Dear Sir or Madam,

Today we would like to provide further information about the following topics:

We are at your disposal, should you require assistance or have further questions.

Best regards

The DiaMed Team

1 DADI: WEB-BASED APPLICATION FORMS

Timelines

The Digital Application Dataset Integration (DADI) Network Project will replace the current pdf-based application forms for variations, marketing authorization applications, and renewals with new web-based application forms for human and veterinary drugs. The new forms will be made available in a portal. The October 2022 "go-live" has been limited to an initial release of the web-based application form for variations for centrally authorized medicinal products (CAPs). The second release of the web-based variation application forms (scheduled March 2023) will then support all types of EU variation procedures for CAPs and NAPs. This will be followed by a six-month transition period for CAPs and NAPs. The mandatory use of the web-based variations application forms for all variation types for CAPs and NAPs will then apply from September 2023. More information on the project progress as well as a Q&A document is available on the EMA eSubmission page.

Features of the web-based eAFs

With the launch of the variation application forms, the current interactive PDF formats of the electronic application forms will be converted to the new web-based application forms, where the main change will be the selection of products and packages affected by the variation from the IDMP/SPOR Product Management Service (PMS). Future versions of the web-based application forms will replace more free-text fields with structured data fields. Additionally, the new application forms will include mandatory use of the Organization Management Service (OMS).

Registration and user roles

In order to use the web-based DADI application forms, it is necessary for **employees of the marketing authorization holder to register in the EMA Account Management System**. For this purpose, different user levels can be defined. Detailed information from EMA is available in the "eAF Portal guide to registration". The assigned users of a marketing authorization holder can only select the products of their organization in the the DADI application forms. It should be possible to map complex company structures. Consulting companies must be assigned a corresponding role by marketing authorization holders in order to allow them to perform tasks on their behalf.

Verification of PMS/xEVMPD data

Another prerequisite for the use of the DADI application forms is that the product has been included in the PMS. This data is migrated from the Article 57 database (xEVMPD database), among others. Products that are not included in the Article 57 database should therefore be submitted to xEVMPD, otherwise it will not be possible to use the DADI forms.

In the future, Article 57 submissions will be replaced by use of the DADI forms for variations. Initially, however, the dual submissions from the regulatory process and the Article 57 database update will still be necessary.

We recommend starting now to review the product data in the Article 57 database and the organization data in OMS.

PharmNet.Bund

The application for the submission of variations via the national PharmNet.Bund portal is being reprogrammed. This is to be done by 31.12.2022 due to the Online Access Act (OZG). Due to the DADI form for submission of variations, the portal will focus on purely national variations/notifications. The variations will then be submitted with the DADI form. PharmNet will then no longer need to be maintained as in the past. There will be an announcement from the BfArM (probably second half of the year).

2 NEW APPLICATION FOR THE NOTIFICATION OF THE GRADUDATED PLAN OFFICER

Since 12.07.2022, the new application for reporting the graduated plan officer (StB) has been activated on the national portal PharmNet.Bund. The higher federal authorities are thus fulfilling their obligation to set up a portal network for digital administrative services in accordance with the Online Access Act (OZG).
With the activation of the application, notifications from the StB to BfArM or PEI (registrations, de-registrations and change notifications) will only be made via the portal. A notification can only be made by the pharmaceutical entrepreneur himself or by a person appointed by him.
Since personal data will be entered into the application, it is an application with additional security requirements, which requires 2-factor authentication (password and personal electronic certificate). The access is company-specific. The company's main user must first register in the "RuBen" user administration (also requires an electronic certificate). This main user can then set up access rights for other users, including external service providers. Once they have been activated, they can make notifications for the company via the application.
Initially, the database is still empty. It is recommended to notify the already notified StB, so that the database represents the current status. In this case, the start date of the first notification of the StB must be specified in the comment field (in this case, the report is not subject to a fee). If different persons have the role of the StB (e.g. medical StB and pharmaceutical StB), all StBs and also their deputies should be notified.

The notification of the StB to the regional authorities is not possible via the portal and has to be carried out separately via the previous route, depending on the requirements of the respective regional authority. It is planned to merge these processes in the future.

FAQ on the BfArM-Website (DE only):
https://www.bfarm.de/DE/Arzneimittel/_FAQ/Pharmakovigilanz/Stufenplanbeauftragter/faq-liste.html;jsessionid=74D6340D06908F3DF5F27AB9FFBBF83F.intranet232?nn=595116

Link to the application "Notification of the graduated plan officer":
(DE only) https://www.pharmnet-bund.de/static/de/unternehmen/stufenplanbeauftragter/index.html

Information on user registration and management:
(DE) https://www.pharmnet-bund.de/static/.content/.galleries/downloads/de/anleitung-benutzer-selbstverwaltung.pdf
(EN) Manual User self-administration (Companies / Federal Authority) (pharmnet-bund.de)

Information on certificates:
(DE) https://www.pharmnet-bund.de/static/.content/.galleries/downloads/de/anleitung-zertifikat.pdf
(EN) Manual Certificates (pharmnet-bund.de)