Information on the Total Replacement of AMIS

The current medicinal product information system (AMIS) has been used for many years. Due to technical progress and insufficient assurance of functionality for the future, AMIS will be replaced by a new successor database (AmAnDa). This process has been prepared intensively and is very complex. A timely completion of the replacement is planned, but the availability of sub-functions or special applications may be limited in time beyond the transitional period. We are pursuing the goal of minimising these restrictions as far as possible.

The change-over from AMIS to AmAnDa and its add-on applications is planned for 19 March 2020. The senior federal authorities BfArM, PEI and BVL as well as DIMDI are affected by the changeover. During the transitional period, various specialised applications will be temporarily unavailable or will only be available with the database status of 19.03.2020; individual specialised applications will be switched off before this deadline. We will inform you about the progress of the changeover on a regular basis

The first step will be to convert the internal databases for the senior federal authorities. The medicinal product data of the AMIS database will be frozen to the status of 19.03.2020. From 23.03.2020 the successor database AmAnDa will be the leading system.

What does this mean for the pharmaceutical companies?

1. The online portals and other specialised applications will be switched off
   To assure that all data and documents submitted under PharmNet.Bund can still be correctly transmitted and migrated, it is required to switch these off, even at an earlier time point.

   At first, the batch portal, PEI-CR, is not affected by this, since it will be directed to the new systems at a later time point. Until then, it will continue to access the data stock of 19 March 2020. However, this will mean, that at first, no applications for batch releases can be made via the portal for medicines the marketing authorisations of which were granted on the deadline of 19 March 2020 or later. Any applications for these products must be submitted using alternative channels of communication during this transitional period (email, Eudralink, or paper).

2. The specialised application “Sunset Clause” and the email procedure for the submission of informative texts after the completion of the procedure shall be replaced by new maintenance applications in the PharmNet.Bund portal.

3. Submissions using the following procedures will **not** be affected by the changeover:
   a. Procedures pursuant to Section 42b AMG (German Medicines Act)
   b. Notifications on supply shortages

4. The part of AMIS which has up to now been public will be replaced by a new medicines fact database (AM-FDB) and the new AMIce search surface.

5. Data quality:
   Because of the complex changes in the data model, it cannot be ruled out that so-called migration errors will be introduced into the data model. These shall be corrected with the highest priority. Should any errors be identified by marketing authorisation holders, we would like to request you to transmit the appropriate information to this email address: amis-kontakt@pei.de

6. Authentification and registration for the use of the new specialised applications:
   For access to the new specialised applications, there is a roll-based central authentication and registration via the application RuBen.
   Information on certificates, how to establish access, and user management can be found here:
   a. https://www.pharmnet-bund.de/static/.content/.galleries/downloads/de/anleitung-registrierung.pdf
   b. https://www.pharmnet-bund.de/static/.content/.galleries/downloads/de/anleitung-zertifikat.pdf
   c. https://www.pharmnet-bund.de/static/.content/.galleries/downloads/de/anleitung-benutzer-selbstverwaltung.pdf