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Health Technology and Cosmetics
Unit GROW D.4
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Application for the designation as UDI issuing entity in accordance with Article 27 (2) of Regulation (EU) 2017/745 and Article 24 (2) of Regulation (EU) 2017/746

2019-01-25

[redacted]

first of all thank you for your e-mail of 20. December 2018 transmitting the application form for UDI issuing entities.

In order with the requests listed on the Commissions website we submit our application for the designation as UDI issuing entity.

Enhancing the European perspective for the development of an internationally unique product identifier, IFA expanded in 2010 already the national PZN-numbering system to worldwide uniqueness by adopting the IFA Coding scheme based on internationals ISO/IEC standards. This takes into account the manufacturer's interests in maintaining well established processes and product labelling. This aim is achieved using the IFA Coding scheme for medicines within the scope of the FMD (EU Falsified Medicines Directive 2011/62/EU). IFA will introduce these cost benefits also to manufacturers of medical devices. Aligning the well-established PPN coding, IFA expresses interest being designated as UDI-issuing entity to ensure the smooth functioning of the internal market by opening manufacturers the possibility to reach the UDI requirements without further modifications. An acceptance of the PPN as European UDI code would allow manufacturers to mark medical device products targeting a pharmacy (where PPN is the primary code even for medical devices) with only one code, avoiding an additional UDI code. This is seen as a major improvement to the market. In addition, the PPN may be a solution for UDI for small companies already using PPN which will not require product change (add additional UDI) including additional cost.

Going beyond that, the IFA data base opens up compatibility with national databases to facilitate data transfer to Eudamed for both the Commission and the manufacturers.

1. Name, address, and phone number of the applicant;

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Hamburger Allee 26 – 28
60486 Frankfurt am Main
Germany
Telephone:
Telefax:
E-Mail:
Internet: http://www.ifaffm.de

2. Detailed information regarding the applicant's organisation, including the description of any financial or other relationship between the applicant and any manufacturer or governmental institutions or organisation;

IFA is a “Not for Profit” organisation registered in the commercial register of the local court of Frankfurt am Main under number HRB 29225. Key stakeholders are:

> Bundesvereinigung Deutscher Apothekerverbände – ABDA (*Federal Union of German Associations of Pharmacists)*
> Bundesverband der Pharmazeutischen Industrie e.V. (*German Pharmaceutical Industry Association*)
> Bundesverband des pharmazeutischen Großhandels (PHAGRO e.V.) (C*onfederation of the Pharmaceutical Wholesale Trade*)
> Bundesverband der Arzneimittelhersteller e.V. BAH (*Association of Pharmaceutical Manufacturers)*
> Pro Generika e.V.
> Verband Forschender Arzneimittelhersteller e.V. vfa (*Association of Research-based Pharmaceutical Companies)*

Since 1987, IFA (Information Office for Proprietary Medicinal Products) is a clearing house for the pharmaceutical industry, wholesale and pharmacies in the Federal Republic of Germany. The role of IFA is to gather information about medicinal care products, to keep this data current and to support the market participants in the fulfilment of their legal obligations. It fulfils this role mainly through the assignment of PZN Codes (Pharmazentralnummern) and the exchange of information between all levels of distribution.

IFA stands for a balance of interests between different stakeholders. Conflicts will be handled by the IFA Board of Directors consisting of all associations listed above. A vital role takes the constructive dialogue with healthcare institutions as well as manufacturers. IFA provides health care institutions with substantial information on medical devices. IFA is to be enforced as backbone of health insurers’, health care providers’, entrepreneurs’ and patients’ interest. In the light of national and European obligations regarding social welfare, price setting and billing, security and logistics with its standardised and quality assured information in the purpose of a clearing house, IFA is a neutral and key service provider for players in the healthcare system with its various requirements related to medical devices and other pharmacy products. IFA stands for an effective and efficient data management that spares state and social community from burdens.

IFA is a founder member of “securPharm e.V.”, the stakeholder organization (NMVO) implementing the national repository system following the FMD (EU Falsified Medicines Directive 2011/62/EU).

There is no financial relationship to manufacturers or governmental entities. For cost contribution see section 7 below. Shareholders of IFA are the first three associations listed above, each holding one third of the shares.

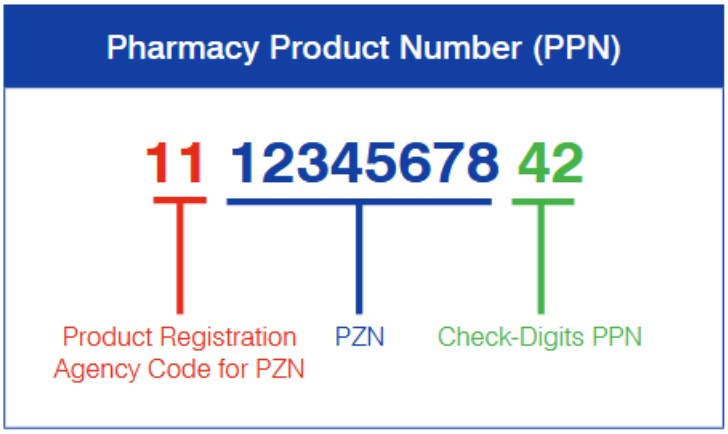
IFA has the legal mandate of the Federal Government of Germany for the registration of products and associated product codes and IFA is acting as an Issuing Agency according to ISO/IEC 15459-2.

In the IFA Board of Directors, consisting of all associations mentioned above, the rule of consent obtains which means that decisions are jointly met. As on the IFA Board of Directors there are representatives of industry, wholesale and pharmacies governing by the rule of consent, reconciliation of interests is inbuilt. In addition for key decisions, the associations of the statutory health insurance as well as the German Ministry of Health have a say in the decision making process.

3. Detailed description of its system for the assignment of UDIs, including description of any standard or criteria applied;

a) General

The PPN (Pharmacy Product Number), containing the national product code PZN, is the primary data element of the IFA Coding System, designed to meet the requirements for uniqueness in the global market.



The PPN consists of three parts that are highlighted above in red, blue and green. The “11” stands for IFA’s Product Registration Agency Code (PRAC) and is reserved for the PZN. The national article number PZN follows after the “11” and is represented in blue. This is the unmodified PZN. The subsequent digits (shown in the figure in green) form the two-digit, calculated check sum across the entire data field (including the “11”). The check digit of the PPN is calculated in Modulo 97.

Unlike all other numbers used on the market a PPN as well as the embedded PZN remains uniquely identifiable throughout its entire lifetime, even if the manufacturer responsible for the product changed in the meantime. IFA guarantees the uniqueness as well as the consistency by centralised issuing of the PPN/PZN combined with data notification in accordance with guidelines and quality assurance. Thus, the PZN contributes to the safety in use of medical devices and secures order processing.

As stated above, a PPN as well as the embedded PZN remains uniquely identifiable throughout its entire lifetime. In a nutshell, IFA is safeguarding this by

- Syntax in Code according ISO/IEC 15434; Format 06
  Use of widespread Data Identifier (DI) according ISO/IEC 15418 (ANSI MH10.8.2, Section I)
- dedicated Data Identifier (DI) „9N“ assigned by MH10.8 Maintenance Committee for PPN,
- Data Matrix Code ECC 200 according ISO/IEC 16022
- fix during the whole life cycle
  independent from mergers & aquisitions and product transfers
  (important for market-withdrawals)
- no recycling of PPNs/PZNs
- issued according generally accepted rules (high dependability)
- master data generated by manufacturer and reviewed by IFA (and market)
- permanent quality assurance
- advantage of centralized assignment

Since IFA administers PPN-allocations centrally, regard needs to be had to tasks and procedures performed by IFA.

IFA was founded in 1987 due to the increasing significance of unique product identifying characteristics and related information.

IFA’s range of tasks includes allocation of PPN/PZN, gathering and normalisation of notifications by pharmaceutical manufacturers and suppliers of other pharmacy-typical goods like medical devices and issuing IFA Information Services for eligible data recipients such as wholesalers, pharmacies, health insurers and others. The IFA Information Services are based on data maintained exclusively by IFA (‘the IFA database’).The allocation of the PPN/PZN is linked to a publication of a product in the IFA database. The IFA database contains information on medicinal products and other pharmacy typical products. The information is updated regularly according to suppliers’ notifications. IFA`s database includes approx. 560,000 products bearing the PPN/PZN and their master data (approx. 200,000 of them are medical devices, approx. 750 manufacturers and distributors of medical devices).
IFA receives the information from manufacturers or distributors of the products ('the suppliers'). IFA provides substantial support for the stakeholders’ implementation of national and international regulations within the healthcare sector as well as support for their information and notification obligations. For example, IFA’s Information Services provide the basis for the legitimacy check pursued by the German repository system in order to meet the requirements of the FMD.

As explained in more detail below, PPNs are allocated and administered centrally by IFA.

IFA has the experience of 30 years in

- issuing codes
- collecting master data
- providing data to healthcare systems and stakeholders
- dialogue with authorities, stakeholders and especially small- and middle-sized businesses
- datacare of medical devices
- providing manufacturers with specifications

IFA is acting as an Issuing Agency for different levels of unique code assignments:

- assigning PPN/PZN- product codes
- assigning Product Registration Authority Codes (PRA Code) for national or other bodies [registered ASC-DI: 9N]
- Assigning Company Identification Codes (CIN) according to ISO/IEC 15459 [IAC: “PP”]

The IFA Coding system covers all of these levels being maintained continuously. Furthermore it supplies guidance for printing and printing quality and test methods. It also includes the chapter “Interoperability” underlining full conformity to the relevant ISO/IEC standards for Automatic Identification and Data Capture (AIDC) and to the UDI system of FDA and IMDRF.

Criteria relevant for the assignment of UDIs are laid down in the IFA Coding System.

The IFA Coding System supplies the means of unique identification for products and packages. The system includes “serialization” of product packages for logistical control enabling verification of any individual package. Based on ISO/IEC standards for automatic identification and data capture (AIDC) it facilitates unique identification of items at any logistical level.

The IFA website offers various specifications relevant for product marking:

https://www.ifaffm.de/en/ifa-codingsystem/data-matrix-code-retailpacks.html

However, the key specification is the PPN Code Specification for Retail Packaging.

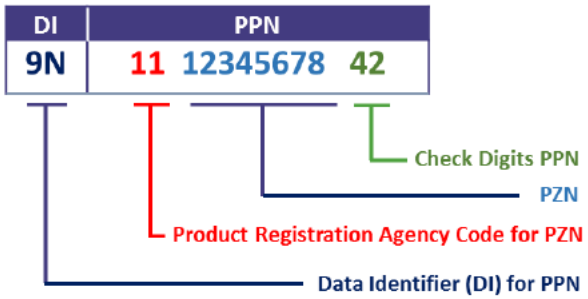
b) Pharmacy Product Number (PPN) as UDI-DI

The PPN is the primary data element of the IFA Coding System, designed to fulfil the requirements of a UDI-DI:

- Assigned by an Issuing Agency according to ISO/IEC 15459-2
- uniqueness in the global market
- Assigned by stringent rules; transparent terms

- monitored use
- fixed during the whole circle of life
- no reuse
- appropriated for use in data carrier;
  specially for Data Matrix Code according ISO/IEC 16022 with
  Data structure according ISO/IEC 15434 and
  Data Identifier (9N) according ISO/IEC 15418.

Structure of a PPN with DI:



The PPN is a license free code key.

The technical details are described in the specification of the PPN, see Annex 1 to this application.

Coding applications are described in the specification for Retail Packaging, see Annex 2.

c) ASC Data elements as UDI-PI

The structure of ISO/IEC 15434, format 06 and the data Identifier (DI) of ISO/IEC 15418 as a core element of the IFA Coding System grant the inclusion of multiple data elements to fulfil the UDI-PI requirements.

Typically these data elements are used for UDI-PI, in relation to the PPN as UDI-DI:

UDI-DI	**Pharmacy Product Number (PPN)**	
UDI-PI	Expiry Date	Examples for UDI-PI
	Batch Number	
	Serial Number	
	Production Date	

Regarding the assignment of a UDI to a device, the main guideline for assignment of unique device identifiers is the PPN-Code Specification for Retail Packaging (see Annex 2). It describes in detail how to construct the data elements for encoding in a Data Matrix Code.

The PPN is unique while identified by the exclusively assigned Data Identifier "9N". The PPN as the primary code will be followed by other data elements also headed by DIs like expiry date, batch number, serial number to complete unique product codes with variable data required for tracking and tracing and verification. The data elements mentioned here are intended as examples.

Under the scope of UDI the UDI-DI is represented by the PPN and the concatenated UDI-PI is represented by the variable data.

d) Basic UDI-DI

IFA supports the manufacturers by its BUDI (Basic UDI) solution.

The structure is proposed as follows:

Basic UDI-DI				
Sub string element	**IAC**	**Manufacturer Code**	**Device Group Code**	**Check Digits**
generated by	**IFA**	**IFA**	**Manufacturer**	**Modulo 97**
Data type	**A**	**Num**	**A/Num**	**Num**
Character set	**PP**	**0-9**	**0 – 9; A – Z; plus special characters**	**0-9**
Character length	**2**	**5**	**1…16**	**2**
String length	**10 ... 25**			
Example	**PP**	**12345**	**ABCD.12345678.90**	**04**

The Basic UDI-DI specification with more specific details and recommendations will be given later. IFA will work in close cooperation to the commission.

4. Copies of the application forms, guidelines, instructions, and other materials the applicant will send to manufacturers who plan to use the applicant's system for the assignment of UDIs. Where those materials are still under preparation, the applicant shall provide a detailed plan for adoption of those materials;

In the following, related documents are listed and briefly described, including a direct link to the IFA website. The most important documents are enclosed with this application. As specified below, not all documents are translated yet. IFA will provide translations into various languages required. Moreover IFA will add a new tab on the IFA website providing guidance to ensure PPNs determined as UDI will be in conformity with the MDR/IVDR and related standards. See below for details. IFA will inform the Commission in case any of this information will be updated.

a) IFA Supplier Contract authentic version (*IFA-Anbietervertrag*)

https://www.ifaffm.de/mandanten/1/documents/02_ifa_anbieter/neukunden/IFA-Vertrag_Anbieter.pdf

https://www.ifaffm.de/en/ifa-suppliers/new-customers.html

https://www.ifaffm.de/mandanten/1/documents/02_ifa_anbieter/neukunden/IFA_SupplierContract_Non-binding_English_convenience_translation.pdf

https://www.ifaffm.de/en/ifa-suppliers/new-customers.html

As stated above, the assignment of a PPN is necessarily linked to the publication of a product in the IFA Information Services. For onboarding, a contract between the manufacturer and IFA – the IFA Supplier Contract (IFA-Anbietervertrag) is concluded.

In this contract, the IFA guidelines are agreed on and the manufacturer is obliged to use the IFA forms for product notifications. According to section 7 of the IFA Supplier Contract manufacturers are obliged to comply with all legal requirements of a notified product. Information for new customers regarding onboarding and FAQs about IFA notifications in general are available in English language on the IFA website.

IFA will add a new tab on the IFA website providing all relevant information in English language for manufacturers intending to assign PPNs for UDI-purposes.

b) IFA-guidelines for the notification of product- and address data (*IFA Richtlinien zur Meldung von Artikel- und Adressdaten*)

https://www.ifaffm.de/mandanten/1/documents/02_ifa_anbieter/richtlinien/IFA-Richtlinien_Datenmeldung.pdf

https://www.ifaffm.de/en/downloads.html

This guideline provides detailed information on how to notify product information to the IFA data base as well as specifications of the individual data fields maintained.

IFA will translate UDI-relevant sections of the guideline into various languages required. Until then, the FAQ section of the IFA website contains in English language an overview of IFA's services and gives an insight into the data required for notification.

Find the FAQs here:

https://www.ifaffm.de/en/faq.html

c) IFA Coding System - PPN-Code Specification for Retail Packaging -

https://www.ifaffm.de/mandanten/1/documents/04_ifa_coding_system/IFA_Spec_PPN_Code_Handelspackung_EN.pdf

https://www.ifaffm.de/en/ifa-codingsystem/data-matrix-code-retailpacks.html

This is the main specification of the IFA Coding System for coding and product marking. This document determines the data content as well as the generation of codes. It obliges the manufacturer to ensure the quality standards. Requirements

and recommendations for clear text are also included. See section 3.b) above for details. IFA will provide this specification in various languages required.

IFA will extend the scope of this specification for UDI purposes.

d) IFA Coding System – PPN Technical Specification

https://www.ifaffm.de/mandanten/1/documents/04_ifa_coding_system/IFA_Spec_PPN_Pharmacy_Product_Number_EN.pdf

https://www.ifaffm.de/en/ifa-codingsystem/global-use-ppn.html

This is the technical specification of the PPN. It contains the definition of the PPN, the rules of assignment of PRA Codes, calculation of the check sum and the specifics of the ASC Data structure. See also section 3.b) above.

This technical specification of the PPN is available in English. It is attached as annex 1 to this application and available on the IFA website, see above.

e) Order form B3 (*Anlage B3*)

https://www.ifaffm.de/mandanten/1/documents/02_ifa_anbieter/formulare_ifa-dateien/IFA-Anlage_B3.pdf

https://www.ifaffm.de/en/downloads.html

To include a specific product in the IFA Information Services the manufacturer has to submit the completed order form “Anlage B3”. Since this form is not yet available in English, see the FAQs on the IFA website related to data elements in this form:

https://www.ifaffm.de/en/faq.html

IFA will provide translations of the Order Form into various languages required. In addition, a new section of FAQs regarding PPNs determined as UDI will be placed on the IFA website.

5. Detailed description of the applicant's policies and procedures for determining whether manufacturers may use the applicant's system;

All requirements for PPN/PZN-allocations are laid down in the IFA Supplier Contract and the IFA-guidelines and specifications.

For onboarding, manufacturers have to submit the signed IFA Supplier Contract alongside a trade register excerpt. IFA matches the manufacturer mentioned in the contract against the trade register excerpt.

Marketing authorisation holders of medicinal products concerned by FMD are additionally synchronised with trade registers online, marketing/ manufacturing/wholesale authorisations submitted are validated as well. In accordance with the securPharm management hand book legitimacy check – annex pharmaceutical entrepreneurs – IFA pursues the legitimacy check in which the manufacturer’s identity is additionally matched against trade registers online.

If required, manufacturing or wholesale authorisations are checked against the EudraGMDP database or national registers online.

All initial identification procedures are carried out in the four-eyes principle. After validation of the manufacturer's data IFA countersigns the contract, maps the entity in the IFA database and allocates an IFA-ID identifying the manufacturer (5 digit number). For this IFA-ID multiple PPNs/PZNs can be ordered.

IFA maps the following data for direct communication with the manufacturer:

company name
Street / No
City
country/country postal code
post box
phone/fax general
e-mail general
VAT ID
managing director name
managing director e-mail
contact person name
contact person phone/mobile/fax
contract person e-mail

6. Description of the applicant's policies/procedures for dealing with manufacturers' deficiencies in using correctly the system for the assignment of UDIs, including for monitoring corrections;

Before PPNs/PZNs are published for the first time, IFA checks the plausibility of the notified product data. For this purpose IFA runs about 450 validation clusters triggering approximately 3.500 plausibility checks to ensure high data quality. For this reason all first-time publications are administered by desk officers in the four-eyes principle.

In the IFA Supplier Contract concluded between the parties, responsibilities of the manufacturer are set out in section 7. IFA, as the organization authorized to assign product numbers, can upon product number violations classify the product as "non-marketable". IFA has to proceed this way if interlocutory injunctions concerning specific PPNs/PZNs are submitted to IFA. For the manufacturer this means these products will not be available for sale and reimbursed until the ban is lifted. In this context IFA is cooperating with national agencies and public bodies.

As noted above, a PPN/PZN-allocation is necessarily linked to a publication in the IFA Information Services. Data recipients such as retail market, health insurance or public authorities report deficiencies in the use of product numbers or incorrect product descriptions to IFA. Thus, IFA can promptly instruct the manufacturer to erase or update inaccurate data in accordance with section 4 of the IFA Supplier Contract.

If manufacturers themselves identify deficiencies, they are required to commence the notification process in accordance with section 7 of the IFA Supplier Contract.

IFA may provide information to the Commission and other authorities when IFA becomes aware of repeated or deliberate misuse of the UDI-requirements.

When it comes to restrictions of prefixes, it must be considered firstly that IFA centrally assigns PPNs. Second, in case of severe violations IFA is obliged to classify specific PPNs as “non-marketable”. In this procedure, there is no means of restricting company prefixes or IFA customer numbers for UDI purposes.

7. Description of business model and fee system, with an explanation and rationale of any fee waiver or reduction available;

IFA is a non-profit-organisation in the sense that costs are covered by fees and not by shareholder’s contributions.

The standing fee is 50,00 € per annum. For the first publication of a single PPN/PZN, a fee in the amount of 6,00 € is charged. All prices are subject to German VAT. Price reductions apply, see the price list for details.

The volume discount for large numbers of notifications contributes to SME baring in mind that medical devices typically offer wide variations in form, size or equipment. To map this variety in the IFA database, vast numbers of products need to be notified. According to the price reduction indicated in the price list, large numbers of notifications do not lead to high costs. For example, when 5.000 PPNs are published for the first time, the cost for one PPN is reduced to 1,26 € net. This price can still be lowered down if orders are submitted by early deadline.

The English version of the price list can be downloaded here:

https://www.ifaffm.de/mandanten/1/documents/02_ifa_anbieter/preisliste_einzugsermaechtigung/IFA-Price_list.pdf

https://www.ifaffm.de/en/downloads.html

8. Detailed description of the applicant's electronic data management system;

IFA has installed a number of safety features to ensure high quality in registration, processing and storing of data.

a) Before PPNs/PZNs are published for the first time, IFA checks the plausibility of the notified product data. To verify a notification the manufacturer is obliged to submit valid product information like package leaflets or print templates.

The product conformity must be attested by the CE marking. All first-time publications are administered by desk officers employed by IFA in the four-eyes principle. Inclusion in the database and data review are exclusively carried out by qualified and trained personnel of IFA. To support the workforce IFA runs various plausibility checks to ensure high data quality (see section 6. above).

b) IFA hosts the IFA database as a central database containing all allocated PPNs/PZNs including all master data and additional product information. IFA has exclusively full access to all relevant product content.

This database holds currently records of roughly 560.000 typical pharmacy products. Depending on the product type, up to 100 different information attributes are administered with the Pharmazentralnummer (PZN) about the product.

This information is updated on a 14day cycle and implemented in various software systems like medical information systems for doctors, pharmacy software, inventory management/logistics of full-line pharmaceutical wholesalers, statutory and private health insurances as well as the German Ministry of Health.

c) To deliver the IFA Information Services IFA runs a push system sending updates to each data recipient. Thus, data availability is not depending on individual access to the IFA database.

d) The system care and maintenance is provided by a team of specially trained system experts.

IFA secures operating the database by technical and organisational measures including the following features.

Firstly, IFA ensures ongoing confidentiality, integrity, availability and resilience of the IFA database while data processing is not logically or physically separated from the data. In addition, access to data is restricted to defined user groups. Also, IFA runs a high-availability system. In the second place IFA is able to restore the availability and access to the IFA database in a timely manner in the event of a physical or technical incident. To assure this, IFA implemented backup copies and has encrypted live remote replication in a failover data centre. Finally, IFA is regularly testing, assessing and evaluating the technical and organisational measures for the security of the IFA database. For these purposes, IFA conducts external security audits.

Taking into account the mentioned steps, IFA ensures the security and availability of the IFA database applying state of the art technology.

9. Description of the tools or services made available by the applicant allowing to check data quality in the EU database (Eudamed);

Following the establishment of Eudamed as the main database on medical devices, IFA supports entirely the efforts of the Commission to ensure full functionality.

To consider compatibility with national databases, IFA is prepared to cooperate with the Commission ensuring that the additional product information maintained in the IFA database is suitable for import and export to Eudamed.

IFA is willing to install further consistency checks to safeguard the quality of data provided from manufacturers.

10. The form “Applicant’s undertakings”, signed by the applicant organisation’s legal representative in the European Union;

Please find the form enclosed with this document, signed by the managing director of IFA.

11. Detailed information and, if available, market studies on the readability of UDI carriers which are compliant with the applicant's technical specification by the readers generally available to economic operators and healthcare institutions within the EU.

Quality in coding has always been a central concern for IFA. In view of the fact that IFA has established the PPN-Coding-System in 2012 to provide an appropriate coding system used within the scope of the FMD in pharmacies, wholesale and health institutions, the performance available on the market is proven by PPN-codes used in the securPharm-System. SecurPharm runs the NMVO-system for the authentication of pharmaceuticals in Germany.

To ensure that PPN-marked products are in conformity with the PPN coding standard, IFA has committed the manufacturers contractually to comply with this standard (see section 7 of the IFA Supplier Contract). More importantly, IFA is consulting manufacturers and coding-operators for 30 years in coding, whenever data recipients report deficiencies to IFA. In this way IFA maintains direct contact with manufacturers and coding operators, heading for permanent optimisation. It should be noted that IFA is a member of securPharm's steering committee. In this body, pharmacies, wholesalers and manufacturers analyse product verification processes in detail.

As IFA ensures maximum accessibility to the information stored in codes, reading the PPN codes has proven to be extremely reliable.

Summarising the above, it should be noted that IFA has the experience in product registration and coding systems since 1987. Thus, we are confidently awaiting the course of the further proceedings and are strengthened in our optimism the Commission will designate IFA as UDI issuing agency.

In case you have any further questions or to clarify specific details our managing director will be glad to be of help under direct line .

Yours sincerely,
Informationsstelle für Arzneispezialitäten – IFA GmbH

Managing Director

Encl.