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 EXTENSION OF THE TRANSITIONAL PERIODS OF THE EUROPEAN MEDICAL DEVICE REGULATION (MDR) FOR PLACING ON THE MARKET

On March 07, 2023, the Council of the European Union approved the European Commission's legislative proposal to extend the transitional provisions of Article 120 of the MDR.

Initially, the transition period for placing devices on the market with a valid certificate according to the Medical Device Directive (MDD) from a notified body would have expired on May 26, 2024.

The new regulation provides for the following:

Medical devices with a certificate or declaration of conformity, issued between May 26, 2017, and May 26, 2021,

of classes Is, Im, Ir, IIa and IIb non-implantable	of class III and IIb implantable
may be placed on the market	
until 31.12.2028	until 31.12.2027

If the manufacturer

- has put in place a quality management system (QMS) in accordance with Article 10(9) of the MDR no later than 26 May 2024
- has lodged a formal application to a notified body for MDR conformity assessment and has entered into a written agreement with the notified body no later than 26 September 2024.

In addition, the previous conditions of Article 120 continue to apply, i.e. that the devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC and that there are no significant changes in design and intended purpose.

Furthermore, the devices must not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health. The concept of an "unacceptable risk to health and safety" is set out in Articles 94 and 95 of the MDR.

In addition, with the approval of the amendment to Article 120, the sell-off deadline (27 May 2025) for all medical devices still on the market will be deleted. All products that were placed on the market before the end of the transition period can be made further available on the market until the end of shelf life.

Class I medical devices that are not subjected to a higher classification under the MDR may only be placed on the market in conformity with the MDR as of May 27, 2021. However, the class I medical devices placed on the market under MDD/AIMDD certificate of conformity until 26.05.2021 may now be sold without a sell-off deadline.

The presidents of the EU Council and Parliament are expected to formally adopt the above-mentioned legislative proposal on March 15, 2023; it will enter into force shortly thereafter.

2 GUIDANCE DOCUMENTS FOR MEDICAL DEVICE VIGILANCE (MEDDEV 2/12-1 REV. 8 NOT APPLICABLE UNDER MDR)

In February 2023 the Medical Device Coordination Group has published the new document MDCG 2023-3 "Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices".

We would like to draw your attention to a noteworthy footnote in this new document. On page 2, footnote 1 states:

"*Please note that the **MEDDEV 2.12/1 rev. 8, January 2013 was in operation under the Directives** (Directive 93/42/EEC concerning medical devices (MDD) and Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices (AIMDD)) **and is not applicable under the MDR**.***"

Thus, the previously used MEDDEV document "Guidelines on a Medical Devices Vigilance System" has now been officially replaced and declared no longer valid.

3 UPDATE OF BESONDERHEITENLISTE

In January 2023, the texts of the Besonderheitenliste for substances that can trigger hypersensitivity were fully adapted to the Excipients Guideline. This further harmonizes the product information texts of the national and MR/DC procedures. The updated documents as well as the versions with the tracked changes (as of January 16th, 2023) are available on the website of the Federal Institute for Drugs and Medical Devices.

There has been a change for the following excipients:

- Azo colouring agents
- Benzyl alcohol
- Chlorocresol
- Fragrances containing allergens
- Heparin
- Macrogolglycerolricinoleate
- Menthol (incl. menthol-containing essential oils, aromas or essences)
- Parahydroxybenzoates
- Peru balsam
- Organic mercury compounds
- Sesame oil
- Soya oil and Soy lecithine
- Sulphites
- Wheat starch
- Cinnamon and Cinnamaldehyde

For the implementation timeline, we recommend following the EMA guidance on the implementation period for adaptions of the Excipients Guideline. According to this, the MAHs should use the first opportunity to implement the changes; for medicinal products for which no regulatory activity is foreseeable, MAHs should submit a type IB variation within 3 years of the revision date of the relevant excipient.

Furthermore, for registered homeopathic medicinal products, for which no dosage information may be given in the product in formation, adjustments were made to the wording of the Besonderheitenliste due

to the frequent dosage reference in the texts. These can be found in the newly included section "Registrierte homöopathische Arzneimittel".

The full information can be found under the following link on the website of the Federal Institute for Drugs and Medical Devices:
https://www.bfarm.de/DE/Arzneimittel/Arzneimittelinformationen/Besonderheitenliste/_artikel.html

4 INTRODUCTION OF A PHARMNET.BUND MAILBOX AND FURTHER DEVELOPMENT OF THE APPLICATION FOR NOTIFICATION OF THE GRADUATED PLAN OFFICER

In an information event on February 22, 2023, the Federal Institute for Drugs and Medical Devices (BfArM) provided information on the introduction of a PharmNet.Bund mailbox in the course of the Online Access Law (OZG). The effective operation of the mailbox is planned for mid-2023. There will be one mailbox per pharmaceutical company/PNR, whereby access can be managed via the already existing user administration "Ruben". This is relevant, for example, for role assignment in the company or in collaboration with consultants. For the use of the digital mailbox, the company will submit a declaration for digital delivery, which will be archived by the BfArM. The terms of use for the PharmNet.Bund mailbox are currently being created and will be announced shortly.
The mailbox is initially intended for notifications from the BfArM. Companies will be given a period of ten days to download the notifications stored in the mailbox. When downloading for the first time, the recipient must confirm that the download was sucessful and that the downloaded documents are readable. This means that the documents are legally considered to have been delivered. The date of downloading and the name of the corresponding user are stored in the system. If there is no download, the notice will be delivered by postal service in the initial phase.
Furthermore, technical innovations of the PharmNet.Bund application for notifying the graduated plan officer were presented at the information event. An overview of the new functions can be found in the presentation.
The pharmaceutical company will receive information about new or not yet downloaded notices or a possible postal delivery by e-mail.

The presentation slides of the event can be downloaded from the following page:
https://www.bfarm.de/SharedDocs/Downloads/DE/Arzneimittel/Zulassung/ZulRelThemen/eSubmission/info_veranstaltung_pharmnetbund_postfach_ozg_20230222.pdf?__blob=publicationFile

5 CHANGES TO EUDRAVIGILANCE ACCESS AND USER MANAGEMENT

In the course of 2023, EMA will introduce changes to access to EudraVigilance and regarding user management to increase the security of the EudraVigilance system and to improve user management by companies.

Thus, access to EudraVigilance (EVWEB, xEVMPD & EVDAS) will be possible in the future only through **multi-factor authentication (MFA)**. This will be introduced for EVWEB and xEVMPD access from 28/03/2023. For EVDAS access, this will be set up in Q2 2023.

How to set up and manage the MFA can be found at
https://register.ema.europa.eu/identityiq/help/signin.html

In the future, to ensure regular review of user access in the **EMA Account Management Portal** by the registered entity, an organization's QPPV/RP (responsible person) will be required twice a year (March and September) to review the list of users in their organization and their assigned access role. The QPPV/RP will need to actively select whether a user should continue to have access or that their access should be revoked.

This process will start in Q2 2023. There will be an initial demonstration run followed by the first official review three months later. QPPV/RPs then have to complete their review within one month. If the QPPV/RP does not complete the user access review within the one-month timeframe, access will be automatically revoked for all unassessed users and they will need to reapply through the **EMA Account Management Portal** if they still need it.
The QPPV/RP may also delegate the periodic review to a Trusted Deputy.

Furthermore, in the future you will need to agree to the **updated EudraVigilance Terms and Conditions** (check box) to access the EudraVigilance systems. This will be implemented in March 2023. Users are requested to read the updated terms and conditions carefully.