

REGISTRATION FOR THE ONLINE VARIATION SUBMISSION APPLICATION

Introduction

In order to be able to use the online variation submission application, you must first be registered.

This first version of the application only records the medicinal products that are authorised by the BfArM as the Competent Authority. This means that only pharmaceutical companies, which have at least one valid Marketing Authorisation with BfArM as the Competent Authority, are entitled to register. Marketing Authorisations under the authority of the PEI and the BVL will be integrated at a second step.

Important notices:

1. Only one registration is permissible per PNR (= Marketing Authorisation Holder Number). The decision as to who will be assigned the user code and password is in the Marketing Authorisation Holder's sole discretion.
2. The registration may also be carried out by an authorised representative. For reasons of security, the user code and password will always be sent to the Marketing Authorisation Holder's address as stored in the local database of BfArM (AMIS).
3. As ENR select a drug, for which no variation for an assignment to another or from another Marketing Authorisation Holder is pending.
4. If the registration has been carried out without the permission of the Marketing Authorisation Holder, this party should contact the BfArM promptly so that the registration can be cancelled.
5. If you suspect that your user code and your password have been used in an unauthorised manner, change your password without delay or contact BfArM to block the access at short notice.



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Registration

The following steps are required for registration:

1. To register, call up the online variation submission application on the www.pharmnet-bund.de website. There, click on the “apply for their user code” field.

PharmNet.Bund » Online Variation Submission

Online Variation Submission

The "Online Variation Submission" application is a sub-project of the "**Electronic Submission**" application. Once fully developed, "Electronic Submission" will support the submission of applications to the competent authorities (pursuant to legal regulation) for all procedures including the submission of marketing authorisation documentation. Together with other PharmNet.Bund applications, "Electronic Submission" will be part of the communication platform for competent authorities and applicants.

Supporting Information:

- [Registration guide \(PDF, 328 kB\)](#) (in German; English Version in preparation)
- ["Online Variation Submission" User Manual \(PDF, 2.2 MB\)](#)
- ["Online Variation Submission" FAQ \(PDF, 76 kB\)](#)

Attention please!

Due to necessary adjustments variation applications according to the variation regulation are currently not possible.

Online Variation Submission

User code:
Password:
[Forgot password?](#)

Here, pharmaceutical companies can

2. Complete the fields in the registration screen. Mandatory fields are indicated with an asterisk *. Please have a valid ENR ready together with the PNR of the Marketing Authorisation Holder for which the registration is to be undertaken. The registration can only be completed provided these two details are correct.

Address data

Salutation *	<input type="text"/>
Title	<input type="text"/>
First name	<input type="text"/>
Last name *	<input type="text"/>
Company *	<input type="text"/>
Suffix	<input type="text"/>
Street, house no. *	<input type="text"/>
Postcode * / Town/City *	<input type="text"/> / <input type="text"/>
PO box ZIP code / PO box no.	<input type="text"/> / <input type="text"/>
Country	Germany <input type="text"/>
Telephone *	<input type="text"/>
Fax	<input type="text"/>
Email-address *	<input type="text"/>

Entrepreneur data

PNR *	<input type="text"/>
ENR *	<input type="text"/>

(For example, enter an ENR from your inventory.)

3. Click on "continue".

- If one or more mandatory fields have not been completed, a notice will appear above the relevant mandatory field.

✘ This mandatory field is empty.

Salutation *

Title

First name

✘ This mandatory field is empty.

Last name *

✘ This mandatory field is empty.

Company *

Suffix

✘ This mandatory field is empty.

Street, house no. *

✘ This mandatory field is empty.

Postcode * / Town/City * /

PO box ZIP code / PO box no. /

Country

✘ This mandatory field is empty.

Telephone *

Fax

✘ This mandatory field is empty.

Email-address *

Entrepreneur data

✘ This mandatory field is empty.

PNR *

✘ This mandatory field is empty.

ENR *

- Once all required data has been provided, you have the opportunity to check this once more.
- If corrections are required, click on “back”, otherwise click on “continue”.
- Following the successful transmission of the data, you will receive a confirmation that you have applied for a user code. The Marketing Authorisation Holder will receive an access code by registered mail next few days. This letter will contain the access data in a separate closed envelop. **IMPORTANT:** The access data will always be sent to the Marketing Authorisation Holder’s address as stored by AMIS.