Extension of the IFA database 01 Dec. 2022: Information for supplier of medicinal products

INFORMATION

Foreword

In this information you will find all relevant information concerning additions, updates and deletions of data fields in the IFA database relevant for medicinal products that will become valid from 01 December 2022. Please check your products' data and submit additions and corrections. Note: PZNs registered as marketing ceased (AV- außer Vertrieb) are still issued in the IFA information services and therefore affected by the updates as well.

Please find more detailed information in our IFA Guidelines for Notifying Product and Address data. Please submit additions and changes to ead@ifaffm.de exclusively.

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1. Value area extensions

Value area 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 indicated whether a reimbursement amount applies to them in accordance with Section 130b of German Social Code Book V (SGB V). Value 0 and 1 have been specified and value 2 has been added.

IFA GmbH did not do any data entries for this field. Please check your products especially for value 2.

Values	Definition
0	no, reimbursement amount does not apply
1	yes, ~~medicinal products with reimbursement amount medicines with reimbursement amount in accordance with Section 130b of German Social Code Book V (SGB V)~~ product is a medicinal product for which a reimbursement amount applies (Section 1 (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)

2. New data fields

A few new data fields will be published in the IFA Database for the first time. IFA already added your products' data for the new data fields, if suitable. Please check the data submitted by EAD file and possibly add or correct data, if necessary.

2.1 Preisstrukturmodell – Pricing Structure Model

For medicinal products for which their reimbursement amount continues to apply as the maximum permissible selling price (see Arzneimittel mit Erstattungsbetrag § 130b SGB V – Medicinal products with reimbursement amount according to Section 130b SGB V, value 2) additional information concerning the *Pricing Structure Model* must be submitted. More detailed information can be found in the framework agreement according to Section 130b (9) SGB V.

For Pharmacy only (but not prescription only) medicinal products and products which are no medicinal products IFA GmbH populated this data field with the value 0 = *not affected*. We kindly ask you to check your products' data in the attached EAD file in relation to the advised aspects listed below, because IFA GmbH did not enter any data for prescription only medicinal products.

- Medicinal products that are registered with value 0 = *no* in the data field Arzneimittel mit Erstattungsbetrag § 130b SGB V – Medicinal products with reimbursement amount according to Section 130b SGB V need to be registered with the value 0 = *not affected* in the data field *Preisstrukturmodell – Pricing Structure Model.*
- According to Section 130b (1), (3), (3a) and (4) SGB V the Pricing Structure Model needs not be notified for medicinal products for which a reimbursement amount is negotiated or defined.
- Medicinal products that have to be notified with value 2 in the data field Arzneimittel mit Erstattungsbetrag § 130b SGB V – Medicinal products with reimbursement amount according to Section 130b SGB V need to be notified with the value 1, 2 or 3 of the following table:

Values	Definition
0	not affected
1	Linear Pricing Structure Model (*linear pricing*)
2	Flat Pricing Structure Model (*flat pricing*)
3	Complex Pricing Structure Model

2.2 Multi Market Pack – Multi market pack

Medical products subject to mandatory verification that are distributed in Germany are bound by the coding rules applicable in Germany and must bear a PPN or NTIN. However, if the medicinal product is a multi-market pack that is also distributed in other European markets, verification can be carried out using a different product code (e.g. GTIN).

Please check your medicinal products which are subject to mandatory verification in relation to the advised aspects listed below and add the deviating product code when needed.

- For medicinal products which have been notified as multi market packs, IFA GmbH preassigned the value 1 = *yes*, insofar IFA GmbH has been informed thereof.
- For all other products value 0 = *no* has been preassigned.

Values	Definition
0	no
1	yes

2.3 Eingangsnummer (ENR)-Nachmeldung – Processing number (ENR) supplementary notification

This data field is used to indicate if the processing number (ENR) of the marketing authorisation documents is not yet available. As soon as the number is available, it must be submitted immediately.

IFA GmbH has already populated this new data field for you. To check the current entries please request a current product range file. To change the value please use IFA-Auftragstabelle C – Product Changes and attach the marketing authorisation documents or excerpts from the Medicinal Products Information System AMIce.

For medicinal products which have proven their marketing authorisation but do not bear an ENR IFA GmbH preassigned the value 1 = *yes, ENR will be registered in a supplementary notification*.

- For medicinal products which already have an ENR entered and for products which are no medicinal products IFA GmbH preassigned the value 0 = *no* in the sense of *ENR is not available yet* or *is not necessary* respectively.

Values	Definition
0	no
1	yes, ENR will be submitted in a subsequent notification

3. Renaming of current data fields

Current data fields have been renamed due to law changes or necessary specifications. As no need for changes is expected for the affected products, the corresponding data fields are not included in the EAD file.

- **§ 47 Abs. 1c AMG – Tierarzneimittel-Abgabemengen-Register – Section 47 (1c) of the German Medicinal Product Act – Delivery quantities register for veterinary medicinal products**:
  The data field has been renamed to: *Tierarzneimittel-Abgabemengen-Register (TAR) – Sales quantities register for veterinary medicinal products (TAR)*. The legal reference changed from Section 47 (1c) AMG to *Section 45 (6) TAMG*.

- **BfArM-Eingangs-Nr. der Zulassungsunterlagen – BfArM processing number (ENR) of the marketing authorisation documents**:
  The data field has been renamed to: *Eingangsnummer (ENR) der Zulassungsunterlagen – Processing number (ENR) of the marketing authorisation documents*.
  For medicinal products the processing number (ENR) published in Medicinal Products Information System AMIce hosted by BfArM has to be submitted. This applies for market authorisation by BfArM, PEI and EMA.