

## FAQ ELECTRONIC VARIATION NOTIFICATIONS

### **Technical Questions:**

**As well as the name designated by the server for an uploaded file, is it also possible to have the path name of the original file displayed on the print-out?**

The navigation bar on the left contains the *Preferences* tab. This allows the user to decide whether or not the local path is displayed for the file name during upload.

**Why is an error message displayed in the variation form when a telephone number is entered?**

For variations it is necessary to enter telephone numbers according to the international standard (e.g.. +49 228 207-30, i.e. national code, space, location area code without preceding zero, telephone number and, where applicable, the extension).

**Why is the input window displaced within the form and the input mask of the Daten tab moved downwards.**

The optimal font size has not been set for the browser. This can be done in the browser by using the menu View -> Font Size.  
Recommended: medium or small.

**Why am I unable to access the document that has just been processed?**

A variation notification/ variation that is being processed will be blocked for a given day, if an authorised user has incorrectly initiated the variation notification/ variation or has "crashed". With a renewed attempt to call up the variation notification/ variation, the user will see an automatic system message saying that the document is being processed. The data can be accessed as usual on the next day. The basic problem is the use of the browser. Only in exceptional cases should several windows be opened simultaneously for one browser. It is recommended that two different browsers are used (e.g. Internet Explorer + Firefox).



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### **Contact for Electronic Variation Notifications**

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**Why are not all the Variation notifications currently being processed listed?**

The left navigation bar contains the *Preferences* tab. This can be used to preset the number of electronic Variation notifications currently in process displayed in the list.

**Why does the system generate regular error messages upon the registration of the *Electronic Variation Notifications* application?**

Registration can only be performed properly if pop-ups are allowed. The registration tool is a self-contained application and is not part of the *Electronic Variation Notifications* product.

**Why is deleted information (e.g. SKNR) still visible in the draft and final version of the Variation notification?**

To enable the *Electronic Variation Notifications* application to function properly, it is imperative that all pop-up blockers are deactivated. All deletions have to be confirmed in an additional dialog step. If pop-up blockers are active data may not be properly deleted because the deletion could not be confirmed.

**Why is it that although all instructions regarding the deletion of SKNRs are observed, individual SKNRs cannot be deleted?**

It is probably a consequence - SKNR, which cannot be eliminated. If a sequence - SKNR does not apply, please tick "SKNR not relevant for this advertisement". Since this field is not offered for all sequence SKNR, you can alternatively note in the comment field or in the fields "present" and "proposed" that the SKNR is not relevant for the change display. In the case of processing by our employees, this fact of change will not be taken into account. With one of the next updates of the application we will offer the possibility of deselecting sequence - SKNR.

**In what format can data be attached to the Electronic variation notification/ variation?**

With regard to various structure numbers uploads are possible in RTF or PDF file format (up to 10 MB). We request that data not available in this format be sent on CD-ROM or in paper form. Other methods for submitting data will be made available in subsequent development phases of the *Electronic Variation notification* application.

**Are users able to use the application outside of service hours?**

The availability time of the application has been increased. The application can be used daily from 7:00 - 5:00 (21h). It should be noted that data transferred on Monday-Friday before 18.10 hrs will be available in AMIS (drug information system of the German NCA's) on the following day. Variations sent after 18.10 hrs will not be available in AMIS directly on the following day. The Helpdesk is open from 9.00 to 16.00 hrs on Mondays to Fridays.

**How can I insert a company logo or letter head?**

Currently it is not possible to insert a letter head or a company logo in the notification form or to perform re-formats in the form. Users do have the option, however, of attaching a separate document containing the company logo etc. A standard upload function (e.g. Annex) can be used for this purpose.

**Why is it not possible to generate the final form of an Electronic Variation notification? (e.g. error message "current security settings do not permit download".)**

To be able to generate the final form without any problems, the following Internet Explorer settings may NOT be selected: Extras- Internet options - Enhanced - Security - Encrypted pages may not be stored on the hard drive.

As a rule the final form can only be printed out after the Electronic Variation notification or Variation has been sent.

### **Why does the status of an Electronic variation notification change?**

Electronic variations receive the status "sent" after they have been sent. As soon as an employee of the BOB starts processing, the submission receives the status "in process". For all variations submitted after 20.04.2007, the pharmaceutical company will receive a status e-mail from [amis@dimdi.de](mailto:amis@dimdi.de) in its electronic mailbox.

### **Specialist questions:**

#### **Where can I insert a cover letter?**

Within the variation notification a letter/cover letter can be uploaded under the tab "Send/Submit".

#### **It is not possible to upload the required number of documents. Where can I upload additional files?**

Because there is not separate upload area, all the available options for upload for each SKNR can be utilised. If the data files still to be submitted are not covered by the remaining "free" upload fields, data can still be uploaded under the categories (e.g. a file can be uploaded as a clean version even though it is not actually a clean version). We also recommend that various files be conflated into one file (e.g.: different modules). It should be noted that the total size of uploaded files may not exceed 10 MB. Freely selectable upload options are planned for the future.

#### **Where can I find detailed instructions and advice?**

The *Electronic Variation Notifications* manual is available from the PharmNet.Bund portal along with instructions on registration and a form for contacting the Helpdesk.

#### **Where can I make changes/additions in relation to the application "Variation Submission"?**

Revisions and enhancements of features can be found in the application "Variation Submission" in the upper right screen area deposited in the "Release Notes".

#### **We have applied for a new PNR for our company. What is the processing status?**

If you have already applied for a new PNR from us, please contact: [amis-pu@bfarm.de](mailto:amis-pu@bfarm.de). If the BfArM does not yet know the new marketing authorisation holder/manufacture, please send a copy of the extract from the commercial register to the above-mentioned e-mail-address.

#### **How can I search within the worklist?**

You can search by notification number, title, ENR, drug name or send date.

The search can be masked both front and end via a question mark. With an end masking, a "?" is set at the end of the entered numerical sequence. In front masking, a "?" is set at the beginning of the numerical sequence. With front end masking, a sequence of numbers is bracketed by two "?". When searching for a transmission date, this is entered into the search field with "yyyy-mm-dd" or "dd.mm.yyyy" and the search is started. In the date search, you can only mask in the search with "equal sign" and in combination with the line notation "yyyy-mm-dd".

## **Where can I find the EoP letter sent electronically?**

You will find our EoP letter in your PharmNet.Bund P.O. Box in the column BOB letter as a pdf file. This column is located to the right of the column with the Info button. If you do not see this column on your screen, please check your screen settings. The column BOB has been added to the report "sent variation notifications" column. Furthermore, BOB documents can be sorted by date of setting into the mailbox.

## **Why does the name of the medicinal product not appear in the subject line?**

The subject line of electronic change notices differs from the subject line of conventionally submitted notifications. Among other things, the drug name (or the first 10 characters thereof) is ONLY included in the subject line of electronic submitted variation notifications. For conventionally submitted variation notifications, the drug name is not listed in the subject line.

## **Is it possible to make correction requests yourself?**

The user chooses the option "list sent notifications" in the work list. Then a correction can be requested from the BOB for notifications that have already been sent. To do this, mark the desired change display and then press the "Continue" button.

The "BOB" tab allows you to view comments and any attached BOB text documents that are to be taken into account for corrections. Correction specifications of the BOB are also visible there.

## **Is it possible to delete notification already sent?**

If you want to delete a notification that has already been sent, you can submit a deletion request in the same way as a correction request. However, this only applies as long as the display has only been sent but not yet processed by the BOB. To do this, select the desired change notification in the worklist under "List sent notifications" and select the option "Request deletion".

If it is no longer possible to delete the display because processing by the BOB has already started, the following message appears immediately: Deletion is no longer possible for the selected notification.

## **The password for the application cannot be found anymore. What to do?**

You have two options. If a login has already been attempted several times, access is automatically blocked after the sixth incorrect entry. You will then automatically receive an e-mail from DIMDI in which the further procedure for unblocking the access is described. Or click on the link "Forgot password?" on the PharmNet.Bund home page. Then you will also receive an e-mail from DIMDI. In both cases, a one-time password is assigned, which you can use to log in.

## **Happens the deletion of no longer needed accounts for the application "Electronic variation notifications" automatically?**

The deletion of accounts no longer required for the application "Electronic variation notifications" does not take place automatically. This can be applied for via the contact form of the PharmNet.Bund portal. However, you will not receive any notification about the deletion because the e-mail address of the deleted account will no longer be used.

Once the access has been deleted, access to this mailbox is no longer possible. The information on the variation notifications made up to this point is then no longer available. A pragmatic solution would be to maintain the account that is no longer needed.

## **In which cases is bulk processing suitable?**

In the current stage of expansion, the use is suitable in cases where company-specific changes have to be submitted that do not require an individual document upload.

**Legal questions:****If uploaded documents are deleted in the notification, are these also removed from the PharmNet.Bund server?**

Yes. If the notification has not yet been submitted to the NCA, documents can be deleted from the variation notification/ variation form and these will also be deleted in file form from the PharmNet.Bund server. NCA employees have no access to the data of the particular variation notification/ variation until it has actually been submitted to the NCA.

**Is there an option available for selective release of ENR's for co-distributors?**

No this facility is not currently available.

**Can an authorised representative be appointed to use the application?**

For reasons of security, user codes and passwords will only be sent to the address of the marketing authorization holder as stored in AMIS. Every pharmaceutical company is only allowed to register its PNR once. The marketing authorization holder is responsible for any communication of its user code and password to an authorised representative.

**A new PNR has been assigned to our company. How to replace the PNR in the Application "Electronic change notifications"?**

If a new, valid PNR is provided in AMIS, it is automatically made available in the PharmNet.Bund portal. A PNR is inextricably linked to a pharmaceutical company. A new PNR is issued, for example, after the company has been renamed. These are usually two different legal entities.

As the PNR is linked to the company as described above, the access data is also inseparably linked to the PNR and cannot be transferred to another PNR. In this case we ask you to register the new PNR (which was issued by the BfArM after the name change etc.). If the access data for the former PNR (before the change of name, etc.) is not needed anymore, an authorized user of the application can initiate the deletion of this data..For this purpose, an e-mail can be sent to the contact e-mail address stored in the PharmNet-Bund portal.