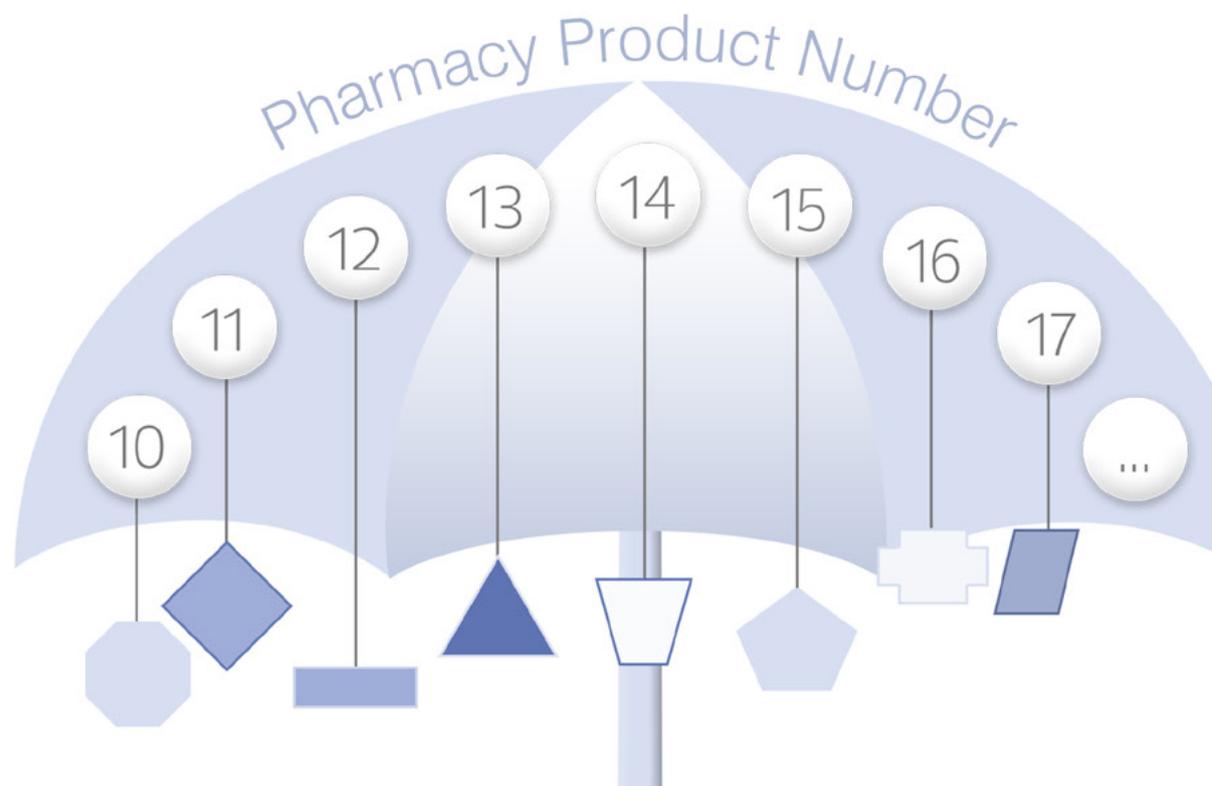


Using the PPN for harmonizing various coding systems in Europe's pharmaceutical market



Enabling unchanged usage of national coding systems, while complying at the same time with the EU directive 2011/62/EU strengthening the protection against counterfeits.

Established national product codes can be kept unchanged regarding packaging and accounting systems requirements in health care.

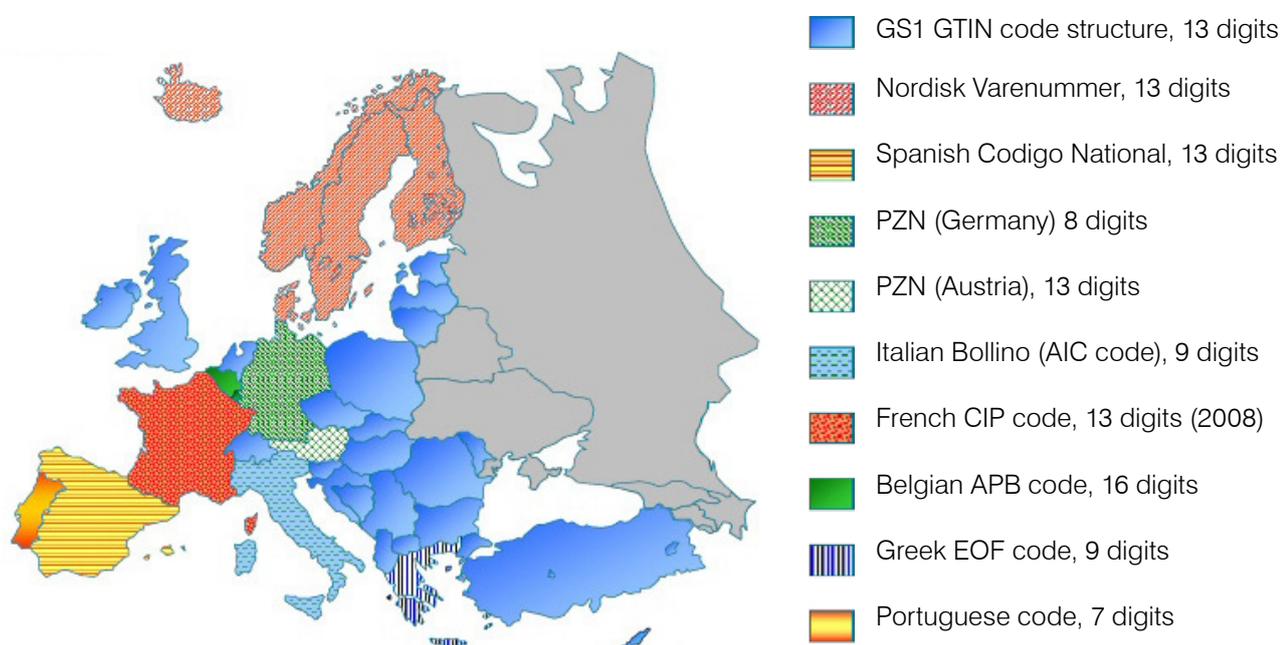
Equally applicable e.g. for medical devices and blood products, without the necessity of changing existing number systems.

No Licensing fees – open application

Product codes in the European health care sector were developed on a national level based on local factors and realities. Often, depending on the product category (e.g. medicinal products, medical devices or blood products), various coding systems can be in use in one single country.

These coding systems are firmly enrooted in various processes like material logistics, accounting/invoicing, registration procedures, etc. The directive 2011/62/EU (8th of June 2011) requires measures to increase protection of medicinal products against counterfeits. One result is the need of product codes being unique on an international level. Additionally, clear product codes do simplify logistics for internationally traded pharmaceuticals.

Currently there are 10 different medicinal product coding systems across Europe, which cannot be transferred into one existing system (see chart below):



On behalf of its stake holders in the German pharmaceutical market¹⁾, the IFA has developed a system embedding existing coding systems (based on international standards - ISO/IEC) and therefore meeting the requirements resulting from the EU's directive on a cross-national level.

Assigning any given coding system a distinct prefix, the so called Product Registration Agency Code (PRA-Code) lies at the heart of this system. For detecting errors due to manual usage or during data transfer, a double digit check-digit is attached. The hereby created new number is called Pharmacy Product Number (PPN). The PRA-Code '11' is assigned to the German PZN.



For the purpose of transferring the PPN by Matrix Code and RFID, the international distinct Data Identifier (DI) „9N“ (according the ISO/IEC 15418 rules) has been assigned to the PPN. The complete methodology for generating the PPN and its check-digit is described in the following document: 'Technical Specification – PPN'

http://www.ifa-coding-system.org/downloads/de/PPN_Number_Spec_English_V1_4a.pdf.

The length of the PPN is specified with max 22 alphanumeric characters. It might be extended on demand.

The PRA code guarantees global uniqueness

The following table shows which PRA-Codes are registered and reserved:

PRA Code	Assigned to	Reserved for	Used for
00-09	Reserved		
10		GS1	GTIN / NTIN
11	IFA; Germany		PZN - medicinal and other pharmacy products Germany
12	EUROCODE IBLS		Registered Blood Product Number
13	Reserved		
14		Association Pharmaceutique Belge (APB)	CNK code
15		Italian Ministry of Health	AIC code
16		Austria Association of Pharmacists	PZN-Austria
17		INFARMED	Portugal Registration Number of Medicine Presentation
18		Z-Index; Netherland	Z-Index - pharmaceutical products Netherland
19	NENSI d.o.o.; Slovenia		NENSI code - pharmaceutical products Slovenia
20	CIP; France		CIP Code - medicinal products France
21	CIP; France		CIP Code - pharmaceutical services France
22	ACL; France		ACL Code - other pharmacy products France
23	ACL; France		ACL Code - pharmaceutical services France
24-99			
AA-ZZ			

PRA Code usage and PPN generation is free for open application. Distribution and registration of the PRA-Code is managed by the IFA as issuing agency. No licensing fees are demanded.

The PPN enables all national code systems as well as existing international code systems like 'GTIN', to be transferred into one common and unique code system.

SecurPharm e.V.'s pharmaceutical verification project (implementing the requirements of the EU's anti counterfeit directive 2011/62/EU) already uses the PPN to map the German PZN.

For further information:

<http://www.ifa-coding-system.org/de/home>

IIFA Contact Details:

Informationsstelle für Arzneispezialitäten - IFA GmbH

Hamburger Allee 26-28

60486 Frankfurt

Managing Director: Klaus Appel

Registergericht: Frankfurt / M HRB 29225

Chief of supervisory board: Lothar Jenne

Klaus Appel

Phone: +49 69 979919-20

Fax: +49 69 979919-39

<mailto:klaus.appel@ifaffm.de>

<http://www.ifaffm.de>

¹⁾ Represented by the associations:

ABDA-Bundesvereinigung Deutscher Apothekenverbände
(German Federal Association of Pharmacists)

Bundesverband der Arzneimittel-Hersteller e.V. (BAH)
(German Medicines Manufactures' Association)

Bundesverband der Pharmazeutischen Industrie e.V. (BPI)
(German Pharmaceutical Industry Association)

Bundesverband des Pharmazeutischen Großhandels-PHAGRO-e.V.
(Association of Pharmaceutical Wholesalers)

Pro Generika e.V.
(Association of Generic Medical Manufacturers)

Verband Forschender Arzneimittelhersteller e.V.-VFA
(Association of Researching Manufacturers of Pharmaceutical Products)