IFA GmbH

Guidelines for Notifying Product and Address Data

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Foreword

The information notified by suppliers and pharmaceutical companies to *Informationsstelle für Arzneispezialitäten – IFA GmbH (IFA)* represents the necessary and practical prerequisite for all participants in the health care sector, e.g. physicians, pharmacies, pharmaceutical wholesalers and health insurance funds, to be able to fulfil their tasks in the market in accordance with legal requirements. It is in the immediate interest of suppliers and pharmaceutical companies, if trade companies, service providers and cost payors trade, use or invoice the items safely and in a legally compliant manner. Among others, this meets notifying obligations, specifically according to Section 131 (4) of German Social Code Book V (SGB V).

Therefore, IFA requests in the interest of the data users – the customers of IFA and the suppliers – that data be notified completely, correctly and in a timely manner.

The legal regulations (including the German Medicinal Products Act (AMG); Medical Devices Implementing Act; German Food, Commodities and Feedstuffs Act; German Social Code Book and the corresponding ordinances and standards) and the logistical and market-relevant necessities require that comprehensive information be incorporated in the IFA Database and continuously updated. This also applies to information whose purpose may not be obvious at first glance. These guidelines explain the data to be notified and the notifying procedure and are meant to make supplier notifications easier. If you have any questions, please do not hesitate to contact the IFA staff.

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1. Datenfelder der IFA-Datenbank – Data fields of the IFA database

1.1 Artikeldaten – Product data

This chapter describes each data field and the acceptable values to be taken into account when placing orders.

Data fields with product-identifying characteristics may no longer be changed for published PZN (Pharmazentralnummer). These are:

- Produktbezeichnung – 26-digit product name;
- Darreichungsform – Pharmaceutical form;
- Packungsgröße (Menge und Einheit) – Packaging size (quantity and unit)
- Artikeltyp – Product type
- Information Arzneimittel – Information *medicinal product*

Due to in-depth quality assurance, some data fields can be changed exclusively with *Auftragstabelle C – Änderungen von Artikeldaten (Order Table for product changes)*. The following descriptions show which data fields can also be changed in *IFA portal* or via *EAD*.

1.1.1 Artikelgrunddaten – Basic product data

Anbieter – Supplier

Suppliers within the meaning of IFA are companies that offer and market products typically sold in pharmacies in the Federal Republic of Germany. The supplier may be the manufacturer, the distributor, a co-distributor, a local representative, an importer or retailer. For medicinal products, this can be the pharmaceutical entrepreneur specifically or the holder of a Community authorisation (MAH – *marketing authorisation holder*). The supplier is the contractual partner of IFA with regard to the supplier agreement.

PZN (Pharmazentralnummer)

Each product in the IFA Database receives a Pharmazentralnummer **(**PZN). The PZN is a reversibly unambiguous identification key in the German market for medicinal products, medical devices and other health products (merchandise typically sold in pharmacies). It is used for streamlined, internal and external product-related communication (including supply chain, billing) of trading partners and organizations active in the health care sector.

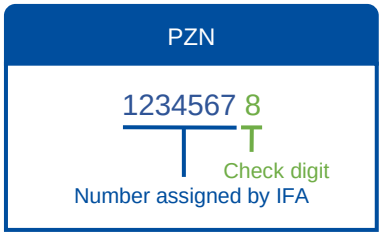

Figure 1: Structure of the PZN

At the same time, the PZN is the standardised national identifier according to Section 300 of German Social Code Book (SGB V), which pharmaceutical companies are required to apply to the outer packaging of medicinal products' packs according to Section 131 of German Social Code Book V (SGB V) For this reason and due to its versatile use, the PZN is of central significance in the pharmaceutical market and in the health care system.

Detailed information on the PZN and coding can be found on the website under IFA information on PZN.

PPN – Pharmacy Product Number

As an issuing agency (internationally recognised) in accordance with ISO/IEC standards, IFA issues the PPN. The PPN enables the PZN and any other national product number to be used reversibly uniquely worldwide.

IFA generates the PPN automatically when the PZN is recorded.

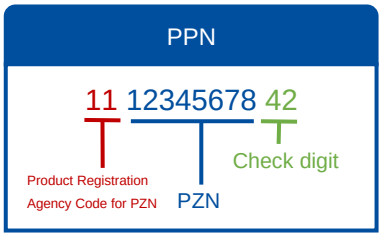

Figure 2: Structure of the PPN

The 12-digit PPN starts with the 2-digit Product Registration Agency Code 11, followed by the 8-digit PZN and a 2-digit check digit. The check digit safeguards the PPN against faulty entries or data transmissions.

As issuing agency, IFA assigns the Product Registration Agency Code (PRA Code) for each national number system in the pharmaceutical sector. With the PRA code as a prefix, each national product number is converted to the internationally unique product number (PPN). The standardised data identifier 9N, assigned by the ANSI MH10 Maintenance Committee, identifies the PPN in any data carrier, such as the Data Matrix Code.

For detailed information on the PPN, please visit the IFA Coding System section on our website.

UDI-DI gemäß MDR – UDI-DI according to MDR

If available, a PPN can be entered into this data field as the UDI-DI. If a UDI-DI was not assigned by IFA, a code by another issuing agency can be entered.

With Regulation (EU) No. 2017/745 on medical devices (Medical Device Regulation – MDR) and Regulation (EU) No. 2017/746 on *in-vitro* diagnostics (IVDR), the labelling of medical devices with a unique product identification (Unique Device Identification – UDI) becomes mandatory. This also applies to products not distributed in Germany. According to these regulations, the UDI-DI (Device Identifier – DI) is a numeric or alphanumeric code for identifying the product and the manufacturer and is therefore a component of a unique identifier that must be assigned to the product itself or its packaging.

With the Commission Implementing Decision of 6 June 2019, the IFA was designated by the Commission as the issuing agency for the UDI-DI. As a result, a Pharmacy Product Number (PPN) coded on the pack in accordance with the IFA Coding System represents an MDR-compliant UDI-DI. Each binding PZN assignment is automatically associated with the assignment of a binding PPN that can be used for registration in the EU Commission's medical device database EUDAMED. A notification to IFA does not eliminate the obligation to register packs with EUDAMED.

Detailed information on the UDI-compliant use of the IFA Coding System is provided by the UDI Specification UDI Use of the IFA Coding System for Medical Devices.

Acceptable values	120-character alphanumeric data field
Changing via IFA portal	is possible
Changing via EAD file	is possible

Produktbezeichnung/Produktname – 26-digit product name/product name

Each product is labelled with a 26-digit product name and a product name.

The 26-digit product name corresponds to the product name and is assigned with a maximum of 26 characters including spaces. Only capital letters without special characters and umlaut characters are represented. These restrictions are required due to certain application programs, specifically in the medical field. If necessary, abbreviations are made by IFA based on harmonisation and readability criteria.

In addition, each product is provided with a product name with 50 characters including spaces. Uppercase and lowercase, umlaut and "ß" characters are permitted. It must be indicated in its complete form and without abbreviations, if possible, while preserving the given uppercase and lowercase spelling (for medicinal products according to Section 1 of the summary of product characteristics).

For medicinal products, in principle, the 26-digit product name resp. product name corresponds to Section 1 of the summary of product characteristics or the package insert. The sequence of the designation components must also match the summary of product characteristics. Supplementary characteristics from the summary of product characteristics can be added after the designation, if this serves the safe identification and use of the product (e.g. application aid).

For medical devices and other pharmacy-typical products, the 26-digit product name resp. product name is based on the product information. If necessary, additional distinguishing characteristics, such as colour, size or texture, may be indicated to differentiate the product from other products. The sequence of the elements may vary, e.g. brand or company name plus descriptive characteristics. In principle, the elements included in the product name should appear in the same sequence in the 26-digit product name. User systems can use different search algorithms.

Acceptable values	26- or 50-character data field
Unacceptable characters	Semicolon, comma, special characters (e. g. @, €, ©)
Changing via IFA portal	is not possible
Changing via EAD file	is not possible
Special characteristic	The *26-digit product name* is a characteristic that identifies the product and can generally no longer be changed for published PZNs.

Darreichungsform – Pharmaceutical form

The pharmaceutical form is the pharmaceutical and technological preparation in which a pharmaceutical-like product is dispensed (e.g. tablets, drops, ointment). For the possible pharmaceutical forms, please consult Richtlinien zu IFA-Darreichungsformen (Guidelines on IFA Pharmaceutical Forms (German)).

- **Arzneimittel (medicinal products)**: According to an agreement of the associations of the pharmaceutical industry and the GKV-Spitzenverband (SHI Head Association), the information in Section 3 of the summary of product characteristics is decisive for the notifications of the pharmaceutical companies according to Section 131 (4) of German Social Code Book V (SGB V).
- **Sonstige apothekenübliche Artikel (other pharmacy-typical products)**: The pharmaceutical form should correspond to the information in the product information.

Acceptable values	3-character data field (spreadsheet *Darreichungsformen & Verpackung (pharmaceutical forms & packaging)*)
Changing via IFA portal	is not possible
Changing via EAD file	is not possible
Special characteristic	Product-identifying characteristic, can generally no longer be changed for published PZNs.

Packungsgröße (Menge und Einheit) – Packaging size (quantity and unit)

The packaging size is notified in terms of quantity and unit. Acceptable units include:

- Kilogram [KG]
- Gram [G]
- Milligram [MG]
- Microgram [UG]
- Litre [L]
- Millilitre [ML]
- Metre [M]
- Centimetre [CM]
- Pack [P]
- Piece [ST]
- Bottle [FL]

The size of the unit to which the PZN refers must be specified – not the size of a higher-level shipping or packaging unit.

Acceptable values	7-character data field for the quantity + 2-character data field for the consumption unit
Example	100 ML, 25 ST, 145 G, 2 FL, 1 P
Changing via IFA Portal	is not possible
Changing via EAD file	is not possible
Special characteristic	Product-identifying characteristic, can generally no longer be changed for published PZNs.

Artikeltyp – Product type

The product type distinguishes products with otherwise identical information in the data fields “Produktbezeichnung” (26-digit product name), “Packungsgröße (Menge und Einheit)” (Packaging size (quantity and unit)), “Darreichungsform” (pharmaceutical form), “Information Arzneimittel” (Information *medicinal product*) and “Anbieternummer” (supplier number). The following item types can be indicated:

- **Standard**: This product type represents the standard and must be indicated, if the product can be distributed via the distribution channels of pharmaceutical wholesalers, community pharmacies and clinics and if the product is not distributed exclusively via hospitals.
- **Klinikpackung (clinic pack)**: This item type must be indicated for items that are exclusively distributed to hospitals. Furthermore, this product type can be selected if e.g. different PZNs are to be used for hospital merchandise than for pharmacy/wholesale merchandise for technical reasons. Clinical merchandise, specifically medicinal products, should be externally labelled as such.
- **Klinikbaustein (clinic pack component)**: This product type must be indicated, if an product represents a unit (a component) of a clinic pack and is neither sold individually nor bundled via the pharmaceutical wholesaler/community pharmacy. A clinic pack component is defined as the smallest unit of a clinic pack. When registering a clinic pack component, the product-identifying characteristics and the PZN of the associated clinic pack must be notified. 26-digit product name, pharmaceutical form and the information *medicinal product* must be identical to the clinic pack. If the clinic pack is changed, the clinic pack component must also be updated (e.g. product is taken out of distribution, is no longer marketable or deleted).
- **Pandemieartikel (pandemic products)**: This product type must be indicated if the product is used in the event of a pandemic (mass occurrence of a disease across countries and/or continents), mainly in connection with official recommendations or measures. Items that are offered in a pandemic situation but are usually distributed by pharmaceutical wholesalers or pharmacies should be labelled with the *Standard* item type. The order for a first publication of pandemic products can be placed by a pharmaceutical company or by the agencies of the federal states.
- **Schüttware (bulk product)**: This product type must be indicated if the goods are exclusively packed in large volumes (so-called canned goods), which are not intended for end consumers but for the production of patient-specific secondary blisters.
- **Ärztemuster gemäß AMG (physicians’ samples according to the German Medicinal Products Act (AMG))**: This product type must be indicated for medicinal products that are dispensed as physicians’ samples according to Section 47 (3) and (4) of the German Medicinal Products Act (AMG).
- **Marketingbedarf (marketing supplies):** This product type must be indicated for products that are not sold as sales packs. Examples: free samples (e.g. testers) promotional merchandise (e.g. paper tissues), displays, large packagings for separating out, shipping units. Excluded from this are narcotics (BtM) and medicinal products subject to documentation requirement according to the Transfusion Act (TFG).

Acceptable values	0	Standard
	1	Klinikpackung (clinic pack)
	2	Klinikbaustein (clinic pack component)
	3	Pandemieartikel (pandemic product)
	4	Schüttware (bulk product)
	5	Ärztemuster gemäß AMG (physicians' samples according to the German Medicinal Products Act (AMG))
	6	Marketingbedarf (marketing supplies)
Changing via IFA portal	is not possible	
Changing via EAD file	is not possible	
Special characteristic	Product-identifying characteristic, can generally no longer be changed for published PZNs.	

NTIN – National Trade Item Number

For medicinal products, an NTIN enveloping a German PZN can be indicated.

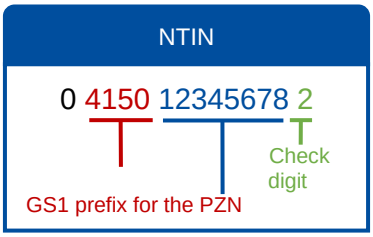

Figure 3: Structure of the NTIN

Acceptable values	14-character numeric data field
Example	04150123456782
Changing via IFA portal	is possible
Changing via EAD file	is possible

UPC und GTIN – UPC and GTIN

For items that can be distributed outside of pharmacies (e.g. medical devices and other pharmacy-typical products), a UPC or GTIN may be entered.

- UPC: Universal Product Code: a barcode used in the United States and Canada – 12 digits
- GTIN: Global Trade Item Number (formerly EAN): globally used number which identifies the item in its specific version (colour, size, etc.) – 8 to 14 digits

cceptable values	14-digit numeric data field
Example	9012345600003
Changing via IFA portal	is possible
Changing via EAD file	is possible

(Kunden-)Artikel-Nr. – (Customer) product number

If a company's own product number is available for the product, it can be notified for easier identification, e.g. in product overviews.

Acceptable values	18-character data field
Unacceptable characters	e. g. round bracket, colon
Example	1234, 679245 897126, AB-123
Changing via IFA portal	is possible
Changing via EAD file	is possible

1.1.2 Preisinformationen – Pricing information

Pricing information is interpreted as prices in EUR. The unit price for a consumption unit must be indicated. The consumption unit corresponds to the size indicated in the data field Packungsgröße (Menge und Einheit) (packaging size (quantity and unit)). Price quotations in notification order documents with more than two decimal places shall be commercially rounded to the full cent within the scope of order processing.

To avoid misunderstandings, all prices to be published should be indicated for each order. This applies especially if a price is to remain unchanged. Otherwise, there is a risk that desired price information will be deleted.

AMPreisV – Pharmaceutical Price Ordinance

It must be indicated whether the product is subject to the Pharmaceutical Price Ordinance (AMPreisV) as a prescription-only drug according to Section 78 of the German Medicinal Products Act (AMG) or as a non-prescription but pharmacy-only drug subject to the price regulation according to Section 129 (5a) of German Social Code Book V (SGB V) – which corresponds to the AMPreisV as of 31 December 2003.

For affected medicinal products:

- At least the sales price of the pharmaceutical entrepreneur (APU), the pharmacy purchase price (AEP) and the pharmacy sales price (AVP) are published,
- AEP and AVP must be calculated based on the notified APU in accordance with pricing regulations.

If the legal price information is incomplete or does not correspond to the applicable pricing regulation, IFA will accept only the APU and calculate the AEP and AVP on this basis. The pricing regulations require that rounding is carried out commercially to a full cent at each stage of the calculation. Therefore,

the calculated price may differ from the desired price in the cent range. If the supplier wants IFA to calculate the AEP and AVP in accordance with the applicable pricing regulation, notifying the APU shall suffice.

Over-the-counter medicinal products or other pharmacy-typical products are not subject to any price regulations according to AMPreisV or Section 129 (5a) of German Social Code Book V (SGB V). For these,

- The hospital pharmacy purchase price (KHAEP), APU, AEP and/or the manufacturer's suggested retail price (UVP) can be freely calculated and optionally indicated;
- No AVP can be indicated, since it would have to be calculated according to the AMPreisV or another price regulation.

Acceptable values	0	no
	1	yes, the price ranges must correspond to the AMPreisV AMG or the AMPreisV SGB V.
Changing via IFA portal	is possible, proof required	
Changing via EAD file	is not possible	

Besonderheit bei Arzneimitteln im Direktvertrieb – Special characteristic for medicinal products in direct sales

The wholesale surcharge must also be levied if the medicinal product is supplied directly to pharmacies by the pharmaceutical entrepreneur or other natural/legal persons. The sale to others within the scope of the exemption clauses of Section 47 of the German Medicinal Products Act (AMG) is equivalent to this, insofar as the Pharmaceutical Price Ordinance (AMPreisV) applies. The wholesale surcharge must be calculated in these cases – regardless of whether a finished medicinal product is sold via pharmaceutical wholesale distribution or not.

According to the exemption clause of Section 3 (2) no. 2 of the Pharmaceutical Price Ordinance (AMPreisV), the wholesale surcharge does not apply and the AEP is equal to the APU: This exemption can only be applied to finished medicinal products,

- Which are subject to price maintenance subject to Section 1 of the Pharmaceutical Price Ordinance (AMPreisV);
- For which a legally binding prohibition on sale to pharmaceutical wholesalers applies in accordance with the provision in Section 52b (2) clause 3 of the German Medicinal Products Act (AMG); or
- Which cannot be delivered via pharmaceutical wholesalers for actual reasons in accordance with this regulation.

Regulations are in particular Section 47a and 47b of the German Medicinal Products Act (AMG) and binding requirements of the regulatory authorities for dispensing.

KHAEP – Hospital pharmacy purchase price (excl. VAT)

For the KHAEP, the unit price for a consumption unit must be indicated – i.e. for the value in the data field Packungsgröße (Menge und Einheit) (packaging size (quantity and unit)).

Acceptable values	11-digit data field with 8 numeric characters before the decimal comma (Euro, German format with comma instead of period) and 2 numeric characters after the comma (full cents), separated by a comma (German format: 0,00 to 99999999,99 without currency symbol or code)
Example	0,00 = not specified
Changing via IFA portal	is possible
Changing via EAD file	is possible

APU – Sales price of the pharmaceutical entrepreneur (excl. VAT)

The indication of the APU depends on the legal classification of the product:

- For pharmacy-only and prescription-only drugs, the APU must be indicated in accordance with Section 78 (3) of the German Medicinal Products Act (AMG);
- For medicinal products subject to a reimbursement amount according to Section 130b of German Social Code Book V (SGB V) the APU gemäß § 78 Abs. 3a Satz 1 AMG (APU according to Section 78 (3a) clause 1 of the German Medicinal Products Act (AMG)) must be indicated additionally;
- For over-the-counter medicinal products and other pharmacy-typical products, the price indicated shall be considered the supplier's sales price.

The APU must be indicated for medicinal products that are subject to the Pharmaceutical Price Ordinance (AMPreisV) (Section 78 (2) and (3) of the German Medicinal Products Act (AMG): Indication of a uniform sales price of the pharmaceutical entrepreneur):

Distribution via pharmaceutical wholesalers: For medicinal products that are subject to the Pharmaceutical Price Ordinance (AMPreisV) and sold via pharmaceutical wholesalers, the APU is lower than the AEP.

Distribution to pharmacies only (direct sale): For medicinal products that are subject to the Pharmaceutical Price Ordinance (AMPreisV) and are not sold via pharmaceutical wholesalers according to Section 52b (2) and (3), the APU is identical to the AEP.

The APU need not be indicated for products that are not subject to the Pharmaceutical Price Ordinance (AMPreisV) or another price regulation:

- It is possible to publish just some of the prices (e.g. only APU or only the UVP).
- For products that are not subject to a price regulation, no AVP can be indicated. If a non-binding manufacturer's suggested retail price is to be recommended, it must be listed in the UVP price field.
- An additional indication of the KHAEP is possible.

Acceptable values	11-digit data field with 8 numeric characters before the decimal comma (Euro) and 2 numeric characters after the comma (full cents), separated by a comma (German format: 0,00 to 99999999,99 without currency symbol or code)
Example	0,00 = not specified
Changing via IFA portal	is possible
Changing via EAD file	is possible

AEP – Pharmacy purchase price (excl. VAT)

For medicinal products that are subject to a price regulation, indicating the AEP is obligatory. This applies to prescription-only drugs and pharmacy-only drugs that do not require a prescription. The surcharges are calculated based on the applicable price regulation. For products that are not subject to any price regulation, the AEP can be freely chosen. Attention must be paid to a possible dependence on the APU.

Acceptable values	11-digit data field with 8 numeric characters before the decimal comma (Euro) and 2 numeric characters after the comma (full cents), separated by a comma (German format: 0,00 to 99999999,99 without currency symbol or code)
Example	0,00 = not specified
Changing via IFA portal	is possible
Changing via EAD file	is possible

AVP – Pharmacy retail price (incl. VAT)

For medicinal products that are subject to a price regulation, indicating the AVP is obligatory. The surcharges are calculated based on the applicable price regulation. For products that are not subject to any price regulation, the KHAEP, APU, AEP or UVP can be freely calculated and optionally indicated. An AVP can only be indicated for:

- Pharmacy-only and prescription-only drugs that are subject to the price regulations AMPreisV or Section 129 (5a) of German Social Code Book V (SGB V);
- Other products with price maintenance (e.g. books).

Acceptable values	11-digit data field with 8 numeric characters before the decimal comma (Euro) and 2 numeric characters after the comma (full cents), separated by a comma (German format: 0,00 to 99999999,99 without currency symbol or code)
Example	0,00 = not specified
Changing via IFA portal	is possible
Changing via EAD file	is possible

UVP – Recommended retail price (incl. VAT)

For prescription-only drugs, a UVP cannot be indicated. For pharmacy-only, non-prescription drugs, a UVP can be indicated in addition to the AVP. For other pharmacy-typical products, a UVP can be indicated if a sales price is to be recommended. Indication of an AVP is not possible for other pharmacy-typical products.

Acceptable values	11-digit data field with 8 numeric characters before the decimal comma (Euro) and 2 numeric characters after the comma (full cents), separated by a comma (German format: 0,00 to 99999999,99 without currency symbol or code)
Example	0,00 = not specified
Changing via IFA portal	is possible
Changing via EAD file	is possible

APU § 78 Abs. 3a Satz 1 AMG – APU Section 78 (3a) clause 1 AMG – Sales price of the pharmaceutical entrepreneur according to Section 78 (3a) clause 1 of the German Medicinal Products Act (AMG)

If a reimbursement amount applies to the medicinal product in accordance with Section 130b of German Social Code Book V (SGB V), it must be indicated. This value is equal to or greater than the APU and the KHAEP (see 14th Amendment Act for Social Code Book V (SGB V)). In this case, “Yes” must be entered for the data field Arzneimittel mit Erstattungsbetrag (medicinal product with reimbursement amount).

The reimbursement amount according to Section 130b of German Social Code Book V (SGB V) is agreed upon between the GKV-Spitzenverband (SHI Head Association) and the pharmaceutical entrepreneur concerned – or determined by arbitration, if no agreement is reached. The reimbursement amount agreement or arbitration award is based on the results of an early benefit assessment by the Federal Joint Committee (G-BA) in accordance with Section 35a of German Social Code Book V (SGB V).

Acceptable values	11-digit data field with 8 numeric characters before the decimal comma (Euro) and 2 numeric characters after the comma (full cents), separated by a comma (German format: 0,00 to 99999999,99 without currency symbol or code)
Example	0,00 = not specified
Changing via IFA portal	is possible
Changing via EAD file	is possible

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

If a reimbursement amount is agreed or set for medicinal products in accordance with Section 130b of German Social Code Book V (SGB V), the date from which this price applies in accordance with Section 130b (3a) SGB V must be stated.

Acceptable values	DD.MM.YYYY (D = day, M = month, Y = year)
Example	07.01.2024
Changing via IFA portal	possible
Changing via EAD file	possible

KHAEP PPU – Hospital pharmacy purchase price of the pharmaceutical entrepreneur (excl. VAT)

If a reimbursement amount according to Section 130b of German Social Code Book V (SGB V) has been agreed upon/assigned, it must be indicated in the data fields APU and APU § 78 Abs. 3a Satz 1 AMG (APU Section 78 (3a) clause 1 of the German Medicinal Products Act (AMG)). If a KHAEP is listed, it must also correspond to the reimbursement amount. In this case, however, the supplier can additionally set a self-selected (higher) hospital pharmacy purchase price of the pharmaceutical entrepreneur (KHAEP PPU). This takes into account that the legislator explicitly grants the pharmaceutical entrepreneur free pricing.

If no reimbursement amount according to Section 130b of German Social Code Book V (SGB V) has been agreed upon/assigned, the KHAEP PPU corresponds to the KHAEP.

Acceptable values	11-digit data field with 8 numeric characters before the decimal comma (Euro) and 2 numeric characters after the comma (full cents), separated by a comma (German format: 0,00 to 99999999,99 without currency symbol or code)
Example	0,00 = not specified
Changing via IFA portal	is possible
Changing via EAD file	is possible

PPU – Price of the pharmaceutical entrepreneur (excl. VAT)

If a reimbursement amount according to Section 130b of German Social Code Book V (SGB V) has been agreed upon/assigned, it must be indicated in the data fields APU and APU § 78 Abs. 3a Satz 1 AMG (APU Section 78 (3a) clause 1 of the German Medicinal Products Act (AMG)). In this case, however, the supplier can additionally set a self-selected (higher) hospital pharmacy purchase price of the pharmaceutical entrepreneur (PPU). This takes into account that the legislator explicitly grants the pharmaceutical entrepreneur free pricing.

If no reimbursement amount according to Section 130b of German Social Code Book V (SGB V) has been agreed upon/assigned for a prescription-only medicinal product, the PPU corresponds to the APU.

Acceptable values	11-digit data field with 8 numeric characters before the decimal comma (Euro) and 2 numeric characters after the comma (full cents), separated by a comma (German format: 0,00 to 99999999,99 without currency symbol or code)
Example	0,00 = not specified
Changing via IFA portal	is possible
Changing via EAD file	is possible

AEP PPU – Pharmacy purchase price of the pharmaceutical entrepreneur (excl. VAT)

The pharmacy purchase price of the pharmaceutical entrepreneur (AEP PPU) can deviate from the AEP for medicinal products for which a reimbursement amount according to Section 130b of German Social Code Book V (SGB V) applies. It is calculated based on the PPU in accordance with the Pharmaceutical Price Ordinance (AMPreisV).

Acceptable values	11-digit data field with 8 numeric characters before the decimal comma (Euro) and 2 numeric characters after the comma (full cents), separated by a comma (German format: 0,00 to 99999999,99 without currency symbol or code)
Example	0,00 = not specified
Changing via IFA portal	is possible
Changing via EAD file	is possible

AVP PPU – Pharmacy retail price of the pharmaceutical entrepreneur (excl. VAT)

The pharmacy retail price of the pharmaceutical entrepreneur (AVP PPU) may deviate from the AVP for medicinal products for which a reimbursement amount applies in accordance with Section 130b of German Social Code Book V (SGB V). It is calculated based on the PPU in accordance with the Pharmaceutical Price Ordinance (AMPreisV).

Acceptable values	11-digit data field with 8 numeric characters before the decimal comma (Euro) and 2 numeric characters after the comma (full cents), separated by a comma (German format: 0,00 to 99999999,99 without currency symbol or code)
Example	0,00 = not specified
Changing via IFA portal	is possible
Changing via EAD file	is possible

MwSt. – Mehrwertsteuersatz – Value-added tax rate

The applicable VAT rate must be notified. If an AVP or UVP is indicated, the supplier must take into account the indicated VAT rate.

Acceptable values	0	full
	1	reduced
	2	none
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

Diff. PPU-APU § 78 Abs. 3a Satz 1 AMG

– Difference between the price of the pharmaceutical entrepreneur [PPU] and the sales price of the pharmaceutical entrepreneur according to Section 78 (3a) clause 1 of the German Medicinal Products Act (AMG) [APU Section 78 (3a) clause 1 of the German Medicinal Products Act (AMG)]

For medicinal products for which a PPU and a sales price according to Section 78 (3a) clause 1 of the German Medicinal Products Act (AMG) were notified, IFA additionally lists the differences between these two price listings in the IFA information services. Notifying is not possible.

§ 130a Abs. 2 SGB V – Impfstoffabschlag – Section 130a (2) of German Social Code Book V (SGB V) – Vaccine discount

If applicable, the amount of the vaccine discount according to Section 130a (2) of German Social Code Book V (SGB V) must be indicated.

Health insurance funds receive a discount on the APU from pharmacies for vaccines for preventive immunisations which were dispensed by pharmacies at the expense of the health insurance funds. This discount is meant to compensate for the difference to a lower average price per unit of quantity.

The average price per unit of quantity is derived from the pharmaceutical entrepreneur's actually valid sales prices in the four member states of the European Union with the closest gross national incomes, weighted based on sales and purchasing parities. Pharmaceutical companies will be required to determine the amount of the discount.

Acceptable values	11-digit data field with 8 numeric characters before the decimal comma (Euro) and 2 numeric characters after the comma (full cents), separated by a comma (German format: 0,00 to 99999999,99 without currency symbol or code)
Example	0,00 = not specified
Changing via IFA portal	is possible
Changing via EAD file	is possible

PAngV – Preisangabenverordnung – Price Indication Ordinance

If an product is subject to the Price Indication Ordinance (PAngV), the basic price must be shown to the end consumer, e.g. at the pharmacy (e.g. the price converted to 100 grams).

Prescription-only drugs are exempt from the Price Indication Ordinance. Non-prescription drugs (over-the-counter or pharmacy-only) and other pharmacy-typical products are generally subject to the Price Indication Ordinance (PAngV). However, exemptions apply to them. For example, small packages of less than 10 grams or 10 ml or products offered in piece counts (e.g. tablets or capsules) are not subject to the Price Indication Ordinance (PAngV).

Acceptable values	0	no
	1	yes, subject to the PAngV
Changing via IFA portal	is not possible	
Changing via EAD file	is not possible	

Preisbindung für Bücher – Book price fixing

According to Section 5 German Book Price Fixing Act books must have a binding and stable price for all merchants. If the product is subjekt to this an AVP has to be submitted instead of an UVP.

Acceptable values	0	no
	1	yes
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

1.1.3 Rechtsinformationen – Legal information

Arzneimittel – Medicinal product

It must be indicated whether a product is a medicinal product (finished medicinal product) according to Section 2 of the German Medicinal Products Act (AMG) or a veterinary medicinal product according to Section 3 of the Veterinary Medicinal Products Act (TAMG). Some products that are marketed abroad, e.g. as dietary food, diet products or cosmetics, are classified as medicinal products in Germany and require marketing authorisation or registration. For any uncertainties, the legal product status in Germany should be ascertained with the supervisory authority in charge (district government) before applying for a PZN.

Acceptable values	0	no
	1	yes, medicinal product according to Section 2 of the German Medicinal Products Act (AMG) or veterinary medicinal product according to Section 3 of the Veterinary Medicinal Products Act (TAMG)
Changing via IFA portal	is not possible	
Changing via EAD file	is not possible	
Special characteristic	Product-identifying characteristic, can generally no longer be changed for published PZNs.	

TAMG Tierarzneimittelgesetz – TAMG Veterinary medicinal products Act

It must be stated whether the product is subject to Section 3 of the Veterinary Medicinal Products Act (TAMG) as a veterinary medicinal product or as a veterinary medical technology device (VMTP) subject to authorization. The regulations of the TAMG are applicable to both product types. The marketing authorization as a veterinary medicinal product or VMTP must be proven, e.g. by the proof of marketing authorisation of the Federal Office of Consumer Protection and Food Safety (BVL).

Acceptable values	0	no
	1	yes, veterinary medicinal products
	2	yes, veterinary medical technology device (VMTP)
Changing via IFA portal	is not possible	
Changing via EAD file	is not possible	

Anthroposophikum – Anthroposophic medicinal product

It must be indicated whether an product is a registered or approved medicinal product according to the German Medicinal Products Act, which is manufactured in accordance with officially recognised anthroposophic preparation methods.

Acceptable values	0	no
	1	yes, anthroposophic medicinal product
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

Homöopathikum – Homeopathic medicinal product

It must be indicated whether an product is a registered or approved medicinal product according to the German Medicinal Products Act, which is manufactured in accordance with officially recognised homeopathic preparation methods.

Acceptable values	0	no
	1	yes, homeopathic medicinal product
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

Phytopharmakon – Herbal medicinal product

It must be indicated whether a product is a registered or approved herbal medicinal product according to the German Medicinal Products Act, which exclusively contains botanical preparations/plant extracts.

Acceptable values	0	no
	1	yes, herbal medical product
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

biotechnol. herg. AM – Biotechnologically produced medicinal product

It must be indicated whether the product is a medicinal product developed by means of one of the following biotechnological processes (see Annex to Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004, in the version of 5 June 2013):

- Recombinant DNA technology
- controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cell
- hybridoma and monoclonal antibody methods.

The following distinctions must be taken into account:

- Biosimilars: biotechnologically produced medicinal products that resemble the original products but are not identical with them
- Biotechnologically produced medicinal products that are identical to another biotechnologically produced medicinal products in terms of starting materials and production process

This information provides no reference regarding substitution.

It is determined via the data field biologisches Arzneimittel (biological medicinal product) within the meaning of Leitfaden zur Ermittlung des Generikaabschlags (Guideline for the definition of the generic discount (German)) whether a discount according to Section 130a (3b) of German Social Code Book V (SGB V) applies.

Acceptable values	0	no
	1	yes, biotechnologically produced original medicinal product
	2	yes, biosimilar
	3	yes, biotechnologically produced medicinal product that is identical to another biotechnologically produced medicinal product in terms of starting materials and production process
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

ATMP – Advanced Therapy Medicinal Products

It must be indicated whether the product is a medicinal product for novel therapies (ATMP – *Advanced Therapy Medicinal Products*) in accordance with Regulation (EC) No. 1394/2007.

According to Article 2, ATMPs include:

- Gene therapy medicinal products;
- Somatic cell therapy medicinal products (including tumour vaccines);
- tissue-engineered products (TEP – *Tissue-Engineered Products*).

According to Article 7 of Regulation (EC) No. 1394/2007, the group of ATMPs also includes combined ATMPs that meet certain prerequisites. Combined ATMPs are combinations of ATMPs and medical devices. In accordance with Annex I of Delegated Regulation (EU) 2016/161 (DR) associated with the Falsified Medicines Directive 2011/62/EU (FMD), ATMPs are among the prescription-only medicinal products that must not bear the safety features (exceptions from the verification obligation).

Acceptable values	0	no
	1	yes, gene therapy medicinal product
	2	yes, somatic cell therapy medicinal product
	3	yes, tumour vaccine
	4	yes, tissue engineered product
	5	yes, combined ATMP
	99	yes, other ATMP
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

Arzneimittel für seltene Leiden (Orphan medicines) – Medicinal products for rare diseases (orphan medicines)

It must be indicated whether the product is a medicinal product for the treatment of a rare disease in accordance with Regulation (EC) no. 141/2000.

A medicinal product is designated for rare diseases, if

- The medicinal product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating disease that affects not more than five in ten thousand people in the Community at the time of application, or the medicinal product is intended for the diagnosis, prevention or treatment of a life-threatening condition, a condition resulting in serious disability, or a serious and chronic condition in the Community and that, in the absence of incentives, marketing the medicinal product in the Community would not be likely to generate sufficient profits to justify the required investments; and
- No satisfactory method of diagnosis, prevention or treatment of the condition in question has yet been approved in the Community or the medicinal product in question, if such a method exists, will be of significant benefit to those affected by this condition.

Designated orphan medicines are entered into the *Community Register of Orphan Medicinal Products.*

Acceptable values	0	no, the product is not a medicinal product for rare diseases (no orphan medicine)
	1	yes, the product is a medicinal product for rare diseases (orphan medicine)
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

apothekenpflichtig – Pharmacy-only

It must be indicated whether the product is subject to mandatory dispensation through pharmacies:

- As a medicinal product according to Section 43 (1) and Section 46 of the German Medicinal Products Act (AMG)

- As a medical device in accordance with Section 2 of the Ordinance for Governing the Sale of Medical Devices (MPAV) or other sales restrictions according to Section 3 of the Ordinance for Governing the Sale of Medical Devices (MPAV)

Acceptable values	0	no, not pharmacy-only
	1	yes, pharmacy-only
	2	no, exemption rule according to Section 3 (1) clause 2 of the Ordinance for Governing the Sale of Medical Devices (MPAV)
Changing via IFA portal	is possible, proof required	
Changing via EAD file	is not possible	

verschreibungspflichtig – Prescription-only

It must be indicated whether the product is subject to mandatory prescriptions:

- As a medicinal product according to Section 48 (1) of the German Medicinal Products Act (AMG)
- As a medical device in accordance with Section 1 (1) of the Ordinance for Governing the Sale of Medical Devices (MPAV) or other sales restrictions according to Section 3 of the Ordinance for Governing the Sale of Medical Devices (MPAV)

Acceptable values	0	no, not prescription-only
	1	yes, prescription-only
	2	yes, prescription-only (Section 48 (1) of the German Medicinal Products Act (AMG) or Section 1 (1) of the Ordinance for Governing the Sale of Medical Devices (MPAV) with the exception of midwives and physician assistants in obstetrics (Section 48 (3) clause 2 of the German Medicinal Products Act (AMG)
	3	no, not prescription-only with the exception according to Section 3 (1) clause 2 of the Ordinance for Governing the Sale of Medical Devices (MPAV)
Changing via IFA portal	is possible, proof required	
Changing via EAD file	is not possible	

BtM – Betäubungsmittel – Narcotics

It must be indicated whether the product is a narcotic (BtM) according to Section 1 of the German Narcotics Act (BtMG) or an exempt preparation according to Section 3 in connection with Section 2 of the German Narcotics Act (BtMG).

Acceptable values	0	no
	1	yes, narcotic according to Section 1 of the German Narcotics Act (BtMG), no exempt preparation
	2	yes, exempt preparation according to Section 3 of the German Narcotics Act (BtMG)
Changing via IFA portal	is not possible	
Changing via EAD file	is not possible	

BOPST-Nr. – Number of the Federal Opium Agency for the international trading of narcotics (BtM)

For narcotics meant for international trading, the BOPST number must be indicated. The 8-digit BOPST number is issued by the Federal Opium Agency of the Federal Institute for Drugs and Medical Devices (BfArM) and is used for the international trading of narcotics (BtM). It does not serve as a Pharmazentralnummer (PZN) and is not to be equated with it. The BOPST number can be assigned to the product in question in the IFA Database.

Acceptable values	8-digit numeric data field
Changing via IFA portal	is not possible
Changing via EAD file	is not possible

TFG – Dokumentationspflicht gemäß Transfusionsgesetz – TFG – Documentation requirement according to the Transfusion Act

It must be indicated whether the product is a medicinal product subject to the documentation requirement according to Section 14 (2) clause 1 of the Transfusion Act (TFG).

Acceptable values	0	no
	1	yes, blood product
	2	yes, medicinal products for the specific therapy of clotting disorders with haemophilia
Changing via IFA portal	is not possible	
Changing via EAD file	is not possible	

T-Rezept-Arzneimittel – T-prescription medicinal products

For medicinal products it must be indicated whether they can only be prescribed with a T-prescription. This is governed in Section 3a of the Medicinal Product Prescription Ordinance (AMVV). A T-prescription is a numbered, two-part official form of the Federal Institute for Drugs and Medical Devices (BfArM).

Acceptable values	0	no
	1	yes, T-prescription required
Changing via IFA portal	is not possible	
Changing via EAD file	is not possible	

Eingangsnummer (ENR) der Zulassungsunterlagen – Processing number (ENR) of the marketing authorisation documents

In the case of medicinal products, the processing number (ENR) from the Medicinal Products Information System AMIce operated by the BfArM must be indicated. This applies to marketing authorisations of BfArM, PEI and EMA. If this processing number is not yet available when submitting first publications for reasons attributable to the process of the regulatory authorities, it must be notified in the data field *processing number (ENR) late submission* and the ENR must be submitted immediately upon receipt.

Acceptable values	7-digit numeric data field
Changing via IFA portal	is possible, proof required
Changing via EAD file	is not possible

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. The reasons for this are the processes of the regulatory authorities. As soon as the number is available, it must be submitted immediately.

Acceptable values	0	no
	1	yes, ENR will be submitted in a subsequent notification
Changing via IFA Portal	is possible, proof required	
Changing via EAD file	is not possible	

Zulassungs-/Registrierungs-Nr. – Marketing authorisation/registration number

For medicinal products, the marketing authorisation and registration number must be indicated mandatorily.

Acceptable values	30-character data field
Example	12345.00.00, EU/1/23/456/001
Changing IFA portal	is possible, proof required
Changing EAD file	is not possible

Bezugnehmende Zulassung als Generikum – Referenced marketing authorisation as a generic medicinal product

For medicinal products, it must be indicated whether they are a generic medicinal product with a referenced marketing authorisation according to Section 24b (2) of the German Medicinal Products Act (AMG).

Acceptable values	0	no
	1	yes, referenced marketing authorisation as a generic medicinal product
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

Bedingte Zulassung – Conditional marketing authorisation

For medicinal products, it must be stated whether they have received a conditional marketing authorisation in accordance with Article 14 (7) of Regulation (EC) No. 726/2004. With this authorisation, they can be launched on the market before the full clinical trial is completed.

A conditional marketing authorisation is possible for medicinal products, which

- Are intended for the treatment, prevention or medical diagnosis of serious debilitating or life-threatening diseases;
- Are to be used in crisis situations against a threat to public health;
- Are used for the treatment of rare diseases.

Conditional marketing authorisations can only be granted as part of a centralised marketing authorisation procedure and are valid for one year. The aim is to give patients suffering from life-threatening diseases access to new therapies, provided there is sufficient evidence that the therapies have a positive risk-benefit ratio. Conditional marketing authorisations are subject to particularly close monitoring until a regular marketing authorisation is granted. They are subject to certain conditions and must be labelled accordingly.

Acceptable values	0	no, the product is not a medicinal product or not subject to a conditional marketing authorisation for medicinal products
	1	yes, product is a medicinal product and as such is subject to conditional marketing authorisation
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

Zulassung in Ausnahmefällen – Marketing authorisation under exceptional circumstances

For medicinal products, it must be stated whether they have received a marketing authorisation under exceptional circumstances according to Article 14 (8) of Regulation (EC) No. 726/2004.

This marketing authorisation is possible under certain conditions if an applicant is unable, even in the future, to submit complete data on the efficacy and safety of his medicinal product for human or

veterinary use for objective and verifiable reasons. This may be the case, for example, in very rare tumour diseases or small patient collectives. Marketing authorisations under exceptional circumstances can only be granted as part of a centralised marketing authorisation procedure. The conditions are reassessed on a yearly basis.

Acceptable values	0	no, the product is not a medicinal product or not subject to a marketing authorisation under exceptional circumstances
	1	yes, the product is a medicinal product and as such as is subject to a marketing authorisation under exceptional circumstances
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

Patentablaufdatum des Originalarzneimittels – Patent expiration date of the original medicinal product

For a medicinal product with a refered marketing authorisation as a generic medicinal product according to Section 24b (2) of the German Medicinal Products Act (AMG), the patent expiration date of the original medicinal product must additionally be indicated.

Acceptable values	DD.MM.YYYY (D = day, M = month, Y = year)
Example	01.01.2011
Changing via IFA portal	is not possible
Changing via EAD file	is not possible

Tierarzneimittel-Abgabemengen-Register (TAR) – Delivery quantities register for veterinary medicinal products (TAR)

For veterinary medicinal products, it must be stated which notifying obligation they are subject to in accordance with Section 45 (6) of the Veterinary Medicinal Products Act (TAMG). The notification is made to the Federal Office of Consumer Protection and Food Safety (BVL). According to TAMG, manufacturers and pharmaceutical wholesalers are obligated to notify the delivery quantities of certain medicinal products to the *TAM delivery quantity register* of the BVL. The BVL provides a *list of medicinal products subject to notification.*

In the notification to be submitted to the BVL, a distinction is made between two medicinal product classifications in accordance with the provisions of Section 45 (6) TAMG:

- Medicinal product classification BVL-P45ABS6NR1 according to Section 45 (6) clause 1 TAMG
- Medicinal product classification BVL-P45ABS6NR2 according to Section 45 (6) clause 2 TAMG

Acceptable values	0	no
	1	yes, subject to the notifying obligation according to Section 45 (6) clause 1 TAMG
	2	yes, subject to the notifying obligation according to Section 45 (6) clause 2 TAMG
	3	yes, subject to the notifying obligation according to Section 45 (6) clause 1 and 2 TAMG
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

Ausnahmereg. § 51 AMG – Ausnahmeregelung bei Abgabe im Reisegewerbe – Exemption according to Section 51 of the German Medicinal Products Act (AMG) – Exemption rule for dispensation in the travel sector

It must be indicated whether the product is a non-pharmacy-only finished medicinal product that is exempt from the ban according to Section 51 of the German Medicinal Products Act (AMG).

Finished medicinal products that are not pharmacy-only and fall under the exemption according to Section 51 of the German Medicinal Products Act (AMG), do not require a manufacturing or wholesale permit.

With each new registration, deletion or change in the legal classification of an product, the obligation to obtain a manufacturing or wholesale permit may also change.

Acceptable values	0	no
	1	yes, subject to the exemption in the travel sector
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

Ausnahme nach § 52b Abs. 2 Satz 3 AMG – Abgabeverbot an pharm. Großhandel – Exemption according to Section 52b (2) clause 3 of the German Medicinal Products Act (AMG) – Prohibition of dispensing to pharmaceutical wholesalers

It must be indicated whether the product is a medicinal product for which a legally binding ban on delivery to pharmaceutical wholesalers applies in accordance with the provision in Section 52b (2) of the German Medicinal Products Act (AMG) or which cannot be delivered via pharmaceutical wholesalers for actual reasons in accordance with this provision.

In this context, the notes on price listings must also be observed.

Acceptable values	0	no
	1	yes, subject to the exemption in the obligation to supply
Changing via IFA portal	is possible, proof required	
Changing via EAD file	is not possible	

PackungsV – Packungsgrößenverordnung – Packaging Size Ordinance

It must be indicated which packaging size a pharmacy-only or prescription-only medicinal product is subject to, according to the Packaging Size Ordinance (PackungsV). In conjunction with the *General Administrative Regulation for the Determination of Packaging Sizes according to Section 5 of the Packaging Size Ordinance (PackungsV)* plus appendices, the measurement figures defined in Appendix 1 must be taken into account. Depending on this, the following values are distinguished in the IFA Database:

- blank – not specified: The packaging size is smaller than the largest specified measurement number and at the same time does not correspond to any of the specified measurement numbers; e.g. medicinal products that cannot or can no longer be assigned to levels N1, N2 or N3.
- No therapy-appropriate packaging size: Packaging size is larger than the largest stipulated measure
- N1: Packaging size corresponds to the stipulated measure for N1
- N2: Packaging size corresponds to the stipulated measure for N2
- N3: Packaging size corresponds to the stipulated measure for N3
- Not affected: Items not affected by the Packaging size Ordinance
    - Over-the-counter (non-prescription and non-pharmacy-only) finished medicinal products
    - medicinal products for the exclusive distribution to hospital pharmacies or pharmacies supplying hospitals (clinic products)
    - Veterinary medicinal products according to TAMG
    - Physicians' samples
    - Pandemieartikel (pandemic product)
    - Schüttware (bulk product)
    - Other pharmacy-typical products (e.g. medical devices, drugs/chemicals, VTMP according to TAMG)

Acceptable values	blank	not specified
	0	no therapy-appropriate packaging size
	1	N1
	2	N2
	3	N3
	4	not affected
Changing via IFA portal	is not possible	
Changing via EAD file	is not possible	

Importiertes Arzneimittel lt. SGB V – Imported medicinal product according to German Social Code Book V (SGB V)

It must be indicated whether a medicinal product is parallel imported or parallel distributed, for both of which separate regulations apply according to Section 129 (1) clause 1 no. 2 of German Social Code Book V (SGB V). Individual imports according to Section 73 of the German Medicinal Products Act (AMG) are not addressed here.

Acceptable values	0	no
	1	yes, imported medicinal product
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

Kontrazeptivum mit alleiniger Indikation – Contraceptives with a single indication

For medicinal products or medical devices, it must be indicated whether they exclusively claim the indication of “contraception”.

Acceptable values	0	no
	1	yes, contraceptive
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

Lifestyle-Arzneimittel – Lifestyle medicinal product

It must be indicated whether the product is a lifestyle medicinal product according to Section 34 (1) of German Social Code Book V (SGB V), which is excluded from reimbursement at the expense of statutory health insurance with or without an exemption.

Acceptable values	0	no
	1	yes, excluded from reimbursement according to Section 34 (1) without exemptions
	2	yes, excluded from reimbursement according to Section 34 (1) with exemptions
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

AMNOG-Verfahren (§ 35a SGB V) – AMNOG procedure (Section 35a of German Social Code Book V (SGB V))

For medicinal products, it must be indicated whether the Federal Joint Committee (G-BA) is conducting or has completed a benefit assessment according to Section 35a of German Social Code Book V (SGB V).

The Federal Joint Committee (G-BA) assesses the benefit of medicinal products with new active ingredients that are eligible for reimbursement (Section 35 of German Social Code Book V (SGB V)). This includes in particular the assessment of the additional benefit compared to the appropriate comparative therapy, the extent of the additional benefit and its therapeutic significance.

Acceptable values	0	no, the product is not a medicinal product or is not affected by the benefit assessment
	1	yes, the product is a medicinal product that is currently undergoing a benefit assessment procedure
	2	yes, the product is a medicinal product for which a benefit assessment procedure has been completed
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

APU § 130a Abs. 3c Satz 6 SGB V vereinbart – sales price of the pharmaceutical entrepreneur Section 130a (3c) clause 6 German Social Code Book V (SGB V) agreed

In the case of medicinal products, it must be stated whether a sales price of the pharmaceutical entrepreneur has been agreed for them in accordance with Section 130a (3c) clause 6 SGB V.

For medicinal products that are subject to a discount pursuant to Section 130a (3a) clause 4 or clause 5 SGB V ("extended price moratorium") may be exempted if a new marketing authorisation has been granted for this medicinal product that covers a new patient population or a new therapeutic indicationcompared to already approved medicinal products with the same active substance and if an improvement in care is to be expected. For exempt medicinal products, the GKV-Spitzenverband agrees with the pharmaceutical entrepreneur, in consultation with the Association of Private Health Insurance Funds and with effect for all health insurance funds, a sales price of the pharmaceutical entrepreneur in accordance with Section 130a (3c) clause 6 SGB V.

The value 1 is also used to identify those medicinal products for which a discount applies in accordance with Section 130a (3a) clause 1 SGB V and which are exempted from this in accordance with Section 130a (3c) clause 13 SGB V ("supply-critical off-patent medicinal products/children's medicinal products without alternative therapy") and for which a sales price of the pharmaceutical entrepreneur is agreed in accordance with (3c) clause 14 in conjunction with clause 6 or set pursuant to (3c) clause 15.

Acceptable values	0	no
	1	yes
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

Datum, ab dem der vereinbarte APU § 130a Abs. 3c Satz 6 SGB V gilt – Date from which the agreed APU Section 130a (3c) clause 6 German Social Code Book V (SGB V) applies

For medicinal products for which a new sales price has been agreed by the pharmaceutical entrepreneur with the GKV-Spitzenverband on the basis of Section 130a (3c) clause 6 SGB V, the date from which this price applies must be stated.

Acceptable values	DD.MM.YYYY (D = day, M = month, Y = year)
Example	15.04.2023
Changing via IFA portal	is possible
Changing via EAD file	is possible

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). 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.

Acceptable values	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 Abs. 3b SGB V)
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

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 modell* must be submitted. More detailed information can be found in the framework agreement according to Section 130b (9) SGB V.

- Linear Pricing Structure Model: the price per package increases with each additional unit of the total amount of the active substance in a package
- Flat Pricing Structure Model: different strengths of the active substance per unit of a pharmaceutical form have the same price
- Complex Pricing Structure Model: the pricing modell of the medicinal product is neither uniquely linear nor flat.

Additional information on specifying medicinal products in IFA Database:

- 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 does not need to 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:

Acceptable values	0	not affected
	1	Linear Pricing Structure Model (*linear pricing*)
	2	Flat Pricing Structure Model (*flat pricing*)
	3	Complex Pricing Structure model
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

Kennzeichen Abschlag nach § 130a Abs. 2 SGB V – Data field for discounts according to Section 130a (2) of German Social Code Book V (SGB V)

It must be indicated whether and to what extent the product is subject to the provisions of the Impfstoffabschlag nach § 130a Abs. 2 SGB V (vaccine discount according to Section 130a (2) of German Social Code Book V (SGB V)).

A value of 0 must be used to label products that are not vaccines according to Section 20i of German Social Code Book V (SGB V) and are consequently not subject to provisions concerning the vaccine discount according to Section 130a (2) of German Social Code Book V (SGB V).

A value of 1 must be used to label vaccines according to Section 20i of German Social Code Book V (SGB V),

- Which are subject to the provisions of the vaccine discount according to Section 130a (2) of German Social Code Book V (SGB V); and
- For which a discount can be determined according to Section 130a (2) of German Social Code Book V (SGB V). The guideline of the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) for Section 130a (2) of German Social Code Book V (SGB V) should be consulted for determining the discount in accordance with Section 130a (2) of German Social Code Book V (SGB V).
- The corresponding euro value must be entered in the data field § 130a Abs. 2 SGB V – Impfstoffabschlag (Section 130a (2) of German Social Code Book V (SGB V) – Vaccine discount). The discount according to Section 130a (1) of German Social Code Book V (SGB V) does not apply.

A value of 2 must be used to label vaccines according to Section 20i of German Social Code Book V (SGB V),

- Which are not subject to the provisions of the vaccine discount according to Section 130a (2) of German Social Code Book V (SGB V), since the actually valid sales price per unit of quantity is smaller than or equal to the determined average price per unit of quantity in the European Economic Area.
- To determine the average price per unit of quantity in the European Economic Area, the guideline of the National Association of Statutory Health Insurance Funds (GKV-

Spitzenverband) for Section 130a (2) of German Social Code Book V (SGB V) should be consulted.
- A discount according to Section 130a (2) of German Social Code Book V (SGB V) does not apply. No euro value is to be entered in the data field § 130a Abs. 2 SGB V – Impfstoffabschlag (Section 130a (2) of German Social Code Book V (SGB V) – Vaccine discount).

A value of 3 must be used to label vaccines according to Section 20i of German Social Code Book V (SGB V),

- Which are subject to the provisions of the vaccine discount according to Section 130a (2) of German Social Code Book V (SGB V); and
- For which a discount cannot be determined according to Section 130a (2) of German Social Code Book V (SGB V). The guideline of the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) for Section 130a (2) of German Social Code Book V (SGB V) should be consulted to judge to what extent a discount in accordance with Section 130a (2) of German Social Code Book V (SGB V) can or cannot be determined.
- No euro value is to be entered in the data field § 130a Abs. 2 SGB V – Impfstoffabschlag (Section 130a (2) of German Social Code Book V (SGB V) – Vaccine discount). The discount according to Section 130a (1) of German Social Code Book V (SGB V) applies according to Section 130a (2) clause 5.

A value of 4 must be used to label vaccines according to Section 20i of German Social Code Book V (SGB V),

- Which are not subject to the provisions of the vaccine discount according to Section 130a (2) of German Social Code Book V (SGB V), since the vaccine is distributed in less than 4 countries or only in Germany.
- A discount according to Section 130a (2) of German Social Code Book V (SGB V) does not apply. No euro value is to be entered in the data field § 130a Abs. 2 SGB V – Impfstoffabschlag (Section 130a (2) of German Social Code Book V (SGB V) – Vaccine discount).

Acceptable values	0	no vaccine according to Section 20i of German Social Code Book V (SGB V), not subject to a mandatory discount
	1	Vaccine according to Section 20i of German Social Code Book V (SGB V), subject to mandatory discount, discount can be determined according to Section 130a (2) of German Social Code Book V (SGB V)
	2	Vaccine according to Section 20i of German Social Code Book V (SGB V), not subject to mandatory discount, since actually valid sales price per unit of quantity ≤ average price per unit of quantity in the European Economic Area
	3	Vaccine according to Section 20i of German Social Code Book V (SGB V), subject to mandatory discount, discount cannot be determined according to Section 130a (2) of German Social Code Book V (SGB V)
	4	Vaccine according to Section 20i of German Social Code Book V (SGB V), not subject to mandatory discount, since it is distributed in less than 4 countries or exclusively in Germany
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

Abschlagsbefreiung – Exemption of Deduction

- **according to Section 130a (4) of German Social Code Book V (SGB V) from discounts according to Section 130a (1), (1a) or (1b) of German Social Code Book V (SGB V):** If a medicinal product is exempt from the deduction according to Section 130a (1), (1a) or (1b) of German Social Code Book V (SGB V), it must be indicated in what amount the exemption according to Section 130a (4) of German Social Code Book V (SGB V) is claimed.
- **according to Section 130a (4) of German Social Code Book V (SGB V) from discounts according to Section 130a (3a) of German Social Code Book V (SGB V):** If a medicinal product is exempt from the deduction according to Section 130a (3a) of German Social Code Book V (SGB V), it must be indicated in what amount the exemption according to Section 130a (4) of German Social Code Book V (SGB V) is claimed.
- **according to Section 130a (9) of German Social Code Book V (SGB V) from discounts according to Section 130a (1) or (1a) of German Social Code Book V (SGB V):** If a medicinal product is exempt from the deduction according to Section 130a (1) or (1a) of German Social Code Book V (SGB V), it must be indicated in what amount the exemption according to Section 130a (9) of German Social Code Book V (SGB V) is claimed.
- **according to Section 130a (9) of German Social Code Book V (SGB V) from discounts according to Section 130a (3a) of German Social Code Book V (SGB V):** If a medicinal product is exempt from the deduction according to Section 130a (3a) of German Social Code Book V (SGB V), it must be indicated in what amount the exemption according to Section 130a (9) of German Social Code Book V (SGB V) is claimed.

A exemption of deduction according to Section 130a (4) or (9) of German Social Code Book V (SGB V) never applies to the reimbursement amount according to Section 130b of German Social Code Book V or the generic drug discount according to Section 130a (3b) of German Social Code Book V (SGB V).

When calculating the exemption of deduction according to Section 130a (4) and (9) of German Social Code Book V (SGB V), the percentage reduction compared to the full discount must always be notified. The amount of the waiver must be indicated in percent with three digital places after the decimal comma (German format).

Acceptable values	7-digit data field with 3 numeric characters before the decimal comma and 3 numeric characters after the comma (percent), separated by a comma (German format: 0,0 to 100,000 without a percent symbol)	
Examples	100,000	Medicinal product is fully exempt of deduction
	66,667	Medicinal product is two-thirds exempt of deduction
	0,000	Medicinal product is not exempt of deduction
Changing via IFA portal	is not possible	
Changing via EAD file	is not possible	

Ablösung Abschlag § 130a SGB V – Overruled discount Section 130a SGB V

Overruled discount pursuant to Section 130a (1) SGB V in accordance with Section 130b (1) clause 4 SGB V in combination with Section 130a (8) clause 6 SGB V

For medicinal products, it must be indicated whether the discount according to Section 130a (1) SGB V or if discounts according to Section 130a (1b) SGB V have been overruled in a reimbursement amount agreement.

A value of 1 must be registered for medicinal products if their discount according to Section 130a (1) SGB V has been overruled in a reimbursement amount agreement according to Section 130b (1) clause 4 SGB V in combination with Section 130a (8) clause 6 SGB V.

Acceptable values	0	no
	1	yes, agreement to overrule the discount according to Section 130a (1/8) SGB V
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

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, the date from which the overrule applies must be stated.

Acceptable values	DD.MM.YYYY (D = day, M = month, Y = year)
Example	17.01.2024
Changing via IFA portal	is possible
Changing via EAD file	is possible

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.

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

Acceptable values	0	no
	1	yes, medicinal product with fictious fixed reference price (fictious reference price on APU basis + 50 % = base price)
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

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).

Acceptable values	0	no
	1	yes, medicinal product with repealed reference price (last valid reference price on APU basis + 50 % = new base price)
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

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 (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.

Acceptable values	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)
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

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).

Acceptable values	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)
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

Wirkstoffpatent – Compound patent

For medicinal products, it must be indicated whether there is a compound patent within the meaning of Leitfaden zur Definition des Generikaabschlages (Guideline for definition of the generic drug discount (German)) according to Section 130a (3b) of German Social Code Book V (SGB V). Indication is required for determining the discount obligation according to Section 130a (3b) of German Social Code Book V (SGB V) (generic discount). For further information, please consult the guideline.

Acceptable values	0	no
	1	yes, compound patent available
Changing via IFA portal	is possible – with the exception of the change from value 0 (no) to value 1 (yes)	
Changing via EAD file	is possible – with the exception of the change from value 0 (no) to value 1 (yes)	

Unterlagenschutz – Data exclusivity

For medicinal products, it must be indicated whether there is data exclusivity within the meaning of Leitfaden zur Definition des Generikaabschlages (Guideline for definition of the generic drug discount (German)). Indication is required for determining the discount obligation according to Section 130a (3b) of German Social Code Book V (SGB V) (generic discount). For further information, please consult the guideline.

Acceptable values	0	no
	1	yes, data exclusivity in effect
Changing via IFA portal	is possible – with the exception of the change from value 0 (no) to value 1 (yes)	
Changing via EAD file	is possible – with the exception of the change from value 0 (no) to value 1 (yes)	

biologisches AM – Biological medicinal product

It must be indicated whether a product is a biological medicinal product within the meaning of Leitfaden zur Definition des Generikaabschlages (Guideline for definition of the generic drug discount (German)). Indication is required for determining the discount obligation according to Section 130a (3b) of German Social Code Book V (SGB V) (generic discount). For further information, please consult the guideline.

Acceptable values	0	no
	1	yes, biological medicinal product
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

solitäres Fertig-AM – Unique finished medicinal product

For medicinal products, it must be indicated whether they are a unique finished medicinal product within the meaning of Leitfaden zur Definition des Generikaabschlages (Guideline for definition of the generic drug discount (German)). Indication is required for determining the discount obligation according to Section 130a (3b) of German Social Code Book V (SGB V) (generic discount). For further information, please consult the guideline.

Acceptable values	0	no, identical active ingredients
	1	yes, no identical active ingredients
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

Medizinprodukt gemäß § 3 MPDG – Medical device in accordance with Section 3 of the German Medical Devices Implementing Act (MPDG)

It must be indicated whether the product is a medical device in accordance with Section 3 of the German Medical Devices Implementing Act (MPDG). According to Article 20 Regulation (EU) 2017/745 (MDR), only medical devices with a valid CE marking can be marketed. Therefore, proof of a CE marking is required for a first publication of a medical device. In addition, the special characteristics for sterile medical devices must be observed.

Acceptable values	0	no
	1	yes, medical device in accordance with Section 3 MPDG
Changing via IFA portal	is possible, proof required	
Changing via EAD file	is not possible	

CE-Kennzeichnung – CE marking

For each medical device, a CE marking is required according to Article 20 Regulation (EU) 2017/745 (MDR). This CE marking must be confirmed in this data field. For any first publication of a medical device, proof of the CE marking must be enclosed.

Acceptable values	0	no
	1	yes, has a CE marking
Changing via IFA portal	is possible, proof required	
Changing via EAD file	is not possible	

Medizinprodukt gemäß § 31 Abs. 1 Satz 2 SGB V – Medical device in accordance with Section 31 (1) clause 2 of German Social Code Book V (SGB V)

It must be indicated whether the product is a medicine-like/material medical device in accordance with Section 31 (1) clause 2 of German Social Code Book V (SGB V). The Federal Joint Committee stipulates in the Pharmaceutical Guidelines (Section 92 (1) clause 2 no. 6) in what medically necessary cases materials and preparations from these materials, which are intended as medical devices according to Section 3 No. 1 of the Medical Devices Implementing Act for use on or in the human body, can be included in medicinal care as an exception.

Since a medical device in accordance with Section 31 (1) clause 2 of German Social Code Book V (SGB V) is additionally a Medizinprodukt gemäß § 3 MPDG (medical device in accordance with Section 3 of the German Medical Devices Implementing Act (MPDG)), proof of the CE marking must be enclosed with any order for a first publication.

Acceptable values	0	no
	1	yes, medical device in accordance with Section 31 (1) clause 2 of German Social Code Book V (SGB V)
Changing via IFA portal	is possible, proof required	
Changing via EAD file	is not possible	

Verbandmittel – Bandages and dressings

It must be indicated whether the product is a bandage/dressing according to Section 31 (1a) of German Social Code Book V (SGB V). Bandages and dressings are objects including fixing materials whose main impact is the

- coverage of body parts with surface damage,
- absorption of bodily fluids,
- or both.

Specifically, an object is still considered a dressing when it additionally maintains a wound's moisture. This also includes objects:

- For the individual creation of one-time dressings on body parts without surface damage;
- That are possibly used multiple times;
- For stabilizing, immobilizing or compressing body parts.

For wound care products that are reimbursed by statutory health insurance, the pharmacy purchase price is among the pieces of information that must be notified according to Section 131 (4) of German Social Code Book V (SGB V).

Additional details regarding the distinction from *Miscellaneous products for would care* are governed by the Federal Joint Committee.

Acceptable values	0	no
	1	yes, bandages/dressings according to Section 31 (1a) of German Social Code Book V (SGB V)
Changing via IFA portal	is possible, proof required	
Changing via EAD file	is not possible	

Sonstiges Produkt zur Wundbehandlung gemäß § 31 (1a) SGB V – Miscellaneous product for would care according to Section 31 (1a) of German Social Code Book V (SGB V)

It must be indicated whether the product belongs in the category "Miscellaneous product for wound care" according to Section 31 (1a) of German Social Code Book V (SGB V). For this purpose, the Federal Joint Committee (G-BA) will publicise additional details regarding the distinction of bandages/dressings from "Miscellaneous product for wound care" in its medicinal Guidelines. Therefore, IFA has proactively expanded its database and will inform the suppliers of medical devices in due course and support them during notifying.

Acceptable values	0	no
	1	yes, miscellaneous product for wound care according to Section 31 (1a) of German Social Code Book V (SGB V)
Changing via IFA portal	is not possible	
Changing via EAD file	is not possible	

Hilfsmittel zum Verbrauch – Devices for consumption

It must be indicated whether the product is a device for consumption according to German Social Code Book V (SGB V). In contrast to aids according to Section 33 of German Social Code Book V (SGB V) without further specification, devices for consumption are only used once. Since this data field is significant for charging copayments, e.g. in pharmacies and health care supply stores, it directly affects patients.

Among other things, devices for consumption include certain application aids, incontinence aids, stoma care products, tracheostoma aids and disposable diapers. Bandages/dressings (e.g. gauze bandages, patches) and testing strips are not considered devices for consumption.

Guidance as to what products constitute devices for consumption is provided by the GKV-Spitzenverband (SHI Head Association) (see Annex 2).

Acceptable values	0	no
	1	yes, device for consumption
Changing via IFA portal	is not possible	
Changing via EAD file	is not possible	

Medizinprodukte-Klasse – Medical device class

If the product is a medical device in accordance with Section 3 of the MPDG, the medical device class in accordance with the currently applicable legal situation, or in the future according to Regulation (EU) No. 2017/745 on medical devices (Annex VIII), must be indicated.

The products are categorised into classes I, IIa, IIb and III in consideration of their intended purpose and the associated risks.

Acceptable values	1	Class I
	2	Class IIa
	3	Class IIb
	4	Class III
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

In-vitro-Diagnostika-Klasse – In-vitro diagnostics class

If the product is a medical device in accordance with Section 3 of the MPDG, the in-vitro diagnostics class in accordance with the currently applicable legal situation, or in the future according to Regulation (EU) No. 2017/746 on medical devices (Annex VIII), must be indicated. The products are categorised into classes A, B, C and D in consideration of their intended purpose and the associated risks.

Acceptable values	1	Class A
	2	Class B
	3	Class C
	4	Class D
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

steril – sterile

It must be indicated whether the product is sterile. Sterile means that the product is free of viable microorganisms (DIN EN 556-1). Sterile products are labelled as such.

Special characteristics for sterile disposable products: According to DIN 58953-8:2010-05, sterile medical devices must be delivered, transported and stored in a packaging system consisting of a primary (sterile barrier system) and additional (non-sterile) outer secondary packaging (protective packaging). Therefore, only two versions for assigning the PZN are possible:

- PZN for individual, sterile medical devices that are properly packed in a sterile barrier system and protective packaging.
- PZN for protective packaging. The protective packaging (e.g. with a packaging size of 10 units) contains several sterile medical devices without individual protective packaging. The PZN can only be affixed to the protective packaging, since the individual, sterile packed medical devices do not have individual protective packaging.

Acceptable values	0	no
	1	yes, sterile
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

Lebensmittel – Food Stuff

It must be indicated whether the product is a food supplement (NEM), dietary food or another food item typically sold in pharmacies, which is marketed in accordance with the Foods, Consumer Goods and Feedstuffs Code (LFGB) (see also Food supplement, Dietary food).

Acceptable values	0	no
	1	yes, food stuff in terms of NEM or dietary food
	99	yes, other food stuff
Changing via IFA portal	is possible, proof required	
Changing via EAD file	is not possible	

EU-Novel-Food-Verordnung – EU Novel Foods Regulation

It must be indicated whether the product is a novel food in accordance with the Novel Foods Regulation (EU) 2015/2283. Novel foods are defined as food that is classified in Article 3 of the regulation and has not been consumed to a significant degree by humans in the EU before 15 May 1997.

Only authorised novel foods may be marketed in the EU. The novel foods that have received authorisation to date are identified in Commission Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods. For foods approved under the old Regulation (EC) 258/97 or which did not fall within its scope, certain transitional provisions apply in accordance with Article 35 (1) (EU) 2015/2283 and Article 8 (5) of Commission Implementing Regulation (EU) 2017/2469.

Food companies are responsible for checking whether a food falls under the Novel Foods Regulation. In case of uncertainty about the classification, the competent authority of the member state where the product is to be marketed first may be consulted. The authority in charge in Germany is the Federal Office of Consumer Protection and Food Safety (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, BVL).

If the item is a novel food, it must also be identified as Lebensmittel (food stuff).

Acceptable values	0	not a food, therefore not affected
	1	not a novel food according to the Novel Foods Regulation
	2	It is questionable whether the product is affected; it is marketed in accordance with transitional provisions.
	3	yes, novel food according to the Novel Foods Regulation
Changing via IFA portal	is possible, proof required	
Changing via EAD file	is not possible	

NEM – Nahrungsergänzungsmittel – Food supplement

It must be indicated whether the product is a food supplement (NEM) in accordance with the Nutritional Supplement Ordinance (NemV). If the supplier of the NEM is not also the manufacturer (in the proper sense), the supplier is requested to indicate the address of the manufacturer.

Acceptable values	0	no
	1	yes, nutritional supplement
Changing via IFA portal	is possible, proof required	
Changing via EAD file	is not possible	

Diätetikum – Dietary supplement

It must be indicated whether the product is a balanced diet for enteral nutrition according to Section 31 (5) of German Social Code Book V (SGB V) (Diet or hospital food products such as amino acid mixtures, protein hydrolysates, elemental diets, tube-fed nutrition) or whether it is another type of dietetic supplement.

Acceptable values	0	no
	1	yes, dietary supplement according to Section 31 (5) of German Social Code Book V (SGB V)
	99	yes, other dietetic supplement
Changing via IFA portal	is possible, proof required	
Changing via EAD file	is not possible	

Biozid – Biocidal product

It must be indicated whether the product is an approved biocidal product. Biocidal products are for pest control or disinfection, e.g. ant baits, insect sprays, disinfectants or wood preservatives. These products are typically not applied to live crops. (Distinction: Plant protection products are usually used to protect crops or their harvested products.)

Decisive for the classification of a product is its function as perceived by an observer. For example, it is possible that a chemically identical substance may fall under the Biocides Directive in one case (e.g. if the product is offered as a disinfectant) and not in another (e.g. if the substance has been added to the product in the function of a pH regulator).

Acceptable values	0	no
	1	yes, biocidal product
Changing via IFA portal	is not possible	
Changing via EAD file	is not possible	

Droge/Chemikalie – Drugs/chemicals

It must be indicated whether the product is a drug or a chemical. Within the meaning of Section 3 of the German Medicinal Products Act (AMG), these are compounds that are generally used in the production of medicinal products. Finished medicinal products within the meaning of Section 4 of the German Medicinal Products Act (AMG) are not drugs or chemicals.

Acceptable values	0	no
	1	yes, drug/chemical
Changing via IFA portal	is not possible	
Changing via EAD file	is not possible	

Wirkstoff – Active substance

It must be indicated whether the product is an active substance according to EU Directive 2001/83/EC Article 1 (3a) or Section 4 (19) of the German Medicinal Products Act (AMG).

Establishments and facilities that manufacture, import or trade in active substances (e.g. pharmaceutical wholesalers or pharmacies) must be registered according to Section 64 (3g) of the German Medicinal Products Act (AMG), if they do not require a permit in accordance with Sections 13 or 72 (1) of the German Medicinal Products Act (AMG). According to the Guidelines of 19 March 2015 on Principles of Good Distribution Practice of active substances for medicinal products for human use (2015/C 95/01), pharmaceutical wholesalers must be able to identify active pharmaceutical ingredients within the meaning of Section 4 (19) of the German Medicinal Products Act (AMG).

Active substances are substances that are intended to be used as medicinally active ingredients in the manufacture of medicinal products or to become medicinally active ingredients of medicinal products when used in the manufacture of medicinal products (e.g. erythromycin, tincture of myrrh or also chamomile flowers).

It follows from the definition that active substances are Drogen/Chemikalien (drugs/chemicals). Active substances are not pharmacy-only.

Acceptable values	0	no
	1	yes, active substance
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

Pflanzenschutzmittel – Plant protection products

It must be indicated whether the product is an approved plant protection product. Plant protection products are usually used to protect crops or their harvested products. For the distinction between plant protection products and biocides, see Biocide.

Acceptable values	0	no
	1	yes, plant protection product
Changing via IFA portal	is not possible	
Changing via EAD file	is not possible	

Sicherheitsdatenblatt erforderlich – Safety data sheet required

It must be indicated whether a safety data sheet (SDS) for hazardous substances is required or available for the product.

Safety data sheets convey safety-related information about substances and mixtures. They facilitate the handling of substances and mixtures in order to be able to take measures for occupational health protection and safety in the workplace. According to Article 31 (1) of the REACH Regulation (EC) No. 1907/2006, suppliers of the dangerous substances, preparations or mixtures concerned must make safety data sheets available to the parties involved in the subsequent supply chain.

Safety data sheets are also prepared voluntarily for chemical substances, mixtures and products classified as non-hazardous in order to inform the buyer of the products about certain properties.

Acceptable values	0	no
	1	yes, safety data sheet required
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

UN-Nr. – UN Number

If a UN number was assigned to the product, it must be indicated. This identification number is defined for all hazardous substances that are considered dangerous goods (hazardous materials). It describes the composition (type) of a commodity from which a hazard potential emanates. The UN number is indicated on safety data sheets for products containing hazardous substances and can also be found on the orange-coloured warning signs (hazard signs) affixed to hazardous goods transports.

Acceptable values	4-digit numeric data field
Example	1203 = petrol, 2901 = bromine chloride
Changing via IFA portal	is possible
Changing via EAD file	is possible

cmr-Gefahrstoff – CMR hazardous substance

It must be indicated whether the product contains one or multiple ingredients according to Section 2 (3) of the Ordinance on Hazardous Substances (GefStoffV), which individually or in combination or as a mixture are:

- Carcinogenic;
- Germ cell mutagenic; or
- Toxic for reproduction.

The abbreviation stands for **c**arcinogenic, **m**utagenic and toxic for **r**eproduction. Packs of finished medicinal products and active substances are also affected.

For finished medicinal products with CMR-relevant ingredients, a consideration limit according to the Technical Rules for Hazardous Substances (TRGS) 525 applies: Packs of finished medicinal products are affected if a carcinogenic or mutagenic ingredient in a preparation or mixture exceeds a concentration limit of 0.1 % or if an ingredient that is toxic for reproduction exceeds a concentration limit of 0.3 %.

Labelling is required to ensure that people take into account appropriate and legally mandated measures during the use, further processing or transport of affected products, in order to protect themselves and any third parties from health hazards posed by CMR substances. This also and in particular applies in the event of an average.

Acceptable values	0	no
	1	yes
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

Explosivgrundstoff – Explosives precursor

It must be indicated whether the product contains substances in accordance with Annex I and II to Article 2 of Regulation (EU) No. 2019/1148. For each product in the IFA database, pharmacies, pharmaceutical wholesalers and other commerce operations must know whether it contains an explosive precursor. Commerce must report any suspicious transactions to the state office for criminal investigation in charge. The aim is to prevent the illegal production of explosives and criminal acts as a result.

Chemicals, biocides, plant protection products, medical devices or cosmetics, among others, may be affected by this regulation. Medicinal products are excluded by definition.

Acceptable values	0	no
	1	yes, the product contains substances according to the Annexes to Article 2 of Regulation (EU) No. 2019/1148
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

EU-Bio-Siegel – EU organic logo

It must be indicated whether the product is subject to and complies with the EC Organic Products Regulation and whether an EU organic label in accordance with REGULATION (EU) 2018/848 is available.

According to this regulation, companies trading in organic/biological products (EU organic label) need a certification (permit) and have to document which of their products fall under the EC Organic Products Regulation.

Acceptable values	0	no
	1	yes, EU organic logo according to the EC Organic Products Regulation available
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

EG-Kosmetik-Verordnung – EC Cosmetics Regulation

It must be indicated whether the product is subject to and complies with Regulation (EC) No. 1223/2009 on cosmetic products.

According to this regulation, distributors (e.g. pharmaceutical wholesalers, pharmacies) are obligated to:

- Verify certain components of the product's labelling information for accuracy (Article 6 (2));
- Ensure appropriate storage and transport conditions (Article 6 (4));
- Cooperate with the responsible person and the competent national authorities whenever necessary to ensure compliance with the regulation (Article 6 (3), Articles 23 and 26);
- Verify the products' packaging and to ensure that certain information is included on the label – including verification that it is written in the language required by national law;
- Identify at the request of the competent authorities the responsible persons/distributors from whom the cosmetic product was obtained and to whom it was delivered (Article 7); and
- Document batches accordingly.

Acceptable values	0	no
	1	yes, is subject to and complies with the EC Cosmetics Regulation
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

stiftung ear – stiftung ear

Stiftung ear is in charge for the registration obligations of suppliers of batteries (according to BattG) and electric and electronic equipment (according to ElektroG). Without prior registration at *stiftung ear* a supplier may neither market batteries nor market electric and electronic equipment.

If one of the following aspects applies for the product it is mandatory to register in the online portal of *stiftung ear*:

- The product is subject to the registration obligation according to the Batteries Act (BattG). The *battery registration number by stiftung ear* must be submitted.
- The product is subject to the registration obligation according to the eletric and electronic equiment (ElektroG). The *WEEE-Reg.-Nr. DE* must be submitted.

Acceptable values	0	no
	1	yes, is subject to the registration obligation by *stiftung ear*
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

Batterie-Registrierungsnummer der *stiftung ear* – Battery registration number by *stiftung ear*

The battery registration number by *stiftung ear* must be submitted, if the product is subject to the registration obligation according to BattG. The registration takes place in the online portal of *stiftung ear*:

Acceptable values	8-digit numeric data field
Changing via IFA portal	is possible
Changing via EAD file	is possible

WEEE-Registrierungsnummer DE – WEEE Registration number DE

The WEEE-Reg.-Nr. DE must be submitted, if the product is subject to the registration obligation according to ElektroG. The registration takes place in the online portal of *stiftung ear*:

The registration number is an eight-digit numeric character set. It is issued by *stiftung ear* in the following format: e.g. WEEE Reg. No. *DE 12345678*. The suffix DE shows that the manufacturer/authorised representative (Section 3 No. 10 of the Electrical and Electronic Equipment Act (ElektroG)) is registered in Germany.

Acceptable values	8-digit numeric data field
Changing via IFA portal	is possible
Changing via EAD file	is possible

ElektroStoffV – Electrical and Electronic Equipment Substance Ordinance

It must be indicated whether the product constitutes electrical or electronic equipment within the meaning of the Electrical and Electronic Equipment Substance Ordinance (ElektroStoffV) and is subject to this ordinance as such. This includes devices which need electric currents or electromagnetic fields to be operated.

Electrical or electronic equipment subject to the Electrical and Electronic Equipment Substance Ordinance (ElektroStoffV) have to be labled explicitly and verified by the distributor.

Acceptable values	0	no
	1	yes, subject to the Electrical and Electronic Equipment Substance Ordinance (ElektroStoffV)
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

1.1.4 Verifizierungsinformationen – Verification information

The implementation of the Falsified Medicines Directive 2011/62/EU (FMD) and Delegated Regulation (EU) 2016/161 requires that information for the identification of medicinal products subject to mandatory verification be indicated in the IFA database. Additional explanations regarding the FMD can be found at www.securPharm.de.

As part of the implementation, data from IFA are transmitted to ACS PharmaProtect GmbH (ACS). ACS is the system operator commissioned by securPharm e. V. and responsible for the contractual and technical connection of the pharmaceutical companies concerned to the system for the implementation of the FMD with regard to the German market.

Verifiz Pflicht ab Hochlade – Verification mandatory from upload date onward

For medicinal products that are subject to mandatory verification, the date must be indicated after which serial numbers are uploaded to the system of ACS PharmaProtect GmbH (ACS) via the EU Hub for the

first time (the so-called upload date). The typical value in this data field is 9 February 2019 (in the format 09.02.2019), the effective date of the FMD.

By notifying an entry in this data field, the pharmaceutical entrepreneur/supplier determines the general verification requirement for the medicinal product item.

For first publications of medicinal products subject to mandatory verification in the IFA Database, the following requirements apply since 15.02.2019:

- If all packs got released after 9 February 2019, there is no existing merchandise without DMC. The information *Verifiz Pflicht ab Hochlade* (Verification in mandatory operations from upload date onward) must be notified as follows:

  The recommended standard value is *09.02.2019*. As a result, the pharmaceutical entrepreneur/supplier declares all packs subject to mandatory verification. All data uploads are considered subject to mandatory verification by the so-called MAH system.

- If packs remain in the market which got released prior to 9 February 2019 it is a first publication with existing merchandise. Only subsequent batches released after 9 February 2019 must be manufactured in compliance with the FMD. The information *Verifiz Pflicht ab Hochlade* (Verification in mandatory operations from upload date onward) must be notified as follows:

  The date on which the pharmaceutical entrepreneur uploaded the serial numbers for the first FMD-compliant batch to the ACS system via the EU Hub. The notified date can be greater than *09.02.2019*.

Acceptable values	DD.MM.YYYY (D = day, M = month, Y = year)
Example	09.02.2019
Changing via IFA portal	is possible
Changing via EAD file	is possible

Verifiz Pflicht ab Verfall – Verification mandatory from expiry date onward

For medicinal products subject to mandatory verification, the expiry date of the first batch subject to mandatory verification must be indicated. Products with an expiry date equal to or greater than the indicated value can no longer be existing merchandise and are therefore subject to mandatory verification.

For first publications subject to mandatory verification in the IFA Database, the following requirements apply since 15 February 2019:

- If all packs got released after 9 February 2019, there is no existing merchandise without DMC. The information *Verifiz Pflicht ab Verfall* (Verification mandatory from expiry date onward) must be notified as follows:

  The recommended standard value is *022019*. The information must be smaller or even to the expiry date of the first released batch.

- If packs remain in the market which got released prior to 9 February 2019 it is a first publication with existing merchandise. Only subsequent batches released after 9 February 2019 must be

manufactured in compliance with the FMD. The information *Verifiz Pflicht ab Verfall* (Verification mandatory from expiry date onward) must be notified as follows:

The expiry date of the first FMD-compliant batch. An equally usable value can also be calculated from the effective date of the FMD 9 February 2019 plus expiry term.

Acceptable values	MMYYYY (M = month, Y = year)
Example	022019
Changing via IFA portal	is possible
Changing via EAD file	is possible

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).

Acceptable values	0	no
	1	yes
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

1.1.5 Lagerungsinformationen – Storage information

Verfalldatum – Expiry date

It must be indicated whether the expiry date is printed on the product or its outer packaging (for medicinal products, Section 10 of the German Medicinal Products Act (AMG) applies). If that is the case, indication of the expiry term of the product is mandatory.

Acceptable values	0	no
	1	yes, an expiry date is affixed to the product or its outer packaging
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

Laufzeit – Expiry term

The shelf life of an product after production must be indicated in months. Indication of the expiry term is mandatory for all products bearing an expiry date.

Acceptable values	3-digit numeric data field
Example	36 = 3 years of shelf life
Changing via IFA portal	is possible
Changing via EAD file	is possible

Kühlkette – Cold chain

It must be indicated whether the product is a particularly temperature-sensitive product for which a cold chain is required. *Cold chain* means uninterrupted refrigeration during storage and transportation. The information must be consistent with the marketing authorisation or the summary of product characteristics or other relevant product information.

Acceptable values	0	no
	1	yes, cold chain required
Changing via IFA portal	is possible, proof required	
Changing via EAD file	is not possible	

Lagertemperatur minimal/maximal – Storage temperature minimum/maximum

If certain storage temperatures are to be maintained for the product, they must be specified in the data field. The information should be consistent with the marketing authorisation or the summary of product characteristics or other relevant product information.

- minimum temperature: the lowest temperature in °C at which an product can be stored
- maximum temperature: the highest temperature in °C at which an product can be stored

Example temperatures for common designations:

- Store at room temperature: at least 15°C, maximum 25°C
- Store in a cold or cool place: at least 8°C, maximum 15°C
- Keep refrigerated: at least 2°C, maximum 8°C
- Do not freeze: at least 2°C

Acceptable values	4-digit numeric data field including the minus sign
Example	0 = 0 °C; -5 = -5°C
Changing via IFA portal	is possible
Changing via EAD file	is possible

Lichtempfindlichkeit – Light sensitivity

If special precautions against exposure to light or sunlight are mandatory for the product, it must be notified as *“Store protected from light”* or *“Store protected from sunlight”.*

Acceptable values	0	not light-sensitive
	1	store protected from light
	2	store protected from sunlight
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

Feuchteempfindlichkeit – Moisture sensitivity

If special precautions against moisture are mandatory for the product, it must be notified as *"Store in a dry place"*.

Acceptable values	0	not moisture-sensitive
	1	store in a dry place
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

Lageempfindlichkeit – Position sensitivity

If special precautions must be taken for the product with regard to position sensitivity, *"Store upright"* or *"Store lying down"* must be notified. Only a few products cannot be stored or transported lying down due to their consistency or ingredients. *"Store upright"* should only be indicated, if there is a risk to the quality of the product. Marketing-based reasons must not play a role in this respect.

Acceptable values	0	not position-sensitive
	1	store lying down
	2	store upright
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

Zerbrechlichkeit – Fragility

If special precautions against breakage are mandatory for the product, it must be notified as *fragile.*

Acceptable values	0	not fragile
	1	fragile
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

Eichung – Calibration

It must be indicated whether the product is calibrated or subject to mandatory calibration, such as scales or thermometers. Since the product must be recalibrated after a certain time period, the calibration term must also be indicated.

Acceptable values	0	no
	1	yes, the product is calibrated
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

Laufzeit der Eichung – Calibration term

For products that need to be calibrated, the calibration term must be indicated in months. This is the term after which a calibrated product must be recalibrated.

Acceptable values	3-digit numeric data field (1 to 240)
Example	120 = calibrated for 120 months (10 years)
Changing via IFA portal	is possible
Changing via EAD file	is possible

1.1.6 Packungsinformationen – Pack information

Mindestbestellmenge – Minimum order quantity

In this data field, the number of consumption units (= value in the data field Packungsgröße (packaging size)) that must be ordered as a minimum is to be indicated. Minimum order values, different minimum order quantities for different customer groups (e.g. different for pharmacies than for pharmaceutical wholesalers) or price scales (e.g. discounts for certain order quantities) cannot be represented.

Acceptable values	6-digit numeric data field
Example	12 = 12 consumption units
Changing via IFA portal	is possible
Changing via EAD file	is possible

Verpackungsart – Package type

The package type/outer wrapping of the consumption unit, for which the PZN was assigned, must be indicated. The packaging type of the shipping unit, if different from the consumption unit packaging, is not recorded.

Acceptable values	2-digit numeric data field (spreadsheet *Pharmaceutical forms & packaging*)
Changing via IFA portal	is possible

Acceptable values	2-digit numeric data field (spreadsheet *Pharmaceutical forms & packaging*)
Changing via EAD file	is possible

Länge, Höhe, Breite – Length, height, width

The dimensions of the product must be given in millimetres as a whole number including packaging. The *face* of the pack must be used when determining the length, height and width. This is defined as the side that the consumer uses to comprehensively identify the pack (e.g. large-scale application of the trademark). The length is the front bottom side edge, the height is the vertical side and the width of the pack is its depth.

Maximum dimensions are to be specified for non-rectangular packaging. Example: A round bottle with a diameter of 40 mm and a height of 200 mm has the dimensions: L = 40 mm; W = 40 mm; H = 200 mm.

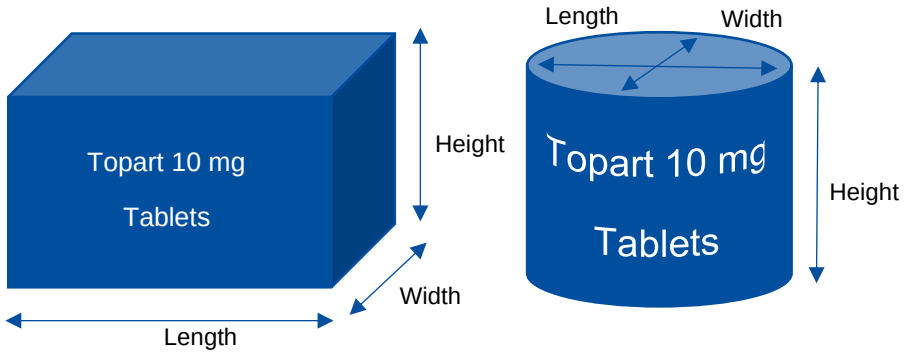

Figure 4: Examples of length, width and height depending on the face of a pack

Acceptable values	6-digit numeric data field
Example	12 = 12 mm; 243 = 243 mm = 2.43 cm
Changing via IFA portal	is possible
Changing via EAD file	is possible

Gewicht – Weight

The entire weight of the product must be indicated in full grams (gross weight). This includes the weight of the filling quantity and packaging. The filling quantity (net weight) is recorded in the data field Packungsgröße (Menge und Einheit) (packaging size (quantity and unit).

Acceptable values	8-digit numeric data field
Example	1200 = 1200 grams = 1.2 kilograms
Changing via IFA portal	is possible
Changing via EAD file	is possible

Kombinationspackung – Combination pack

It must be indicated, if the item is a combination pack containing more than one medicinal product. Sets consisting of several other pharmacy-typical products (e.g. two cosmetic products) are not considered *combination packs.* Information regarding a combination pack must be indicated during registration and cannot be changed subsequently.

Acceptable values	0	no
	1	combination pack with more than one medicinal product
Changing via IFA portal	is not possible	
Changing via EAD file	is not possible	

1.1.7 Vertriebsinformationen – Distribution information

Vertriebswege – Distribution channels

Four distribution channels can be indicated:

- Pharmaceutical wholesalers
- Public pharmacies
- Hospital pharmacies or pharmacies supplying hospitals (KVA)
- Other retailers (drugstores, health food stores, health care supply stores, etc.)

According to Section 52b (2) clause 4 of the German Medicinal Products Act (AMG), pharmacy-only medicinal products may only be sold to pharmacies directly by pharmaceutical companies in exceptional cases. This exemption applies to medicinal products for which a special distribution channel is provided by law (e.g. Section 47a and 47b of the German Medicinal Products Act (AMG)) or for which other special and objective circumstances apply (regulatory requirements).

If an product that was previously exclusively supplied directly to pharmacies by a supplier (so-called direct sales) is to be additionally supplied via pharmaceutical wholesalers in the future, the distribution channel *Wholesale* must also be marked *Yes*.

The dependence between pricing and distribution channels is explained in Pricing information.

If a distribution channel is removed or added, the associated price listings may also need to be deleted or added. For example, the KHAEP must be deleted once an product is no longer distributed through hospital pharmacies or pharmacies supplying hospitals.

Products that are not pharmacy-only but are sold to pharmacies either exclusively directly or through pharmaceutical wholesalers are considered pharmacy-exclusive.

Acceptable values	0	no
	1	yes, delivery to wholesalers or public pharmacies or hospital pharmacies or other retailers
Changing via IFA portal	is possible	
Changing via EAD file	is possible	

Vertriebsstatus – Distribution status

It must be indicated whether the product is *marketed* or *marketing ceased* or was *withdrawn*.

- **Außer Vertrieb – Marketing Ceased** (AV): The product has been taken out of distribution by the supplier and will no longer be delivered. Taking an product out of marketing is final and distribution is not resumed at a later time. Stock items may be sold provided the product is marketable. Products labelled “AV” cannot be reactivated, i.e. they cannot be reset to the status *marketed*.
- **Zurückgezogen – Withdrawn** (ZG): This status is only possible for a medicinal product for which the pharmaceutical entrepreneur has notified the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) in accordance with Section 4 (7) of the framework agreement according to Section 130b (9) of German Social Code Book V (SGB V) that it will not or no longer conduct the negotiation procedure and declares that it will withdraw the medicinal product from the market. This must be explicitly confirmed to IFA at the time of notification.

For additional information, please consult Richtlinien zum Artikelstatus und Statuswechsel (German) (Guidelines on Product Status and Status Change).

Acceptable values	0	marketing ceased
	1	marketed
	2	withdrawn
Changing via IFA portal	is possible, with the following exception: Distribution status *Withdrawn* not possible	
Changing via EAD file	is possible, with the following exception: Distribution status Withdrawn not possible	

Verkehrsfähigkeitsstatus - Marketability status

It must be indicated whether the product is *marketable, non-marketable* or whether its *marketability is under review*.

Non-marketable (NV) must be notified when the marketability of an product no longer applies in its entirety or is no longer permitted. This is the case as soon as all batches in distribution are affected by the non-marketability and no additional batches are produced. In that case, stock merchandise may no longer be sold.

When notifying with “*Auftragstabelle C – Änderungen von Artikeldaten”* (Order table C – Changing product data), the use of abbreviations is recommended:

- NV non-marketable: Stock merchandise in commerce may not be sold.
- VP Marketability is under review.

For additional information, please consult Richtlinien zum Artikelstatus und Statuswechsel (German) (Guidelines on Product Status and Status Change).

Acceptable values	0	non-marketable
	1	marketable
	2	marketability under review
Changing via IFA portal	is possible, proof required	
Changing via EAD file	is not possible	

1.1.8 Verweisinformationen – Reference information

PZN des Vorgängers/Nachfolgers – PZN of the predecessor/successor

If the product is a successor product of an product already listed in the IFA information services, the PZN of the predecessor product can be indicated. In order for a reference to be set up between the predecessor product and the successor product, the predecessor product must have the status *marketing ceased.* When accessing the product ceased to be marketed, users of the IFA information services will be linked to the successor product. Deleted products cannot be referenced.

The successor product should represent a plausible alternative to the predecessor product, i.e. it should not differ significantly from the predecessor product in terms of its purpose, composition, make, etc. For medicinal products and medical devices, this must be interpreted so narrowly that their application safety remains comprehensively guaranteed. For narcotics according to Section 1 of the German Narcotics Act (BtMG), a reference may only be made to a substitute/successor product that is identical in terms of active ingredient, active strength, pharmaceutical form and packaging size.

For additional information, please see Richtlinien zum Artikelstatus und Statuswechsel (German) (Guidelines on Product Status and Status Change).

Acceptable values	8-digit numeric data field
Changing via IFA portal	is possible
Changing via EAD file	is possible

PZN der Klinikpackung – PZN of the clinic pack

If a clinic component is registered, the PZN of the associated clinic pack must be indicated.

Acceptable values	8-digit numeric data field
Changing via IFA portal	is possible
Changing via EAD file	is possible

PZN des Originals – PZN of the original product

If parallel distributed medicinal products or parallel imports (imported medicinal products within the meaning of Section 129 (1) No. 2 of German Social Code Book V (SGB V)) are registered, the PZN of the reference original medicinal product must be indicated.

Acceptable values	8-digit numeric data field
Changing via IFA portal	is possible
Changing via EAD file	is possible

PZN des Voranbieters – PZN of the previous supplier

The PZN of the previous supplier's medicinal product based on the same marketing authorisation must be indicated.

Acceptable values	8-digit numeric data field
Changing via IFA portal	is possible
Changing via EAD file	is possible

Hinweise zur Löschung von Verweisinformationen – Information regarding the deletion of reference information

When products are deleted, this may result in references that become invalid. Therefore, IFA deletes invalid references in order to clean up the data inventory.

1.1.9 Pharmazeutische Informationen – Pharmaceutical information

Zweckbestimmung – Intended purpose

If the product is a medical device in accordance with Section 3 of the Medical Devices Implementing Act (MPDG) and is affected by the requirements of Section 131 (4) of German Social Code Book V (SGB V), the *intended purpose* must be indicated. This complies, among other things, with the catalogue of requirements for prescription software according to Section 73 of German Social Code Book V (SGB V).

This information is required for:

- Medical devices according to Section 31 (1) clause 2 of German Social Code Book V (SGB V) (so-called material medical devices)
- Bandages/dressings according to Section 31 (1a) of German Social Code Book V (SGB V)

Acceptable values	free text with a maximum of 32,767 characters, character set according to ISO 8859-1 without semicolons
Non-acceptable values	promotional texts, images, PDF files, tables, formatting
Changing via IFA portal	is possible
Changing via EAD file	is possible

Zusammensetzung nach Art und Menge – Qualitative and quantitative composition

If the product is a medical device in accordance with Section 3 of the Medical Devices Implementing Act (MPDG) and is affected by the requirements of Section 131 (4) of German Social Code Book V (SGB V), the qualitative and quantitative *composition* must be indicated. This complies, among other things, with the catalogue of requirements for prescription software according to Section 73 of German Social Code Book V (SGB V).

This information is required for:

- Medical devices according to Section 31 (1) clause 2 of German Social Code Book V (SGB V) (so-called material medical devices)
- Bandages/dressings according to Section 31 (1a) of German Social Code Book V (SGB V)
- Testing strips (in-vitro diagnostics) included in healthcare according to Section 31 of German Social Code Book V (SGB V)

In this context and particularly in the case of bandages/dressings, the term *composition* is also to be understood in terms of constituent parts, materials or components.

Acceptable values	free text with a maximum of 32,767 characters, character set according to ISO 8859-1 without semicolons
Non-acceptable values	promotional texts, images, PDF files, tables, formatting
Changing via IFA portal	is possible
Changing via EAD file	Is possible

1.1.10 Artikelbezogene Adressinformationen – Product-related address information

Angaben zu artikelbezogenen Adressdaten – Information about product-related address data

For certain products, additional address data are captured by third parties. This concerns the following:

- For medicinal products for human use that require a prescription, marketing authorisation or registration, the marketing authorisation holder and the local representative;
- For nutritional supplements (NEM), the manufacturer.

In each case, the address number must be entered. If it is not known, the company name and the address data must be indicated. For medicinal products the address of the legal entity notified to the higher federal authority must be entered.

Zulassungsinhaber – Marketing authorisation holder

For prescription-only medicinal products for human use, the following information on the marketing authorization holder is required:

- Address number of the markteting authorisation holder (5-digit)

- Address data of the markteting authorisation holder
- PNR (Pharmazeutische Unternehmernummer) of the markteting authorisation holder (7-digit Pharmaceutical entrepreneur number assigned by the Federal Institute for Drugs and Medical Devices (BfArM)

Örtlicher Vertreter – Local representative

In accordance with Section 9 (2) of the German Medicinal Products Act (AMG), the pharmaceutical entrepreneur can appoint a local representative. For medicinal products for human use that require a prescription, marketing authorisation or registration, the following information on the local representative is required - if applicable:

- Address number of the local representive (5-digit)
- Address data of the local representive
- PNR (Pharmazeutische Unternehmernummer) of the local reprentative (7-digit Pharmaceutical entrepreneur number assigned by the Federal Institute for Drugs and Medical Devices (BfArM)

The appointment of a local representative does not release the pharmaceutical entrepreneur from its responsibility (Section 9 (2) of the German Medicinal Products Act (AMG)), because it remains the party responsible for placing the product on the market (Section 9 (1) of the German Medicinal Products Act (AMG).

Hersteller – Manufacturer

Exclusively in the case of nutritional supplements, the manufacturer must be indicated, if it differs from the supplier. Required information about the manufacturer:

- Address number of the manufacturer (5-digit)
- Address data of the manufacturer

1.2 Adressdaten Anbieter – Address data supplier

In the IFA information services, the address of the supplier is published for each PZN. Only one address can be listed. However, it is possible to store up to 2 telephone and 2 fax numbers as well as up to 2 email addresses and 3 homepage addresses. The address data intended for publication in the information systems is available at Request for EAD, product and address data.

Herstellungserlaubnis – Manufacturing authorisation

If the supplier has a manufacturing authorisation according to Section 13 of the German Medicinal Products Act (AMG) or an authorisation granted by another member state of the European Union according to Product 40 (1) of Directive 2001/83/EC, IFA requests that a copy be provided. New customers are asked to note the following in "*Auftragstabelle D – Adressdaten Anbieter"* (Order table D – Supplier's address data): "*nicht erforderlich"* (not required) or "*ja, ist beigefügt"* (yes, is enclosed).

Großhandelserlaubnis – Wholesale authorisation

If the supplier has a wholesale authorisation according to Section 52a of the German Medicinal Products Act (AMG) or an authorisation granted by another member state of the European Union according to Product 77 (1) of Directive 2001/83/EC, IFA requests that a copy be provided. New customers are asked to note the following in "*Auftragstabelle D – Adressdaten Anbieter"* (Order table D – Supplier's address data): "*nicht erforderlich"* (not required) or "*ja, ist beigefügt"* (yes, is enclosed).

Umsatzsteuer-Identifikationsnummer – VAT identification number

The VAT identification number of the supplier must be indicated, if available.This is only used internally for invoicing and is not issued with the IFA information services.

Registrierung gemäß § 9 Abs. 1 VerpackG – Registration according to Section 9 (1) of the German Packaging Act (VerpackG)

Since 1 January 2019, the Act on Marketing, Return and High-Quality Recycling of Packaging (German Packaging Act (VerpackG) has applied to all packaging. In accordance with Section 9, manufacturers according to Section 7 (1) clause 1 are obligated to register with *Zentrale Stelle Verpackungsregister* (Central Packaging Register) prior to placing packaging on the market that is subject to mandatory system participation. The initial registration as well as notifications of changes shall be made via the electronic data processing system made available on the website of *Zentrale Stelle Verpackungsregister*. *Zentrale Stelle* confirms the registration and informs the manufacturer of his registration number. Suppliers may not offer packaging subject to mandatory system participation for sale if, contrary to paragraph 1, the manufacturers of such packaging are not registered or not properly registered.

This registration number represents a significant piece of information for retailers in order to avoid or reduce the impact of packaging waste on the environment.

Acceptable values	15-character data field, starting with a 2-character country code, followed by a 13-digit number
Example	DE0123456789123
Changing via IFA portal	is not possible
Changing via EAD file	is not possible

1.3 Sonstige Daten – Other data

Veröffentlichungsdatum – Publication date

For each order, the desired publication date (the 1st or 15th day of the month) must be indicated. If the indicated date lies in the past or is not indicated at all, the order is carried out for the next possible date. The notifying deadlines can be viewed in the IFA publication calendar.

For orders regarding the assignment of a PZN, this information is omitted.

Acceptable values	DD.MM.YYYY (D = day, M = month, Y = year)
Example	15.04.2020

Sperrfrist – Blocking period

Product data that are tagged with an blocking period will be forwarded to the data recipients on the latest possible provision date (typically 5 business days before publication). Product data without blocking period are usually provided to pharmaceutical wholesalers 10 business days before publication.

Address data are generally issued to pharmaceutical wholesalers without a blocking period.

Acceptable values	0	without blocking period
	1	With blocking period

Auftrag zur Ausgabe der Zuteilung – Order for issuing the pre-allocation

For PZN pre-allocations for medicinal products subject to mandatory verification, the supplier can request that IFA communicate the numbers early to ACS PharmaProtect GmbH (ACS). *Early* means before a later first publication of the PZN in the IFA information services.

Even if PZN pre-allocations were already transmitted to ACS, the first publication must be ordered for fist publication of the product/PZN in the IFA information services.

It must be indicated in the order for PZN pre-allocation whether the release of the PZN pre-allocation is desired. Even for existing PZN pre-allocations, the release can still be requested.

Acceptable values	0	no, PZN pre-allocation without publication
	1	yes, medicinal product subject to mandatory verification with release to ACS
Notifying via EAD file	is not possible	

2. Auftragserteilung – Submission of notification orders

2.1 Voraussetzung für die Auftragserteilung – Prerequisites for submission of notification orders

The prerequisite for placing an order for product and address data is the conclusion of an IFA supplier contract between the supplier and IFA. For additional information on concluding a contract, please visit our website: www.ifaffm.de.

Detailed conditions for notifying product and address data can be found in Guidelines for the Pre-Allocation of PZNs.

For an order to be processed by the requested publication date, all notification order documents must be received in full by IFA by the notifying deadline. The IFA publication calendar provides a binding overview of notifying deadlines for each publication date.

The IFA Price List for IFA services for suppliers shows the prices for inclusion and maintenance of product and address data in the IFA Database.

2.2 Auftragsübermittlung – notification order submission

Orders can be placed via IFA portal, EAD files or IFA Excel order files.

IFA-Portal – IFA portal

More detailed information on working with IFA portal is described in chapter Working with IFA portal. Via IFA Portal access is with customer number, user ID and password. Please note that IFA portal platform and support is only available in German.

Auftragstabellen und EAD-Dateien – Excel order files and EAD files

All notification order files are provided on the website under Notification Order Documents. Supplier-specific EAD files can be requested via website Request for EAD, product and address data. Depending on the order, supplementary documents, e.g. product information, must be attached. These are presented in detail in chapter Produktinformation/Nachweise - Product Information/proofs chapter. In addition, reference is made to them in chapter Auftragsarten - Order Types.

The data structure and data format of the order files must not be modified. Otherwise, error-free processing cannot be guaranteed.

For IT security reasons, only files without macro function are processed. Therefore, e.g. XLSM files are rejected.

The order files contain a column for comments. Here, comments, labels, etc. can be entered for the supplier's own purposes. The contents of the comments field will not be taken into account during processing.

Produktinformationen/Nachweise – Product information/proofs

Product information must be enclosed and sent along for first publications and for certain product changes. It serves to review and classify the products and their characteristics.

During processing, the documents will be viewed by various offices. Therefore, they must be sent electronically to IFA:

- in readable form;
- in German language;
- as a PDF, image or Word file.

Original cartons, printed vessels or merchandise samples will not be accepted. Publication can only occur when all required documents have been submitted. Depending on the type of product, different information will be required.

For **Arzneimittel** (medicinal products), the documents serve to verify the name, pharmaceutical form, marketing authorisation holder, pharmacy-only or prescription-only status and marketing authorisation or registration number and the processing number (ENR).

Type of product: Medicinal product	Required product information
Neither pharmacy-only nor prescription-only ("over-the-counter")	Package leaflet, Excerpt from AMIce database (or similar proof of authorisation, marketing authorisation/registration no., processing number (ENR))*
Pharmacy-only ("OTC medicinal products")	Package leaflet or summary of product characteristics (SmPC), Excerpt from AMIce database (or similar proof of authorisation, marketing authorisation/registration no., processing number (ENR))*
Pharmacy-only and prescription-only ("RX medicinal products")	Summary of product characteristics (SmPC), Excerpt from AMIce database (or similar proof of authorisation, marketing authorisation no., processing number (ENR))*

*for additional information, please consult Richtlinien für die Neuaufnahme von Arzneimitteln
(Guidelines for New Pharmaceutical Entries (in German))

For the verification of **Medizinprodukte** (medical devices), information regarding the composition, intended purpose, indication and handling is required. If medical devices are pharmacy-only and/or prescription-only, this must also be mentioned in the product information.

Type of product: Medizinprodukte (medical devices)	Required product information
All medical devices	Label with information on composition, intended purpose and handling, proof of CE marking
In-vitro diagnostics, specifically testing strips	Label and package leaflet/insert, proof of CE marking

Sonstige apothekenübliche Artikel (other pharmacy-typical products) include all products that are neither medicinal products nor medical devices. Required for verification are documents about the composition, intended purpose resp. indication and for VMTP the proof of marketing authorisation. In addition, mandatory information, e.g. for food supplements, is reviewed. This information is typically found on the labels or outer packaging or in the package inserts. Depending on the type of product, the following information is particularly appropriate:

Type of product: Other pharmacy-typical products	Required product information/proofs
Drugs/chemicals	Certificate of analysis
Food stuff, food supplements, dietary supplement	Label with ingredients, dosage information, mandatory information – as a supplement possibly also the package insert/the package leaflet
Cosmetics	Label with INCIs
Biocidal products	Label and package insert/package leaflet
Veterinary medical technology device (VMTP)	proof of marketing authorisation of BVL

Zulassungsnachweise – Proof of marketing authorisation

For the first publication of medicinal products subject to mandatory marketing authorisation or registration, proof of marketing authorisation or registration must be provided for each order. For additional information, please consult Richtlinien für die Neuaufnahme von Arzneimitteln (Guidelines for New Pharmaceutical Entries (in German)).

Missing proof of marketing authorisation or registration or a declaration that the medicinal product is neither subject to mandatory marketing authorisation nor registration can be provided subsequently by the notifying deadline for changes of product data. Publication can only occur when all required documents have been submitted.

Übermittlung der Aufträge – Submission of notification orders

Orders are submitted electronically either in IFA portal (including necessary documents) or via EAD file to ead@ifaffm.de. IFA notification order files (including necessary documents) should be transmitted by email including a personal signature to ifa@ifaffm.de.

Orders must not be sent in duplicate. If an order that has already been sent must be corrected, it must be pointed out unambiguously that the later version is a correction and what order it is to replace. Mentioning the transaction numbers from the IFA confirmations of receipt will make assignment easier.

2.3 Auftragsbestätigung – Order confirmation

Following order processing, the supplier receives an order confirmation (in German), which contains the product data meant for publication. First publications will be listed with all data fields entered for the product. For changing product data, the changed information will be highlighted.

Order confirmations can be sent in Excel format or PDF. If the supplier wishes to request a particular confirmation format, it can inform IFA of this request in writing.

The supplier must check the data listed in the order confirmation for completeness and correctness. If all data are correct, no response is required. Correction notices must be submitted by indicating any information that would allow clear identification of the data to be corrected.

If the supplier submits a complaint prior to the notifying deadline, the complaint will be reviewed and any permissible corrections will be made before the editorial deadline. If the supplier submits the complaint at a later date, corrections can only be made by the next publication date. The supplier must complain about any deviations in text form. If it submits his complaint by telephone as an exception, it must document the complaint in text form.

For any particularities during EAD notifying, please see Order confirmation for EAD orders.

2.4 Auftragsarten – Order types

Zuteilung von PZN – PZN pre-allocation

If the PZN is required before market launch (e.g. for creating the package leaflet or information materials), it can be allocated prior to product publication (pre-allocation). The pre-allocated PZN can be used during the later first publication for publication in the IFA information services.

Product information need not be available yet when the PZN is assigned. However, it should be enclosed for verification purposes if it is uncertain whether the product meets the criteria for entry in the IFA database – e.g. whether it is a product typically sold in pharmacies. In such cases, this must be noted in the email with which the order is submitted. Allocation is subject to compliance with the Guidelines for the Pre-Allocation of PZNs.

For PZN allocation, it is sufficient to indicate the product-identifying characteristics. Since assigned PZNs are unpublished, no publication date needs to be indicated in the order. Data may be changed until the product is published.

For PZN allocation for medicinal products subject to mandatory verification, the supplier can request that IFA communicates the numbers early to ACS PharmaProtect GmbH (ACS). *Early* means before a later first publication of the PZN in the IFA information services.

If a certain medical device is not intended for marketing in Germany, a PPN for this medical device can nonetheless be pre-allocated in light of Regulations (EU) No. 2017/745 (MDR) and (EU) No. 2017/746 (IVDR). In this case, no order is placed with IFA for publishing this PPN in the IFA information services relevant for the German market. The unique coding of the medical device and its worldwide identification are guaranteed in any case by the centralised PPN pre-allocation by IFA. For PPN pre-allocations without publication in the IFA information services, Section 5 of the IFA Supplier Contract does not apply. The obligation in Section 7 (7) of the IFA supplier contract to hold IFA harmless from damages refers for such PPN pre-allocations to those countries in which the medical device is distributed.

If the PZN is no longer listed in the IFA database (e.g. in the event of deletion), it reverts to IFA.

Table 1: Notification order placement for PZN allocations

Auftragsart (order type)	Auftragstabelle (Exel order file)	Zusätzliche Unterlagen (additional documents)
PZN-Zuteilung (PZN assignment)	Auftragstabelle A – PZN-Zuteilungen (Order file A – PZN pre-allocations)	Only if it is uncertain whether the product meets the criteria for inclusion in the IFA database: Product information

Neuaufnahme von Artikeln – First publication of products

With the first publication of products in the IFA database, PZN and product data are published in the IFA information services for the first time. This entry is made at the time of market launch. The order submission must be complete by the notifying deadline for first publications (see IFA publication calendar).

If the supplier has already allocated PZNs – from a previous order for *PZN pre-allocation* – these must be entered in the file. If the supplier does not have a PZN for the product yet, it will be allocated at the time of entry into the IFA database.

Table 2: Notification order placement for new PZN entries

Type of product	Auftragstabelle (order file)	Elektronische Auftragsbearbeitung (Electronic order processing)	Zusätzliche Unterlagen (additional documents)
Medicinal product	Auftragstabelle B1 – Neuaufnahmen Arzneimittel (First publication medicinal product)	IFA portal	Summary of product characteristics and extract from AMIce database (or similar proof of authorisation, marketing authorisation/registration no., processing number (ENR))
Medizinprodukte (medical devices)	Auftragstabelle B3 – Neuaufnahmen Medizinprodukte (First publication medical device)	IFA portal	Product information and proof of CE marking
Other pharmacy-typical products	Auftragstabelle B2 – Neuaufnahmen sonstige apothekenübliche Artikel (First publication other pharmacy-typical products)	IFA portal	Product information, for VMTP: proof of marketing authorisation of BVL

Änderung von Artikeldaten – Changing product data

Published product data can be changed and information can be added, e.g. price changes or marketing cessation notifications. The order submission must be complete by the notifying deadline for product changes (see IFA publication calendar).

If there are multiple modifications/additions for data fields of a PZN within one EAD or order file, only the price for one product change is charged (e.g. *length, width, height* and *explosives precursor*).

The deletion of prices is also done via order for product change:

- Via IFA portal: The value must be deleted or value of *0,00* must be entered into the price field.
- Via EAD file: The value of *0,00* must be entered into the price field.
- Per order file: It must be indicated for *Type of change* what price must be deleted, and the value *0,00* must be entered in the price field.

Changing product-identifying characteristics cannot be made while maintaining the PZN. These product changes require that a new PZN be allocated and will be treated like first publications.

When product data are to be changed, product information shall be included for verification purposes only if changes are made to the legal classification of the product. This concerns changes in the following data fields:

- *AMPreisV AMG* and *AMPreisV SGB V*
- Imported medicinal product according to German Social Code Book V (SGB V)
- T-prescription medicinal product
- Medical device in accordance with Section 3 of the Medical Devices Implementing Act (MPDG)

- CE marking
- Medical device in accordance with Section 31 (1) clause 2 of German Social Code Book V (SGB V)
- Bandages and dressings
- Drugs/chemicals
- Pharmacy-only
- Prescription-only
- BtM – Narcotics
- TFG – Documentation requirement according to the Transfusion Act
- Food stuff
- EU Novel Foods Regulation
- Food supplement
- Dietary supplement
- Biocidal product
- Plant protection product
- VTMP according to TAMG

Table 3: Notification order placement for changing product data

Auftragsart (order type)	Auftragstabelle (order file)	Elektronische Auftragsbearbeitung (Electronic order processing)	Zusätzliche Unterlagen (additional documents)
Changing product data	Auftragstabelle C – Änderungen von Artikeldaten (Order Table for product changes)	IFA portal	Only if the legal classification of the product is changed: Product information
		EAD-Dateien – EAD files	

PZN-Übertrag auf einen anderen Anbieter – PZN transfer to another supplier

If another supplier assumes distribution of the product, the product data can be transferred to the new supplier while maintaining the PZN. An order for a PZN transfer can be placed with IFA by the former or future supplier. Both suppliers must include a PZA transfer consent form addressed to IFA with the order.

The order submission must be complete by the notifying deadline for product changes (see IFA publication calendar). If the future supplier is not yet a contractual partner of IFA, it must first conclude a contract.

The PZN transfer can be made in IFA portal or the products concerned must be entered into an Exceltable or "*Auftragstabelle C – Änderungen von Artikeldaten*" (Order Table for product changes). If the entire product range is affected, the mention that all products of the previous supplier must be transferred will suffice.

Both suppliers receive an order confirmation.

The registered supplier is always the party eligible to place the order. With the PZN transfer, the former supplier's right to place orders with IFA regarding the products concerned is transferred to the new supplier. If a former supplier wishes to continue to be in control of the data, it should make contractual arrangements to this effect with the new supplier.

Table 4: Notification order placement for PZN transfers

Auftragsart (order type)	Auftragstabelle (order file)	Elektronische Auftragsbearbeitung (Electronic order processing)	Zusätzliche Unterlagen (additional documents)
PZN transfer	Auftragstabelle C – Änderungen von Artikeldaten (Order Table for product changes) or: Supplier's own Excel spreadsheet with a list of the PZNs in question is possible	IFA portal: Tick off the relevant PZN via Multi Select with upload of the required documents/proofs	Declaration of consent of the former and the future supplier

Löschung von Artikeln – Deletion of products

If an product is no longer marketed, it can be deleted from the IFA database. The order submission must be complete by the notifying deadline for product changes (see IFA publication calendar).

Certain conditions apply to the deletions of medicinal products which can be found in Richtlinien zum Artikelstatus und Statuswechsel (German) (Guidelines on Product Status and Status Change).

Orders are placed with "*Auftragstabelle C – Änderungen von Artikeldaten*" (Order Table for product changes). In the free text field *Art der Änderung,* the order for deletion must be clearly noted, e.g. with the abbreviation *LÖ*. If the product is to be labelled *marketing ceased* or *withdrawn* instead, the abbreviations *AV* or *ZG* must be chosen.

Table 5: Notification order placement for PZN deletion

Auftragsart (order type)	Auftragstabelle (order file)	Zusätzliche Unterlagen (additional documents)
PZN deletion	Auftragstabelle C – Änderungen von Artikeldaten (Order Table for product changes) or: Supplier's own Excel spreadsheet with a list of the PZNs in question is possible Deletion not possible via IFA portal or EAD file	

Aufnahme oder Änderung von Adressdaten – First publication or changing of address data

Together with the product data, the supplier's address data are published in the IFA information services. Therefore, the address data must be published, changed and supplemented.

First publications, modifications and corporate name changes can be ordered via order file. Orders for modifications or corporate name changes must be submitted completely by the notifying deadline for changes of product data (see IFA publication calendar).

During the conclusion of the supplier contract, the following must also be submitted:

- *Auftragstabelle D – Adressdaten Anbieter* (Order file Supplier's address data)
- *Antrag auf Abschluss des IFA-Anbietervertrags* (Application for concluding an IFA supplier contract)
- Copy of the trade register excerpt or business registration
- Copy of the manufacturing authorisation according to Section 13 of the German Medicinal Products Act (AMG) (if applicable)
- Copy of the wholesale authorisation according to Section 52a of the German Medicinal Products Act (AMG) (if applicable)

A copy of the trade register excerpt must be enclosed with the order for a corporate name change. If the company with the changed corporate name enters into the universal succession of the company with the previous company name or if a change of legal form has taken place that preserves the company's identity, this must be documented.

If the universal succession/conversion is not confirmed, a new contract will be concluded and a new customer number will be allocated. The products can be transferred from the previous customer number to the new customer number (see PZN transfer).

Table 6: Notification order placement for address processing

Auftragsart (order type)	Auftragstabelle (order table)	Elektronische Auftragsbearbeitung (Electronic order processing)	Zusätzliche Unterlagen (additional documents)
First publication of address data for suppliers	Auftragstabelle D – Adressdaten Anbieter (Order table D – Supplier's address data)		Antrag auf Abschluss des IFA-Anbietervertrags (Onboarding application for conclusion), Trade register excerpt or business registration, manufacturing permit and/or wholesale permit, if applicable
Supplier's address change	Auftragstabelle D – Adressdaten Anbieter (Order table D – Supplier's address data)		Only for corporate name changes: Trade register excerpt or business registration
Change of IFA contact	Auftragstabelle D – Adressdaten Anbieter (Order table D – Supplier's address data)		
First publication of address data for manufacturers, marketing authorisation holders or local representatives	In context of first publication: Auftragstabelle B1 – Neuaufnahme Arzneimittel (Order table B1 – First publication Medicinal Product)	Bei Arzneimittel Neuaufnahme (For First publication of medicinal product): IFA portal	See: Neuaufnahme von Artikeln – First publication of products

Auftragsart (order type)	Auftragstabelle (order table)	Elektronische Auftragsbearbeitung (Electronic order processing)	Zusätzliche Unterlagen (additional documents)
Address change for manufacturers, marketing authorisation holders or local representatives	Product-related address data: Auftragstabelle C – Änderungen von Artikeldaten (Order table C – Product changes)		

2.5 Elektronische Auftragserteilung – Electronic order placement

2.5.1 Arbeiten mit dem IFA-Portal – Working with IFA portal

IFA portal is available for electronic order placement. Here you have direct access to your own already published product range data. First publications of product data as well as changes to these can be ordered online in the portal and transmitted electronically.

The functions of IFA portal are constantly being expanded. At a later point in time, it will also be possible to order *PZN pre-allocations* prior to market launch. Please note that IFA portal platform and support is only available in German.

Zugang zum IFA-Portal – Access to IFA portal

IFA portal can be accessed directly via https://www.ifa-portal.de. A user ID can be requested via https://www.ifa-portal.de/de/registrierung.

Funktionen – Features

The following features are available for editing and adding product data:

- View of published product data in status marketed (IV), marketing ceased (AV), withdrawn (ZG) and non marketable (NV)
- Order of First publication of product data in the IFA database and the IFA information services. Only the data fields relevant to the product type in question must be entered. In addition, it can be selected whether the first publication is requested according to template of a product that is already published.
- Order changes and additions to product data - including changes that require a proof document
- PZN transfer to another supplier (consent forms required)
- Upload option for required documents/proofs
- Checking of new entries for plausibility with information to the client to prevent the publication of inadmissible values or value combinations
- Price calculator for calculating prices for medicinal products according to AMPreisV - based on APU as well as AEP and AVP (data initially non-binding)

- Reminder function for orders not yet sent
- Display of newly entered as well as already confirmed first publications and product data changes - both for the current as well as for a future publication date
- Choice of format for order confirmations (Excel format, PDF or both)
- Archiving of order files and order confirmations

Benutzerverwaltung – User administration

The IFA portal contains the user administration area for the independent administration of user data and the allocation of individual authorisations for employees.

Of great importance is the integrated option to block assigned user IDs if necessary. This is relevant, for example, for portal accesses of persons formerly working in the company. Blocking access is important for the protection of data and against unauthorised access.

2.5.2 Arbeiten mit EAD-Dateien – Working with EAD files

Product data can be changed using Electronic Order Data Processing (EAD). This enables fast, automated changes, even outside regular business hours.

EAD-Dateien anfordern – Requesting EAD files

On the website, www.ifaffm.de, a request for the current EAD, product and address data range file can be submitted via the menu items *IFA for suppliers* and *Request for EAD, product and address data*.

In order for EAD, product and address data range files to be provided, security criteria must be met for data privacy considerations. Therefore, only a supplier contact known to IFA is an authorised data recipient. If not all criteria are met at the time of the request, the supplier will receive a notification in lieu of the EAD/product range files.

The EAD file contains all data on products with the status *marketed (IV)* and *marketing ceased (AV)* as of the next possible publication date. All data that can be changed via EAD can be commissioned with this file. An overview of all modifiable data fields is provided by the file *EAD-Gesamt.xlsx*. Alternatively, a specific EAD file can be requested (e.g. *EAD-Preis.xlsx* for changes to pricing information and out-of-distribution labels).

For internal purposes, various product range files and files with *PZN pre-allocations,* which also contain data fields that cannot be changed, can be requested as well. Product range files are therefore inappropriate for ordering product changes.

Änderungen in einer EAD-Datei vornehmen – Making changes to an EAD file

The original EAD file must be opened and saved under a name that can be freely chosen. The desired changes are to be made and saved in the EAD file.

The following conditions must be taken into account so that the change can be made:

- Unchanged products can be deleted from the file. For this purpose, the complete data record (i.e. the entire line) must be deleted. Data records that were only hidden in Excel are still recognised and processed.
- Only files with a current data status are to be used. This ensures that the currently notified product data are retained and that outdated data are not inadvertently imported. Each file contains the data status down to the last second in the "*Daten vom"* field.
- Data structure and data format must not be changed. For example, line 8 with the data field explanations is not to be deleted. If needed, it can be hidden. Excel functions (e.g. references, formulas) may not be used.
- Accompanying texts, formatting and notes are not recognised by the electronic order data processing system and will not be considered.
- The file may only contain published products. Products to which only a PZN was pre-assigned (without publication) must not be included.
- The information on client and products must be correct and complete.
- Products must not be included multiple times.
- For medicinal products that are subject to a price regulation, the price listings must be compliant with it.
- Price quotations with more than two decimal places shall be commercially rounded to the full cent.

EAD-Datei per E-mail einreichen – EAD file submission via email

The EAD file must be sent to ead@ifaffm.de to enable automated processing. By inputting the EAD file the product data will be changed in accordance with the entered information.

Informationen zur Verarbeitung eines EAD-Auftrages – Information regarding processing of an EAD order

Upon processing, the supplier will automatically receive an order processing notice. This notice may consist of up to three file attachments:

- Auftragsbestätigung.xlsx – an order confirmation that contains the changed products
- Fehler.xlsx – an error file that contains the products for which product changes cannot be processed; the supplier is asked to read the explanatory error texts in the righthand area of the file.
- Keine_Änderungen.xlsx – a no-changes file that contains the products for which no changes were ascertained

For correction requests, the data must be corrected in the error file(s), the error texts must be deleted and the file must be saved and resubmitted to ead@ifaffm.de.

2.5.3 Elektronisch nicht verarbeitbare Aufträge – Orders that cannot be processed electronically

First publications, *PZN pre-allocations*, *deletions* and *address changes* must be ordered with order files. *PZN transfers* can be ordered with corresponding proofs in IFA portal, but not via EAD file.

The data fields listed in Table 7 *Data fields that cannot be changed via EAD file and IFA portal - incl. deviations for changes in IFA portal* cannot be changed via EAD file due to in-depth quality assurance. The table "*Auftragstabelle C – Änderungen von Artikeldaten*" (Order Table for product changes) must be used for this purpose. Some of these can be changed with appropriate proofs in IFA portal. These carry a note in the table in column *Deviation in IFA portal*. Product-identifying characteristics can generally not be changed for published PZNs.

Table 7: Data fields that cannot be changed via EAD file and IFA portal - incl. deviations for changes in IFA portal

Data field	Deviation in IFA portal
Data field group: Product-identifying characteristics	
Produktbezeichnung – 26-digit product name	
Darreichungsform – Pharmaceutical form	
Packungsgröße (Menge und Einheit) – Packaging size (quantity and unit)	
Artikeltyp – Product type	
Arzneimittel – Medicinal product	
Data field group: Pricing information	
Arzneimittelpreisverordnung AMG bzw. SGB V – Pharmaceutical Price Ordinance according to AMG or SGB V	changeable with proof
Festbetrag – Reference price	
Preisangabenverordnung (PAngV) – Price Indication Ordinance (PAngV)	
Data field group: Legal information	
Arzneimittel – Medicinal product	
Tierarzneimittel (TAMG) – Veterinary medicinal products act (TAMG)	
apothekenpflichtig – Pharmacy-only	changeable with proof
verschreibungspflichtig – Prescription-only	changeable with proof
Betäubungsmittel (BTM) – Narcotic	
BOPST number	
Transfusionsgesetz – Transfusion Act (TFG)	
T-Rezept-Arzneimittel – T-prescription medicinal product	
Eingangsnummer (ENR) der Zulassungsunterlagen – Processing number (ENR) of the marketing authorisation documents	changeable with proof
Eingangsnummer (ENR)-Nachmeldung – Processing number (ENR) supplementary notification	changeable with proof
Zulassungs-/Registrierungs-Nr. – Marketing authorisation/registration number	changeable with proof
Ausnahme nach § 52b Abs. 2 Satz 3 AMG – Abgabeverbot an pharm. Großhandel – Exemption according to Section 52b (2) clause 3 of the German Medicinal Products Act (AMG) – Prohibition of dispensing to pharmaceutical wholesalers	changeable with proof

Data field	Deviation in IFA portal
Packungsgrößenverordnung – Packaging Size Ordinance (PackungsV)	
Abschlagsbefreiung – Exemption of Deduction	
Wirkstoffpatent – Compound patent: exclusively the change from value 0 (no) to value 1 (yes)	
Unterlagenschutz – Data exclusivity: exclusively the change from value 0 (no) to value 1 (yes)	
Medizinprodukt gemäß § 3 MPDG – Medical device in accordance with Section 3 of the Medical Devices Implementing Act (MPDG)	changeable with proof
Sonstiges Produkt zur Wundbehandlung gemäß § 31 (1a) SGB V – Miscellaneous product for wound care according to Section 31 (1a) of German Social Code Book V (SGB V)	
CE-Kennzeichnung – CE marking	changeable with proof
Medizinprodukt gemäß § 31 Abs. 1 Satz 2 SGB V – Medical device in accordance with Section 31 (1) clause 2 of German Social Code Book V (SGB V)	changeable with proof
Verbandmittel – Bandages and dressings	changeable with proof
Hilfsmittel zum Verbrauch – Device for consumption	
Lebensmittel – Food stuff	changeable with proof
EU-Novel-Food-Verordnung – EU Novel Foods Regulation	changeable with proof
Nahrungsergänzungsmittel – Food supplements	changeable with proof
Diätetikum – Dietary supplement	changeable with proof
Biozid – Biocidal product	
Droge/Chemikalie – Drug/chemical	
Pflanzenschutzmittel – Plant protection product	
Data field group: Storage information	
Kühlkette – Cold chain	changeable with proof
Data field group: Pack information	
Kombinationspackung – Combination pack	
Data field group: Distribution information	
Vertriebsstatus *zurückgezogen* – Distribution status *withdrawn*	
Artikellöschungen – Product deletions	
Verkehrsfähigkeitsstatus – Marketability status	changeable with proof
Additional information	
Anbieter bei Vertriebsübernahme (PZN-Übertrag) – Supplier takes over distribution (PZN transfer)	changeable with proof
Adressdaten vom Anbieter (Address data of supplier)	
Artikelbezogene Adressinformationen vom Zulassungsinhaber, Örtlichen Vertreter und Hersteller (Product-related address data of marketing authorisation holder, local representative and manufacturer)	

3. Abbreviations

The text mentions the following terms in abbreviated form:

- Arzneimittelgesetz – German Medicinal Products Act (AMG)
- Arzneimittelpreisverordnung – Pharmaceutical Price Ordinance (AMPreisV)
- Batteriegesetz – Battery Act (BattG)
- Betäubungsmittelgesetz – German Narcotics Act (BtMG)
- Bundesamt für Verbraucherschutz und Lebensmittelsicherheit – Federal Office of Consumer Protection and Food Safety (BVL)
- Bundesinstitut für Arzneimittel und Medizinprodukte – Federal Institute for Drugs and Medical Devices (BfArM)
- Elektro- und Elektronikgerätegesetz – Electrical and Electronic Equipment Act (ElektroG)
- Elektro- u. Elektronikgeräte-Stoff-Verordnung – Electrical and Electronic Equipment Substance Ordinance (ElektroStoffV)
- Fälschungsschutzrichtlinie – Falsified Medicines Directive 2011/62/EU (FMD)
- Gefahrstoffverordnung – Ordinance on Hazardous Substances (GefStoffV)
- Informationsstelle für Arzneispezialitäten – IFA GmbH (IFA)
- Medizinprodukterecht-Durchführungsgesetz – Medical Devices Implementing Act (MPDG)
- Medizinprodukte-Verordnung – Medical Device Regulation (EU) 2017/745 (MDR)
- Nahrungsergänzungsmittelverordnung – Nutritional Supplement Ordinance (NemV)
- Packungsgrößenverordnung – Packaging Size Ordinance (PackungsV)
- Preisangabenverordnung – Price Indication Ordinance (PAngV)
- Sozialgesetzbuch Fünftes Buch – German Social Code Book V (SGB V)
- Tierarzneimittelgesetz – Veterinary medicinal products act (TAMG)
- Verpackungsgesetz – Packaging Act (VerpackG)

4. Change log

Date	Type of modification
Valid from 27 March 2024 Last edit 5 March 2024	■ Addition: (Kunden-)Artikel-Nr. – (Customer) product number ■ Addition: APU § 130a Abs. 3c Satz 6 SGB V vereinbart – sales price of the pharmaceutical entrepreneur Section 130a (3c) clause 6 German Social Code Book V (SGB V) agreed ■ Addition: Arzneimittel mit altersgerechter Darreichungsform oder Wirkstärke für Kinder – Medicinal products with age-appropriate pharmaceutical form or strength for children ■ Addition: Arzneimittel mit aufgehobenem Festbetrag – Medicinal products with repealed reference price ■ Addition: Arzneimittel zur Behandlung von Kindern nach BfArM-Liste – Medicinal products for the treatment of children according to BfArM list ■ Addition: Arzneimittel mit versorgungskritischem Wirkstoff nach BfArM-Liste – Medicinal products with a supply-critical active substance according to BfArM list ■ Update: biotechnol. herg. AM – Biotechnologically produced medicinal product (Link to *Leitfaden zur Ermittlung des Generikaabschlags* (Guideline for the definition of the generic discount) removed) ■ Update: Wirkstoffpatent – Compound patent (Link removed; IFA portal-/EAD information) ■ Update: Unterlagenschutz – Data exclusivity (Link removed; IFA portal-/EAD information) ■ Update: biologisches AM – Biological medicinal product (Link removed) ■ Update: Solitäres Fertig-AM – Unique finished medicinal product (Link removed

Valid from 1 February 2024 Last edit 15 December 2023	■ Data field added: 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 ■ Data field added: Datum, ab dem die Ablösung des Abschlags § 130a SGB V gilt – Date from which the overruled discount Section 130a SGB V applies ■ Data field added: Arzneimittel mit altersgerechter Darreichungsform oder Wirkstärke für Kinder – Medicinal products with age-appropriate pharmaceutical form or strength for children ■ Data field added: Arzneimittel mit aufgehobenem Festbetrag – Medicinal products with cancelled reference price ■ Data field added: Arzneimittel zur Behandlung von Kindern nach BfArM-Liste – Medicinal products for the treatment of children according to BfArM list ■ Data field added: Arzneimittel mit versorgungskritischem Wirkstoff nach BfArM-Liste – Medicinal products with a supply-critical active s according to BfArM list ■ Value range change and extension in data field: Tierarzneimittel-Abgabemengen-Register (TAR) – Delivery quantities register for veterinary medicinal products (TAR) ■ Value range extension in data field: Arzneimittel mit Erstattungsbetrag § 130b SGB V – Medicinal products with reimbursement amount according to Section 130b of German Social Code Book V (SGB V) ■ Value range reduction: Ablösung Abschlag § 130a SGB V – Overruled discount Section 130a SGB V ■ Clarification for data field: APU § 130a Abs. 3c Satz 6 SGB V vereinbart – sales price of the pharmaceutical entrepreneur Section 130a (3c) clause 6 German Social Code Book V (SGB V) agreed
Valid from 20 November 2023 Last edit 15 November 2023	■ IFA portal-relevant information added - in particular information on notification of first publications via the IFA portal
Valid from 1 July 2023 Last edit 30 June 2023	■ Updating of relevant passages, as the legitimation check carried out by IFA GmbH for ACS PharmaProtect GmbH within the framework of FMD is no longer required ■ Changes in the use of order documents: e.g. notification order based on IFA order forms incl. order cover sheet discontinued; updates of relevant positions ■ Information on the use of IFA Portal; relevant passages changed

17 March 2023	■ Value range extensions and renaming in data field: TAMG Tierarzneimittelgesetz – TAMG Veterinary medicinal products Act (former: *Tierarzneimittel – Veterinary medicinal product*): Value 2 added; relevant passages changed ■ Data field added: APU § 130a Abs. 3c Satz 6 SGB V vereinbart – sales price of the pharmaceutical entrepreneur Section 130a (3c) clause 6 German Social Code Book V (SGB V) agreed ■ Data field added: Datum, ab dem der vereinbarte APU § 130a Abs. 3c Satz 6 SGB V gilt – Date from which the agreed APU Section 130a (3c) clause 6 German Social Code Book V (SGB V) applies
30 November 2022	■ Value range extensions and renaming in data field : Ablösung Abschlag § 130a SGB V – Overruled discount Section 130a SGB V (formerly: *field Ablösung Abschlag § 130a (1/8) SGB V – Overruled discount Section 130a (1/8) SGB V*): addition of value 2 and 3, relevant passages changed ■ Update: Abschlagsbefreiung – Exemption of Deduction
28 October 2022	Data field renamed: Medizinprodukt gemäß § 3 MPDG – Medival device in accordance with Section 3 of the Medical Devices Implementing Act (MPDG) (formerly: *Medizinprodukt gemäß § 3 MPG – Medical device pursuant to Section 3 of the Medical Devices Act (MPG)*); relevant passages changed Data field renamed: Tierarzneimittel-Abgabemengen-Register (TAR) – Delivery quantity register for veterinary medicinal products (TAR) (formerly: *47 Abs. 1c AMG – Tierarzneimittel-Abgabemengen-Register – Section 47 (1c) of the German Medicinal Product Act – Sales quantities register for veterinary medicinal products*); reflects modified laws Data field renamed: Eingangsnummer (ENR) der Zulassungsunterlagen – Processing number (ENR) of the marketing authorisation documents (formerly: *BfArM-Eingangs-Nr. der Zulassungsunterlagen – BfArM processing number (ENR) of the marketing authorisation documents*); relevant passages changed Value range on data field Product type changed: Value 6 added; relevant passages changed Value range on data field Arzneimittel mit Erstattungsbetrag § 130b SGB V – Medicinal products with reimbursement amount according to Section 130b of the German Social Code Book V (SGB V): Value 0 and 1 specified and value 2 added Data field added: Pricing structure modell Data field added: *stiftung ear*; relevant passages changed Data field added: Batterie-Registrierungsnummer der *stiftung ear* – Battery registration number by *stiftung ear*; relevant passages changed Data field added: Eingangsnummer (ENR-)Nachmeldung – Processing number (ENR) supplemetary notification Data field added: Preisbindung für Bücher – Book price fixing Data field added: Multi Market Pack – Multi market pack Data field updated: Tierarzneimittel – Veterinary medicinal product; reflects modified laws Chapter updated Verfication information: Editorial revision. In General: Editorial revision of the complete document

13 July 2022	■ Sections on 1.1.2 Pricing information and 2.5 Working with EAD files > Making changes to an EAD file updated: commercial rounding of price quotations with more than 2 decimal places to the full cent ■ Data field removed: *Zulassungsdatum*: proofs of marketing authorisation are required irrespective of the date of authorisation (e.g. as an extract from the *Medicinal Products Information System AMIce*); see also Produkt-informationen – Product information and First publication of products ■ Data field updated: EU-Bio-Siegel – EU organic logo: new REGULATION (EU) 2018/848
20 April 2022	First publication of the english language Version of this document

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