Extension of the IFA database 01 Feb. 2024: Information for supplier of medicinal products

IFA
INFORMATION

Foreword

In this information you will find all relevant information concerning additions and changes of data fields in the IFA database relevant for medicinal products that will become valid from 01 February 2024.

The following applies to all innovations: IFA GmbH already has entered data for your medicinal products as a suggestion for the notification of the new values and data fields, where possible. However, this is not possible for all medicinal products, with the result that in some cases no entry has been made.

We therefore ask you kindly to check your product data in the attached EAD file for corrections and additions according to the instructions described in each case and to enter the correct information. Please note: PZNs registered as *marketing ceased (AV – außer Vertrieb)* are also still published in the IFA information services and are therefore affected by the updates.

Please find more detailed information in our IFA Guidelines for Notifying Product and Address data

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1. Value range extensions

Value range extensions include additions and changes to the value of already existing data fields. Updates are marked blue to support your orientation.

1.1 Arzneimittel mit Erstattungsbetrag § 130b SGB V – Medicinal products with reimbursement amount according to Section 130b of German Social Code Book V (SGB V)

For medicinal products, it must be stated whether a reimbursement amount applies to them in accordance with Section 130b of German Social Code Book V (SGB V). Value 3 has been added.

Reserve antibiotics in accordance with Section 130b (3b) clause 1 SGB V must be notified with the value 3.

If the values 1, 2 or 3 are notified, the *APU gem. § 78 Abs. 3a) Satz 1 AMG* must also be stated.

Values	Definition
0	no, reimbursement amount does not apply
1	yes, product is a medicinal product for which a reimbursement amount applies (Section 130b (1) or (3) or (3a) or (4) SGB V)
2	yes, product is a medicinal product, for which a reimbursement amount continues to apply as the maximum permissible selling price (Section 130b (8a) SGB V)
3	yes, product is a reserve antibiotic (Section 130b (3b) SGB V)

2. New data fields

New data fields will be published in the IFA database for the first time.

2.1 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 fictious 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 fictious 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.

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

2.2 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

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

2.3 Arzneimittel zur Behandlung von Kindern nach BfArM-Liste – Medicinal products for the treatment of children according 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 subsection 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.

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.

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)

2.4 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.

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

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)

2.5 Datum, ab dem der APU § 78 Abs. 3a Satz 1 AMG gilt – Date from which the APU Section 78 (3a) clause 1 of the German Medicinal Products Act (AMG) applies

For medicinal products for which a reimbursement amount has been agreed or set in accordance with Section 130b SGB V, please state the date from which this price applies in accordance with Section 130b (3a) SGB V.

This information is required for the correct billing of medicinal products that can be prescribed at the expense of the statutory health insurance and is based on Section 131 (4) clause 3 no. 2 SGB V.

Acceptable values	DD.MM.YYYY (D = day, M = month, Y = year)
Example	07.01.2024

2.6 Datum, ab dem die Ablösung des Abschlags § 130a SGB V gilt – Date from which the overruled discount Section 130a SGB V applies

For medicinal products for which the discount according to Section 130a SGB V has been overruled, please state the date from which the overrule applies.

This information is required for the correct billing of medicinal products that can be prescribed at the expense of the statutory health insurance and is based on Section 131 (4) clause 3 no. 2 SGB V.

Acceptable values	DD.MM.YYYY (D = day, M = month, Y = year)
Example	07.01.2024