐ Change to Module 4
☐ Change to Module 5

☐ Overview
☐ Summary
☐ Updated
☐ Addendum

BACK
NEXT

After clicking on, the upload function is displayed.

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

Type II Changes

for human medicinal products only _____

☐ Change to Module 1
☐ Change to Module 2
☒ Change to Module 3
☐ Change to Module 4
☐ Change to Module 5

☐ Overview
☐ Summary
☐ Updated
☐ Addendum

☒ upload file(s)

BACK NEXT

If an upload is to be carried out, the appropriate radio button is activated, a title assigned to the upload, and a file selected (*.pdf or *.rtf). The selected file is then uploaded.

Type II Changes

for human medicinal products only _____

☐ Change to Module 1
☐ Change to Module 2
☒ Change to Module 3

☒ upload file(s)

Choose the document type of the upload file:

<input type="radio"/> 1. Upload	Title:	<input type="text"/>
<input type="radio"/> 2. Upload	Title:	<input type="text"/>
<input type="radio"/> 3. Upload	Title:	<input type="text"/>
<input type="radio"/> 4. Upload	Title:	<input type="text"/>
<input type="radio"/> 5. Upload	Title:	<input type="text"/>

Choose a file for upload from your computer (*.rtf/*.pdf):

The upload is displayed in the form with the title freely assigned by the user (in this case: Title 1), the name assigned by the system and the original name, either with or without the file path, depending on the presetsings selected. The uploaded document can be viewed by clicking on the system name, or deleted by clicking on the bin.

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

Choose the document type of the upload file:

☐ 1. Upload Title: Titel 1


☐ 2. Upload Title:

☐ 3. Upload Title:

☐ 4. Upload Title:

☐ 5. Upload Title:

Choose a file for upload from your computer (*.rtf/*.pdf):

Titel 1: [C:\20070430100746_m3upl1.rtf](#) 
 (Original: C:\Dokumente und Einstellungen\horn\Eigene Dateien\Camtasia Studio\Desktop\yÄÄ\Test.rtf)

Systemname der Datei (points to the file name in the list)

Originalname der Datei, hier inkl. Pfad (points to the file path in parentheses)

6.2.5 Variation data

In the fourth step, the information specific to the procedure will be entered. According to the Notice to Applicants, a brief summary of the open and parallel variations is to be entered.

Task Area	1: Basics	2: Basics Var.	3: Changes	4: Var. Data	Status	Submit
-----------	-----------	----------------	------------	--------------	--------	--------

00000008 Variation Notification

Variation Data

Other Application(s)

Please provide brief information on any ongoing variation or other variation(s) submitted in parallel, or renewal application(s), or line-extension(s)

Test-Daten 1

Kurzdarstellung laufender bzw. paralleler Verfahren (points to the text area)

Scope

Please specify scope of the change(s) in a concise way

Test-Daten 2

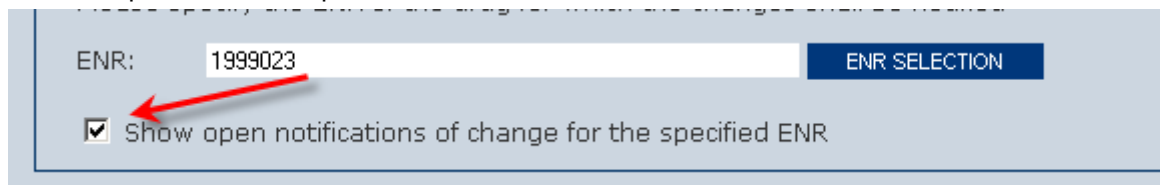
Kurzdarstellung des Rahmens der Änderungen (points to the text area)

The scope of the planned change is briefly stated, and, where necessary, distinguished from other variations.

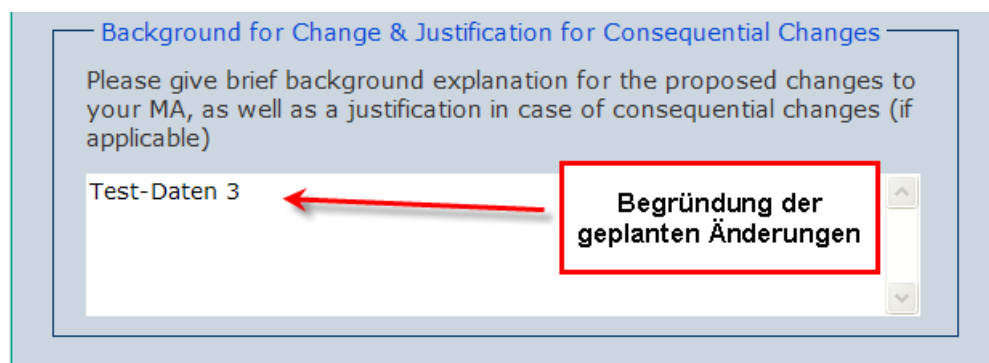
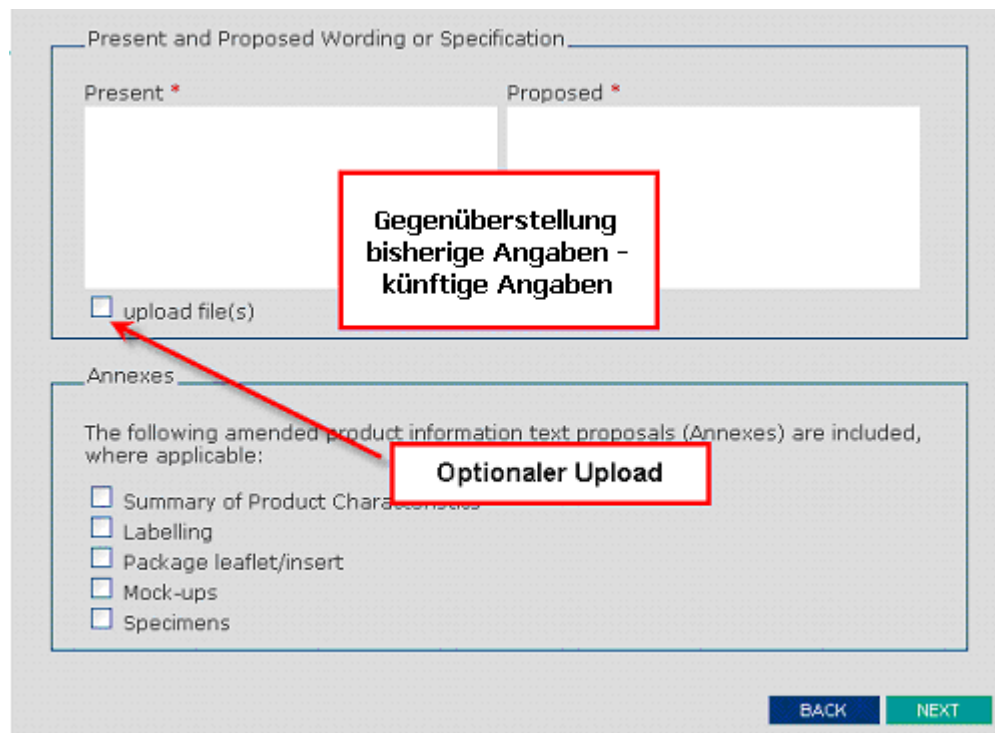
Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

TIP:

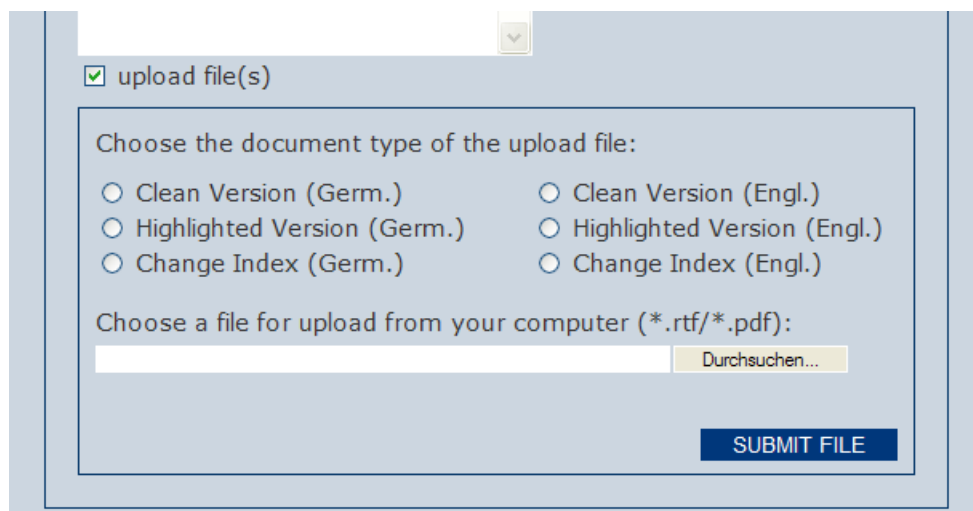
For open variations, the report in Step 1 can be used as the current information source for selecting the medicinal product and the procedure.



A brief justification is then given for the planned changes, including the consequential changes; and the proposed changes are entered verbally. A document can be optionally attached, for example, if describing the change using the form does not prove practical. In that case, the attachment will be referenced in the Present-Proposed fields. Consideration should be taken of the fact that currently only the BfArM receives this document; for other countries, the variation form would require supplementation.

By clicking on the check box, the upload area is opened with upload options for 6 different document types. Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.



☒ upload file(s)

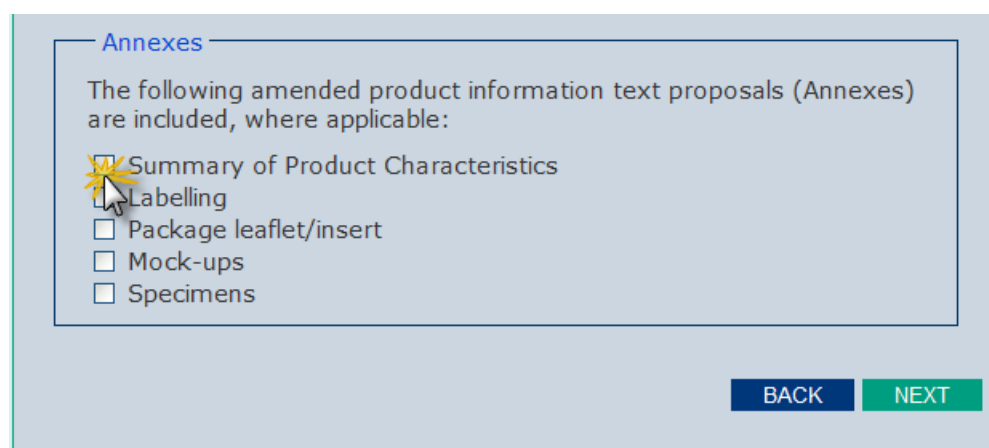
Choose the document type of the upload file:

<input type="radio"/> Clean Version (Germ.)	<input type="radio"/> Clean Version (Engl.)
<input type="radio"/> Highlighted Version (Germ.)	<input type="radio"/> Highlighted Version (Engl.)
<input type="radio"/> Change Index (Germ.)	<input type="radio"/> Change Index (Engl.)

Choose a file for upload from your computer (*.rtf/*.pdf):

In the *Annexes* area the decision is made as to which part of the product information will accompany the variation.

To do so, the required check box is clicked.



Annexes

The following amended product information text proposals (Annexes) are included, where applicable:

- ☒ Summary of Product Characteristics
- ☒ Labelling
- ☐ Package leaflet/insert
- ☐ Mock-ups
- ☐ Specimens

By clicking on *SPC*, for example, a further check box is displayed with which the upload window can be opened.

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

Annexes

The following amended product information text proposals (Annexes) are included, where applicable:

☒ Summary of Product Characteristics
 ☒ upload file(s)

Choose the document type of the upload file:

<input type="radio"/> Clean Version (Germ.)	<input type="radio"/> Clean Version (Engl.)
<input type="radio"/> Highlighted Version (Germ.)	<input type="radio"/> Highlighted Version (Engl.)
<input type="radio"/> Change Index (Germ.)	<input type="radio"/> Change Index (Engl.)

Choose a file for upload from your computer (*.rtf/*.pdf):

☐ Labelling
☐ Package leaflet/insert
☐ Mock-ups
☐ Specimens

6.2.6 Status of variation

As with national variations, with European variations users have the option of generating a status report at any time. The report here is in two parts: The variation form (in Word 2003 format) and the cover letter in pdf-format which contains all other important information, in particular, details of the uploaded documents.

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

Task Area	1: Basics	2: Basics Var.	3: Changes	4: Var. Data	Status	Submit
#00000398	30.04.2007 10:00:27				Notification	
Status of Variation WICHTIG: Bitte kontrollieren Sie vor dem Senden noch einmal genau Ihre Angaben. Nach erfolgreicher Übertragung der Änderungsanzeige gilt die Änderungsanzeige als eingereicht.						
<div>erzeugt Entwurf des Variation-Formulars</div>			<div>WORD 2003-DOC</div>		<div>PRINT STATUS (PDF)</div>	
<h2>Variation</h2>						
Nummer der Anzeige:	00000398					
Titel der Anzeige:	30.04.2007 10:00:27					
Datum Änderungsanzeige:						
Sendedatum der Anzeige:						
Zulassungsinhaber:	Pharmazeutischer Unternehmer Mustermann					
Unternehmensnummer:	0000000					
Online Usernummer:	PEA00023					
Online Username:	Muster Mann					
Bezug Bezug auf Vorgang: <input type="text"/> vom: <input type="text"/> Aktenzeichen: <input type="text"/> Bemerkung: <input type="text"/>						
Ansprechpartner						

The two documents are generated by clicking on the respective fields.

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

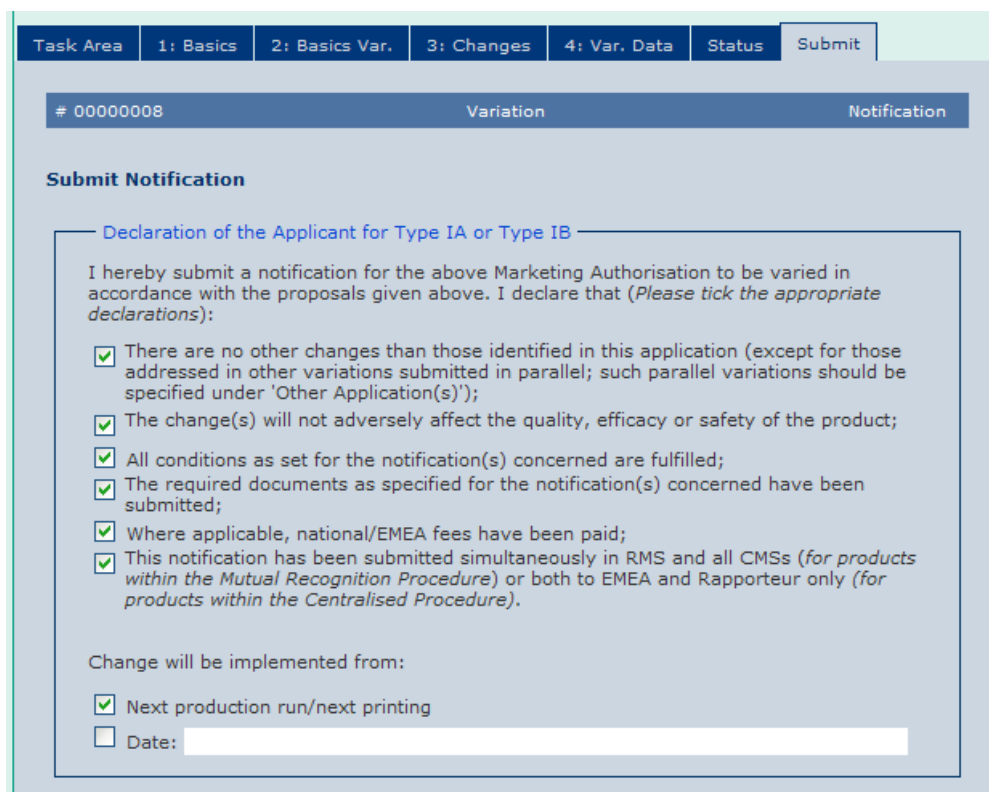
<p>An das</p> <p>Bundesinstitut für Arzneimittel und Medizinprodukte an FG11 Kurt-Georg-Kiesinger-Allee 3 D-53175 Bonn</p>	<div style="border: 1px solid black; height: 150px; margin-bottom: 10px;"></div> <p style="text-align: center; font-weight: bold; font-size: 1.2em;">Variation</p> <p>Nummer der Anzeige: 00000397 Titel der Anzeige: 30.04.2007 10:00:27 Datum Änderungsanzeige: 30.04.2007 Sendedatum der Anzeige: Zulassungsinhaber: Pharmazeutischer Unternehmer Mustermann Unternehmensnummer: 0000000 Online Usernummer: PEA00023 Online Username: Muster Mann</p> <p>Bezug Bezug auf Vorgang: vom: Aktenzeichen: Bemerkung:</p> <p>Ansprechpartner Name: Muster Mann Telefon: 0228 2074332 E-Mail: horn@bfarm.de</p> <p>Angaben zum Arzneimittel Arzneimittelbezeichnung: Test-Arzneimittel für Muster Darreichungsform: Filmtablette</p>
--	---

APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION	
HUMAN <input checked="" type="checkbox"/>	VETERINARY <input type="checkbox"/>
<input checked="" type="checkbox"/> NATIONAL AUTHORISATION IN MRP <input type="checkbox"/> COMMUNITY AUTHORISATION <input type="checkbox"/> NATIONAL AUTHORISATION ONLY	MRP variation number: DE/H//IV/ EMEA variation number:
Reference Member State <input type="checkbox"/> AT <input type="checkbox"/> BE <input type="checkbox"/> BG <input type="checkbox"/> CY <input type="checkbox"/> CZ <input checked="" type="checkbox"/> DE <input type="checkbox"/> DK <input type="checkbox"/> EE <input type="checkbox"/> EL <input type="checkbox"/> ES <input type="checkbox"/> FI <input type="checkbox"/> FR <input type="checkbox"/> HU <input type="checkbox"/> IE <input type="checkbox"/> IS <input type="checkbox"/> IT <input type="checkbox"/> LI <input type="checkbox"/> LT <input type="checkbox"/> LU <input type="checkbox"/> LV <input type="checkbox"/> MT <input type="checkbox"/> NL <input type="checkbox"/> NO <input type="checkbox"/> PL <input type="checkbox"/> PT <input type="checkbox"/> RO <input type="checkbox"/> SE <input type="checkbox"/> SI <input type="checkbox"/> SK <input type="checkbox"/> UK	
Concerned Member State(s) <input checked="" type="checkbox"/> AT <input checked="" type="checkbox"/> BE <input type="checkbox"/> BG <input type="checkbox"/> CY <input type="checkbox"/> CZ <input type="checkbox"/> DE <input type="checkbox"/> DK <input type="checkbox"/> EE <input type="checkbox"/> EL <input type="checkbox"/> ES <input type="checkbox"/> FI <input type="checkbox"/> FR <input type="checkbox"/> HU <input type="checkbox"/> IE <input type="checkbox"/> IS <input type="checkbox"/> IT <input type="checkbox"/> LI <input type="checkbox"/> LT <input type="checkbox"/> LU <input type="checkbox"/> LV <input type="checkbox"/> MT <input checked="" type="checkbox"/> NL <input type="checkbox"/> NO <input type="checkbox"/> PL <input type="checkbox"/> PT <input type="checkbox"/> RO <input type="checkbox"/> SE <input type="checkbox"/> SI <input type="checkbox"/> SK <input type="checkbox"/> UK <input type="checkbox"/> NONE	
Type of Application <input type="checkbox"/> Type IA <input type="checkbox"/> Type IB <input checked="" type="checkbox"/> Type II <input type="checkbox"/> Safety <input type="checkbox"/> Indication Condition (indication) listed in the Human "Register of designated Orphan Medicinal Products"? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> following Urgent Safety Restriction <input checked="" type="checkbox"/> Quality <input type="checkbox"/> Other <input type="checkbox"/> Annual variation for human influenza vaccines	

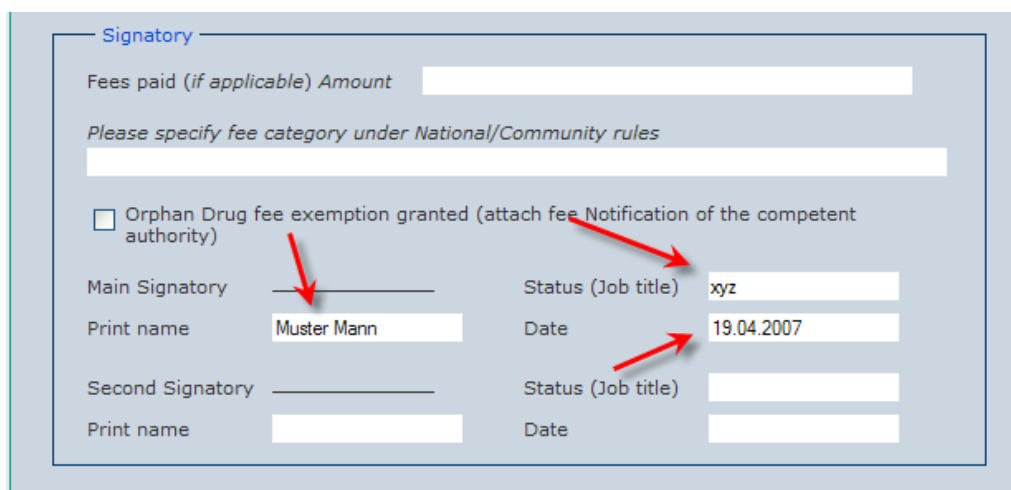
Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

6.2.7 Submit variation

Before the variation can be submitted, the user has to complete specific declarations with respect to the variation.

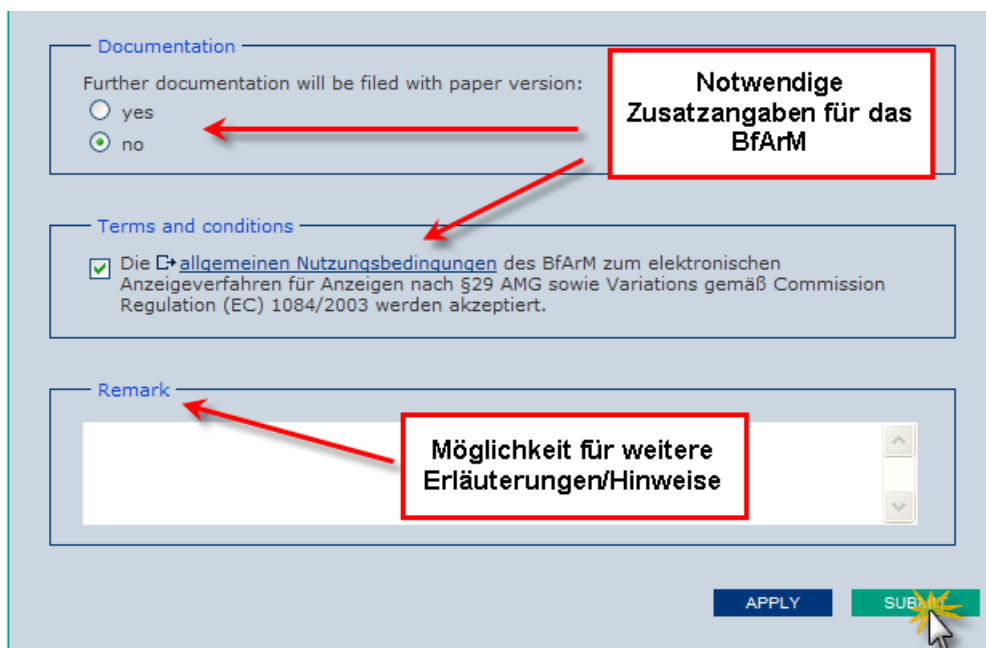


The information regarding the signatory is taken by the tool from the master information.



Finally, as with the national variations, it must be noted whether other documentation will accompany the paper version. The “General Terms and Conditions of Use” must be accepted. Further explanations for the BfArM may also be entered. The variation can then be submitted.

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.



The screenshot shows a web form with three main sections: **Documentation**, **Terms and conditions**, and **Remark**. Red arrows point from text boxes to specific form elements:

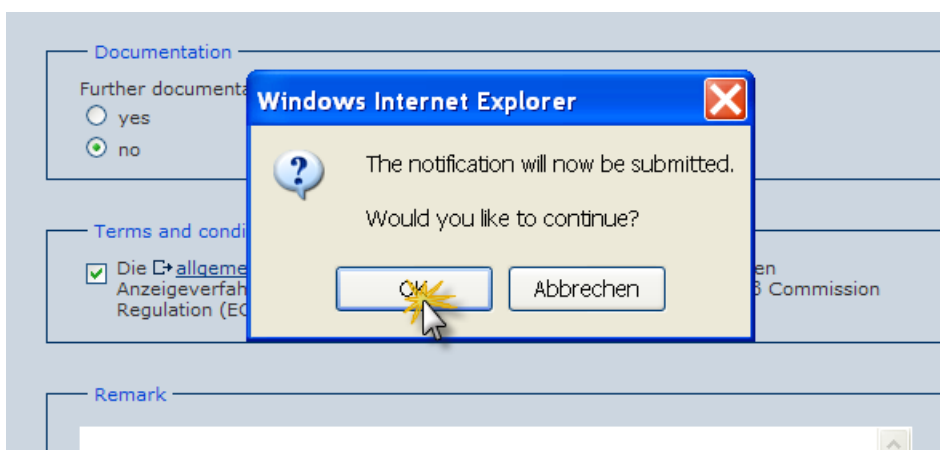
- A red box labeled **Notwendige Zusatzangaben für das BfArM** has an arrow pointing to the **Documentation** section, specifically to the radio button for **no** under "Further documentation will be filed with paper version:".
- Another red box labeled **Möglichkeit für weitere Erläuterungen/Hinweise** has an arrow pointing to the **Remark** text area.

At the bottom right of the form are two buttons: **APPLY** and **SUBMIT**. A mouse cursor is hovering over the **SUBMIT** button.

As with the national procedure, a confirmation dialogue will then be displayed. Once this is confirmed, the data are submitted definitely.

Note:

In the first phase there is a strict interpretation of the Variation Regulation with reference to the resulting conditions and documentation in such a way that, in accordance with the selected main and consequential changes, these are automatically attached to the variation. If, in individual cases, not all conditions and documentations can be fulfilled, then the remarks field can be used to provide information regarding which conditions and documentations are not fulfilled. In this case, the variation form, which is submitted to the BfArM, can be amended to accommodate the changes in the remarks field. If the remarks field does not contain any information, the variation is to be submitted unchanged.



If the data has been successfully transmitted, the user will receive a confirmation message and can print out the document.

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

PHARMNET >>> Notification of change >>> Submit Notification

Task Area | Status | **Submit**

#00000397 30.04.2007 10:00:27 Notification

Submit Notification

Your notification was submitted successfully.
Now you can demand a printable version of your data (pdf-format / MS-Word 2003-format).

☒ PDF "BfArM cover sheet"
☐ MS-Word 2003 "Variation Notification"

Auswahl

PRINT DATA

As with the national procedure, the letter to the BfArM now contains all the required features of the original, including the watermark "FINAL".


 1A210704300000397C

Platz für BfArM-Eingangsstempel

An das
Bundesinstitut für
Arzneimittel und Medizinprodukte
an FG11
Kurt-Georg-Kiesinger-Allee 3
D-53175 Bonn

Papierversion ohne weitere Unterlagen
im Vergleich zu den elektronisch
eingereichten Unterlagen

Variation

Nummer der Anzeige: 00000397
 Titel der Anzeige: 30.04.2007 10:00:27
 Datum Änderungsanzeige: 30.04.2007
 Sendedatum der Anzeige: 2007-04-30 10:13:29:399
 Zulassungsinhaber: Pharmazeutischer Unternehmer Mustermann
 Unternehmensnummer: 0000000
 Online Usernummer: PEA00023
 Online Username: Muster Mann

Bezug
 Bezug auf Vorgang:
 vom:
 Aktenzeichen:
 Bemerkung:

Ansprechpartner

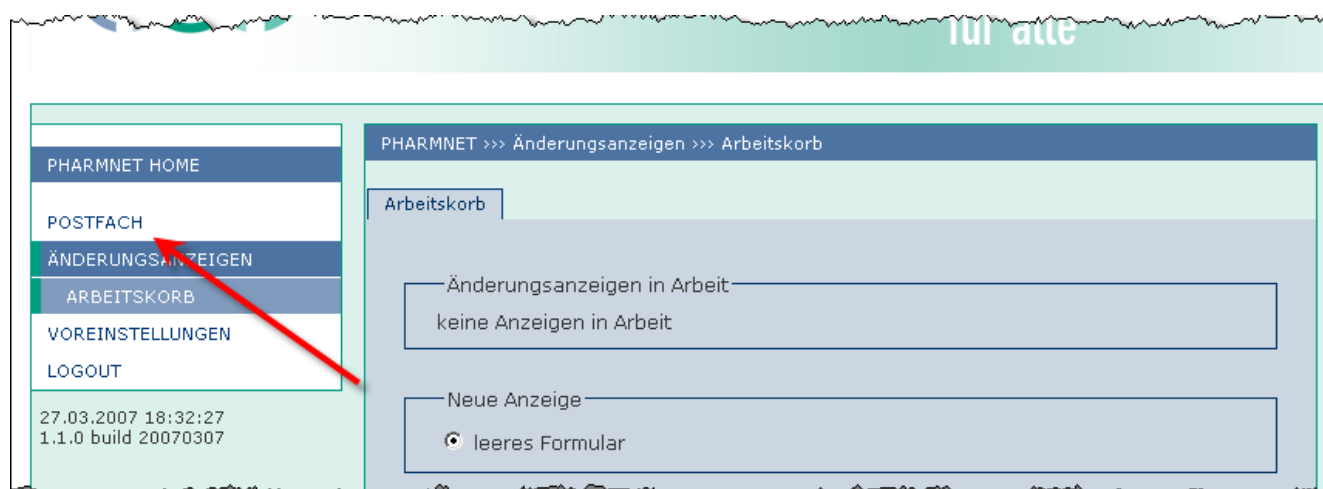
Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

7 Virtual Mailbox

Another component of the first phase of the *Online Variation Submission* application is a Virtual Mailbox which provides the user with an overview of his or her variations, the processing status, and, where applicable, the outcome of the procedure. Here the submitted variations will be made permanently available together with the authorisation letter from the CA which will be available shortly.

The *Virtual Mailbox* made available by the *Online Variation Submission* application is a precursor of the future virtual mailbox which is currently being developed by PharmNet.Bund as its own product.

The *Virtual Mailbox* can be opened via the navigation bar on the left:

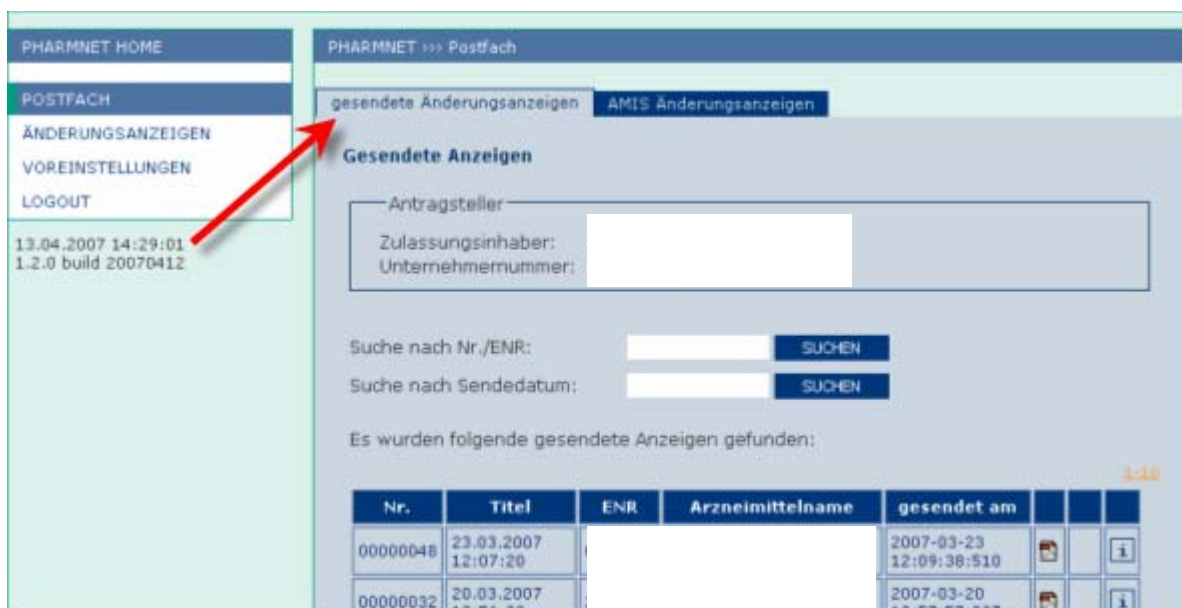


7.1 Structure

The current mailbox consists of two reports which are generated when the mailbox is opened. The user can select between the two reports by using the tab. The *Submitted variations* report contains the data stored by PharmNet.Bund. The *AMIS variations* report provides information on variations stored in the AMIS database operated by the CAs.

7.1.1 Submitted variations report

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.



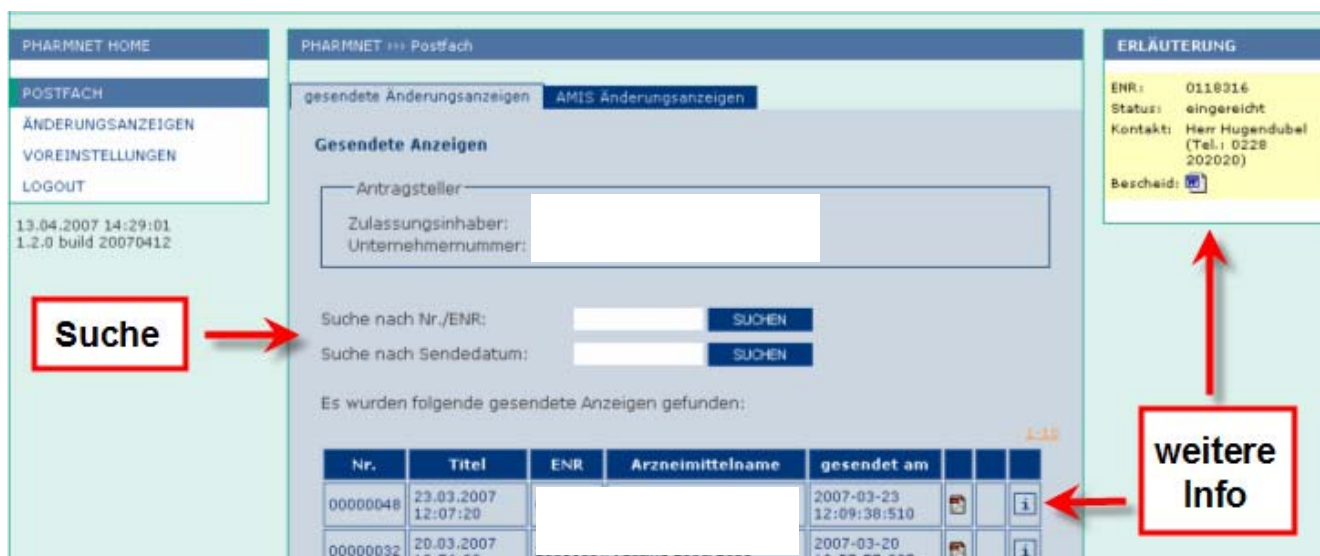
The *Submitted variations* report contains the following information:

- ◆ The automatically assigned registration number (in the form of a unique identifier);
- ◆ The title freely assigned by the user;
- ◆ The unique entry number of the medicinal product (ENR);
- ◆ The name of the medicinal product (as defined in AMIS database);
- ◆ The date of submission;
- ◆ The variation form (and for European variations the additional cover letter).

For filtering the listings two options are available:

1. Search for a registration number or ENR: By entering the first digits of the registration number or ENR, the variations can be filtered for the relevant entry.
2. Search for submission date: The required variations can be searched by entering a specific submission date.

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.



Suche →

→ **weitere Info**

Nr.	Titel	ENR	Arzneimittelname	gesendet am			
00000048	23.03.2007 12:07:20			2007-03-23 12:09:38:510			i
00000032	20.03.2007 12:56:33			2007-03-20 12:57:57:037			i

ERLÄUTERUNG

ENR: 0118316
 Status: eingereicht
 Kontakt: Herr Hugendubel
 (Tel.: 0228 202020)
 Bescheid:

The last column again contains an **i**-field. By hovering the mouse pointer over this field, information from the AMIS database is displayed in the explanatory window, including status information, the contact person at the CA, and, where available, the authorisation letter.

7.1.1.1 Search for registration number or ENR

The search for registration number/ENR can be front-masked or end-masked using a “?”.

Example: End-masking

With end masking a “?” is placed at the end of the entered sequence of digits.



Endmaskiert

Suche nach Nr. oder ENR: 000001? **SUCHEN**

Suche nach Sendedatum: **SUCHEN**

Nr.	Titel	ENR	Arzneimittelname	gesendet am			
00000109	20.04.2007 08:15:05	1999023	Test-Arzneimittel für Muster	2007-04-24 09:06:09:640			i
00000010	20.04.2007 08:17:04	1999023	Test-Arzneimittel für Muster	2007-04-20 08:20:18:876			i
00000009	20.04.2007 08:15:05	1999023	Test-Arzneimittel für Muster	2007-04-20 08:16:34:332			i
00000008	Variation	1999023	Test-Arzneimittel für Muster	2007-04-19 21:45:40:746			i
00000005	Test 1	1999023	Test-Arzneimittel für Muster	2007-04-19 21:25:48:318			i

ZURÜCK **WEITER**

The search result displays all datasets that begin with the number 000001.

Notice: The next version of the user manual will contain screenshots and explanations in English.

It will be published soon.

Antragsteller _____

Zulassungsinhaber: Pharmazeutischer Unternehmer Mustermann
Unternehmernummer: 0000000

Treffer

Suche nach Nr. oder ENR:

Suche nach Sendedatum:

Nr.	Titel	ENR	Arzneimittelname	gesendet am			
00000109	20.04.2007 08:15:05	1999023	Test-Arzneimittel für Muster	2007-04-24 09:06:09:640			

Example: Both front- and end-masking

With front-end-masking the sequence of digits is bracketed with two “?”.

gesendete Änderungsanzeigen **AMIS Änderungsanzeigen**

Gesendete Anzeigen

Antragsteller _____

Zulassungsinhaber: BfArM Bundesinstitut für Arzneimittel und Medizinprodukte
Unternehmensnummer: 8002429

Ziffer 4 Front-Endmaskierung

Suche nach Nr. oder ENR:

Suche nach Sendedatum:

1-10 11-19

Nr.	Titel	ENR	Arzneimittelname	gesendet am			
00000298	26.04.2007 11:02:18	1998986	Testarzneimittel D, 10 mg / ml, Pulver und Lösungsmittel	2007-04-26 11:06:46:000			
00000296	26.04.2007 10:56:37	1999069	Testarzneimittel A, 10 mg / ml, Pulver und	2007-04-26 11:00:17:978			

The search result displays all medicinal products which have this number sequence in the registration number or the ENR.

Notice: The next version of the user manual will contain screenshots and explanations in English.
It will be published soon.

gesendete Änderungsanzeigen **AMIS Änderungsanzeigen**

Gesendete Anzeigen

Antragsteller:

Zulassungsinhaber: BfArM Bundesinstitut fuer Arzneimittel und Medizinprodukte
Unternehmensnummer: 8002429

Suche nach Nr. oder ENR: **SUCHEN**

Suche nach Sendedatum: **Treffer**

1-7

Nr.	Titel	ENR	Arzneimittelname	gesendet am			
00000249	25.04.2007 13:41:46	1998963	Testarzneimittel E, 10 mg / ml, Pulver und Lösungsmittel	2007-04-25 13:50:25:881			
00000194	25.04.2007 08:01:07	1998992	Testarzneimittel C, 10 mg / ml, Pulver und Lösungsmittel	2007-04-25 08:06:43:877			
00000041	OML 9	1998992	Testarzneimittel C, 10 mg / ml, Pulver und Lösungsmittel	2007-04-23 12:05:07:525			
00000024	12.02X - WB-002	1998986	Testarzneimittel D, 10 mg / ml, Pulver und Lösungsmittel	2007-04-20 13:35:45:192			
00000022	AS Test 5	1999046	Testarzneimittel B, 10 mg / ml, Pulver und Lösungsmittel	2007-04-20 13:08:28:162			
00000011	HI Variation Test 20.04.2007 08:43:55	1999046	Testarzneimittel B, 10 mg / ml, Pulver und Lösungsmittel	2007-04-20 08:57:35:440			
	HI Test		Testarzneimittel B, 10	2007-04-19			

7.1.1.2 Search for date

To perform a date search, the date is entered in yyyy-mm-dd-format in the search box and the search function is activated.

gesendete Änderungsanzeigen **AMIS Änderungsanzeigen**

Gesendete Anzeigen

Antragsteller:

Zulassungsinhaber: Pharmazeutischer Unternehmer Mustermann
Unternehmensnummer: 0000000

Suche nach Nr. oder ENR: **SUCHEN**

Suche nach Sendedatum: **SUCHEN**

gesuchtes Datum in
dieser Form eintragen

1-5

Nr.	Titel	ENR	Arzneimittelname	gesendet am			
00000109	20.04.2007 08:15:05	1999023	Test-Arzneimittel für Muster	2007-04-24 09:06:09:640			
00000010	20.04.2007 08:17:04	1999023	Test-Arzneimittel für Muster	2007-04-20 08:20:18:876			
00000009	20.04.2007 08:15:05	1999023	Test-Arzneimittel für Muster	2007-04-20 08:16:34:332			
00000008	Variation	1999023	Test-Arzneimittel für Muster	2007-04-19 21:45:40:746			
00000005	Test 1	1999023	Test-Arzneimittel für Muster	2007-04-19 21:25:48:318			

1-5

ZURÜCK **WEITER**

The matching data are displayed.

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

gesendete Änderungsanzeigen | **AMIS Änderungsanzeigen**

Gesendete Anzeigen

Antragsteller: _____

Zulassungsinhaber: Pharmazeutischer Unternehmer Mustermann
Unternehmensnummer: 0000000

Suche nach Nr. oder ENR: **Treffer**

Suche nach Sendedatum:

Nr.	Titel	ENR	Arzneimittelname	gesendet am			
00000008	Variation	1999023	Test-Arzneimittel für Muster	2007-04-19 21:45:40:746			
00000005	Test 1	1999023	Test-Arzneimittel für Muster	2007-04-19 21:25:48:318			

[1-2](#) [1-2](#)

Date searches may also be end-masked.

gesendete Änderungsanzeigen | **AMIS Änderungsanzeigen**

Gesendete Anzeigen

Antragsteller: _____

Zulassungsinhaber: BfArM Bundesinstitut für Arzneimittel und Medizinprodukte
Unternehmensnummer: 8002429

Suche nach Nr. oder ENR:

Suche nach Sendedatum: 2007-04-?

Endmaskierung

Nr.	Titel	ENR	Arzneimittelname	gesendet am			
00000298	26.04.2007 11:02:18	1998986	Testarzneimittel D, 10 mg / ml, Pulver und Lösungsmittel	2007-04-26 11:06:46:000			
00000296	26.04.2007 10:56:37	1999069	Testarzneimittel A, 10 mg / ml, Pulver und Lösungsmittel	2007-04-26 11:00:17:978			
00000277	26.04.2007 09:04:26	1998963	Testarzneimittel E, 10 mg / ml, Pulver und Lösungsmittel	2007-04-26 09:11:04:536			

[1-10](#) [11-19](#)

All variations which match the search profile are listed. By entering 2007-04?, for example, all variations from April 2007 will be listed.

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

gesendete Änderungsanzeigen **AMIS Änderungsanzeigen**

Gesendete Anzeigen

Antragsteller: _____

Zulassungsinhaber: BfArM Bundesinstitut fuer Arzneimittel und Medizinprodukte
Unternehmensnummer: 8002429

Suche nach Nr. oder ENR: **SUCHEN**

Suche nach Sendedatum: **SUCHEN**

1-10 11-17

Nr.	Titel	ENR	Arzneimittelname	gesendet am			
00000041	OML 9	1998992	Testarzneimittel C, 10 mg / ml, Pulver und Lösungsmittel	2007-04-23 12:05:17:525			
00000024	12.02X - WB-002	1998986	Testarzneimittel D, 10 mg / ml, Pulver und Lösungsmittel	2007-04-20 13:35:45:192			
			Testarzneimittel B, 10	2007-04-20			

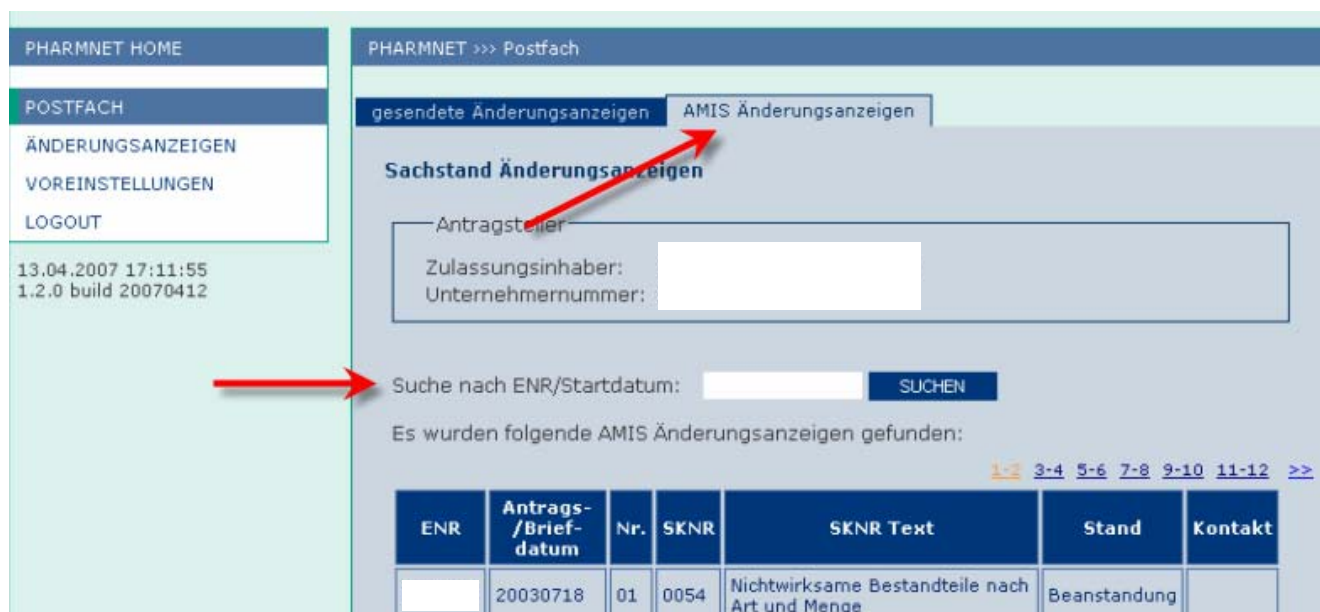
7.1.2 AMIS variation report

The *AMIS variation* report contains the following information:

- ◆ The unique entry number of the medicinal product;
- ◆ The application date freely assigned by the user;
- ◆ The serial number (default value 01, where several variations are made on one day, this value always increases by 1 in each case);
- ◆ The structure number of variation particulars from the AMIS database;
- ◆ The structure number text;
- ◆ The processing status;
- ◆ The contact person at the CA;
- ◆ An authorisation letter where relevant.

With the structure numbers displayed, it should be noted that validation and evaluation can lead to deviations from the originally submitted variations.

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.



The search function corresponds to that of the *Submitted variations* report, except that the date is entered with the following format - *yyyymmdd* i.e. without a hyphen.

7.2 Status information

The following status messages are available:

- ◆ Submitted: The electronic variation was successfully transmitted to the CA.
- ◆ Received: The paper version has been received by the CA.
- ◆ In progress: The validation has been completed. The variation has been transferred for assessment. This status change is accompanied by assignment of a contact person.
- ◆ End of procedure (positive): The variation procedure was positively completed.
- ◆ End of procedure (negative): The variation procedure was negatively completed.
- ◆ Objection: An objection was raised with respect to the variation.
- ◆ Withdrawal of the variation: The variation was withdrawn by the applicant.

Positive decisions for electronically submitted variations will be sent via the virtual mailbox, only in cases of no authorisation letter, by registered mail or instruction on right to appeal as required by law.

Note:

The *AMIS variations* report also includes conventionally posted variations. These paper-based variations will be included into the report only after a status change relevant for the mailbox. The MAH will, therefore, also receive a status report in the same way for conventional variations.

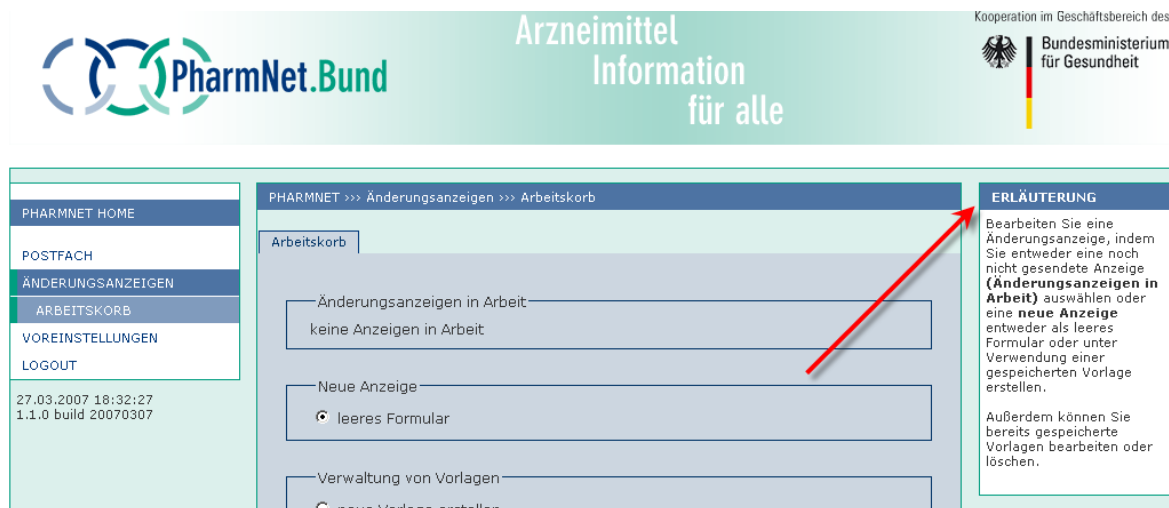
8 Support

In addition to this manual, users are also provided with other forms of assistance; (or these will be added shortly). Suggestions for the improvement of the application will be noted and included into the application development process. Updates on the PharmNet.Bund homepage will inform users about new or changed functionalities.

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

8.1 Online support

At various places within the application itself (under *Explanations* on the right of the screen), there are notes on how to use the application correctly.



8.2 FAQs

Updated answers to frequently asked questions are displayed both on the BfArM homepage, and, in the future, on the PharmNet.Bund homepage. FAQs supplement the information contained in this manual and will be incorporated into future versions of this manual.

8.3 Users' forum

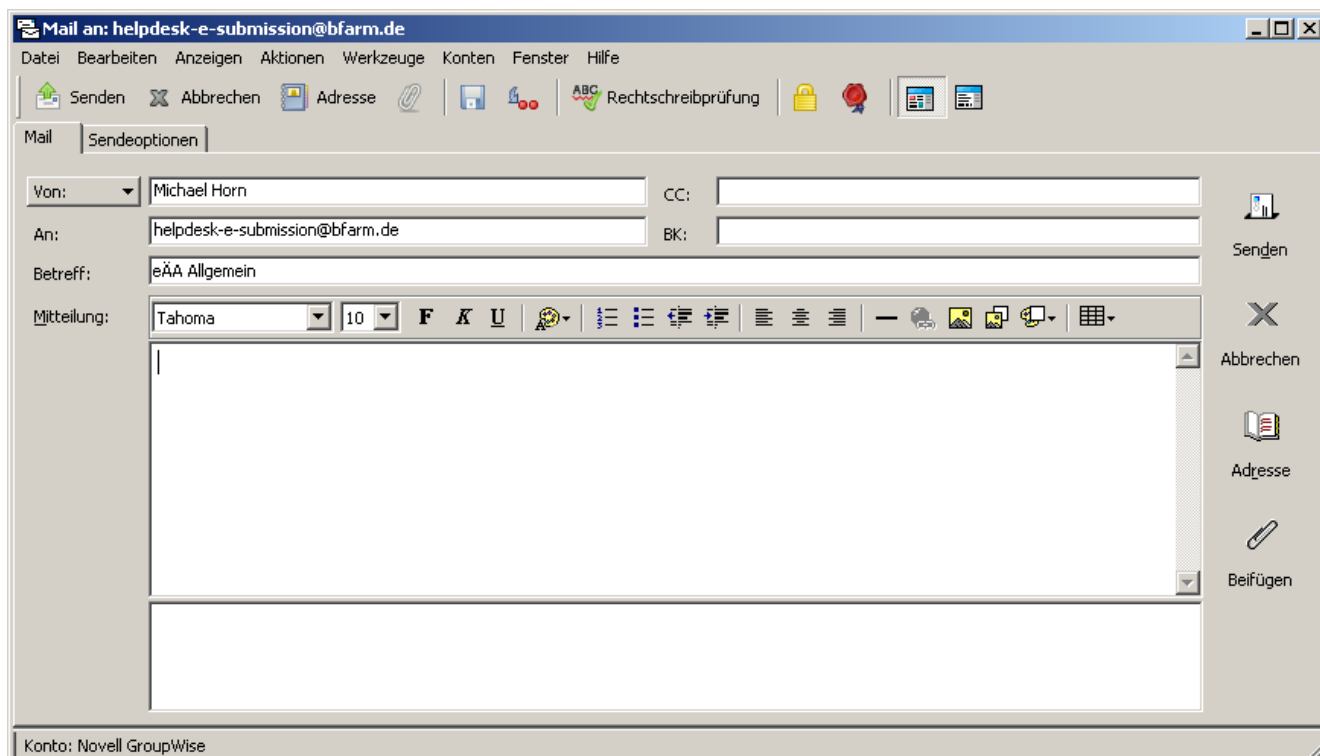
Plans are in place to set up a users' forum in the coming months at PharmNet.Bund.de to provide users with an extra information resource and forum for the exchange of ideas, etc.

8.4 Helpdesk

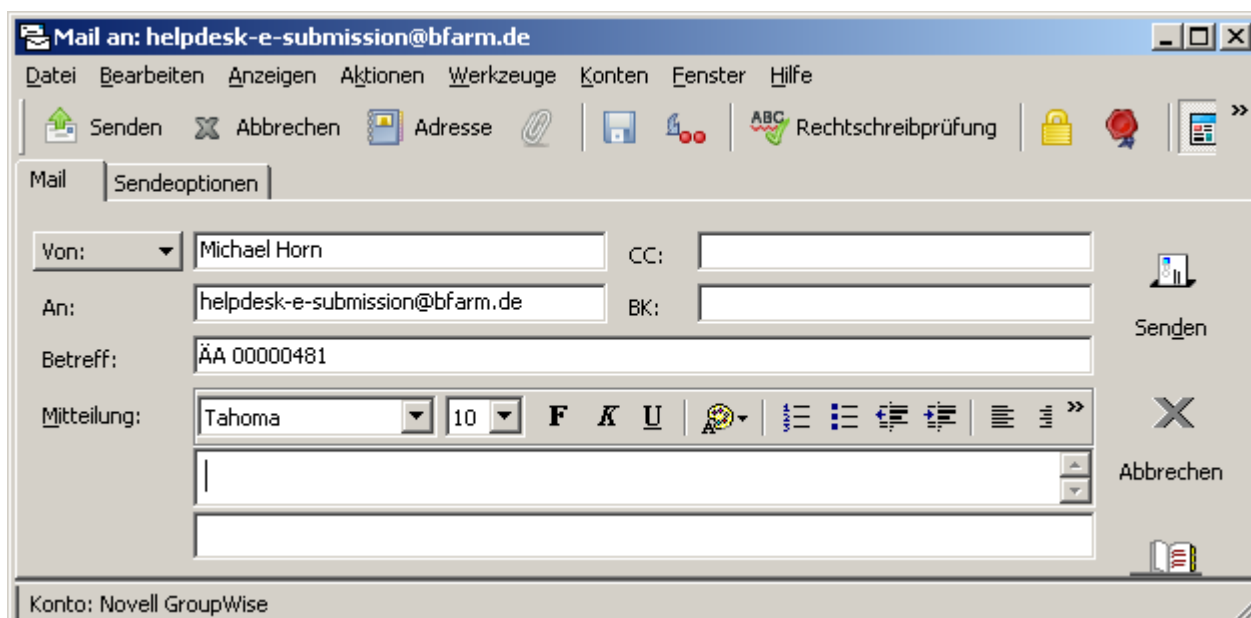
For any problems that may arise with the application, the Helpdesk can be contacted by means of the contact field which is available on every page of the application.

Clicking on *Contact* creates an email for asking the question. Attachments can also be added.

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.



If the email is generated from a status where the registration number is known, this will be automatically added to the Subject field.



In order for the Helpdesk team to deliver an effective response as soon as possible, the following information should be included:

1. Name of the questioner, including relevant contact data (e.g. telephone number);
2. Registration number of the particular variation;
3. Precise description of the problem e.g.,

Notice: The next version of the user manual will contain screenshots and explanations in English. It will be published soon.

- a. What sequence of actions was performed?
- b. Screenshots of the displays, the error messages, etc.;
4. Where there are technical problems, information on what browser (incl. version) is to be used, for example.

Users can also click on the *Contact* button outside the *Online Variation Submission* application to open a contact form that likewise enables questions to be asked regarding the application.



KONTAKTFORMULAR

Bei Fragen zum PharmNet.Bund-Angebot, füllen Sie einfach folgendes Formular aus.
Bitte beachten Sie, dass die gekennzeichneten Pflichtfelder (●) ausgefüllt werden müssen.
Sie erhalten eine Kopie Ihrer Nachricht an die angegebene E-Mailadresse.

Anrede:

Name: ●

E-Mail: ●

Thema:

- ☐ Allgemeine Frage
- ☐ Clinical Trials
- ☒ Elektronische Änderungsanzeige
- ☐ Website

Betreff: ●

Nachricht: ●

Elektronische Änderungsanzeige auswählen

immer Meldungsnummer angeben

Anliegen exakt schildern und ggf. Telefonnummer angeben

Notice: The next version of the user manual will contain screenshots and explanations in English.
It will be published soon.