Magyar
Gyógyszerésztudományi
Társaság

Serialization Information Flow and related IT architecture

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Content

- Assumptions and Memo (EU and RU serialization at a glance)
- An oversimplified model
- A little bit of theory – the levels of manufacturing
- The effect of serialization
- The evolution of the information systems
- The necessary IT changes

Remarks

- Activities of a Manufacturer/MAH will be discussed
- Tasks of authorities, pharmacies, distributors, wholesalers are not discussed in details
- Sorry for the many TLAs (three letter abbreviations/acronyms) ☺

Assumptions

- The audience knows the basics of the on-going worldwide pharmaceutical serialization
- The audience knows the basics of pharmaceutical manufacturing and warehousing activities
- The audience has basic informatic knowledge
- The audience knows the supporting IT solutions of the above processes

TLAs (Three Letter Abbreviations)

- **ERP** – Enterprise Resource Planning
- **MES** – Manufacturing Execution System
- **WMS** – Warehouse Management System
- **LMS** – Line Management System
- **T&T** – Track and Trace
- **CR** – Central Repository
- **MAH** – Marketing Authorization Holder
- **BO** – Brand Owner
- **CMO** – Contract Manufacturing Organization
- **3PL** – 3rd Party Logistic Partner
- **SN** – Serial Number
- **MDLP** – Russian Track & Trace System
- **CRPT** – Operator of MDLP

Memo – EU serialization at a glance #1

The main point of the pharmaceutical serialization

Print a unique identifier on secondary package of certain products (defined in the law)

European Federation of Pharmaceutical Industries and Associations (EFPIA): Recommendation for Coding of Pharmaceutical Products in Europe

Data Matrix – Coding proposal derived from GS1 standards (EAN 128 syntax with Application Identifiers; DataMatrix ECC200)

Manufacturer Product Code (GTIN or NTIN): 14 digits
Unique Serial Number (randomized): up to 20 alpha-numeric characters
Expiry Date: 6 digits (YYMMDD)
Batch Number: up to 20 alpha-numeric characters
+ minimum requirements on quality of randomisation

Example:

GTIN: (01) 07046261398572
Batch: (10) TEST5632
Expiry: (17) 130331
S/N: (21) 19067811811

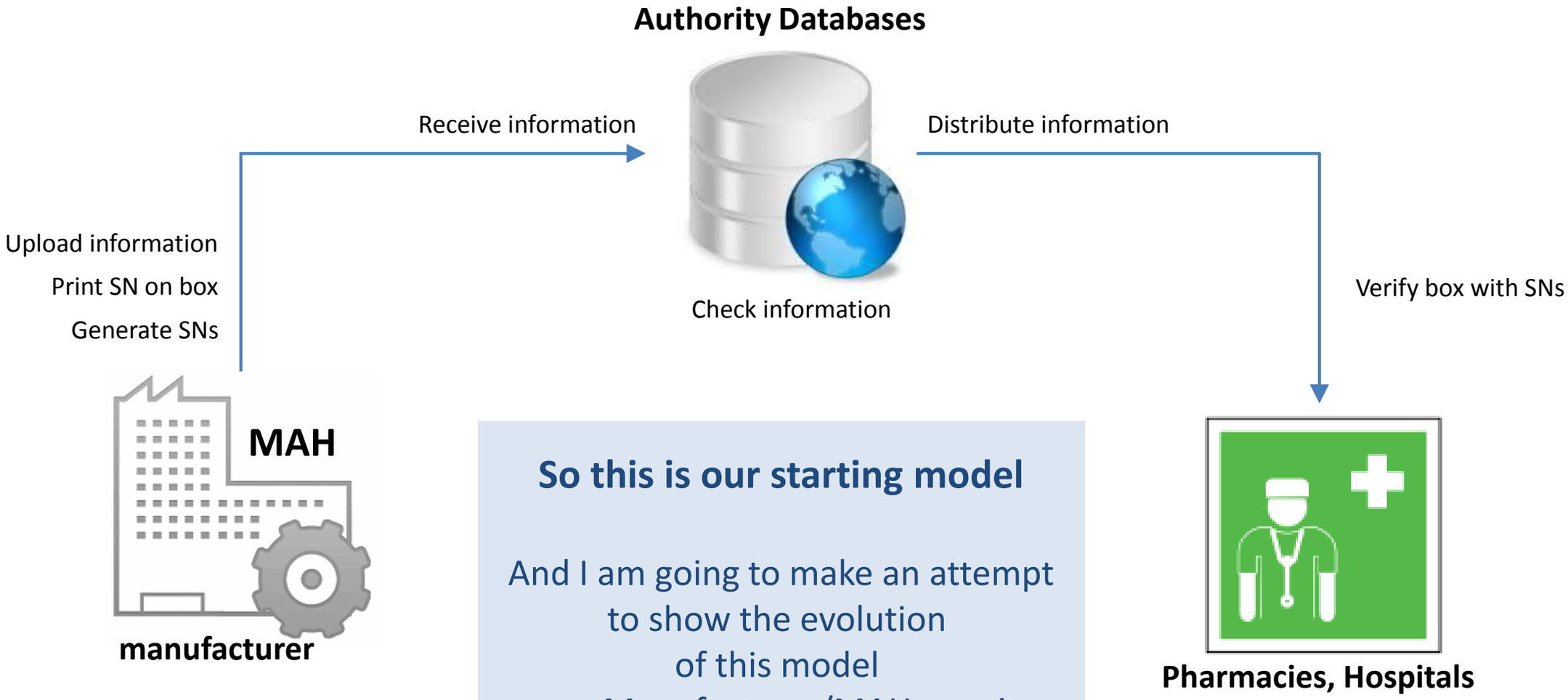
Specifications provided in EFPIA's: "European Pack Coding Guidelines"

AND many other tasks should be performed e.g.

- Regulation
- Set up agencies (e.g. EMVO, NMVOs)
- Design and Implement databases (e.g. EMVS, NMVSs)

- Select/Buy/Implement serialization hardware
- Select/Buy/Develop/Integrate serialization software
- Analyze/Create/Modify the information/data flow and system functionality
- Test and validate the whole system
- Contact your partners (CMOs/BOs/3PL)
- Upload/Download data to/from multiple databases
- Follow and report the status changes of the packages

Oversimplified model of serialization (with endpoint verification)

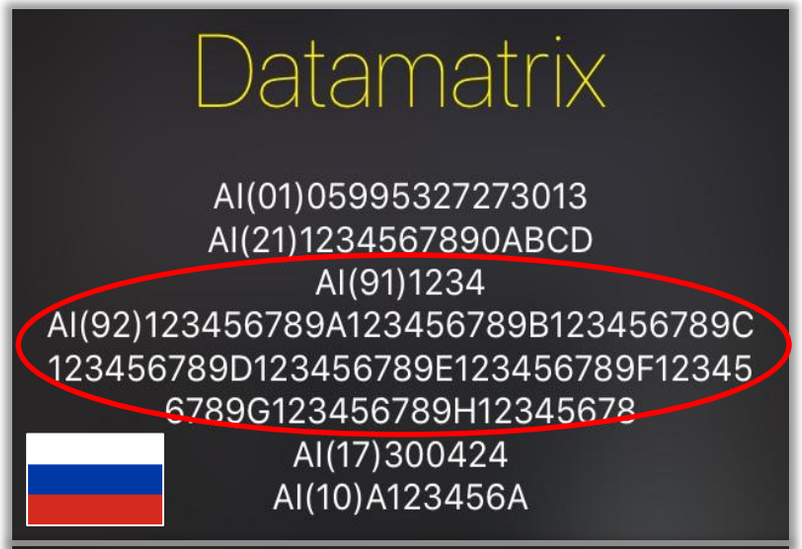


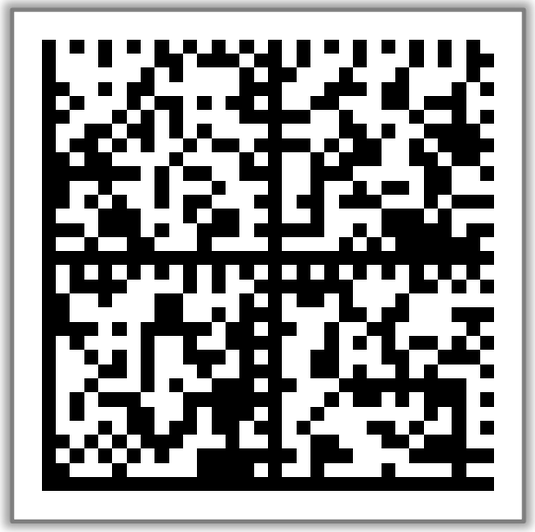
So this is our starting model

And I am going to make an attempt
to show the evolution
of this model
as a Manufacturer/MAH sees it.

Memo – Russian serialization

RU: some key differences as compared to the EU serialization





- all products
- full tracking
- aggregation
- more reports
- no anti-tampering
- crypto codes

AI(91) 4 characters
AI(92) 88 characters

If (EU serialization)

Is a cross-country running (where the place of the Finish line changed time-to-time)

Then (RU serialization)

Is an iron-man triathlon

Endif

But before that (as I promised) – the conventional levels of manufacturing

Enterprise level (ERP)
Interfaces to external
and internal systems

Level 4

Enterprise

S95

Plant/Site level
Manufacturing mgmt. (MES)
Warehouse mgmt. (WMS)

Level 3

Plant

Warehouse

S88

Line level | Software
(SCADA, HMI, PLC, DCS)

Level 2

Monitor and control
the production process

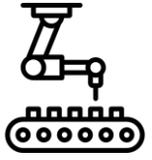
Devices | Sense, Vision, Flow

Level 1

Checkweigher

Machines | Hardware

Level 0



Physical
production process

The impact of serialization on the levels of manufacturing

External level
Communication Interfaces
to Authorities, Partners etc.

Level 5

World

EU, RU and other national systems

Partner IT Systems

Enterprise level
Interfaces to external
and internal systems

Level 4

Enterprise

Enterprise Resource Planning

CR – L4 T&T system
(SN mgmt., connections)

S95

Plant/Site level
Manufacturing mgmt.
Warehouse mgmt.

Level 3

Plant

Manufacturing Execution Systems

Warehouse

Logistic/Warehouse Mgmt. Systems

L3 T&T system

S88

Line level | Software
(SCADA, HMI, PLC, DCS)

Level 2

Line Controller Systems

L2 T&T functions

Devices | Sense, Vision, Flow

Level 1

Checkweigher

Production Line Device(s)

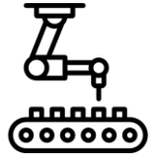
Printer

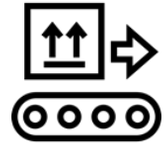
Code reader

Camera

Machines | Hardware

Level 0





Evolution of serialization information architecture – functional components

L5	Other National Systems	CMO/BO T&T Systems	EU National Systems	EU Hub	RU Compliance Report	RU Crypto System
L4	Code Verification	Label Management System	Enterprise Resource Planning	EU T&T system (SN mgmt., connections)	RU T&T system (SN mgmt., reporting)	RU T&T system (crypto mgmt.)
L3		Logistic/Warehouse Mgmt. Systems	Manufacturing Execution Systems	L3 T&T system		RU 3PL/CMO system(s)
L2	**So our system landscape grows rapidly and complicates the integration architecture significantly**		Line Controller Systems			
L1			Production Line(s)			

1. „normal” production/logistic systems
2. EU serialization
3. non-EU serialization
4. RU T&T

Evolution of serialization information architecture

L5

L4

Code Verification CONFIDENTIAL

Label Management System CONFIDENTIAL

Enterprise Resource Planning CONFIDENTIAL

EU T&T system (SN mgmt., connections) CONFIDENTIAL

RU T&T system (SN mgmt., reporting) TO BE IMPLEMENTED

RU T&T system (Crypto mgmt.) TO BE IMPLEMENTED

L3

Logistic/Warehouse Mgmt. Systems CONFIDENTIAL

Manufacturing Execution Systems CONFIDENTIAL

L3 T&T system CONFIDENTIAL

RU 3PL/GMO system(s) TO BE CONNECTED

L2

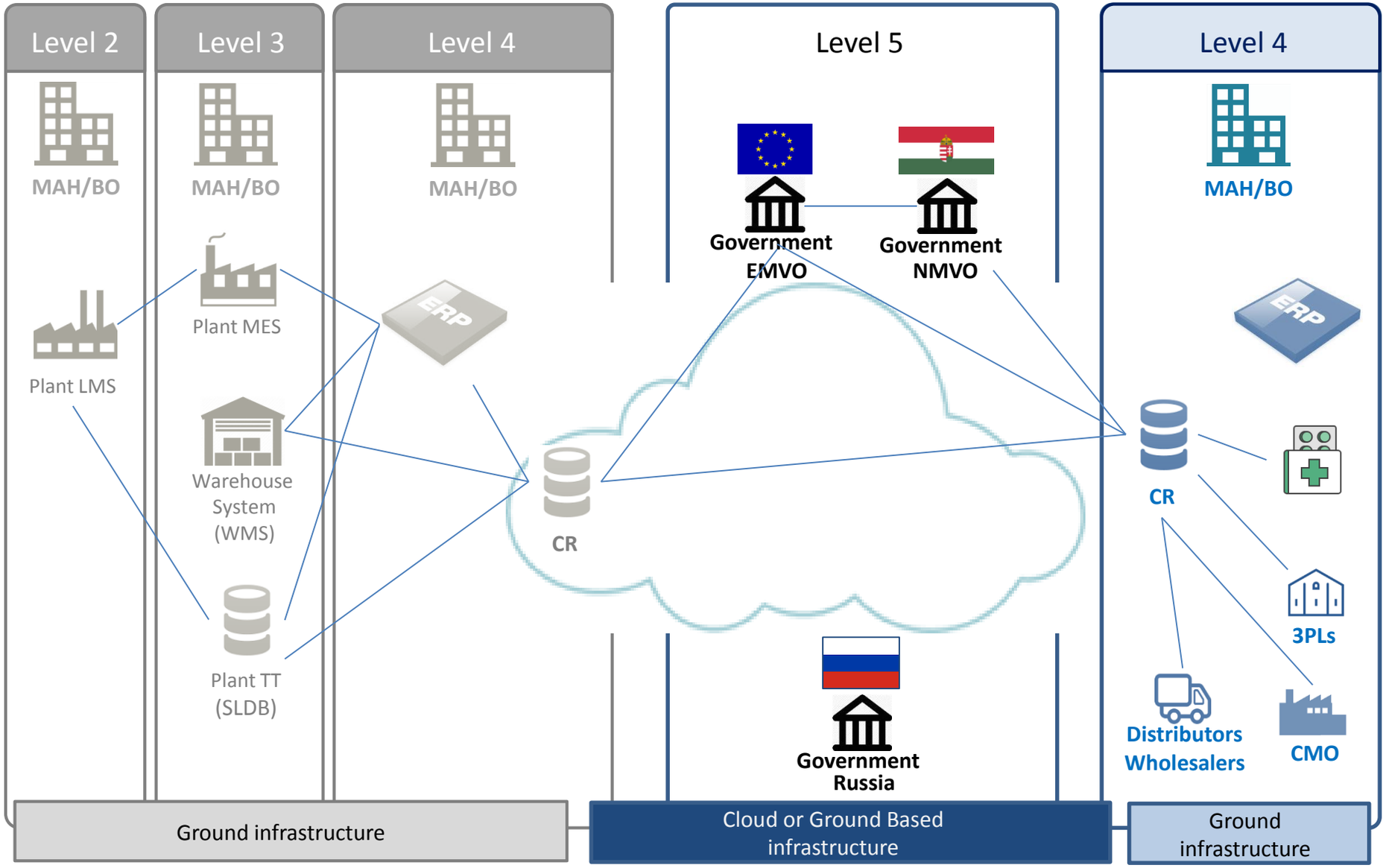
Line Controller Systems CONFIDENTIAL

L1

Production Line(s) CONFIDENTIAL

1. „normal” production/logistic systems
2. EU serialization
3. non-EU serialization
4. RU T&T

A more complex (but still simplified) model of serialization



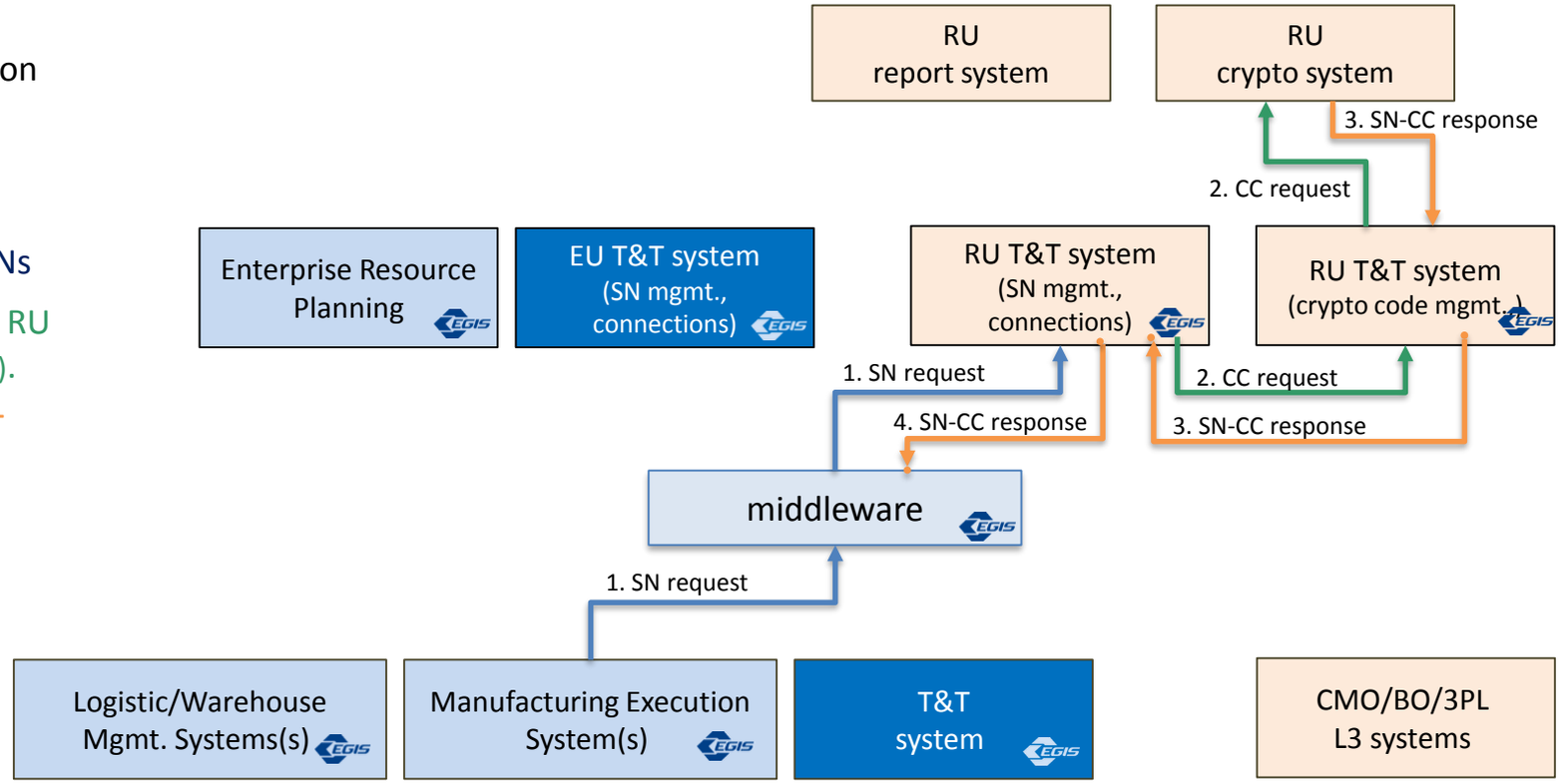
High level data flow #1 - crypto codes (CCs) request

Prerequisites

- Master data are available in the related systems
- Lines and systems are suitable and ready for production
- MES starts production by requesting SNs and CC-s

Information/Data flow

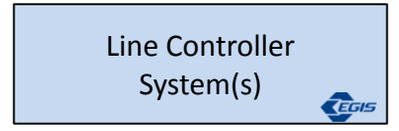
1. MES send request (through middleware) to RU T&T for SNs
2. RU T&T generates SNs and submits request for CCs to RU crypto generation system (through RU T&T crypto module).
3. RU crypto generates CCs, sends them back to RU T&T (through RU T&T crypto module).
4. RU T&T sends SN-CC data to middleware

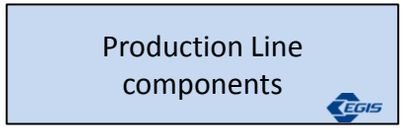


Q: Why do we need a middleware?

A: Multiple reasons

- IT integration principles (especially if you have more sites with multiples MES and WMS)
- On presentation slides all systems speak in standards.
  But as my experienced colleague said:
  One is speaking it with the elegance of an English lord,
  while the other is doing that with the accent of an Irish peasant.
  So you may need to translate.





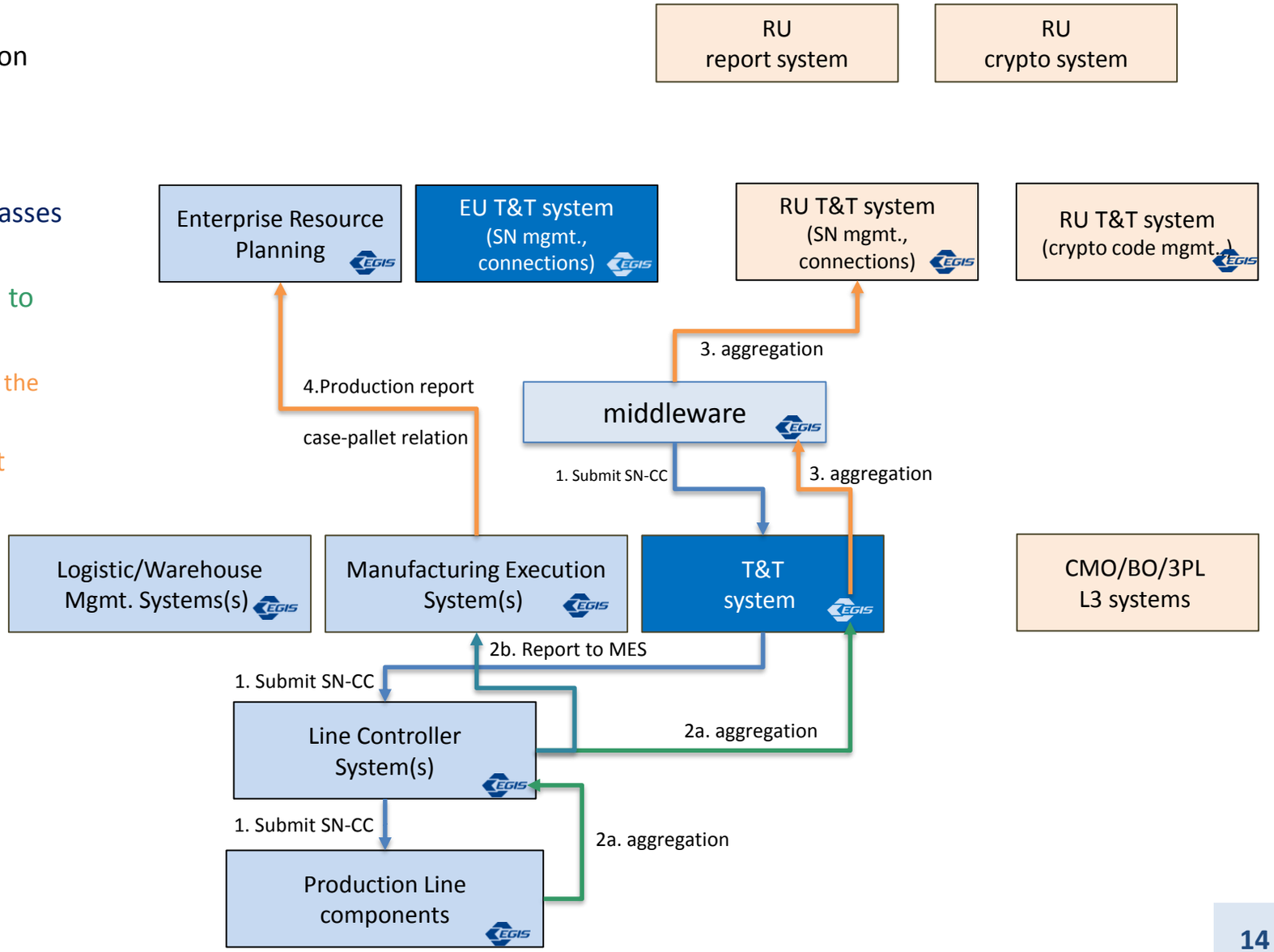
High level data flow #2 - production

Prerequisites

- SNs and CCs are available in Egis middleware
- Lines and systems are suitable and ready for production

Information/Data flow

1. Middleware sends SN-CCs to L3 T&T system; L3 T&T passes SN-CCs to Production Line (L2-L1)
2. Line performs production and (a) submits aggregation to T&T(L3) and (b) reports to MES
3. T&T(L3) sends aggregation info to RU T&T(L4) (through the middleware)
4. MES(L3) sends production information and case-pallet relation to ERP(L4)



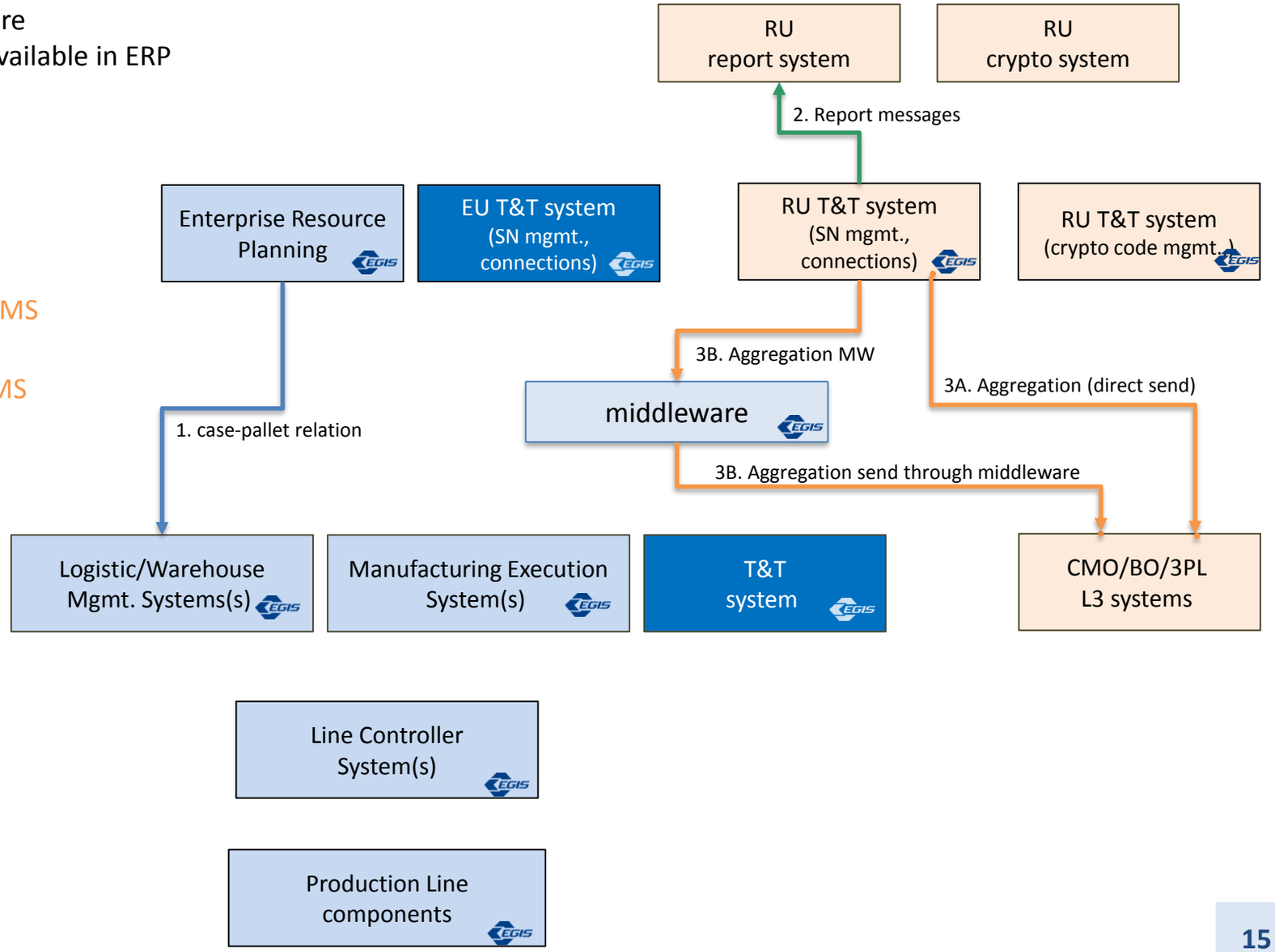
High level data flow #3 – distribution of information to WMS(L3) and RU report system (MDLP)

Prerequisites

- Aggregation information is available in Egis middleware
- Finished production data and case-pallet relation is available in ERP
- ERP-HQ distributes relevant information to ERP RUS

Information/Data flow

1. ERP HQ sends case-pallet relation to HQ WMS
2. RU T&T(L4) sends defined report messages to MDLP
3A. RU T&T(L4) sends aggregation information to 3PL WMS (directly)
3B. RU T&T(L4) sends production information to 3PL WMS (through the middleware)



Serialization information architecture – Geography

Budapest – Anytown, US: 7352 km

Anytown, US – Moscow: 7829 km

Budapest – Moscow: 1569 km

So in our case

A single Serial Number (SN) for RU compliance (including crypto tail) travels **33 220 kms** from generation to first reporting
(based on a very optimistic estimation)

Q: What can be wrong ?

The general effects of serialization on IT systems

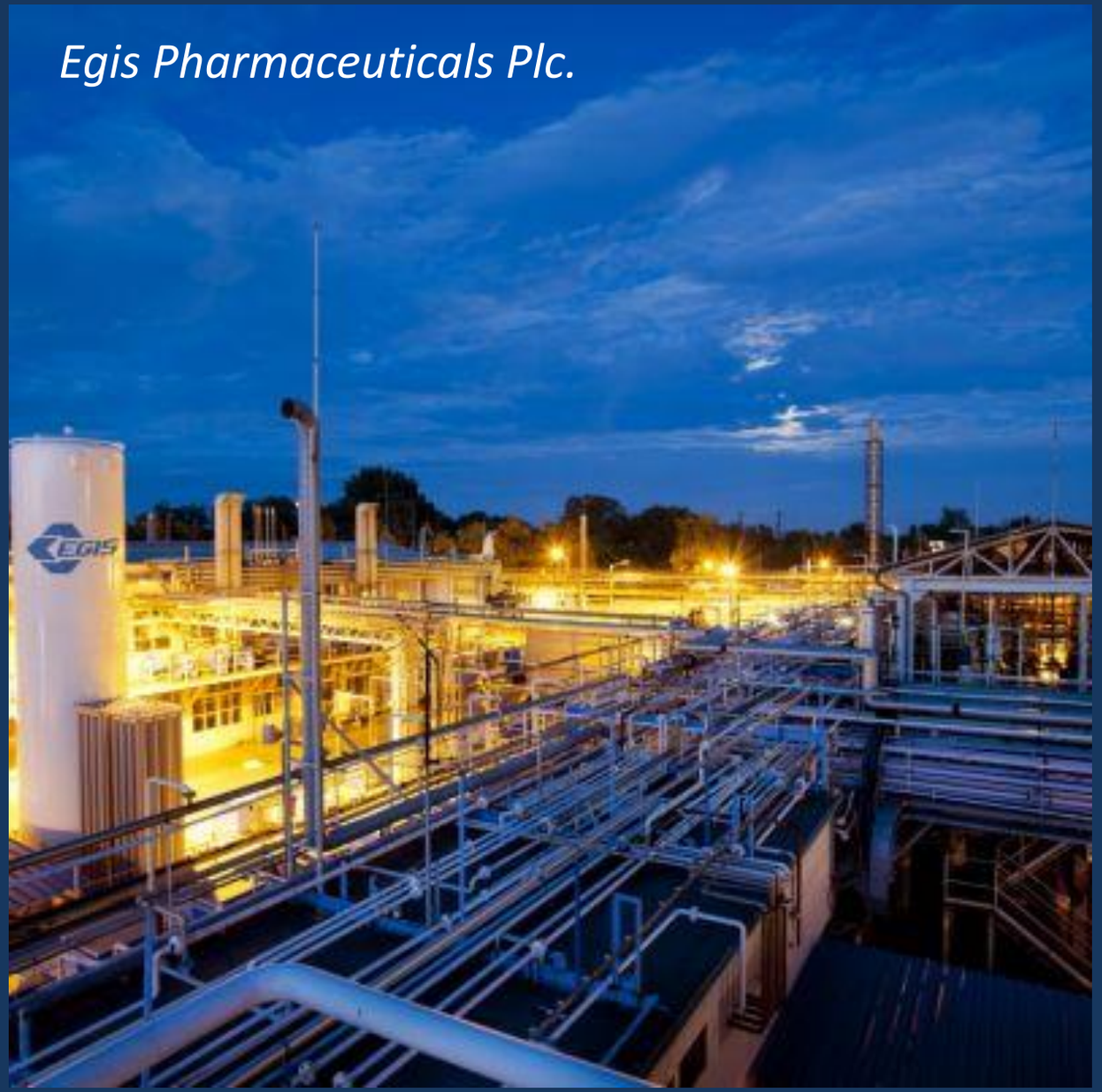
„Usual” IT activities

- Support new business functions/processes
- Develop/Modify existing IT applications
- Implement new IT solutions

Challenging IT tasks

- Connect and tune very different internal and external systems
- Complex system integration with many actors
- Use of new, „unknown” technologies

Thank you !



Foundation: 1913

Employees: ~4400

Three production sites in Hungary

Operation in 17 countries

Product portfolio: 647 products, 150 APIs

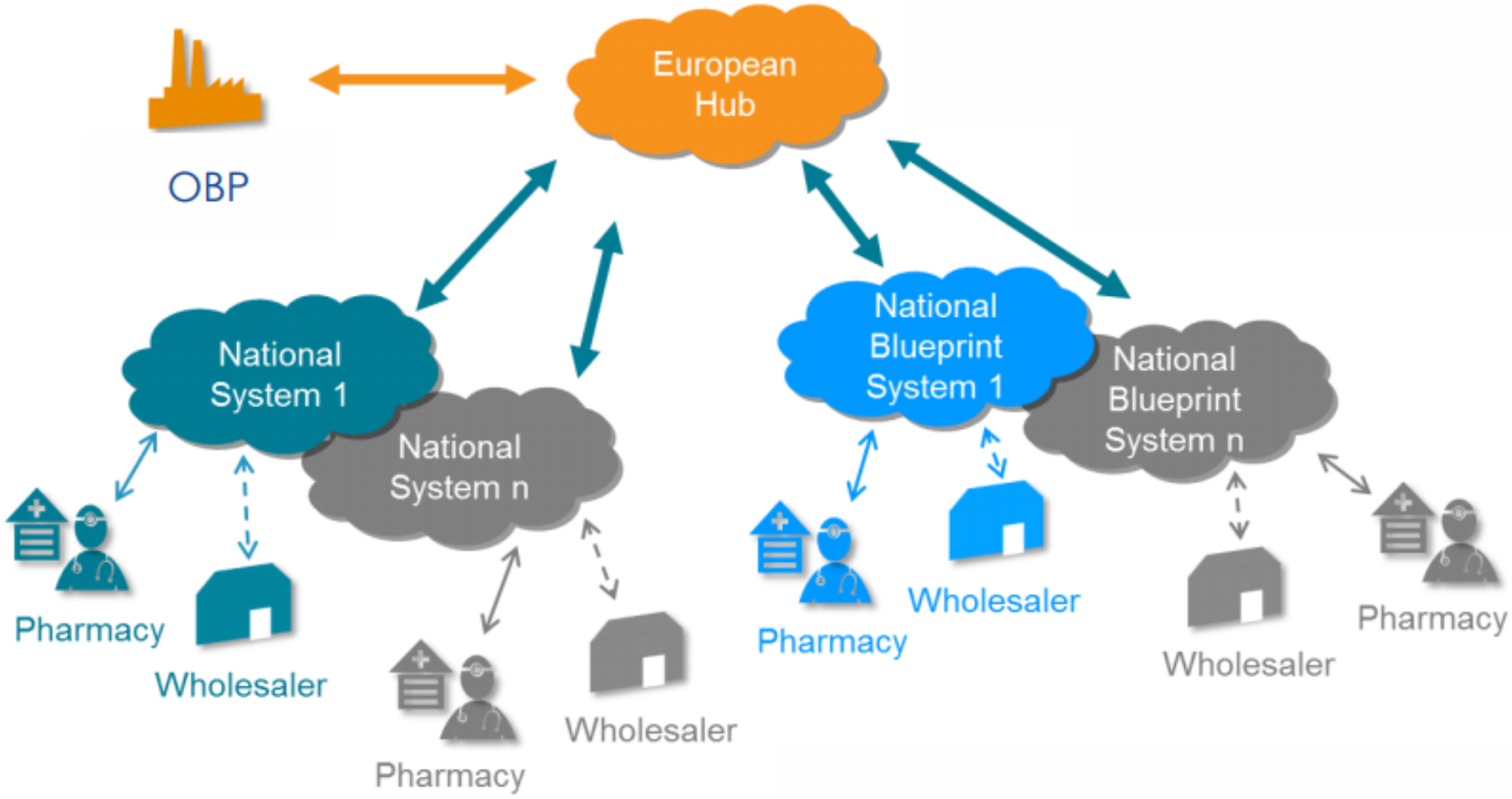
Net income: ~500 million EUR

Part of Servier Group

an independent group governed by a foundation:
Servier International Research Foundation

Backup: EU high level architecture

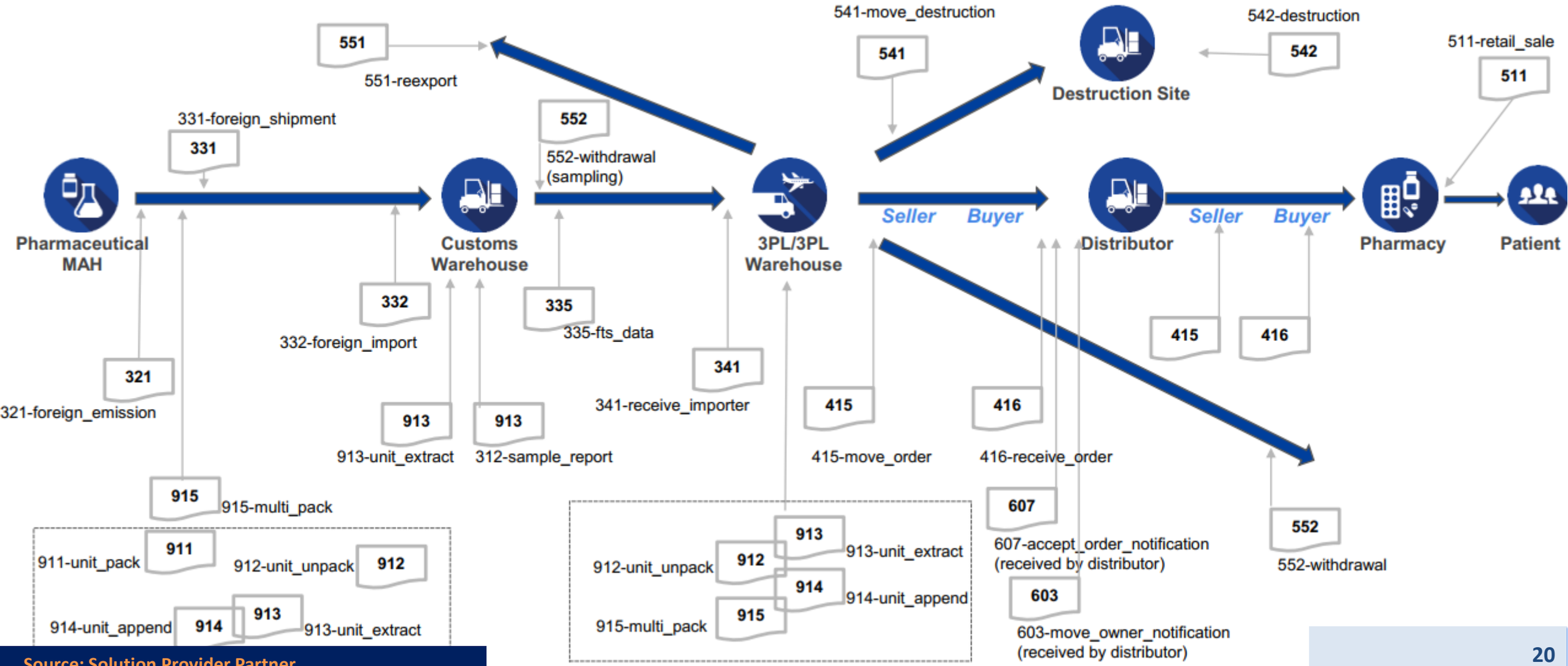
SYSTEM LANDSCAPE



Backup: RU high level architecture

Case: Multinational pharma manufacturing outside of Russia and importing aggregated product to Russia

Perspective
Pharma MAH and Importer

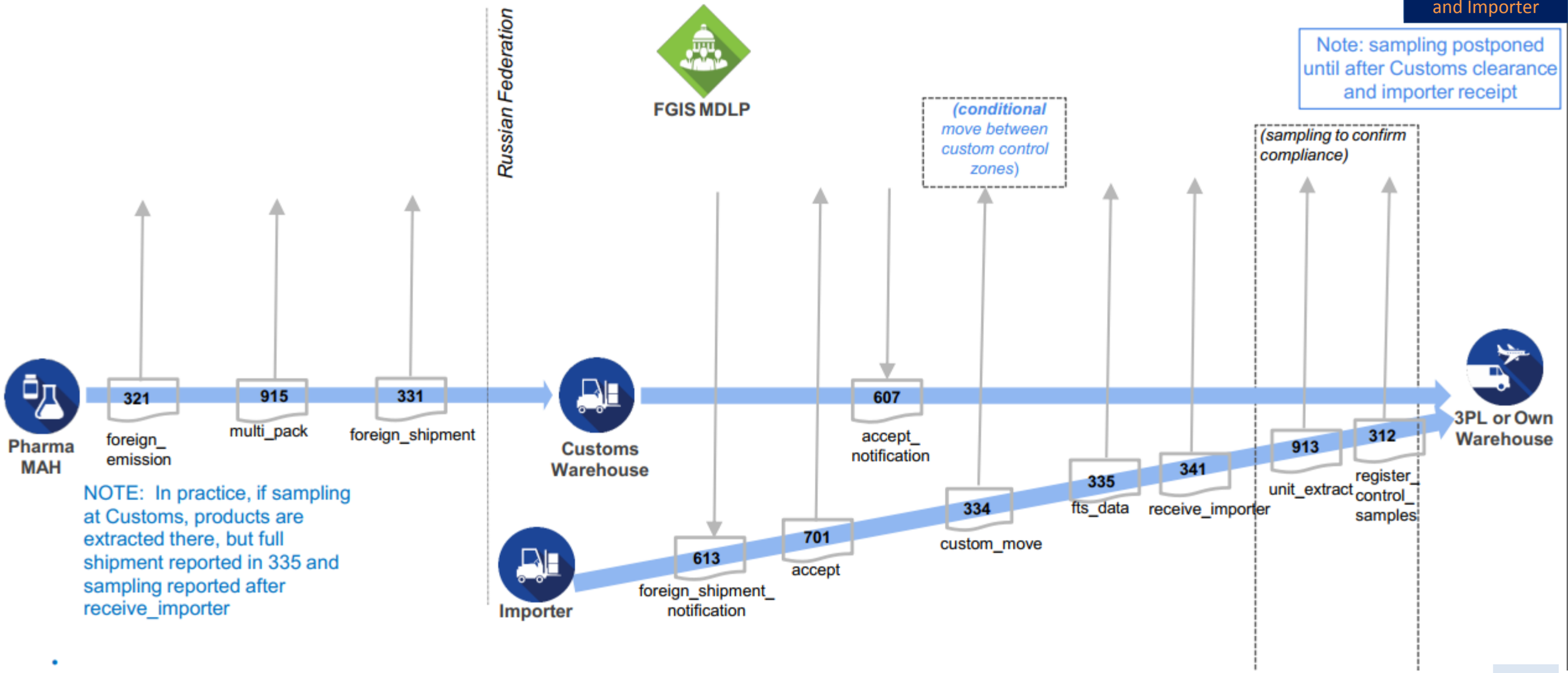


Source: Solution Provider Partner

Backup: RU high level architecture

Case: Production outside Russia, Import into 3PL warehouse in Russia (no direct order)

Perspective
Pharma MAH and Importer



Source: Solution Provider Partner

Backup: Russian serialization – case box aggregation

12,7 mm

35 small boxes
in a layer (bundle)
of a case box
(and we have more)

(00)000000000012345670