Dear Sir or Madam,

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

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

The DiaMed Team

1 ORDINANCE AMENDING THE ANALGESICS WARNING NOTICE ORDINANCE (ANALGETIKAWARNHV) PUBLISHED IN THE FEDERAL LAW GAZETTE ON 25.10.2022

The ordinance amending the Analgesics Warning Notice Ordinance (AnalgetikaWarnHV) has been published in the Federal Law Gazette on 25.10.2022 and has come into force on 1 November 2022.

The ordinance is to be applied to approved medicinal products intended for oral or rectal use that are not subject to prescription according to Section 48 of the German Medicinal Products Act (AMG) and contain the active ingredients acetylsalicylic acid, dexibuprofen, diclofenac, ibuprofen, naproxen, paracetamol, phenazone or propyphenazone, standard approvals as well as prescription medicinal products and officinal formula medicinal products.

The submitted amending regulation **extends** the list of relevant active substances to include **dexibuprofen**, which was recently transferred to self-medication. Furthermore, the scope of the ordinance is extended to **include previously non-covered medicinal products** that contain the above-mentioned active ingredients and are not covered by the exemption regulations (drugs that are intended exclusively for platelet aggregation inhibition or are clinical trial drugs are excluded).

The **additionally covered medicinal products are, in particular, combination preparations which, according to the marketing authorization, have other indications in addition to pain and fever**, and medicinal products with **only one active ingredient** which have **other** approved indications than pain or fever.

Until now, all medicinal products covered by this regulation had a uniformly worded warning. With the amendment, there are two additional, differently worded warnings. Depending on the affiliation to a defined category of medicinal products, a specific wording of the warning is assigned in each case:

Authorized medicinal products or medicinal products on the basis of a standard authorization that are intended **exclusively** for the **treatment of mild to moderately severe headache or fever** may only be marketed if the following warning is affixed to the outer packaging and containers:

"Bei Schmerzen und Fieber ohne ärztlichen Rat nicht länger anwenden als in der Packungsbeilage vorgegeben!“.

There is no need for action for these medicinal products. The previously used warning remains in place.

If these medicinal products are **also intended exclusively or <u>also for indications other than</u> the treatment of mild to moderate pain or fever,** they may be placed on the market only if the following (new) warning is affixed to the outer wrappings and containers:

"Ohne ärztlichen Rat nicht länger anwenden als in der Packungsbeilage vorgegeben!"

Less relevant for the pharmaceutical entrepreneur, but also affected by the amendment and therefore mentioned here for the sake of completeness, is the newly applicable warning for medicinal products manufactured in pharmacies containing one or more of the above-mentioned active substances:

"Ohne ärztlichen Rat nicht länger anwenden als von der Apothekerin oder vom Apotheker empfohlen!".

These mandatory warnings shall be permanently marked in clearly legible characters on the front of the outer container or, if there is only one container, on the container.

Transition deadlines
Authorized medicinal products and medicinal products on the basis of a standard marketing authorization **to which this Ordinance in its version applicable until October 31, 2022 did not yet**

apply may still be placed on the market without a warning by the pharmaceutical entrepreneur until October 31, 2024 within the meaning of Section 4 (17) AMG.
Wholesalers and pharmacies may continue to market these drugs after this date.

Medicinal products manufactured in pharmacies may still be placed on the market without a warning until October 31, 2023.

The amendment regulation has come into force on November 1, 2022. It can be accessed here.