

FAQ

ELECTRONIC VARIATION NOTIFICATIONS

Technical Questions:

Why does the comment field disappear when an upload is started?

The parallel display of the comment field and upload is planned for a later release of the *Electronic Variation Notifications* application.

Can the respective variations form still be accessed after variations have been sent?

The list of variation notifications/ variations sent to the NCA can be accessed via the electronic post box and the respective form viewed. Search criteria (e.g.: ENR, date sent) make it easier to locate variation notifications/ variations that have been sent. When using an earlier version of Word, Word 2003 Viewer will be required to generate paper versions of Variations.

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



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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).

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 when registering for the *Electronic Variation Notifications* application, the required password is not accepted?

Passwords may not include umlauts.

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 8:00 - 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 7.00 to 19.00 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?

The status of an Electronic variation notification / Variations will change from sent to *submitted*, once the paper version of the final form has been received by BfArM and its barcode has been scanned. After the barcode has been scanned the Electronic variation notification / Variation will be assigned to a BfArM employee for processing of contents and it will be given the status *being processed*. For all Variation notifications / Variations completed after 20.04.2007, the pharmaceutical company will receive a status email to from amis@dimdi.de.

Specialist questions:

After sending the Variation notification an error is identified in the uploaded file. How can users submit corrected files?

It will shortly be possible to recall, i.e. delete sent notifications (i.e. those with the status *sent*) where the paper version has not yet been received by the NCA. Unfortunately it is currently only possible to send subsequent deliveries to AMG-EV. The Helpdesk may also be informed about this separate submission in order that the data file can be supplemented accordingly.

What documentation must be included in paper form?

For national variation notifications the signed application form is required along with all documents needed for the complete description of the variation notification, and any necessary expert reports. For variations the signed letter must be included along with the completed and signed variation form as well as all documents required for the complete description of the variation along with any requisite expert reports.

Do documents submitted as part of an Electronic Variation notification also have to be sent to AMG-EV?

No. The documentation does not have to be submitted to AMG-EV if such documentation has already been submitted as part of the Electronic Variation notification.

Do text files (SPC, PIL...), sent as attachments are part of an Electronic Variation notification also have to be submitted in paper form?

Informational text files do not have to be additionally submitted in paper form, if the variation has been comprehensively described in the form. If the variation was not adequately described in the form and the informational text files were referred to, these must then be additionally submitted in paper form.

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.

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.