



2. securPharm European Conference on the Falsified Medicines Directive

National Prerequisites And Their Importance for A Successful Implementation of The FMD

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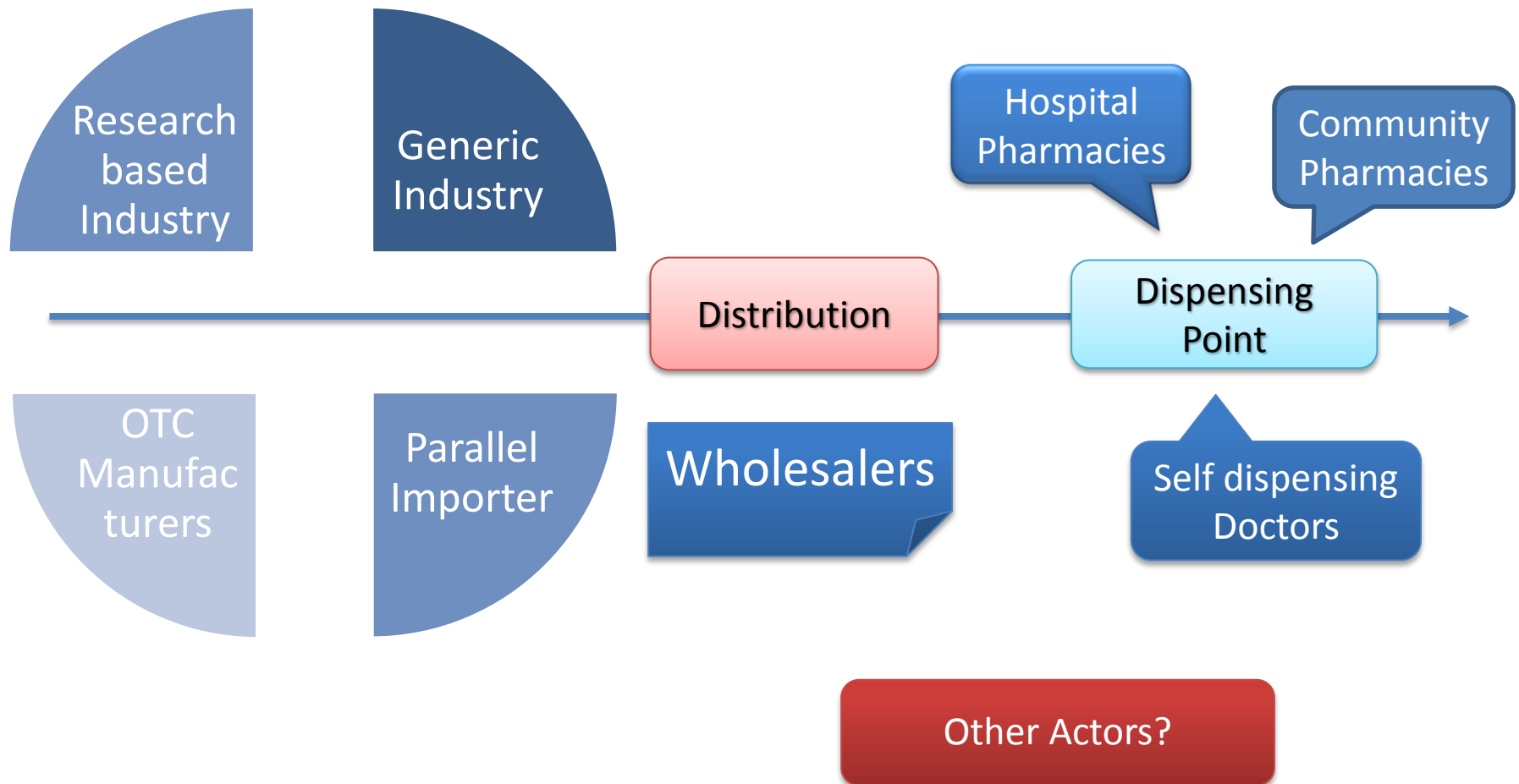
PHAGRO | German Association of Full-line Wholesalers
Member of the board of securPharm
23rd July 2015, Frankfurt

1. Trustworthy and equal cooperation of major players

2. IFA as national register for medicinal products

3. Transformation of PZN into an international product number

Identifying National Supply Chain Actors



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German IFA: Well Established Stakeholder Platform for The Management of MASTERDATA



Shareholders:

- Association of the Pharmaceutical Industry (BPI)
- Association of the Pharmaceutical Wholesalers (PHAGRO)
- Federal Association of German Pharmacists (ABDA)

Company Board:

- Representatives of the shareholders and further associations of the industry (BAH, pro generika, vfa)

- Assignment of product codes (PZN)
- Each PZN identifies a specific SKU (stock keeping unit)
- Compilation of suppliers' masterdata
- PZN and masterdata are commercially used in the supply chain
- PZN and masterdata are exclusively used for reimbursement
- 55,000 PZN for RX-Products
- 60,000 PZN for OTC-Products
- 285,000 PZN for non-medicines sold in the pharmacy

- Basic masterdata
 - PZN
 - Name
 - Quantity
 - Pharmaceutical form
 - Type of article
 - MAH

... and possibly the EU-Hub in the future

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Organisations Managing National Medicines Numbering Systems

C.I.P.



APB (Pharmacists)



Z-Index (Pharmacists)



Pharm. Information
Center (Helsinki)



IFA



Min. of Health



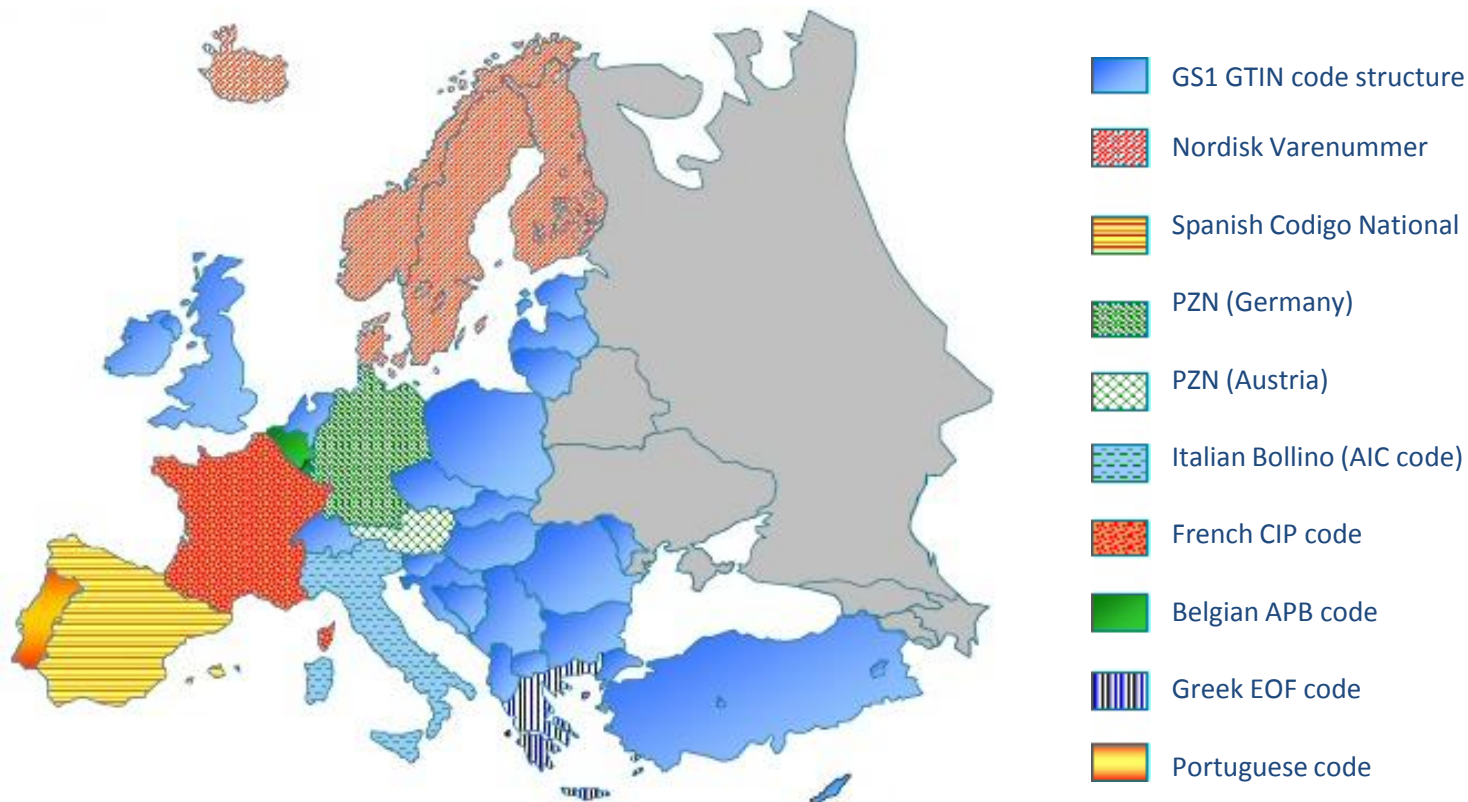
Min. of Health



Pharmacists



National Medicines Numbering Systems



Comparison of Numbering Systems

	national number (NN)	GTIN	NTIN = embedded NN	PPN = embedded NN
nationally unique	X *	(X)	X *	X *
centrally managed, controlled and documented	X *	-	X *	X *
international identification	-	X	X	X
pointing at liable MAH when rights sold	X *	-	X *	X *

* different from country to country, depending on central management

National PZN Can Be Identified Internationally Via Two Coding Variations

IFA-Code



- **PPN** (envelops PZN)
- Serial number
- Batch number
- Expiry date



GS1-Code



- **NTIN** (envelops PZN)
- Serial number
- Batch number
- Expiry date

Approach national authorities to open dialogue

Ask for authority's expectations

Provide clear positions as a reliable basis for planning

Summary: How securPharm Implemented The FMD

1st

- created a stakeholder group
- securPharm e.V.
- non-profit organization

2nd

- common goals and rules for collaboration
- memorandum of understanding
- data protection by separate data bases

3rd

- checked national prerequisites
- master data already available (IFA)
- product code (PZN) integrated in coding system

4th

- selected IT service providers for separate data bases
- Foundation of ACS (MAH-System)

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