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European Union

Challenges for wholesale distributors with FMD & DR implementation on national level

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Who needs to be connected on national level? **Connecting all End-Users**

Who are the End-Users of the system?

- Persons authorized and entitled to supply medicinal products to the public (e.g. pharmacies)
- Wholesale Distribution Authorization holders**
- Art 23 persons/institutions (if applicable)
- Others?

Wholesale Distribution Authorization holders:

- Full-line wholesalers
- Short-line wholesalers
- Traders
- In some countries, pharmacies (holder of WDA)
- Manufacturers carrying out distribution activities for their own products (Directive 2001/83/EC Article 77.3)
- 3PLs / wholesalers
- Others?



Connecting wholesale distribution authorization holders

Lack of consolidated data on WDA holders at national level

	<i>FL ws</i>	<i>GIRP est.</i>	<i>WDA</i>
Austria	6	≈300	305
Belgium	10	?	318
Bulgaria	5	≈220	228
Croatia	4	?	39
Cyprus	0	?	103
Czech Republic	5	?	747
Denmark	2	?	222
Estonia	64	?	62
Finland	2	104	65
France	17	≈600	679
Germany	12	3672	597
Greece	110	?	208
Hungary	12	?	90
Ireland	2	≈350	365
Italy	37	1194	0

	<i>FL ws</i>	<i>GIRP est.</i>	<i>WDA</i>
Latvia	4	?	73
Lithuania	126	?	112
Luxembourg	2	?	0
Malta	0	?	103
Netherlands	5	?	383
Poland	200	?	887
Portugal	6	?	340
Romania	27	432	107
Slovakia	10	?	146
Slovenia	13	?	0
Spain	28	?	594
Sweden	2	?	272
UK	15	2205	2163
TOTAL	761		8353

Legend:

- **FL ws** = full-line wholesalers
 - **GIRP est.** = GIRP estimation of wholesale distribution authorisations
 - **WDA** = Wholesale Distribution Authorisations entries in EudraGMDP
- 3/11/2017



Connecting wholesale distribution authorization holders

Lack of consolidated data on WDA holders at national level

	<i>FL ws</i>	<i>GIRP est.</i>	<i>WDA</i>	<i>GDP</i>
Austria	6	≈300	305	620
Belgium	10	?	318	215
Bulgaria	5	≈220	228	0
Croatia	4	?	39	25
Cyprus	0	?	103	64
Czech Republic	5	?	747	851
Denmark	2	?	222	126
Estonia	64	?	62	34
Finland	2	104	65	91
France	17	≈600	679	241
Germany	12	3672	597	356
Greece	110	?	208	0
Hungary	12	?	90	106
Ireland	2	≈350	365	382
Italy	37	1194	0	0

	<i>FL ws</i>	<i>GIRP est.</i>	<i>WDA</i>	<i>GDP</i>
Latvia	4	?	73	45
Lithuania	126	?	112	78
Luxembourg	2	?	0	0
Malta	0	?	103	104
Netherlands	5	?	383	306
Poland	200	?	887	75
Portugal	6	?	340	339
Romania	27	432	107	138
Slovakia	10	?	146	103
Slovenia	13	?	0	0
Spain	28	?	594	174
Sweden	2	?	272	282
UK	15	2205	2163	3598
TOTAL	761		8353	9209

Legend:

- **FL ws** = full-line wholesalers
- **GIRP est.** = GIRP estimation of wholesale distribution authorisations
- **WDA** = Wholesale Distribution Authorisations entries in EudraGMDP 3/11/2017
- **GDP** = inspection certificates in EudraGMDP databases 3/11/2017



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Connecting wholesale distribution authorization holders

Some inconsistencies to resolve

WDA entries vs GDP entries in the EudraGMDP database:

- Some countries grant 1 WDA/company with multiple sites, but GDP certificates for each individual site
- Duplicate entries for GDP certificates have found their way into the database
- Cases where GDP certificates have been granted for sites not listed on the WDA of the company



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Connecting End-Users to the national repository systems

- ❑ Verification and validation is critical (*“only users whose identity, role and legitimacy has been verified can access the repository”* Art 37b)
- ❑ Technical connection will involve wholesalers software provider
 - Each solution provider will need technical support and access to test systems
- ❑ Control of the connected user locations must be retained by the NMVO (not the software provider)
- ❑ Overall system security is only ever as good as the weakest link (robust end user legitimacy check)

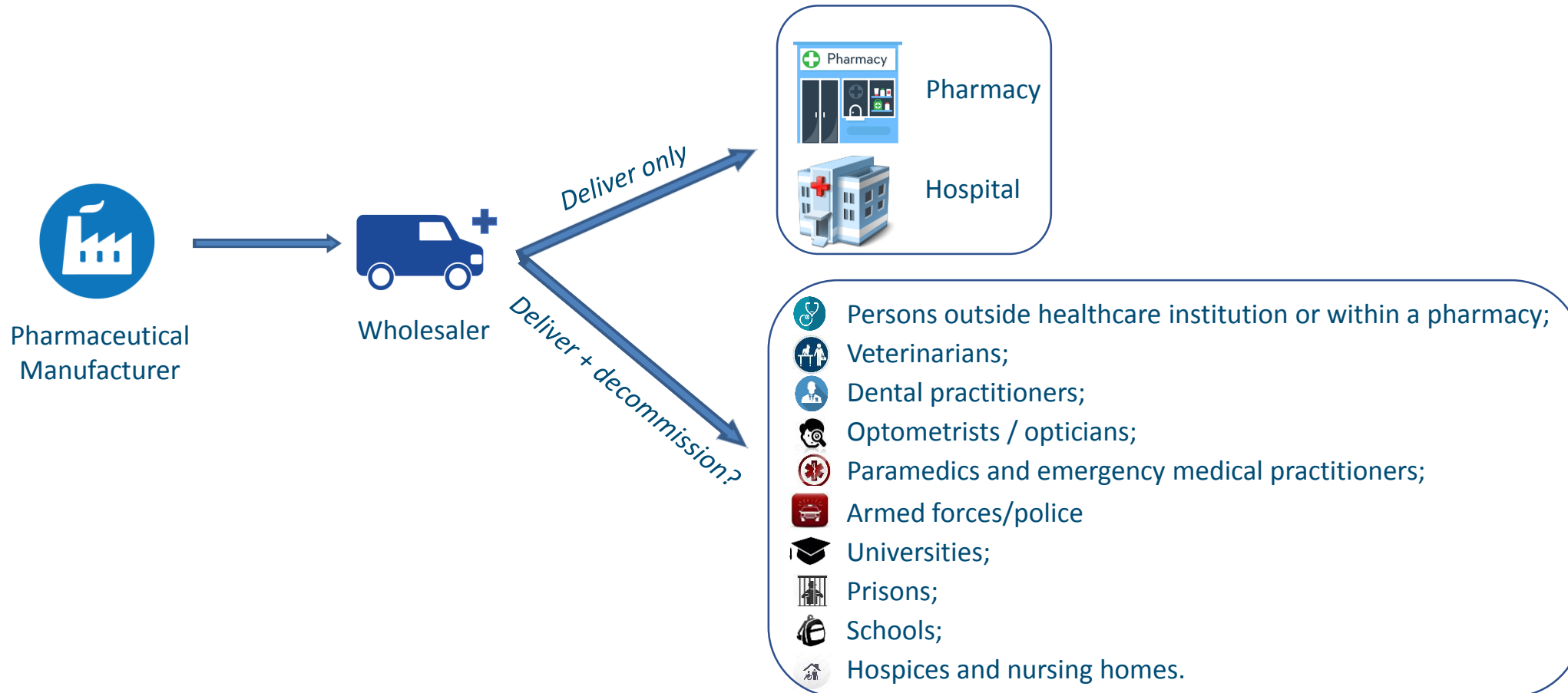


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Provisions to accommodate specific characteristics of Member States' supply chains (Art 23, DR)





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Challenges (Art 23, DR)



“Healthcare institution” is not defined in the FMD or the DR



“Self dispensing doctors” included under Art 23.a?



Lack of clarity which Member States will make use of Art 23 and for which persons/institutions



Room for interpretation on national level for the physical point of decommissioning?



Government purchased stock (e.g. vaccines) and emergency supplies – who decommissions?

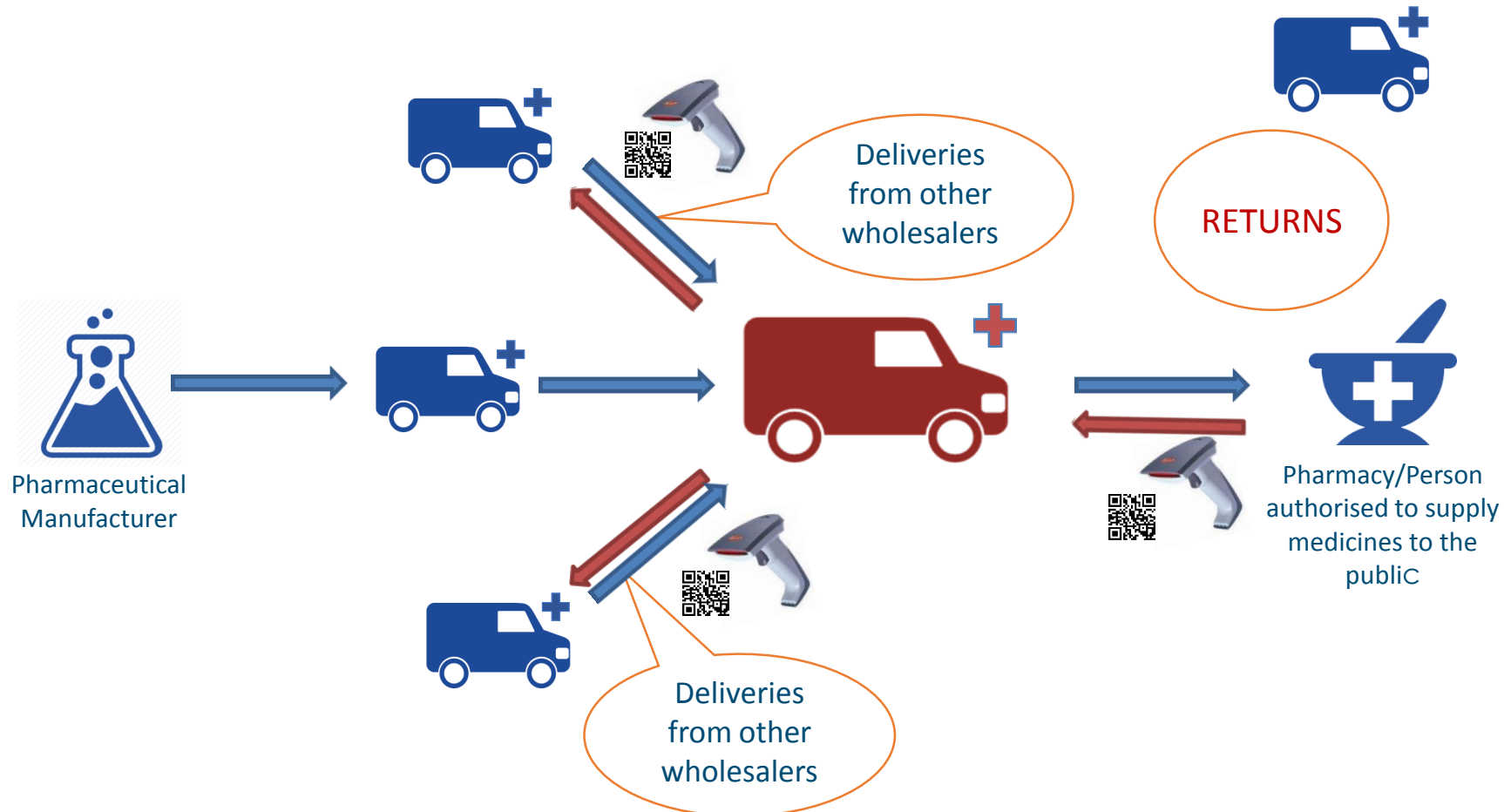


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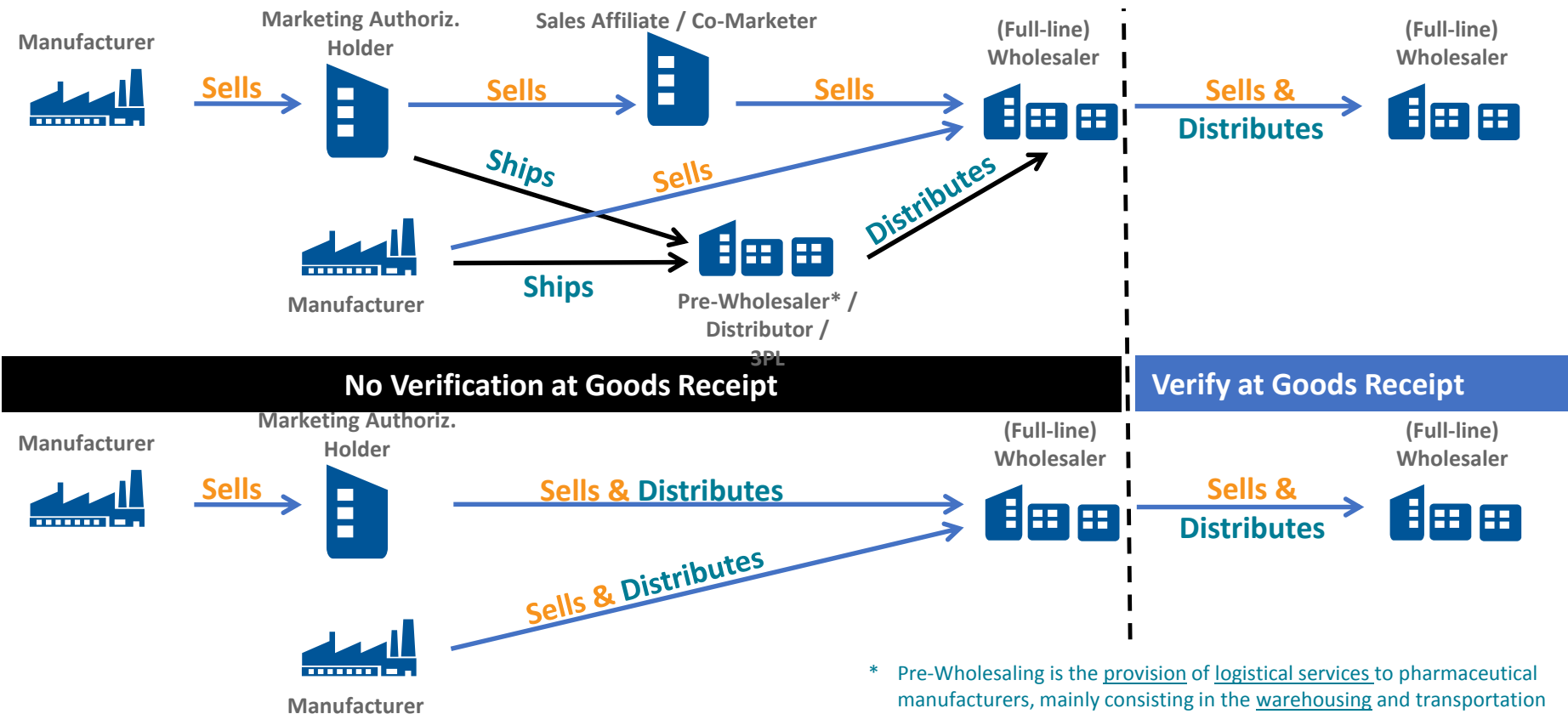
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Risk based verification - Clarity on when to verify and not to verify





List of designated wholesalers (Art 33 2(h))



* Pre-Wholesaling is the provision of logistical services to pharmaceutical manufacturers, mainly consisting in the warehousing and transportation of pharmaceutical products from the manufacturer to wholesalers, ...

List of designated wholesalers must be included in the national repository system



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Thank you!

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