IFA Database and IFA Information Services

Introduction

Informationsstelle für Arzneispezialitäten – IFA GmbH (IFA) maintains a database as source of information to different systems (i. e. pharmacy software, data processing systems of pharmaceutical wholesalers, health insurers). All system users have different requests both contents wise and technically. There are various ways of how data of IFA's database flow to the users.

This brochure contains information on

- IFA's tasks within the pharmaceutical market,
- how product data are published into IFA's database,
- how IFA's information services reach their users,
- IFA's timetable for issuing the information services.

Directory

1. What are IFA's Tasks?

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 different market participants with various requirements and obligations. Furthermore its aids national and European compliances.

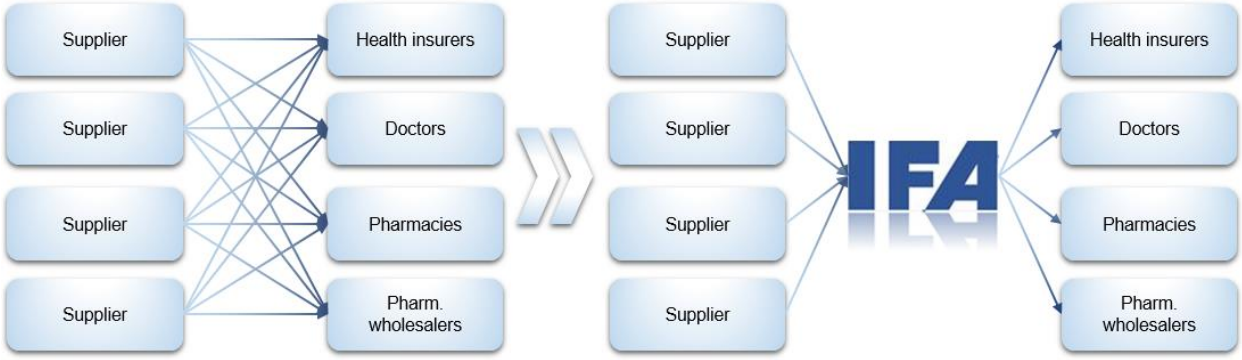

Illustration 1: IFA GmbH as effective and efficient clearing entity

Some of IFA's tasks:

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

2. How are Product Data added into IFA's Database?

Notification by the supplier

First publication and data change in IFA's database is generally notified by the product's supplier. Supplier within the meaning of IFA are all people 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 pre-allocations prior to its product's launch
- *Neuaufnahme*: upon the product's launch, the supplier notifies a first publication of product data to IFA to publish in IFA's Information Services
- *Änderung*: if the product is already being published in IFA's Information Services, the supplier may notify product data changes such as prices, distribution channel

Criteria review

IFA checks whether the product complies with its Guidelines for the pre-allocation of PZNs. In addition, the supplier must submit an informative product information (for medicinal products: German SPC). Cases of doubt and topics that ask for a pharmaceutical expertise, will be communicated with ABDATA Pharma-Daten-Service for further evaluation. If the presented information do not suffice, 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)
- Medizinprodukterecht-Durchführungsgesetz (MPDG)
- Lebensmittel- und Futtermittelgesetzbuch (LFGB)
- Nahrungsergänzungsmittelverordnung (NemV)
- Diätverordnung (DiätV)
- Packungsgrößenverordnung (PackungsV)

Publication of product data into IFA's 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 IFA's Database. IFA allocates a PZN to the product and confirms it to the supplier with the order confirmation.

IFA's 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
- *Lagerungsinformationen* – storage information
- *Packungsinformationen* – packing information
- *Verifizierungsinformationen* – FMD information
- *Vertriebsinformationen* – sales information
- *Verweisinformationen* – reference information
- *Adressdaten* – addesss data

3. How do Data Recipients receive Product Data?

Transmission of IFA's Information Services

Upon completion of the data gathering interval, IFA transfers the data as so-called IFA Information Services to the data recipients. *IFA's 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's contents must not be altered. Some recipients use the data themselves such as pharmaceutical wholesalers. Others do not use data themselves but offer them to specific data recipients such as software providers for doctors. 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 fourtnight data processed by the deadline for the publication date 1st or 15th of every month in IFA's Information Services. Thus creating a regular update frequency whilst retaining orderly processing. Publication dates and their deadlines can be found in IFA's publication calendar IFA-Redaktionskalender.

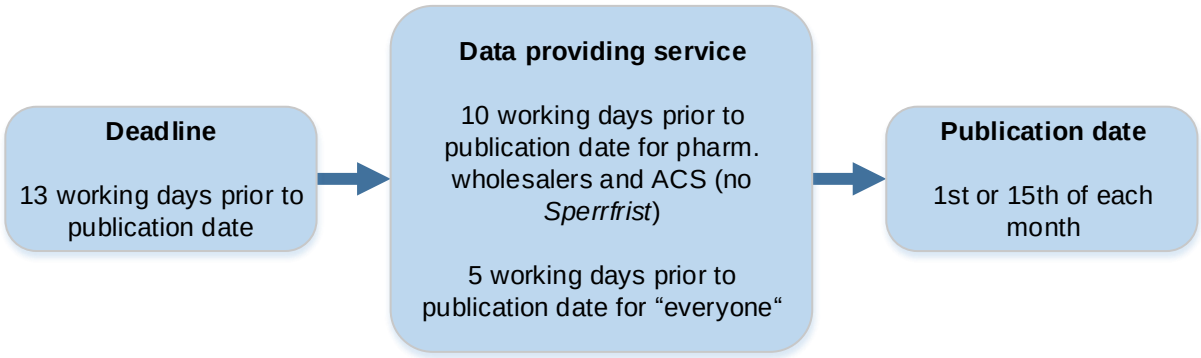

Illustration 2: Chronology of data assessing and processing

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

Arbeitstag	Arbeitsschritt
14 working days prior to publication date	Deadline for first publications – notifications will be accepted that were submitted complete and correctly by the deadline.
13 working days prior to publication date	Deadline for product data change publications – notifications will be accepted that were submitted complete and correctly by the deadline.
11 working days prior to publication date	Production of the Information Services. Data will be transformed into the agreed form for the data recipients.
10 working days prior to publication date	Roll out of IFA's Information Services for pharmaceutical wholesalers (first publications and chnages without blocking period).
5 working days prior to publication date	Roll out of IFA's Information Services for pharmaceutical wholesalers (first publications and chnages with blocking period), doctors' software providers and other data recipients as well as providers of doctors' and pharmacy softwares via ABDATA Pharma-Daten-Service.

5. Summary: Notification and Data Paths

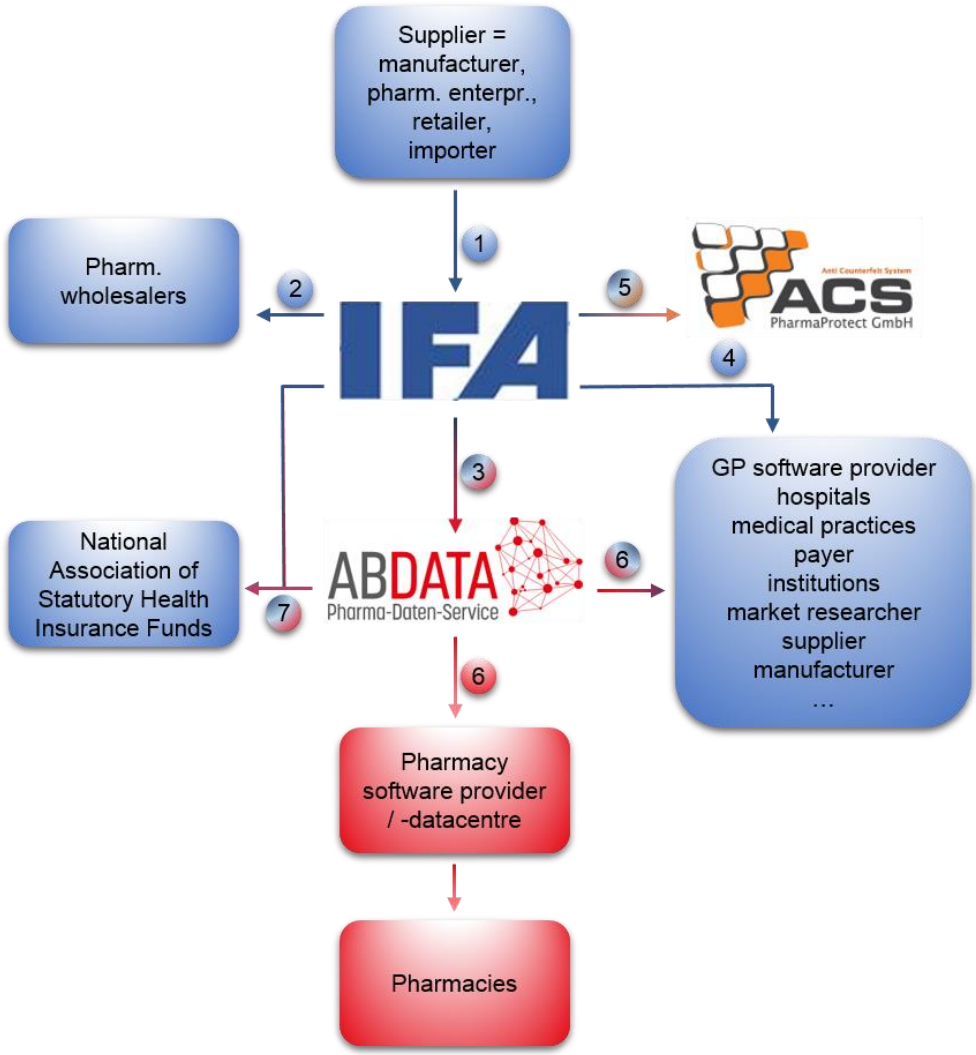

Illustration 3: Overview of notification and data paths

1 Accepting, assessing and gathering of suppliers' notifications to IFA's Datatbase
2 Transmitting of IFA's Information Services to pharmaceutical wholesalers
3 Transmitting to ABDATA Pharma-Daten-Service within co-operation with IFA
4 Transmitting to other data recipients (i. a. doctors' software providers)
5 Transmitting to ACS PharmaProtect GmbH for implementing the FMD
6 Addition of IFA's Information Services by ABDATA Pharma-Daten-Service and transmitting to pharmacy software providers and datacentres as well as eligible data recipients, especially for data usage within pharmacies and doctors' practices
7 Joint transmission of product inventory to GKV-Spitzenverband by IFA and ABDATA Pharma-Daten-Service; on behalf of affected manufacturer associations in combination with notification obligations according to frame agreement § 131 SGB V