

Foreword

As of 01.02.2024, the IFA database was expanded to include the requirements of the Arzneimittel-Lieferengpassbekämpfung- und Versorgungsverbesserungsgesetz (ALBVG). The notification situation for the new four data fields for the elimination of supply bottlenecks suggests that there is still a need for information here. We have therefore explained the characteristics of these fields for you in more detail in this information sheet.

The new data fields are relevant to settle billing of your products. We therefore urge you to check this product data, complete any missing notifications and correct any incorrect information.

The GKV-Spitzenverband (SHI Head Association) would like to point out that it is not technically possible to process a first-time data notification that includes several of the mentioned data fields.

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1. Arzneimittel mit altersgerechter Darreichungsform oder Wirkstärke für Kinder – Medicinal products with age-appropriate pharmaceutical form or strength for children

For medicinal products, it must be stated whether a fictitious fixed reference price applies to them in accordance with Section 35 (1a) clause 4 SGB V.

Value 1 must be used for medicinal products, which are governed by a fictitious fixed reference price and for which the base price of the price moratorium is to be determined in accordance with Section 130a (3d) clause 1 SGB V.

The fictitious fixed reference prices are published in the Bundesanzeiger (Federal Gazette). A list of medicinal products with fictitious reference prices is published on the website of the GKV-Spitzenverband (SHI Head Association).

Values	Definition
0	no
1	yes, medicinal product with fictitious fixed reference price (fictitious reference price on APU basis + 50 % = base price)

2. Arzneimittel mit aufgehobenem Festbetrag – Medicinal products with repealed reference price

For medicinal products, it must be stated whether the reference price has been repealed for them in accordance with Section 35 (5) clause 8 SGB V.

Value 1 must be used for medicinal products, whose fixed reference price has been repealed according to Section 35 (5) clause 8 SGB V. For them the base price of the price moratorium is to be determined in accordance with Section 130a (3d) clause 2 SGB V.

The repealed reference prices in accordance with Section 35 (5) clause 8 SGB V are published in the Bundesanzeiger (Federal Gazette). A list of medicinal products with repealed reference prices in

accordance with Section 35 (5) clause 8 SGB V is published on the website of the GKV-Spitzenverband (SHI Head Association).

Values	Definition
0	no
1	yes, medicinal product with repealed reference price (last valid reference price on APU basis + 50 % = new base price)

3. Arzneimittel zur Behandlung von Kindern nach BfArM-Liste – Medicinal products for the treatment of children to BfArM list

Information on the reference price must be stated for medicinal products on the *List of essential paediatric medicines pursuant to Section 35 (5a) German Social Code Book*. The list contains medicinal products that are essential for the treatment of children due to their authorised pharmaceutical forms and strengths.

Value 1 must be used for medicinal products whose reference price has been repealed in accordance with Section 35 (5a) clause 4 or 5 SGB V. For them, the base price of the price moratorium is determined according to Section 130a (3d) clause 3 SGB V.

The repealed reference prices in accordance with Section 35 (5a) clause 4 SGB V are published in the *Bundesanzeiger* (Federal Gazette). A list of medicinal products with repealed reference prices in accordance with Section 35 (5a) clause 4 SGB V is published on the website of the GKV-Spitzenverband (SHI Head Association).

Value 2 must be used for medicinal products on the lists specified in Section 35 (5a) clause 2 or 3 SGB V for which no reference price previously applied. For them, the base price of the price moratorium is determined according to Section 130a (3d) clause 4 SGB V.

The list of BfArM (Federal Institute for Drugs and Medical Devices) is published in the Federal Gazette and made publicly available on the BfArM website.

Values	Definition
0	no
1	yes, reference price was repealed (last valid reference price on APU basis + 50 % = new base price)
2	yes, previously no reference price (current base price + 50 % = new base price)

4. Arzneimittel mit versorgungskritischem Wirkstoff nach BfArM-Liste – Medicinal products with a supply-critical active substance according to BfArM list

Information on the reference price must be provided for medicinal products with a supply-critical active substance that are subject to a provision of the Federal Ministry of Health in accordance with Section 35 (5b) clause 4 SGB V.

Value 1 must be stated to medicinal products whose reference price has been increased in accordance with Section 35 (5b) clause 5 SGB V.

The determination to increase reference prices is published in the *Bundesanzeiger* (Federal Gazette).

Value 2 must be stated to medicinal products for which no reference price previously applied according to Section 35 (5b) clause 4. For them, the base price of the price moratorium is determined according to Section 130a (3d) clause 5 SGB V.

The determination of the Federal Ministry of Health is published in the *Bundesanzeiger* (Federal Gazette).

Values	Definition
0	no
1	yes, reference price was increased (last valid reference price on APU basis + 50 % = new reference price)
2	yes, previously no reference price (current base price + 50 % = new base price)