# IFA Database and IFA Information Services

## Introduction

Informationsstelle für Arzneispezialitäten – IFA GmbH (IFA) maintains a database as source of information to different systems (e. g. pharmacy software, data processing systems of pharmaceutical wholesalers, health insurances). All system users have different requests both contents wise and technically. Data from the IFA database reaches users through a variety of channels.

This brochure contains information on

- which tasks IFA takes on in the pharmaceutical market,
- how product data are published into the IFA database,
- how IFA information services reach their users,
- the schedule the IFA information services are created.

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# 1. Which tasks does IFA take on?

IFA is a neutral and central service provider for standardised and quality assured information in the legal sector and also in logistics. It supplies its services to various actors with different requirements and obligations. It provides support in complying with national and European regulations.

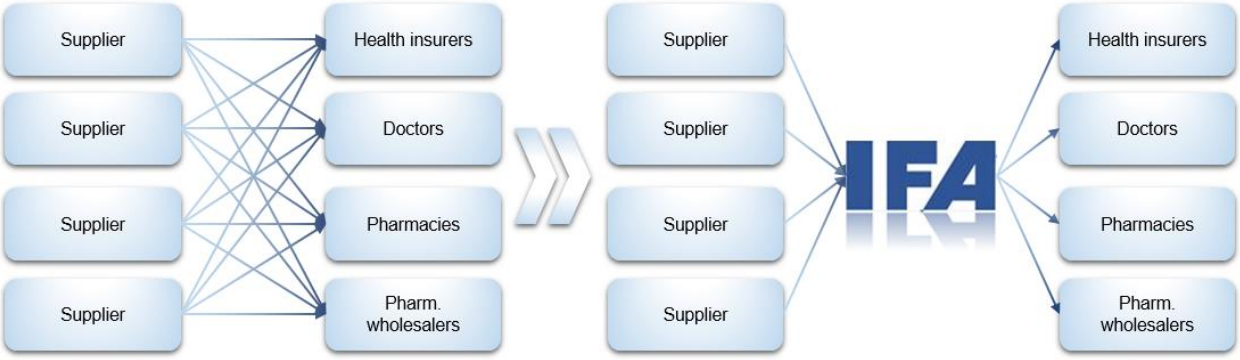


*Illustration 1: IFA GmbH as effective and efficient clearing entity*

The tasks of IFA include:

- Pre-allocating of *Pharmazentralnummer* (PZN) as unique identification key
- Issuing agency according to ISO/IEC standards, issuing of *Pharmacy Product Number* (PPN) and Issuing Entity for UDI
- Recording and normalising of notification orders of the suppliers
- Supplying of Information Services
- Implementing legal prerequisites (national and European)
- Assumption of legal information and notification obligations
- Ensuring market access of medicinal products, medical devices i. a.

# 2. How are Product Data added into the IFA database?

## Notification by the supplier

First publication and product data change in the IFA database is generally notified by the supplier of the product. Supplier within the meaning of IFA are all persons and companies that market medicinal products, medical devices or other pharmacy-typical products in their name (manufacturer, distributor, importer). The following notification orders are possible:

- *PZN-Zuteilung:* the supplier can notify PZN pre-allocations prior to market launch
- *Neuaufnahme*: upon the product launch, the supplier notifies a first publication of product data to IFA to publish in the IFA Information Services
- *Änderung*: if the product is already being published in the IFA Information Services, the supplier may notify product data changes such as prices, distribution channel

## Criteria check

IFA checks whether the product complies with the Guidelines for the pre-allocation of PZNs. In addition, the supplier must submit an informative product information (for medicinal products: Summary of Product Characteristics (SmPC) and Marketing Authorisation (MA)). Cases of doubt and topics that ask for a pharmaceutical expertise, will be communicated with ABDATA Pharma-Daten-Service for further evaluation. If the available information is not sufficient, the supplier is asked for a statement respectively one of a supervisory authority in concern.

The criteria review especially includes the following regulations to meet legal prerequisites:

- Arzneimittelgesetz (AMG)
- Sozialgesetzbuch V (SGB V)
- Arzneimittelpreisverordnung (AMPreisV)
- Apothekenbetriebsordnung (ApBetrO)
- Regulation (EU) 2017/745 MDR
- Lebensmittel- und Futtermittelgesetzbuch (LFGB)
- Nahrungsergänzungsmittelverordnung (NemV)
- Diätverordnung (DiätV)
- Packungsgrößenverordnung (PackungsV)

## Publication of product data into the IFA database

If the notification order documents are submitted complete and have been checked, the product data will be published on the desired publication date into the IFA database. IFA pre-allocates a PZN to the product and confirms it to the supplier with the order confirmation.

*IFA database* includes the entirety of data notified by suppliers. It contains information from the following sectors:

- Artikelgrunddaten – basic data
- Preisinformationen – price information
- Rechtliche Informationen – legal information
- Verifizierungsinformationen – FMD information
- Lagerungsinformationen – storage information
- Packungsinformationen – packing information
- Vertriebsinformationen – sales information
- Verweisinformationen – reference information
- Adressdaten – addesss data

# 3. How do Data Recipients receive Product Data?

## Transmission of the IFA Information Services

Upon completion of the data gathering interval, IFA transfers the data as so-called IFA Information Services to the data recipients. *IFA Information Services* are the product based on suppliers' notifications submitted by IFA to eligible data recipients. This product will be submitted as raw data exclusively.

## Data processing, multiplication and transmitting

Data will be further processed, amended, selected and fitted to technical background by data recipients if necessary. The data contents must not be altered. Some recipients use the data themselves such as pharmaceutical wholesalers. Others offer them to specific data recipients such as medical software providers. Data for pharmacies are passed on exclusively via ABDATA Pharma-Daten-Service and pharmacy software providers.

# 4. Chronology of Data Assessing and Processing

IFA publishes every fortnight data processed by the deadline for the publication date 1st or 15th of every month in the IFA Information Services. Thus creating a regular update frequency whilst retaining orderly processing. Publication dates and their notification deadlines can be found in the IFA publication calendar IFA-Redaktionskalender.

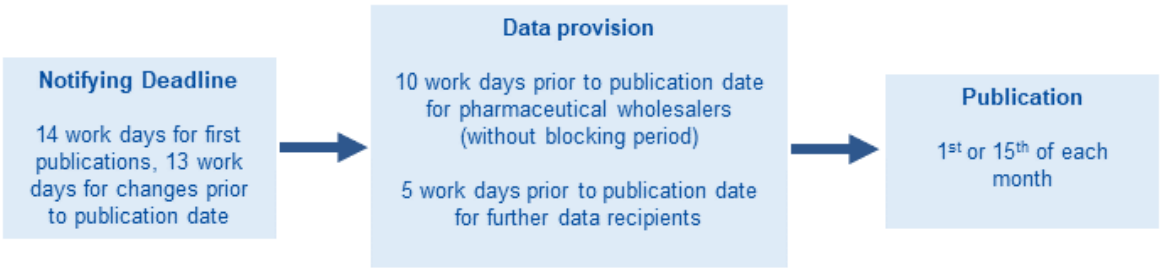


*Illustration 2: Chronology of data assessing and processing*

In order for data recipients to receive data on time, information will generally be assessed and transmitted according to the following chronology:

*Table 1: Chronology of data assessing and processing*

| Work day | Work step |
|---|---|
| 14 work days prior to publication date | Deadline for first publications – notification will be accepted up to this deadline. |
| 13 work days prior to publication date | Deadline for product data change publications – notifications will be accepted by the deadline |
| 11 work days prior to publication date | Production of the Information Services. Data will be transformed into the agreed form for the data recipients. |
| 10 work days prior to publication date | Data provision of IFA Information Services for pharmaceutical wholesalers (first publications and changes without blocking period). |
| 5 work days prior to publication date | Data provision of IFA Information Services for pharmaceutical wholesalers (first publications and chnages with blocking period), medical software providers and other data recipients as well as providers of medical and pharmacy softwares via ABDATA Pharma-Daten-Service. |

# 5. Summary: Notification and Data Paths

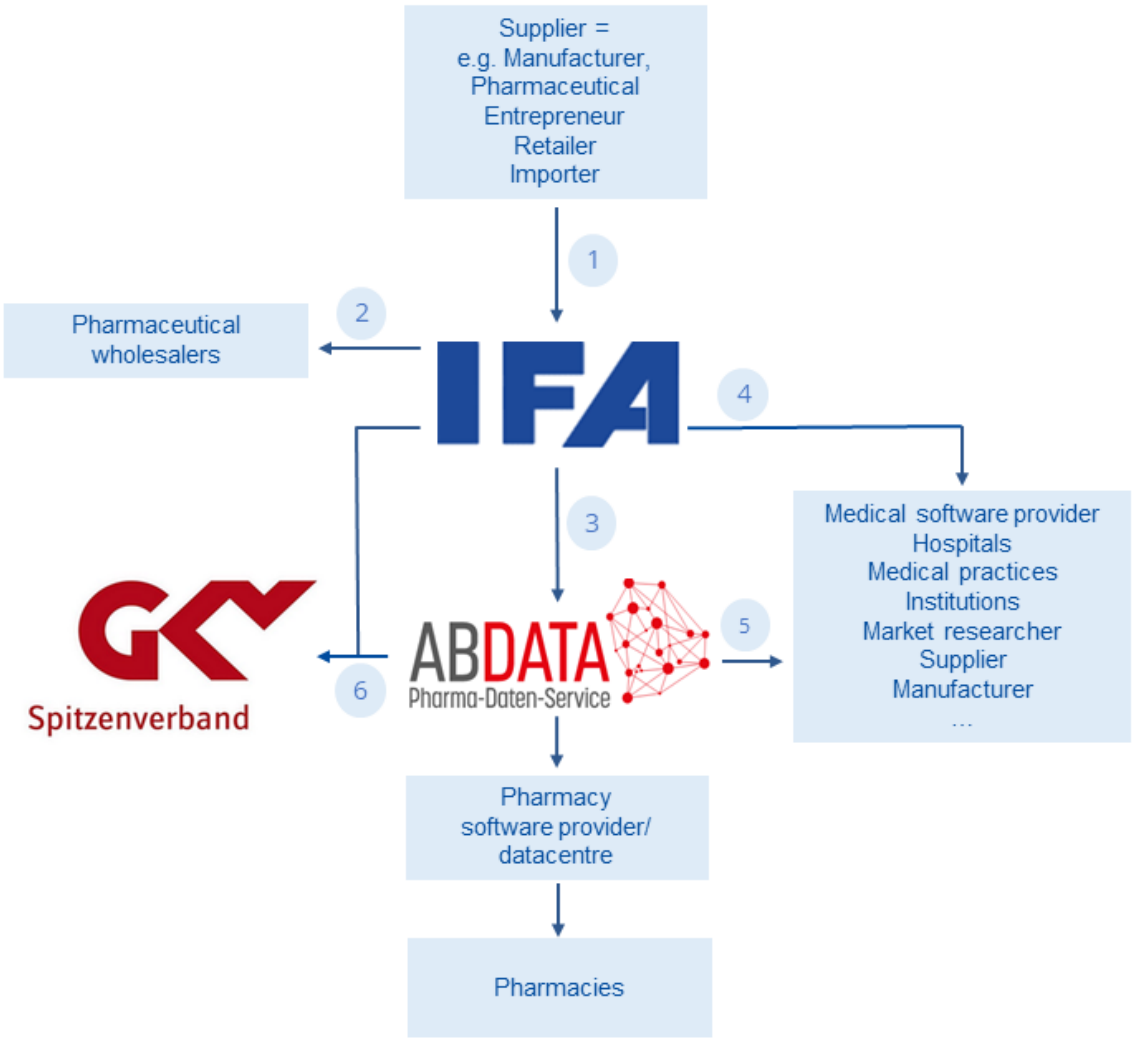


*Illustration 3: Overview of notification and data paths*

**1** Receiving, checking and recording supplier notifications in the IFA database
**2** Output of IFA information services to the pharmaceutical wholesalers
**3** Output to ABDATA Pharma-Daten-Service as part of the cooperation with IFA
**4** Output to other data recipients (including medical software providers)
**5** Supplementation of IFA information services by ABDATA Pharma-Daten-Service and distribution to pharmacy software providers and data centres as well as other authorised data recipients, in particular for data use in pharmacies and physician practices
**6** Joint issue of a product directory to the GKV-Spitzenverband (National Association of Statutory Health Insurance Funds) by IFA and ABDATA Pharma-Daten-Service; on behalf of the relevant manufacturer associations in relation with the notification obligations according to the framework agreement § 131 SGB V