Dear Sir or Madam,

Today we would like to inform you about the following topics:

Best regards

The DiaMed team

1 GUIDELINE ON MANUFACTURE OF THE FINISHED DOSAGE FORM

The *Guideline on manufacture of the finished dosage form* (EMA/CHMP/QWP/245074/2015) will replace the current *Note for Guidance on Manufacture of the Finished Dosage Form* (CPMP/QWP/486/95) on 14th February 2018. The new guideline provides clarification on the type and level of information to be included in CTD module 3.2.P.3.
This guideline is applicable to new marketing authorisations but also to variations for authorised products proposing changes to the manufacturing process.

The manufacturing description should provide a link between the pharmaceutical development, the proposed control strategy and process validation.
In the annex, the guideline presents an exemplary manufacturing description (module 3.2.P.3.3) for a traditional (minimal) and an enhanced development approach.

Compared to the previous note for guidance, the new guideline requires a much more detailed description of the manufacturing process in module 3.2.P.3.
A hitherto very commonly used note in marketing authorisation dossiers, which is cited from the current note for guidance, that "*it is in the interest of both the applicant and the regulatory authority to avoid unnecessary applications for variations*" and that "*very detailed description of the manufacturing process, apparatus and in-process controls should therefore be avoided*" will no longer be accepted in the future.

2 SAFETY FEATURES/PZN FOR SAMPLES

As samples of finished products to be supplied to physicians according to section 47 (3) of the German Medicinal Products Act (AMG) must bear safety features from February 2019, they need a PZN (Pharmazentralnummer). For packs from the regular production dedicated to sample packs, the already registered PZN can be used. Packs which are exclusively used as samples must bear an individual PZN. Such PZN can now be applied for at IFA GmbH. The new PZN will however not be published before 01.02.2018.

From February 2019, any sample which is supplied to a physician, the pharmaceutical entrepreneur must deactivate the serial number, which has previously been generated during the packaging process and which has been uploaded to the repositories system of the pharmaceutical industry.

3 PACKAGING ACT – ESSENTIALS FOR PHARMACEUTICAL MANUFACTURERS

Based on the current **Packaging Ordinance**, participation in one or more take-back systems is compulsory as far as sales packaging is concerned. These typically appear at the private end-user (household and comparable collection points) and can be collected and recycled via the "yellow bag", the "yellow bin", glass containers or waste paper bins and containers.

On the 1st January 2019, this ordinance will be replaced by the new **Packaging Act**. The act requires the establishment of a "central office" as a "registration and standardization center", financed by the systems and owners of industry specific solutions. From 2019 onwards, manufacturers (including those of medicinal products) are required to register at the central department before placing packages obliged to system participation on the market (see section 9). From summer/autumn 2018, the registration is expected to be possible via electronic data processing system. For the registration, the following information must be provided:

- Name, address and contact data of the manufacturer (in particular postal code and city, street and house number, country, telephone and fax number as well as e-mail address),
- Notification of a natural authorized representative,

- National identification number of the manufacturer, including the manufacturer's European or national tax number,
- Brand names under which the manufacturer places his packages obliged to system participation on the market,
- Declaration that the manufacturer performs his take-back obligations by participating in one or more systems or by one or more industry specific solutions,
- Declaration that the claims made are truthful.

In addition to the registration, in the future, manufacturers will also have to immediately submit information which is currently being provided in the course of a system participation also to the central office (§ 10 Data reporting).
Thereby, the following minimum information must be provided:

- Registration number,
- Type of material and mass of the packaging involved,
- Name of the applicable participation system,
- Period of time.

Moreover, from 2019 onwards, the declaration of completeness (§ 11), which is already to be submitted annually by some manufacturers according to the Packaging Regulation, must be submitted to the central office, together with the corresponding inspection reports.

Any manufacturer, who does not participate, participates incompletely or incorrectly in a system, commits an offence and must reckon with a fine of 200,000 €. Even manufacturers who do not register, register incorrectly, incompletely or not in time, commit an offence and may be liable to a fine of 100,000 €. Violation of the Packaging Act is not prosecuted by the central office but rather by the competent authority according to Land law.