

IQVIA Annual Conference for Wholesalers and Pharmacies Serbia,
Belgrade, October 29th 2019

Pharma Market in Serbia from WHS perspective- role, trends and challenges

Lovorka Nikolić, MPharm, MSc.

Shareholder of Farmalogist Holding

Official Delegate of Serbian Group of Pharmaceutical Wholesalers to GIRP

199 legal entities licensed for wholesale & distribution of medicines and medical devices with 212 warehouse locations, among them 11 multinational manufacturers, 5 doing DTH

- **15 members of Group of Pharmaceutical Wholesalers** within Serbian Chamber of Commerce covering around **91 % of the total market, 2.257 employees**
- **3 full-line wholesalers** covering around **70 % of the total market, 7 warehouse locations**
- Over **10,000 products** in stock, of more than **300 manufacturers**

 BEOHEM-3

 **Boehringer
Ingelheim**

 **FARMALOGIST**

 INPHARM

 MEDICOM[®]
Sabac

 NS Pharm 1997 20 2017

 PHARMA SWISS

 PHOENIX
Pharma
a PHOENIX company

 PRIMAX
1997 20 2017

 Sanol S

 sopharma trading
evolution in healthcare

 STIM

 unifarm
medicom

 VEGA

 VELEXFARM
 član HEMOFARM grupe

Group of Pharmaceutical Wholesalers, Serbian Chamber of Commerce- full member since June 2011



The Serbian association of pharmaceutical full-line wholesalers – taking fully part in all relevant EU processes

René Jenny, GIRP President
Belgrade, 13 October 2011



The European Association of Pharmaceutical Full-line Wholesalers

Serbian Association as a GIRP full member...

...a by-law change made it possible

<p>Old Article 4.2 - Full members Admission to the Association as a "full member" is open to national associations of Full-line Wholesalers and Full-line Wholesaling companies from European Union Member States and from countries within the European Economic Area ("EEA")...</p>	<p>New Article 4.2 - Full members ...On a case by case basis, this geographical restriction can be lifted subject to the prior approval of the General Assembly.</p>
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GIRP's General Assembly lifted the criteria for Serbia on 9 November 2011.

The vital link in healthcare



René Jenny, President, GIRP, 10th Anniversary of The Group of Pharmaceutical Wholesalers Belgrade, October 2011



Per Troein, Vice President Strategic Alliances, IMS Health, 10th Anniversary of The Group of Pharmaceutical Wholesalers Belgrade, October 2011

GODIŠNJI IZVEŠTAJ GRUPACIJE VELEDROGERIJA FARMACEUTSKI SEKTOR SRBIJE 2018.

AUTORI: Miljana Vučićević, Bojana Petković, Svetlana Savić, Božena Čučević, Danijela Radmanović, Rođmila Stojanović

Od dobijanja statusa punopravnog člana Evropske asocijacije veleprodajnika sa kompletnim asortimanom farmaceutskih proizvoda (GIRP) 2011. godine, Grupacija veleprodajnika pri Privrednoj komori Srbije priprema i dostavlja GIRP-u godišnji izveštaj o farmaceutskom sektoru Srbije...

So engleskog preveo: Rođmila Stojanović

TRŽIŠNO OKRUŽENJE 2018

Ekonomski i politički aspekti
U 2018. godini u Srbiji je zabeležena značajna stopa rasta bruto domaćeg proizvoda od 4,3%, što nas je vratilo u grupu evropskih zemalja sa najvišim stopama rasta...

APOTEKE

Pret godišnja raskon 17% je potrošnja apotekama u omoguđenim uslovima...
Prvi godišnji izveštaj o potrošnji lekova na recept u Srbiji...

OSTALE INFORMACIJE

U okviru projekata i saradnje započevši Srbije - dodatne finansijske informacije...
U okviru projekata i saradnje započevši Srbije - dodatne finansijske informacije...

FARMACEUTSKO/VELEDROGERIJSKO TRŽIŠTE 2018

Implementacija nacionalnog sistema za verifikaciju lekova i delo sarda preduzete i planirane mere...
Implementacija nacionalnog sistema za verifikaciju lekova i delo sarda preduzete i planirane mere...

Table: PROMET NA VELIKO. Columns: 2017, 2018, promena%. Rows: Ukupno, Farmaceutski proizvodi, Ostali proizvodi, etc.

Table: PROMET NA MALO. Columns: 2017, 2018, promena%. Rows: Ukupno, Farmaceutski proizvodi, Ostali proizvodi, etc.

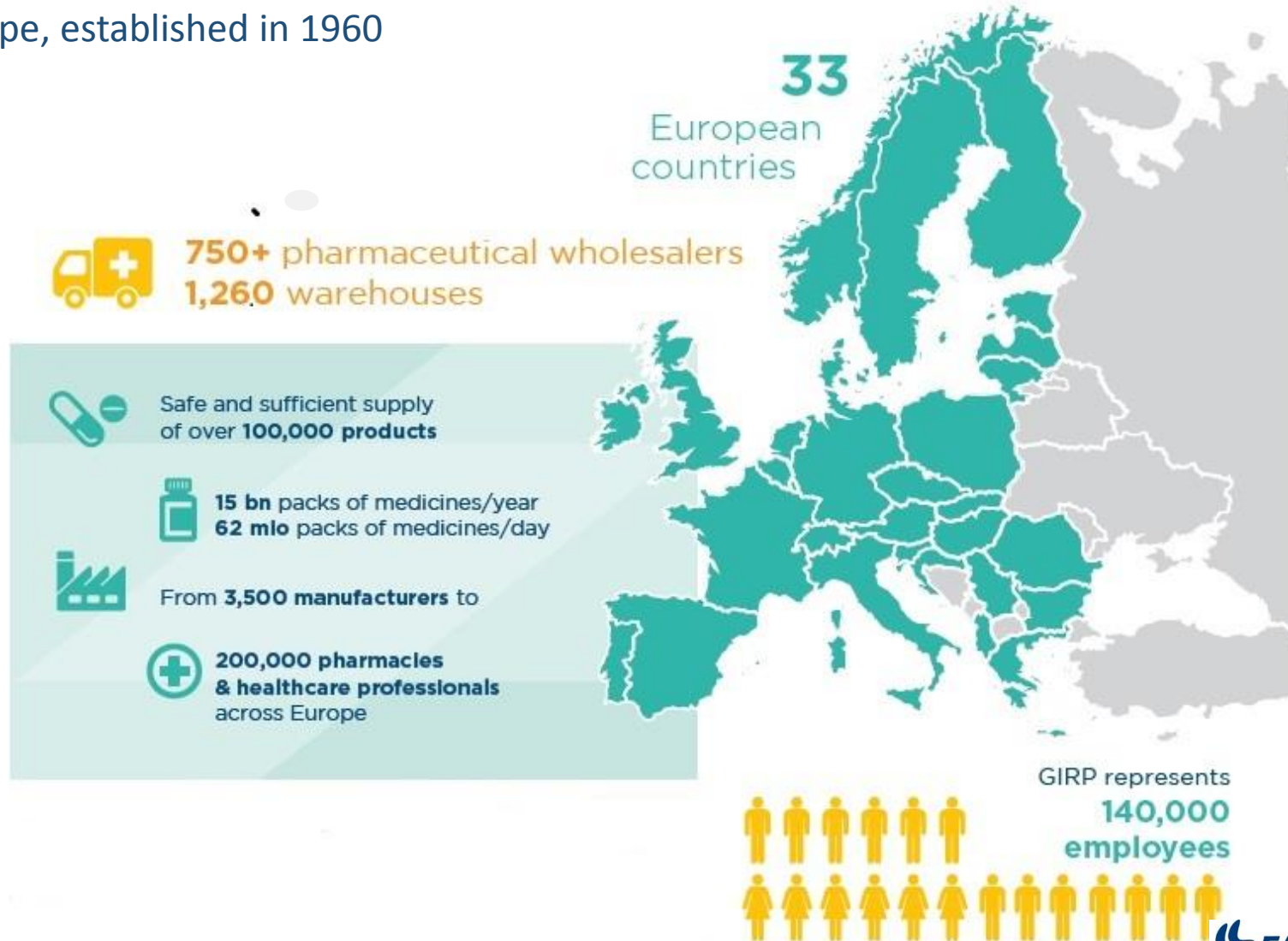
Table: DODATNE USLUGE VELEDROGERIJA. Columns: 2017, 2018, promena%. Rows: Promis apotekama, Informacione usluge, etc.

Table: FARMACEUTSKI OKVIR. Columns: 2017, 2018, promena%. Rows: Da li je važeći, Da li je primenljiv, etc.

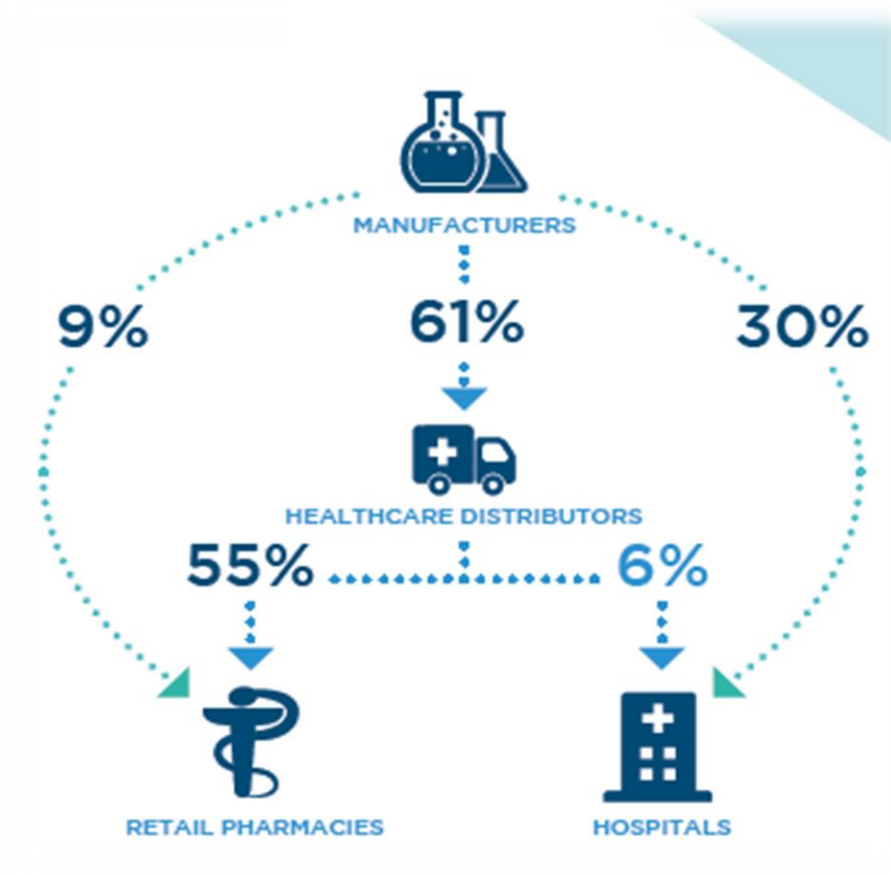
Table: PROMET NA MALO (continued). Columns: 2017, 2018, promena%. Rows: Ukupno, Farmaceutski proizvodi, etc.

Table: DODATNE USLUGE VELEDROGERIJA (continued). Columns: 2017, 2018, promena%. Rows: Promis apotekama, Informacione usluge, etc.

GIRP-the umbrella organisation for pharmaceutical full-line wholesalers and distributors of healthcare products and services in Europe, established in 1960



EUROPEAN MEDICINES MARKET SPLIT PER DISTRIBUTION CHANNEL



Healthcare distributors
the **vital link** in healthcare

Source: IQVIA est 2018- GIRP Annual Report 2018-2019



Groupement International de la Répartition Pharmaceutique

On the Autumn General Assembly meeting, on 12th November 2015, English name of GIRP

the "European Association of Pharmaceutical Full-line Wholesalers"

changed to

the "European Healthcare Distribution Association"

THE 5 CORE FUNCTIONS OF HEALTHCARE DISTRIBUTORS

1. FULL SUPPLY AND STOCK-KEEPING FUNCTION
2. PERMANENT AND IMMEDIATE MEDICINES AVAILABILITY AND DELIVERY FUNCTION
3. BUNDLING FUNCTION: POOLING OF PRODUCTS AND TRANSACTIONS
4. QUALITY ASSURANCE FUNCTION
5. FINANCING FUNCTION

1. FULL SUPPLY AND STOCK-KEEPING FUNCTION

- **Ensure** (predict, plan, order, store) that **the needs** of the pharmacists and of the patients **are met**, guaranteeing **the continuous availability** of a **complete assortment of products** (Rx, OTC, specialty, orphan products, narcotics, cold chain products, medical devices, in-vitro diagnostics, food supplements, para-pharmaceuticals, pharmacocosmetics), in range and depth as set by the authorities and the market.
- Inventory turnover differs from product to product
- DE, ES, FR, IT, NL, UK average:
27 days- stock turnover takes place on average 13 times a year*

























*Source: GIRP Annual Report 2018

2. PERMANENT AND IMMEDIATE MEDICINES AVAILABILITY AND DELIVERY FUNCTION

If medicines are not available when and where needed, patients are unable to start or continue their treatment

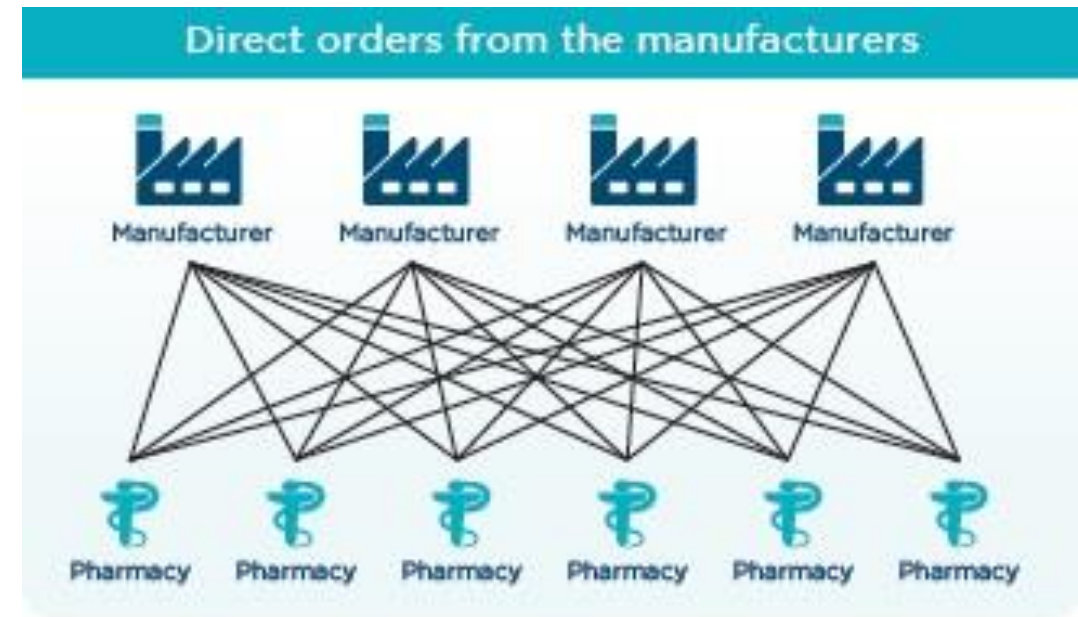
Healthcare distributors:

- guarantee efficacious patient treatments by delivering the needed medicinal products in the required quantity and just-in-time
- protect the healthcare sector from high additional costs that would be caused by delays in delivering urgently needed medicine

Delivery time & frequency	Pharmaceutical full-wholesalers	Short-line wholesalers	Direct sales from manufacturers
Average delivery frequency per day (hours)	2.5 	20.5  	57.86   
Average deliveries per week	15.9      	4.34  	3.66 
Average number of order-lines per delivery	35         		<i>Weighted Average DE, ES, FR, IT,NL, UK</i>

Source: GIRP Annual Report 2018; Annual Questionnaire 2018, *estimation for Serbia

3. BUNDLING FUNCTION: POOLING OF PRODUCTS AND TRANSACTIONS SAVING COSTS FOR CUSTOMERS

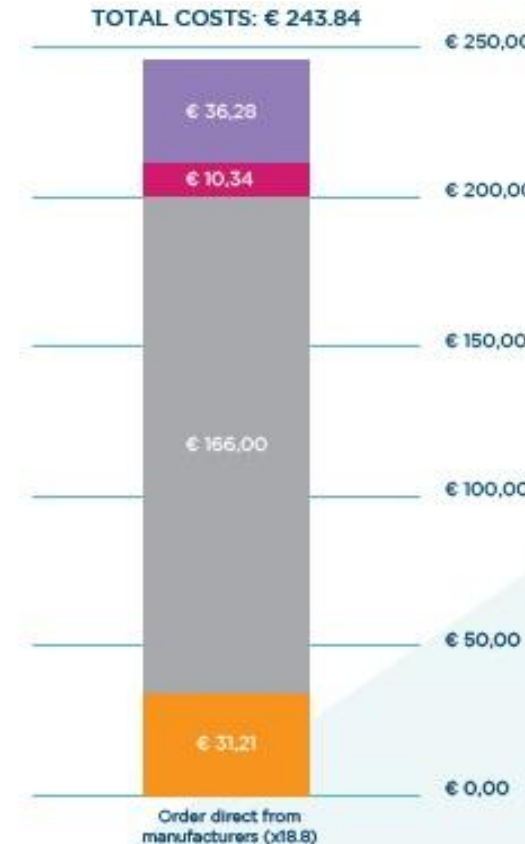


Pharmaceutical full-line wholesalers- on average products of 18.8 manufacturers per delivery.

Countries: DE, ES, FR, IT, NL, UK

Source: GIRP Annual Report 2018

3. BUNDLING FUNCTION: POOLING OF PRODUCTS AND TRANSACTIONS



A wholesaler saves 234.84 € in order management cost for a pharmacy (products of 18.8 mnf per delivery)

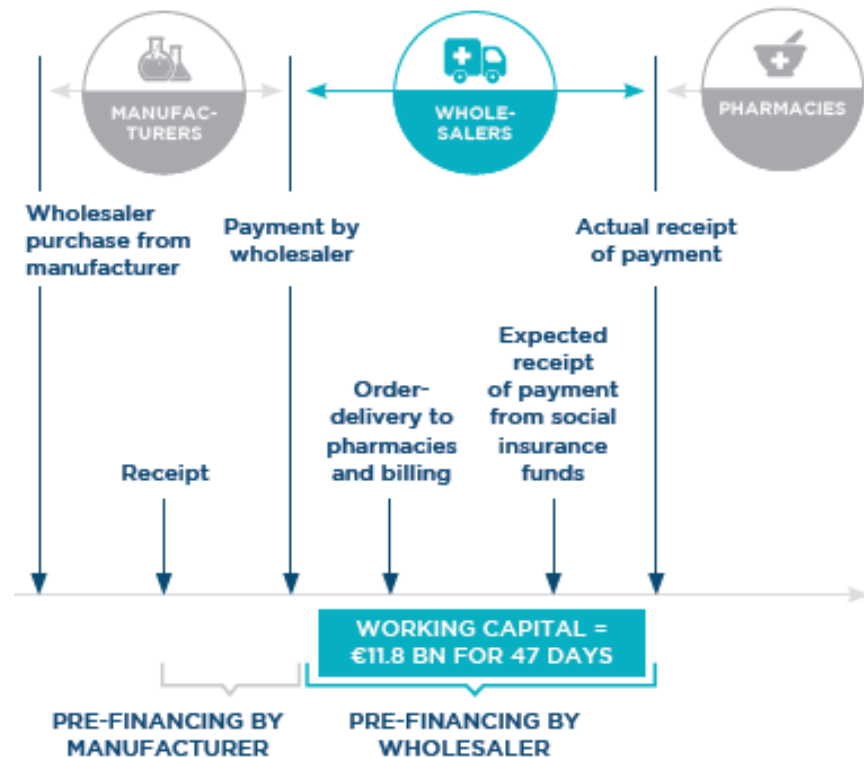
Source: GIRP Annual report 2018

4. QUALITY ASSURANCE FUNCTION

- Medicinal products are procured, held, supplied or exported in a way that is **compliant with the requirements of GDP (2013/C 343/01)**
- Management **responsibilities are clearly specified**
- Products are delivered to the right recipients within a satisfactory time period
- **Records are made and kept** contemporaneously
- Product **track & trace**
- All **personnel** involved in wholesale distribution activities is **continuously trained** and deviations from established procedures are documented and investigated
- Appropriate corrective and preventive actions (commonly known as CAPA) are taken to correct deviations and prevent them in line with the principles of **quality risk management**
- Since February 9th, 2019 and the implementation of the **Falsified Medicines Directive** and its Delegated Regulation, healthcare distributors also have complied to further **protect the supply chain from entry of falsified medicines.**

5. FINANCING FUNCTION

- Healthcare distributors:
 - only ones to assume a financing function towards manufacturers and pharmacies.
 - guarantee the continuous supply of all medicinal products and also secure the cash flow of the social insurers
- The financing function can be expressed in terms of working capital.



Countries: DE, ES, FR, IT, NL, UK

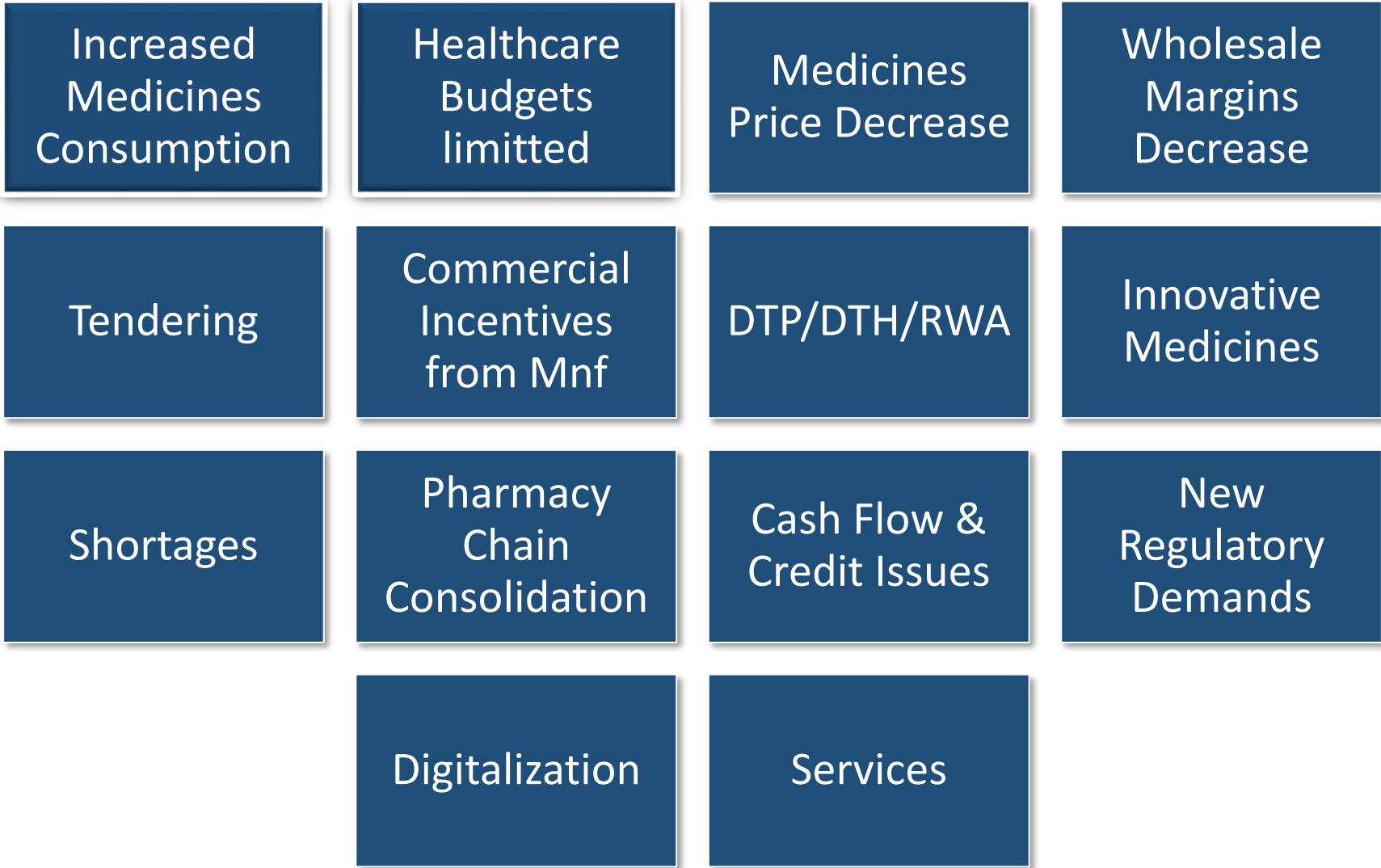
Overdue Debts of State Pharmacies *

Overdue Debt (mill. €)		
30.09.2017.	31.08.2018.	31.08.2019.
29,65	28,23	26,86

Overdue Debts of State Hospitals for invoices issued before Direct Payments*

Overdue Debt for invoices till 31.12.2018 (mill €)	Overdue Debt for invoices from 01.01.2019 till signing the Annexes for Direct Payments (mill €)
5,48	3,27

* Data from Group of Pharmaceutical Wholesalers



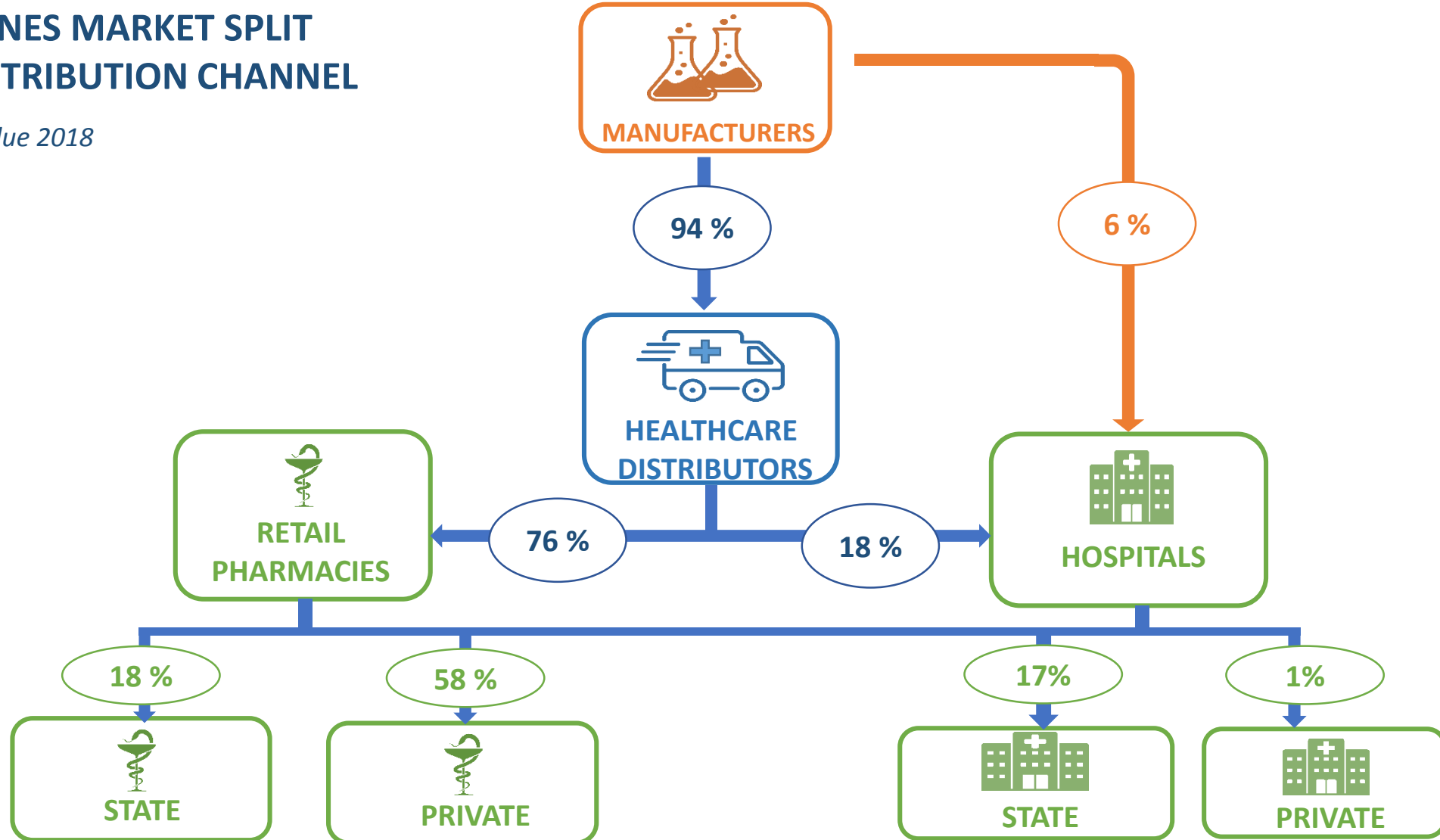
WHOLESALE

	SERBIA	CROATIA	SLOVENIA	BULGARIA	ROMANIA	HUNGARY
Rebating to retailers allowed?	✓	✓	✓	✓	✓	✓
Is there a limit to rebates?	x	x		x	x	✓
Regulation of wholesalers' margins	✓	✓	✓	✓	✓	✓
Do you have a legal Public Service Obligation (PSO) on wholesalers in your country?	✓	x	✓	x	✓	✓
If yes, is the manufacturer obliged to supply full-line wholesalers with products for human use?	x	x	x	x	✓	✓
Are there restricted distribution arrangements imposed by manufacturers in your country?	✓	✓	✓	x	x	✓
Direct to Pharmacy (DTP)	✓	✓	x	x	✓	✓
Reduced Wholesale Arrangements (RWA)	✓	✓	✓	x	x	
If yes, how many manufacturers are imposing such arrangements?		100				
How many products fall under such arrangements?		500				
Which % of the market value is affected?	10%					

Source: GIRP Questionnaire

**MEDICINES MARKET SPLIT
PER DISTRIBUTION CHANNEL**

MS (%) Value 2018



Source: IQVIA; Own Market Research

RETAIL

	SERBIA	CROATIA	SLOVENIA	BULGARIA	ROMANIA	HUNGARY
Is generic substitution by pharmacist allowed?	✓	x	✓	x	✓	✓
If yes, is there an incentive? (y/n)	x	x	x			✓
Is multiple pharmacy ownership allowed?	✓	✓	x	✓	✓	✓
How many pharmacies a person (physical or legal) can own?	unlimited		1	4	unlimited	4
Is ownership by a non-pharmacist allowed?	✓	✓	x	✓	✓	✓
Geodemographic limitations for pharmacy establishment?	x	✓	✓	x	✓	✓
Location criteria	x	✓	✓		x	✓
Population criteria	x	✓	✓		✓	✓
Mail-order allowed	✓	✓	✓	✓	x	✓
Mail-order allowed for RX medicines	x	x	x	x	x	x

Source: GIRP Questionnaire 2018



WHOLESALE & RETAIL MARGINS

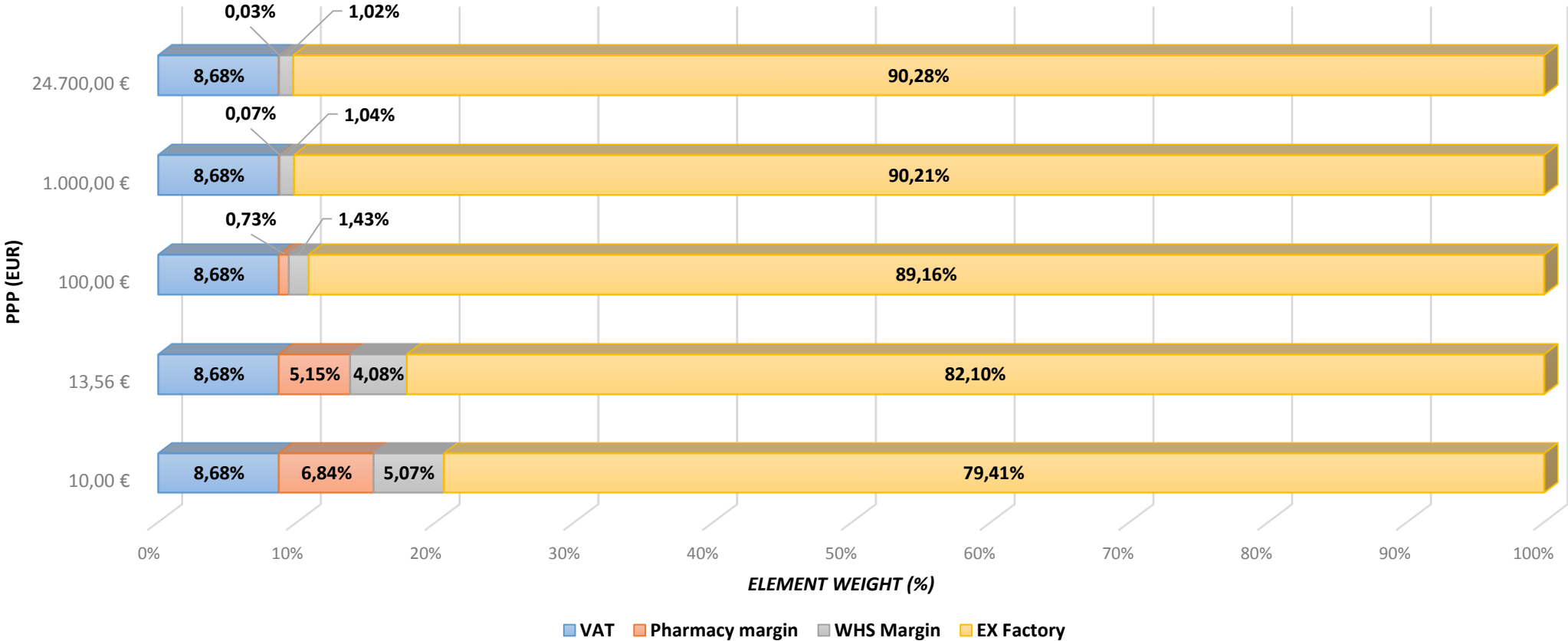
	WHOLESALE		RETAIL		VAT for meds
	Price range/ €	MARK-UP	Price range/ €	MARK-UP	
BULGARIA	0.01-5.11	up to 7%	for 100% reimb. meds- fixed fee 1.02 €/ prescription		20%
	5.12-15.34	up to 6%	0.01-5.11	up to 20%	
	> 15.34	up to 4% max. 5.11 €	5.12-15.34 > 15.34 €	up to 18% up to 16% max. 12.80	
ROMANIA	0.01-10.50	14%	0.01-5.25	24%	9%
	10.51-21.00	12%	5.26-10.50	20%	
	21.01-63.00	10%	10.51-21.00	16%	
	> 63.01	6.30 €	21.01-63 > 63.01	10% 7.35 €	
HUNGARY	up to 1.61	8%	up to 1.61	27%	5%
	1.62-3.23	6%, min. 0.13 €	1.62-1.90	0.44 €	
	3.23 -6.46	5%, min. 0.21 €	1.91-4.84	23%	
	> 6.46	4.4 % min. 0.32 €	4.84 -5.61	1.11 €	
			5.61-11.30	20%	
			11.30-12.62	2.26 €	
			12.63-16.14	18%	
> 16.14	3.20 €				

WHOLESALE & RETAIL MARGINS

	WHOLESALE MARGIN	RETAIL MARK-UP/ FEE		VAT for meds	
SERBIA	6% ??? of wholesale price (max WHS Price/Reimbursement Price/Tender Price)	<i>Reimbursed</i>	<i>Other (not Reimbursed) RX</i>		10.00%
		12%	Price range/ €	MARK-UP	
			0.00- 2.54	up to 25%	
			2.55- 5.08	up to 20%	
			5.09- 15.23	up to 16%	
			15.24- 67.67	up to 12%	
> 67.68	fixed fee: 8.12 €/prescription				
CROATIA	max. 7.83% (8.5% mark-up)	<i>Reimbursed</i>	<i>Other (not Reimbursed) RX and OTC</i>		5.00%
		fixed fee: 0.92 €/prescription	0.00- 13.49 €	35%	
			13.50- 26.99 €	30%	
			27.00- 40.44 €	25%	
			40.45- 67.39 €	20%	
			67.40- 134.79 €	15%	
			> 134.80 €	10%	
Exceptions: anti-cancer and in vitro fertilisation medicines (expensive medicines) – min. 2%, max. 35%					
SLOVENIA	fixed fee 0,5 € + variable part = PEP*1,1 % *PEP = Producer's Element of Pricemax. 27,50 €/unit	fee-for-services measured by points the value of the point depends on the number of employees, salaries, work requirements, material costs, amortization costs, the investment maintenance of pharmacies		9.50%	

MEDICINE RETAIL PRICE STRUCTURE- SLOVENIA

Retail price structure



Source: Slovenian Chamber of Commerce, Association of Pharmaceutical Full line Wholesalers

TO SUPPLIERS

	SERBIA	CROATIA	SLOVENIA	BULGARIA	ROMANIA	HUNGARY
Sales statistics/reports	✓	✓	✓	✓	✓	✓
Medicines registration services	✓	✓	✓	✓	✓	✓
Marketing services	✓	✓	✓	✓	✓	✓
Administrative services	✓	✓	✓	✓	✓	✓
Pre-wholesaling services	✓	✓	✓	✓	✓	✓
Relabeling	✓	✓	✓	✓	✓	✓
Distribution of clinical trials	✓	✓	✓	✓	✓	✓
Reverse logistics (recalls & returns)	✓	✓	✓	✓	✓	✓

Source: GIRP Questionnaire 2018

VALUE-ADDED SERVICES OF HEALTHCARE DISTRIBUTORS

TO PHARMACIES

	SERBIA	CROATIA	SLOVENIA	BULGARIA	ROMANIA	HUNGARY
Emergency services	✓	✓	✓	✓	✓	✓
Transmission of recall messages	✓	✓	✓	✓	✓	✓
Collection of outdated drugs	x	x	✓	✓	✓	✓
Collection of packaging waste	x	x	x	✓	✓	✓
Computer systems for pharmacies	✓	x	x	✓	✓	✓
Own brands	✓	✓	x	✓	✓	✓
Financial services	✓	✓	x	✓	✓	✓
Training	✓	✓	✓	✓	✓	✓
Analysis of purchases (sell in)	✓	✓	✓	✓	✓	✓
Merchandising services	✓	✓	x	✓	✓	✓
Sales analysis (sell out)	✓	✓	x	✓	✓	✓
Wholesalers own marketing support	✓	✓	✓	✓	✓	✓
Marketing support in cooperation with manufacturers	✓	✓	✓	✓	✓	✓
Promotional literature for pharmacists use	✓	✓		✓	✓	✓
Patient information leaflets for pharmacists use	✓	✓	✓	✓	✓	✓
Internet access to data of some wholesalers	✓	✓	✓	✓	✓	✓
Stock counting aid for pharmacies	x	x	x	✓	✓	✓

TO PHARMACIES

- On line portals
 - B2B (mainly used by pharmacy chains)
 - Software for pharmacies
 - ✓ order management
 - ✓ module for data exchange with HIF (updated reimbursing rules, price changes, invoicing to the HIF)
 - ✓ e-prescription
 - ✓ BI tools
 - ✓ loyalty programs support
- 70-80 % of pharmacy orders

TO HEALTHCARE SYSTEM (PAYERS & SOCIETY)

Participation in implementation of The Government Act on direct payments from the HIF to suppliers

- technical support in implementation of HIF web portal
- support in detecting and resolving (operational) issues

Integration with portal of Treasury- Ministry of Finance (for the purpose of reviewing and planning of the budget)

PHARMACEUTICAL MARKET TRENDS = CHALLENGES

Increased Medicines Consumption	Healthcare Budgets limited	Medicines Price Decrease	Wholesale Margins Decrease
Tendering	Commercial Incentives from Mnf	DTP/DTH/RWA	Innovative Medicines
Shortages	Pharmacy Chain Consolidation	Cash Flow & Credit Issues	New Regulatory Demands
Digitalization	Services	Artificial Intelligence	Personalization of Medicines

NEW MEDICAL DEVICES REGULATION

❑ IMPLEMENTATION IN EU

The new Medical Devices Regulation (MDR) and in-vitro Diagnostics Medical Devices Regulation (IVDR)- entered into force on 20th April 2017, deadlines for application on 20th April 2020 and 20th April 2022 respectively.

The Regulations introduce, among others:

- a **new classification system for IVDs**
- the establishment of a **new database for medical devices**
- increased roles and responsibilities for distributors
- **the introduction of the UDI system**

❑ REGULATORY FRAMEWORK FOR MEDICAL DEVICES IN SERBIA

- New **Law on Medical Devices** entered into force in **November 2017, applicable from December 2018.**
- **17 Rulebooks** related to medical devices came into force
- **The Rulebook on GDP Guidelines of medical devices**, applicable from 1st of June 2019. defines obligations of distributor in line with EU regulation
- **Some of the clauses will be applied after admission of Serbia to EU**

PHARMACEUTICAL WASTE MANAGEMENT

Regulatory Framework

The Law on Waste Management, 2009

- **Pharmaceutical Waste** (hazardous and non-hazardous)
- **Pharmacies** are obliged **to take over the pharmaceutical waste from the citizens free of charge** and hand over such waste to the entities carrying out the collection, transport, treatment, and/or storage, recovery, and disposal or export of pharmaceutical waste
- **Costs of Pharmaceutical Waste Management**
 - should be borne by waste producer, except for the costs of the management of pharmaceutical waste collected from the citizens which should be borne by the producer and/or importer placing pharmaceutical products on the market proportionately to their share in the product mass they are placing on the market
 - costs of the management of waste generated from the drugs for which no marketing authorization was issued in the Republic of Serbia shall be borne by the importer of such drugs

PHARMACEUTICAL WASTE MANAGEMENT

Regulatory Framework

The Law on Fees for use of public goods, 2018

The provisions which are related to fee for protection and improvement of the environment also include the **fee for pharmaceutical waste collected from citizens at pharmacy level**

Fee Calculation Model

240 RSD/kg of the total annual manufactured/imported quantity => cca 38 mil € (4.58 % of total medicines turnover in Serbia)

Note

- *In the Law of Fees, medicines are in the category of the products that become waste after use*
- *However, only 1-3% of total medicines end as waste (medicines collected from citizens and pharmacies)*

FALSIFIED MEDICINES DIRECTIVE (FMD)

- published 1 July 2011; entered into force 1 January 2013
- contains measures to increase security of the medicinal supply chain in Europe

NATIONAL LEGISLATION AGAINST FALSIFIED MEDICINES

By-Law on the content and method of labeling of the outer and inner packaging of the **medicinal product**, the **additional labeling** and the contents of the package leaflet, **2013**

Control stamp:

- on every single pack of medicine
- a combination of barcode and hologram technology
- attached to a specially marked place on the outer packaging (Blue Box)
- issued by The Institute for Manufacturing banknotes and coins
- controlled by and reported to Medicines Agency, Ministry of Health and Ministry of Trade



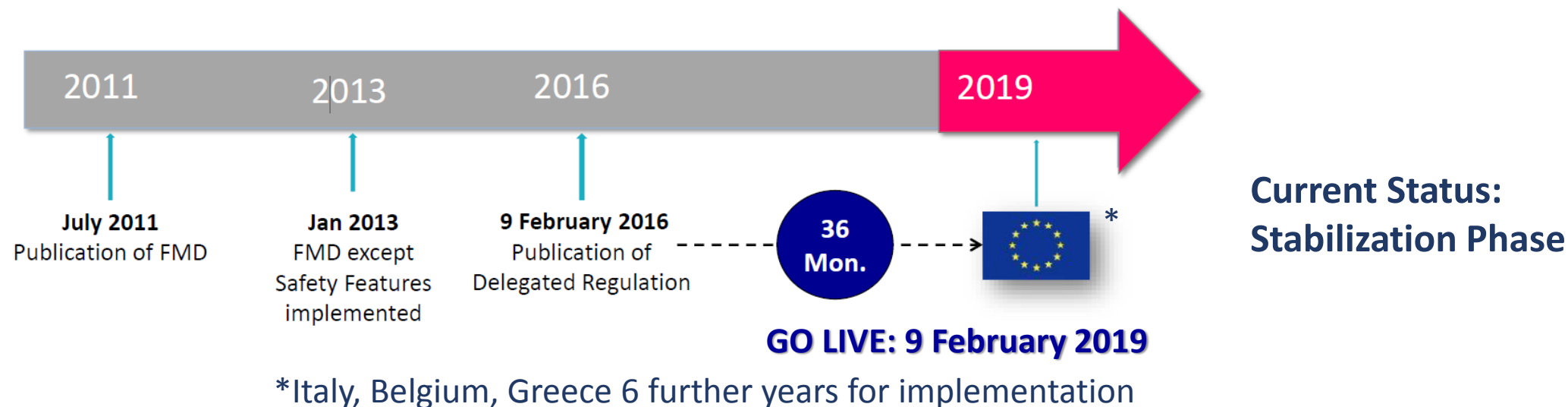
MEDICINES SERIALIZATION

FALSIFIED MEDICINES DIRECTIVE (FMD)

- published 1 July 2011; entered into force 1 January 2013
- contains measures to increase security of the medicinal supply chain in Europe

DELEGATED REGULATION TO THE FMD

- published 9 February 2016; applied from 9 February 2019
- characteristics and technical specifications of the unique identifier
- modalities for the verification of the safety features
- establishment , management and accessibility of the repository systems



MEDICINES SERIALIZATION

Unique Identifier (UI) Composition

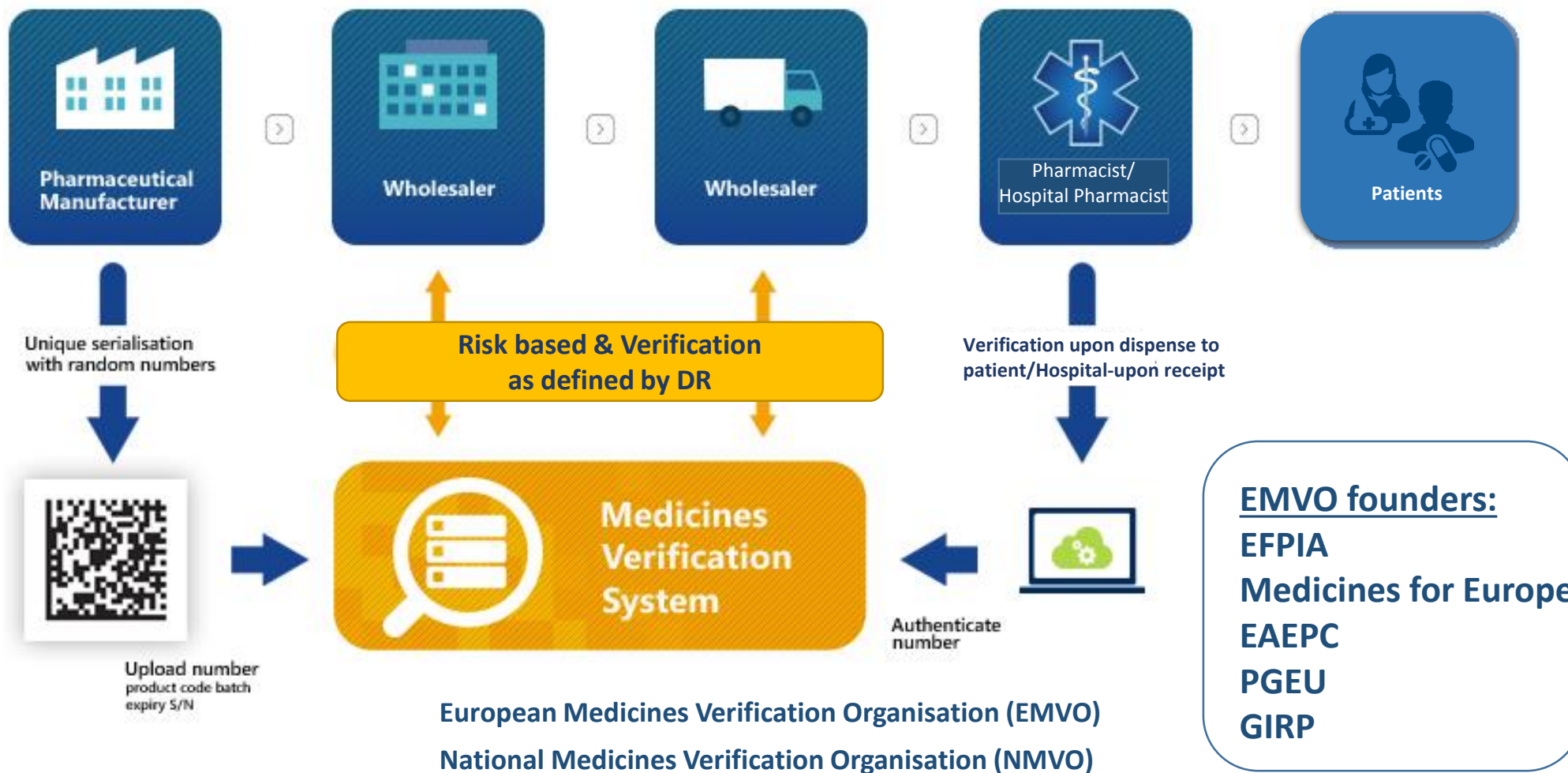
- **PC:** Product code: ISO-compliant (ISO 15459); < 50 characters; globally unique; issued by ISO-compliant coding agencies;
- **SN:** Serial number (max 20 characters; randomised)
- **NN:** A national reimbursement or identification number (optional)
- **Batch** number
- **Expiry** date

PC: 09876543210982
SN: 12345AZRQF1234567890
NN: (optional)
Batch: A1C2E3G4I5
Expiry: 180531



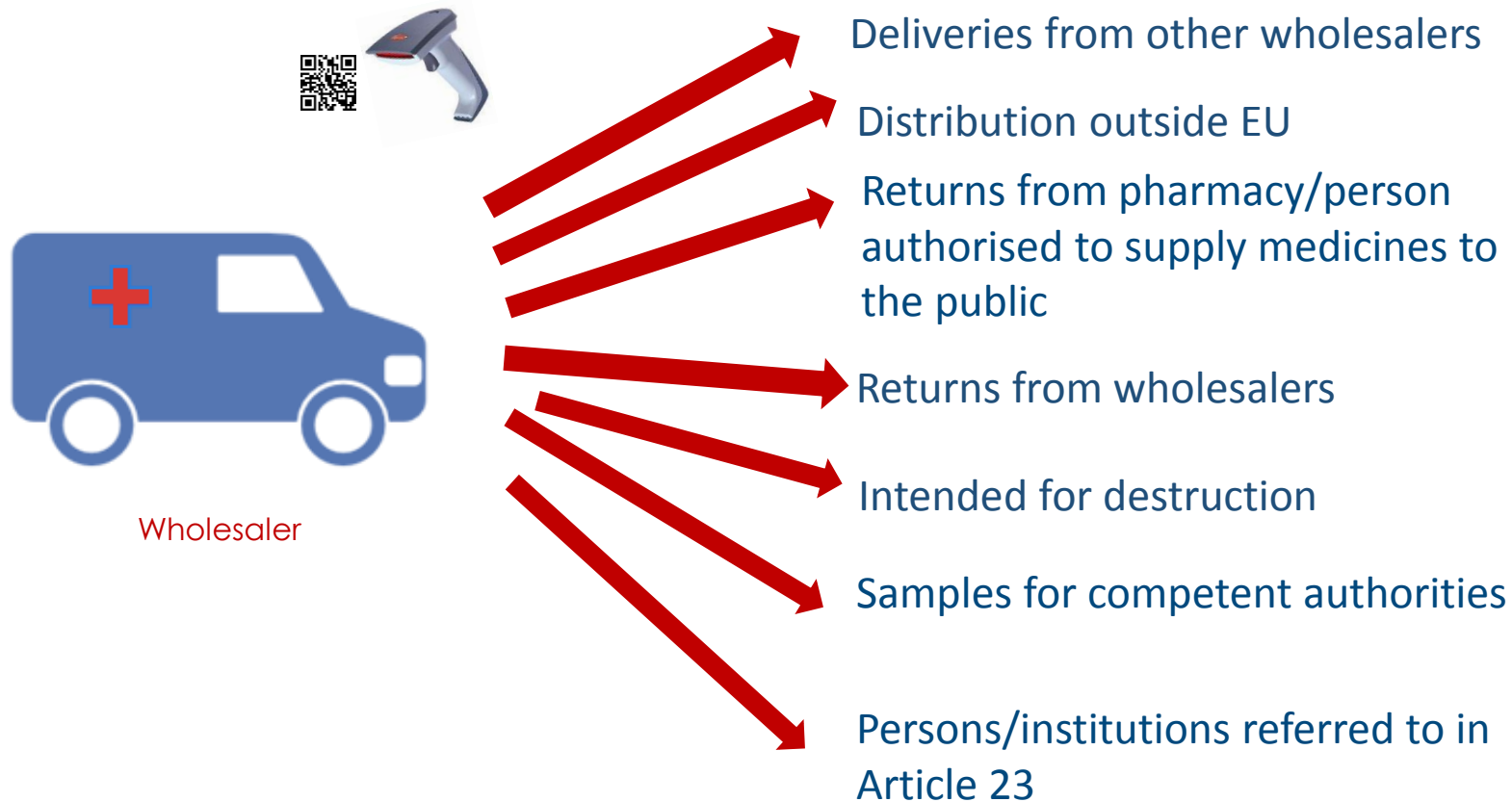
MEDICINES SERIALIZATION

Product Flow



MEDICINES SERIALIZATION

Wholesalers' responsibilities under the Delegated Regulation



MEDICINES SERIALIZATION

Wholesalers' responsibilities under the Delegated Regulation

Persons/institutions referred to in Article 23



(a) persons authorised or entitled to supply medicinal products to the public who do not operate within a healthcare institution or within a pharmacy;



(b) veterinarians and retailers of veterinary medicinal products;



(c) dental practitioners;



(d) optometrists and opticians;



(e) paramedics and emergency medical practitioners;



(f) armed forces, police and other governmental institutions



(g) universities and other higher education establishments using medicinal products for the purposes of research and education



(h) prisons;



(i) schools;



(j) hospices;

(k) nursing homes.

MEDICINES SERIALIZATION

EMVO maintains a central database (EU Hub), which connects all national databases in Europe and serves as a platform for the authentication of medicines in any part of the medicines supply chain in EEA.

Manufacturers/MAH`s hold the main role in the medicines serialization, while the competent authorities / institutions have the role in supervision.

FINANCING

Impact assessment of European Commission showed that medicines production costs will be increased in average for about 3% per pack.

Cost of Manufacturers

- labeling of each box of the medicine with safety features
- costs of implementing and maintaining a drug verification system

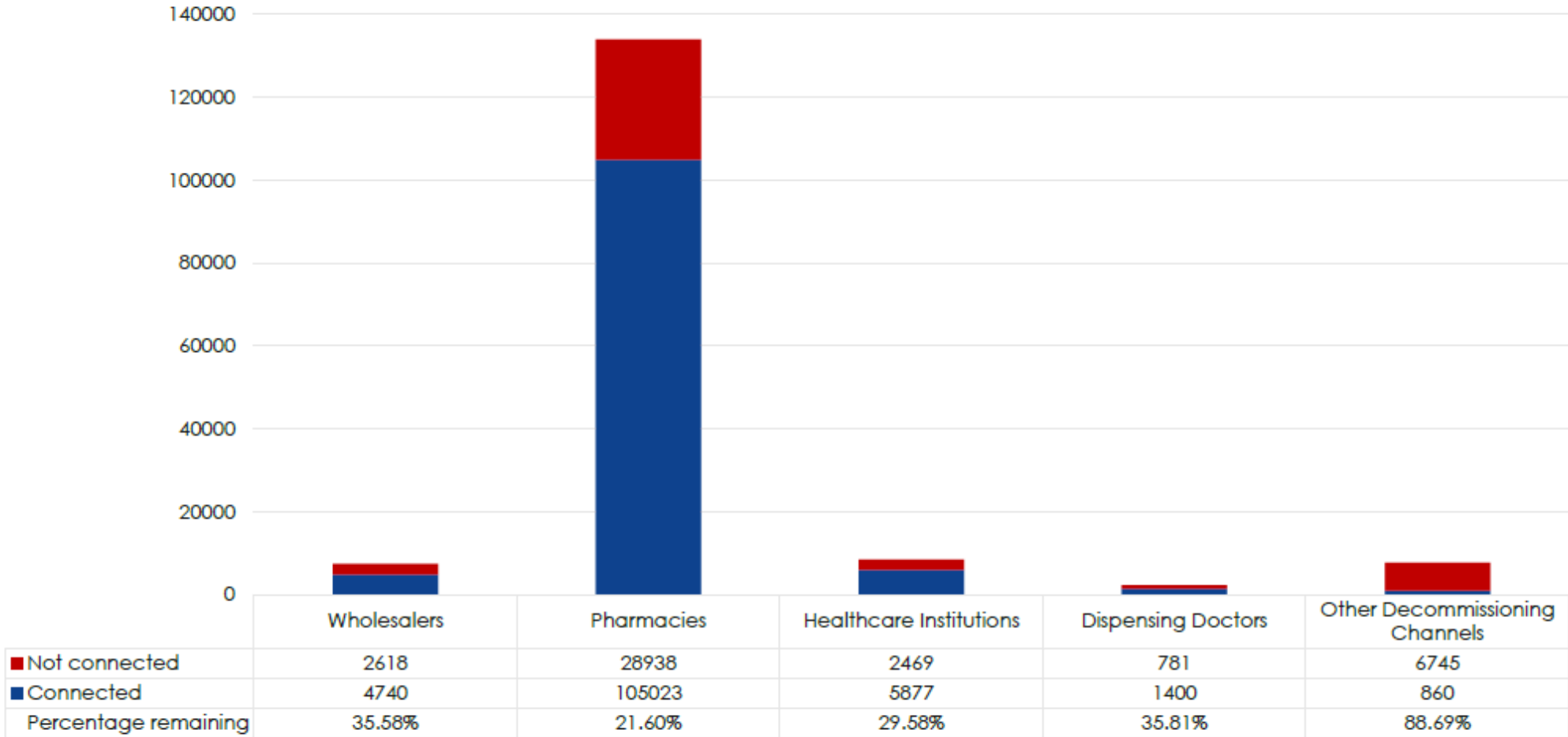
Costs of Wholesalers

- equipment purchasing (scanners)
- connection with the National Medicines Verification System(NMVS)

Public and hospital pharmacies

- equipment purchasing (scanners)
- software modification for connection with NMVS- not a big expense, but it turned out to be a big problem due to a different status of IT equipment

END-USERS CONNECTION OVERVIEW(*)



Calendar Week 41 2019
EMVO MONITORING REPORT



(*)The information figuring hereunder was collected in Calendar Week 40 and will be updated on a monthly basis

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CHALLENGES FOR THE HEALTHCARE DISTRIBUTORS



CHALLENGES FOR SUSTAINABILITY OF THE HEALTHCARE SYSTEM

Thank you for Your Attention !

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