Guidelines for the pre-allocation of PZNs

IFA

GUIDELINES

Directory

1. Introduction

Information in relation to the product notified by suppliers and pharmaceutical entrepreneurs to IFA GmbH form the necessary and handy prerequisite for those affected in the healthcare sector such as doctors, pharmacies, pharmaceutical wholesalers, health insurers and others to successfully fulfil their tasks according to legal allegations within the market. Thus, it is in the suppliers' and pharmaceutical entrepreneurs' interest when traders, care providers and health insurers sell, use or invoice the products in a secure and legally conform manner. With your notification, data correspond to especially legal notification obligations such as those according to § 131 Paragraph 4 SGB V.

This IFA GmbH guideline shall outline the data to be notified and further information and thus ease suppliers' correct notification. IFA GmbH will answer questions on attributes or notification procedures at any time.

2. Terms for publication in IFA's database and pre-allocation of PZN

When a product is introduced into IFA's database, an 8-digit identification number, the Pharmazentralnummer (PZN), is assigned. Pre-allocating PZNs according to the guidelines serve the primary purpose of identifying products in the healthcare sector.

The PZN is an unambiguous key and identifies a specific product (a sales presentation) with a specific name, packaging size (Menge und Einheit), pharmaceutical form, attribute *Arzneimittel* and a specific product type of a designated supplier. If necessary to distinguish from other products, further criteria such as colour, shape, size etc. must be included in the name as product identifying characteristics that call for a new PZN.

Each participant of the market or data user of IFA's Information Services must be able to uniquely identify the product at any time (i. e. for order or billing processes), without having to need additional information such as colour, shape or size with an exception for the above mentioned circumstance.

The following conditions apply for product data to be published in IFA's Database:

- The products are pharmacy typical in accordance with *Apothekenbetriebsordnung* (ApBetrO).

- The products are unconditionally marketable in Germany.

- According to § 73 Paragraph 3 Arzneimittelgesetz (AMG) single imported medicinal products are only considered marketable under the conditions specified under the Section.

Other pharmacy typical products and medical devices fulfil their applicable legal requirements *(i. e. Medizinprodukterecht-Durchführungsgesetz, Diätverordnung, Verordnung über Nahrungsergänzungsmittel).*

- The supplier complies with the legal and actual prerequisites for marketing the products registered under their name.

  Legal prerequisites can be distribution law, trade mark rights, patent law, for medicinal products the requirements for pharmaceutical entrepreneurs etc. Actual prerequisites are that the products are generally available and can be ordered by pharmacies and/or pharmaceutical wholesalers.

- The products are finished products that can be ordered from the information in IFA's Information Services. Thus proprietary medicinal products according to § 4 Paragraph 1 AMG or substances according to § 3 AMG can be published. Magistral formulas that are being produced individually for each patient by the pharmacist upon a doctor's prescription will not receive a PZN. Publication of made to measure or special sizes that can only be manufactured when presented with additional information (such as measurements) cannot receive PZNs.

- The products are sales packs (sales presentations) that are dispensed to the customer without opening the pack and handing out some of the products (product type *Standard*). This also applies for products with product type *clinic packs*, *clinic components* as well as *physician samples according to § 47 Paragraph 3 and 4 AMG*, *bulk products* and *pandemic products*.

  Displays, free samples (e.g. testers), promotional merchandise (e.g. paper tissues), large packagings for separating out and shipping units may receive an individual PZN, if the product type *Marketingbedarf* (marketing supplies) is submitted. Excluded from this are BtM (narcotics) and medicinal products subject to the documentation requirement according to Transfusion Act (TFG).

  A specific minimum order quantities (MOQ) for wholesalers and pharmacies cannot receive a PZN. Please use the attribute *Mindestbestellmenge* (MOQ) in this case.

- Information published in IFA's Information Services refer to actual products that can be ordered. Information on products that cannot be ordered will not be published in IFA's Information Services. IFA's Information Services serve in substance the communication of information regarding the merchandise. Advertising messages and information lacking product relevance etc. cannot receive a PZN.

- Products of one supplier with the same product identifying characteristics cannot be published in IFA's database several times. Product identifying characteristics are:

  - *Produktbezeichnung* (26-digit product name)
  - *Packungsgröße* (packaging size)
  - *Darreichungsform* (pharmaceutical form)
  - attribute *Arzneimittel (*value *medicinal product)*
  - *Artikeltyp* (product type)

  Products that differ in these characteristics receive a separate PZN. Products that do not differ in these characteristics are regarded as identical and thus receive a PZN only once. Other distinctions such as the outer pack's layout do not count as criteria for a different PZN pre-allocation.

If a supplier has to/wants to change a product identifying characteristic, a new PZN must be pre-allocated. This also applies to changing the name. In this case it is irrelevant whether for example the product's composition changes at the same time or whether it stays the same. Crucial is that at any time a data user can be sure that the product with a certain PZN is still the same without having to receive additional information or physically looking at the product.

Changing product identifying characteristics can only be done when pre-assigning a new PZN in the interest of all of the market participants and data users. This will avoid problems in the customer relation such as:

- o billing problems
- o prescription problems in a doctor's surgery
- o uncertainty when allocating newly arrived goods with storage areas
- o not matching prints on goods and delivery note/invoices
- o complaints of customers due to– allegedly – good not matching their order
- o falsified turnover and sales statistics

Conversely, it is absolutely necessary to retain the PZN when the product identifying characteristics remain unchanged. Otherwise a data user would get the impression that the product with a new PZN is a different product (at least by one product identifying characteristic) than the first.

■ The pre-allocation of a PZN prior to the product's launch in the market is done exclusively for products with an intended launch.

■ The supplier can ask IFA GmbH to transfer data of PZN pre-allocations for medicinal products obliged to verification to [ACS PharmaProtect GmbH](#) early. *Early* means prior to the planned launch of the product and the PZN's publication in IFA's Information Services. This information/transfer will be done exclusively to ACS PharmaProtect GmbH. It takes place ten working days prior to the next 1st or 15th of a month. The notification order for transferring data of pre-allocated PZNs from the past to ACS PharmaProtect GmbH can be made belated. Please refer to the guidelines *Richtlinien zur Meldung von Artikel- und Adressdaten*, Chapter *1.3 Sonstige Daten: Auftrag zur Ausgabe der Zuteilung*.

The described process does not affect the notification of a first publication into IFA's Information Services resulting in the publication for eligible data recipients. This notification still remains the same and is carried out according to previous requirements.

■ If a certain medical device is not meant to be marketed in Germany, a PPN may still be pre-allocated to this medical device in the light of delegated regulations (EU) 2017/745 (MDR) and (EU) 2017/746 (IVDR). In this case no order is placed for publication of the PPN to IFA in its relevant Information Services for Germany. The unique encoding of the medical device and its worldwide identification through the centralised PPN issuing are guaranteed in any case. For pre-allocated PPNs without publication in IFA's Information Services § 5 of IFA's Supplier Contract does not apply. Obligations resulting from § 7 par. 7 of IFA's Supplier Contract for PPN pre-allocations applies for countries in which the medical device is marketed.

■ When the PZN is no longer published in IFA's database (for example due to a deletion) they automatically fall back to IFA GmbH.

3. Comply with the guidelines

IFA GmbH bases the compliance with this guidelines on the supplier's notification. It may possibly not be able to correctly validate the submitted documents of each notification in every case. Therefore it cannot be ruled out that individual products published in IFA's database do not meet one or some of the mentioned prerequisites. From these improper isolated cases may not be assumed that these guidelines must not be met.

Examples for the guidelines

Examples: new PZN must be assigned

- The pharmaceutical form is added to the product name for better differentiation.
- Additions to the product name (i. e. *N* or *mit Vitamin X* or *forte*).
- A new product series is introduced. The old series receives an addition to distinguish it from the first (*classic, light, intensive* or similar).
- An addition (i. e. *N* or *mit Vitamin X* or *Milligramm* or *forte*) shall be removed from the product's name.
- Dropping of an element of the product's name (i. e. *Topart eingesiegelt* → *Topart*).
- Changing of an element of the product's name (i. e. *Topart eingesiegelt* → *Topart Kalenderpackung*).
- Changing the packaging size (*Menge* and/or *Einheit* – i. e. *10 ST -> 100 ST*)
- The packaging size changes due to technical reasons (i. e. a propellant in a spray is removed).
- The pharmaceutical form is amended (i. e. from *Tabletten* to *Filmtabletten*).
- Attribute *Arzneimittel* changes due to a different classification (i. e. medicinal product becomes medical device).
- The product type changes (i. e. from *Klinikpackung* to *Standardpackung*).

Examples: PZN remains the same

- The outer packaging/layout (container, carton) changes without changing the product identifying characteristics (product name, pharmaceutical form, product type, attribute *Arzneimittel*).
- The dispensing regulations of a medicinal product change (i. e. not *verschreibungspflichtig* in the future).
- Changing the figure of the packaging size (i. e. 2x30 mg instead of 60 mg)
- The prices of a product change.
- The numeric potency is added (i. e. *Topart* → *Topart 10*).
- The attribute *Packungsgrößenkennzeichen* of a medicinal product changes due to a change in the *Packungsgrößenverordnung* (i. e. *N3* → *N2*).
- The pharmaceutical form is added from a blank entry but the product remains unchanged.

Examples: PZN may remain the same or new PZN can be assigned

- Marketing of the product is taken over by a different supplier. Either the new supplier takes over the PZN or notifies their own.

Caution: These examples are meant as general idea of typical changes in product data. Not all possible changes have been noted. If in doubt please contact IFA GmbH's customer service team.

4.   Modification history

Date	Type of modification
14 February 2024	▪ Updated Kapitel 2 und Kapitel 3: term *Artikelbezeichnung* changed to *Produktbezeichnung*
28 October 2022	▪ Updated Section 2: Added information concerning product type *Marketingbedarf* (marketing needs)
21 October 2021	▪ Updated Section 2: Upload of serial numbers via ACS no longer possible