Dear Sir or Madam,

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

1 LAW TO REDUCE SUPPLY SHORTAGES FOR PATENT-FREE MEDICINAL PRODUCTS AND TO IMPROVE THE SUPPLY OF MEDICINAL PRODUCTS FOR CHILDREN [IN GERMAN: ARZNEIMITTEL-LIEFERENGPASSBEKÄMPFUNGS- UND VERSORGUNGSVERBESSERUNGSGESETZ (ALBVVG)] 2

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

Best regards

The DiaMed Team

1 LAW TO REDUCE SUPPLY SHORTAGES FOR PATENT-FREE MEDICINAL PRODUCTS AND TO IMPROVE THE SUPPLY OF MEDICINAL PRODUCTS FOR CHILDREN [IN GERMAN: ARZNEIMITTEL-LIEFERENGPASSBEKÄMPFUNGS- UND VERSORGUNGSVERBESSERUNGSGESETZ (ALBVVG)]

On 26 July 2023, the law to reduce supply shortages for patent-free medicinal products and to improve the supply of medicinal products for children [in German: **Arzneimittel-Lieferengpassbekämpfungs- und Versorgungsverbesserungsgesetz (ALBVVG)**] was published in the Federal Law Gazette and has been in force in large parts since 27 July 2023.

This law is intended to counteract the supply shortages that have increasingly occurred in the recent past, especially for medicinal products for children.
The changes, which are of importance for manufacturers, pharmaceutical entrepreneurs and pharmaceutical wholesalers, mainly concern amendments to the AMG (German Drug Law), SGB V (German Social Code Book V) and the HWG (German law on the advertising of medicinal products) and make the following regulatory measures necessary or ease the previous regulatory requirements as follows:

Paediatric Medicines List

A central component of the ALBVVG is the so-called paediatric drug list, which is to be compiled by the BfArM similar to the general finished medicinal product list (see below) after consultation of the (extended) advisory board and published on the BfArM homepage and in the Federal Gazette. and in the Federal Gazette.

This is a list of **marketable medicinal products, taking into account age-appropriate dosage forms and strengths, which are particularly necessary for the treatment of children up to the age of twelve.**

On the basis of this list, which is regularly updated, the **following amended regulations result for**:

- **Full-service pharmaceutical wholesalers**: Stockpiling for medicinal products on this list for a consumption period of four weeks (§ 52b (2) sentence 2 AMG), instead of generally two weeks.

- **Pharmaceutical entrepreneurs: Price increase options** have been introduced for the **medicinal products on this list of paediatric medicinal products** (inter alia, through the abolition of reference prices and the prohibition of rebate contracts), which can be made effective for the first time **from 1 February 2024**. Details can be found in the amendments to the SGB V (§§ 35, 35a, 130) published in the Federal Gazette.

Reporting obligations to avert or alleviate an imminent or existing supply-relevant shortage of a medicinal product - early warning system

At the request of the BfArM, pharmaceutical companies, pharmaceutical wholesalers and **manufacturers** must now also electronically report data to avert or alleviate an imminent or existing supply-relevant shortage of a medicinal product.

In addition to the previous obligation to transmit data on available stocks, on sales volume as well as information on impending supply shortages and on production, there is now also an obligation to transmit data on production, **including the manufacturing site of the active substances actually used in the manufacture of the medicinal product.**

The BfArM specifies **the procedure and format requirements for electronic transmission of the data** and publishes them on its website.

The **supply shortages reported** and a **current list of supply shortages for medicinal products with supply-relevant and supply-critical active substances** are also published on the BfArM website.

Furthermore, a so-called early warning system for the detection of impending supply-relevant supply shortages is planned, which is to be set up at the BfArM. The Federal Ministry will organise this by means of a legal directive with the approval of the Bundesrat. The present Amendment Act provides the legal basis for this.

Extended obligation for pharmaceutical companies to report data for the list of finished medicinal products

As before, the BfArM, after hearing the (extended) advisory board, compiles a list of finished medicinal products that is required as a basis for regular data transmission (by pharmaceutical entrepreneurs and at the request of pharmaceutical wholesalers) for the assessment of the supply situation and publishes it on its website.

Up to now, pharmaceutical entrepreneurs have been obliged to electronically transmit to the BfArM data on available stocks, sales volume, production and **now also production, including the manufacturing site of the active substances actually used in the manufacture of the medicinal product**, for the **medicinal products named in the list of finished medicinal products**.

Also new is the exact designation of the "regular" transmission **as a maximum frequency of eight weeks**.

Price increase options are introduced for the medicinal products on this list of finished medicinal products, which can be made effective for the first time **from 1 February 2024**. Instruments include an increase in the reference price or an increase in the price moratorium if there are too few suppliers for supply-critical medicinal products. Details can be found in the amendments to the SGB V published in the Federal Gazette (§§ 35, 35a, 130).

Extended stockholding obligation for off-patent medicines in rebate contracts

Pharmaceutical companies must ensure a continuous and supply-oriented stockpiling of **medicinal products in rebate contracts**, which corresponds to the average quantity of these medicinal products to be dispensed within **a period of six months** from the conclusion of the agreement.

Labelling (§§ 10, 1a, 11 ,1c AMG)

In case of an imminent or existing supply shortage, medicinal products may be placed on the market with **labelling** (folding box and package leaflet) in **a language other than German** upon application by the marketing authorisation holder to the competent authority. The BfArM is then responsible for ensuring consumer access to the required product information.

Amendment of the warning sentence in advertisement of medicinal products

Amendment of the mandatory text according to the German law on the advertising of medicinal products (Heilmittelwerbegesetz; § 4 (3) sentence 1 HWG).

from:

„Zu Risiken und Nebenwirkungen lesen Sie die Packungsbeilage und fragen Sie Ihren Arzt oder Apotheker“

to:

„Zu Risiken und Nebenwirkungen lesen Sie die Packungsbeilage und fragen Sie Ihre **Ärztin, Ihren Arzt oder in Ihrer Apotheke**.“

The mandatory text amendment will come into force with a transitional period from 27 December 2023.