

„Serianet“

Easy and secure delivery of serialization data
from pharmaceutical producers to hospitals

in
meeting the requirements of the
„Falsified Medicines Directive“ (2011/62/EU)

- 1. Delivery of Aggregated Codes for Hospitals (WBDL), Principle and Challenges**

- 2. Serianet - Closing the Gap**
 - Advantages Using Serianet
 - Possible Business-Processes with Serianet
 - Technological Background
 - Regulatory Background

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The Principle Aggregated Codes*

- When supplying packages of a medicinal product to customers supply pharmacies have to verify the authenticity of any package by scanning the 2-D-data-matrix-code on the package and checking it against the national datapool („**verify**“). Subsequently the verified code has to be “**decommissioned**” from the data-base, once the package is supplied to the customer..
- For hospitals, however, wholesalers and manufacturers(with wholesaler-license) could facilitate the decommissioning operation:

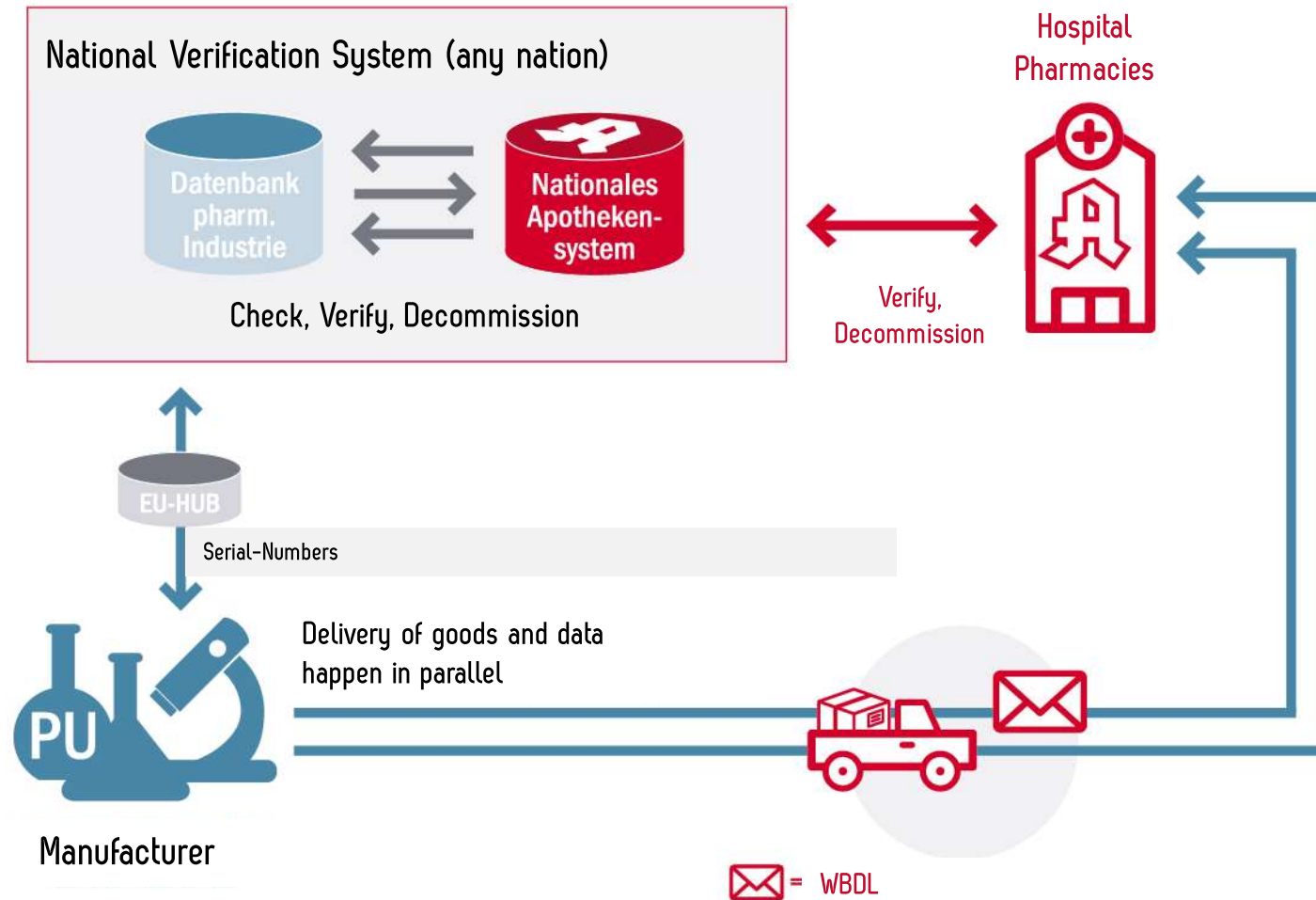
*“Wholesalers could acquire the information on the UIs in the hospital consignment and **make this information available** to the hospital, by secure means. The hospital would then use such information to perform the decommissioning (without having to physically scan the packs).”*

Source: [Safety features for medicinal products for human use, Q&A, Version 17, March 2020, Paragraph 6.6]

- **How** the information should be made available to the hospitals, however, has not been regulated.

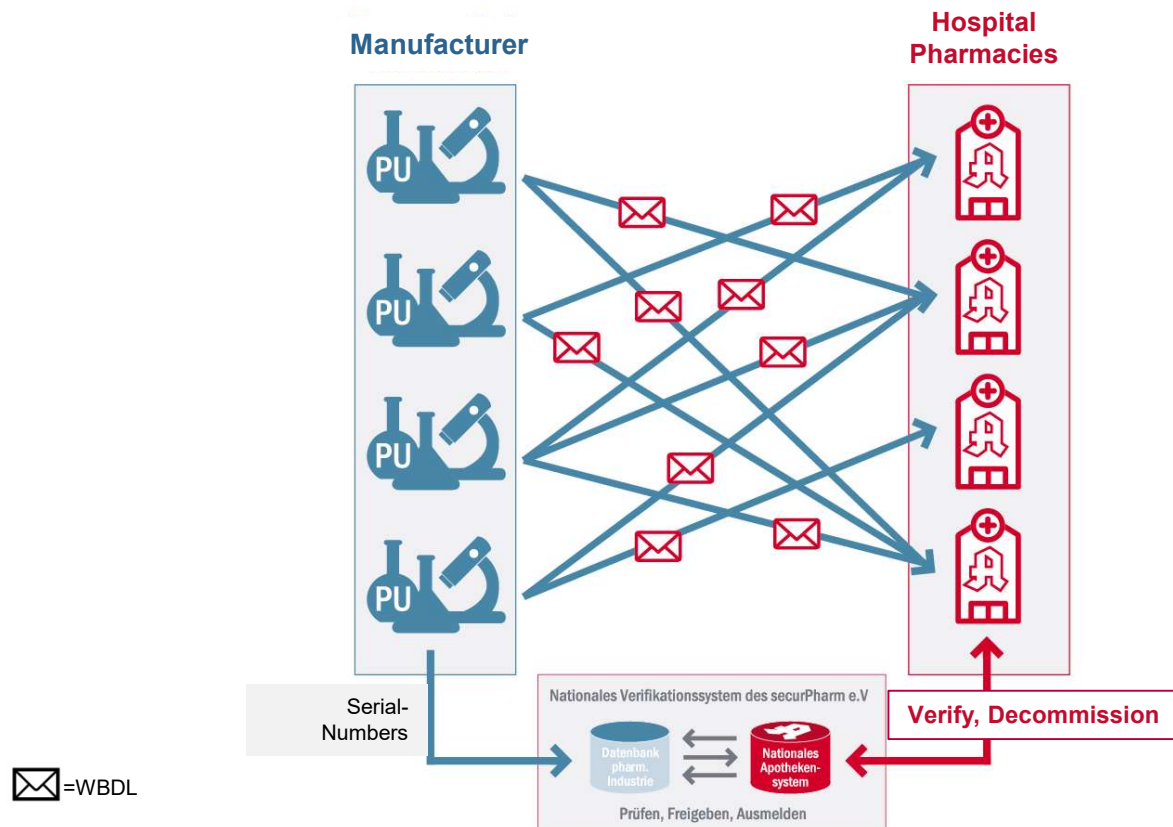
* „Delivery of Aggregated Codes“ => in German „Warenbegleitende Datenlieferung (WBDL)“ – WBDL is used henceforth

The Principle of Delivering Aggregated Codes



Technical and Commercial Challenges

The FMD requires data delivery „**by secure means**”. Thus, whoever wants to exchange serialization data has to establish additional secure and reliable data-connections to all his business contacts affected. On a 1:1-basis this would create massive administrative and commercial overload (for in Germany approx. 600 manufactures and 500 hospital pharmacies).



Technical and Commercial Challenges in Detail

- **All market-players would have to establish countless 1:1-connections to their partners**
 - Commercial **challenging**, administrative **almost unmanageable**
- Substantial **cost** for individual IT-installations on either side
- **New processes** (e.g., decommissioning-logistics at hospital pharmacies)
- Establishment of dedicated **data-logistics** in parallel with goods-logistics
- Handling of numerous **different data-formats** as the technical solutions have not been regulated => many players, many formats, many surprises
- **Unresolved IT-security-issues** (e.g., E-Mail-viruses)

Is there an effective and efficient solution for this dilemma? – Yes!



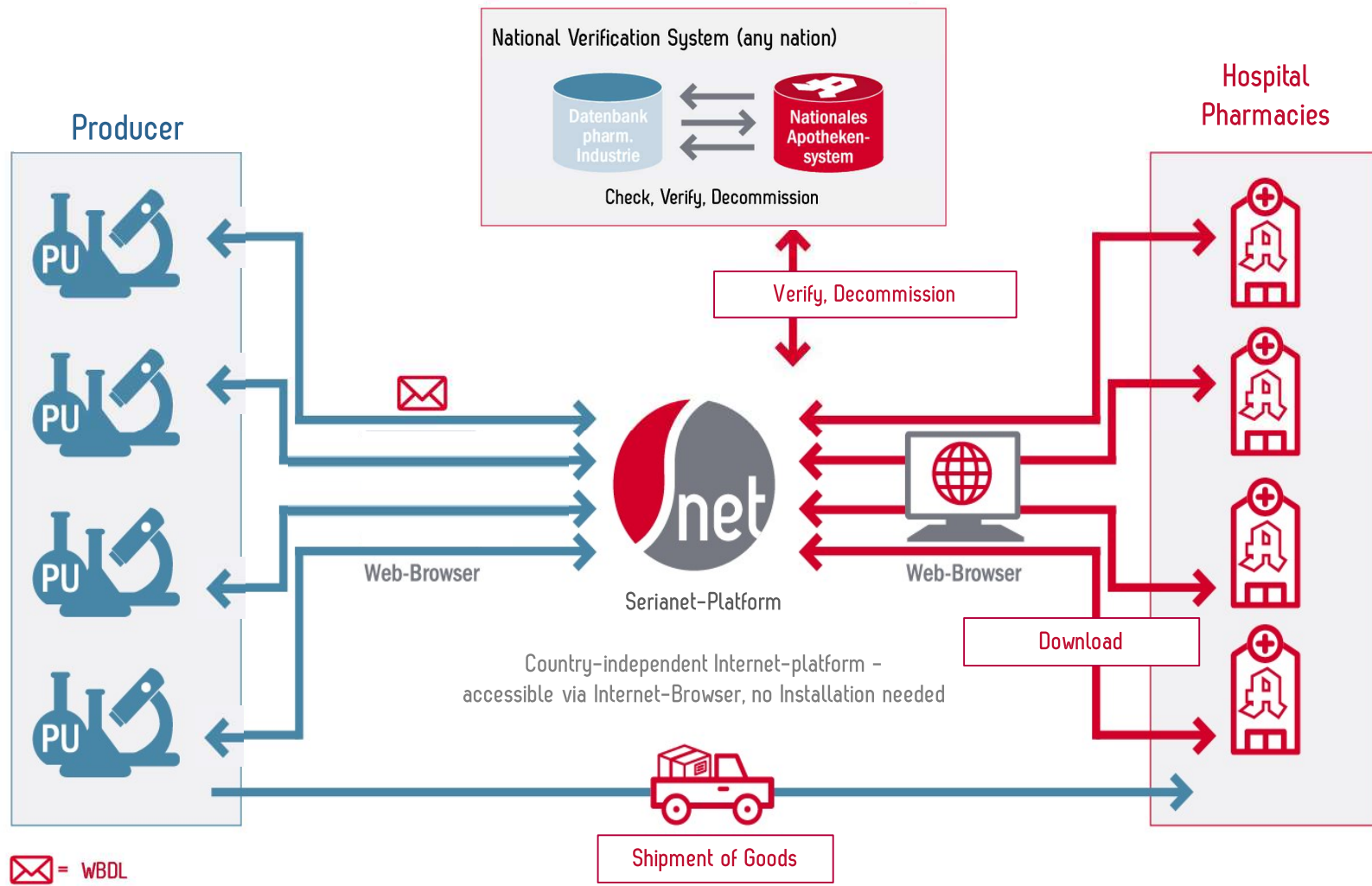
The simple, secure and cost-efficient
Gateway for the management of all
serial-number-related business-processes
between **pharma-manufactures** and their **business-partners**

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Platform for easy Data-Exchange between any Number of Business-Partners



Advantages Using Serianet

- Communication between **all** market-partners via **one common** technology, instead of establishing many individual ways for any partner
- Only administration of **own** credentials, no need to care for partners' credentials.
- Integrated **verification** and **decommissioning** of serial-numbers, no additional tool needed
- **Secure** transmission of data directly on the platform (https://-encryption), waiver of unsecure or cumbersome transport-media (ZIP-File, E-Mail, USB-Sticks)
- **Traceability** of any transactions at any time
- Open **interfaces** to interconnect with ERP-systems (XML, Webservices)
- **Globally** useable without any difference, prepared for **multilingualism**
- Support of any **standard-scanner** for data-capturing (handheld- or mass-scanners)

Possible Business-Processes with Serianet

- Delivery of **aggregated codes** (WBDL) to hospitals
- **Import** and **export** of any given data-format (e.g. DKG, EPCIS)
- **Code-management** for returns of serialized products from customers
- „**In-house**“-**transmission** of serial-numbers, e.g. between CMO, external analysis laboratories and MAH, to prevent manual and cumbersome data maintenance when capturing data from sample packages
- **Decommissioning** of serial-numbers for armed forces, government authorities or charitable institutions by the manufacturer
- Management of serial-numbers for **samples of test** and **reference items**
- Technical integration of upstream- and/or downstream-systems for **process-automation**

- Serianet is built upon the **Microsoft-Azure**-environment
- Data-store is **Microsoft SQL-Server**
- Specifications for **XML-** or **Webservice-Interfaces** are available
- Comprehensive options for the administration of **users, rights** and **roles** are at hand
- **Capturing** of data can be done by any given scanner (single mode, mass mode etc.)
- On capturing data they are instantly checked for **correctness**; incorrect data will not be imported
- **Digital certificates** for the national verification-systems are stored directly on the platform and are the background for the relevant credentials (wholesaler, manufacturer etc.)

- Serianet focusses on the transmission of data which have been released for the market. Thus, this process is not part of the pharmaceutical manufacturing process (GxP) and in consequence is **not subject for validation**.
- Generally, the issue of **delivering aggregated codes** (WBDL) has not been outlined in the FMD. The option for WBDL has been opened in the Q&A-document of the European Commission **“Safety features for medicinal products for human use”, chapter 6.6**. The chapter requires the transmission of encoded data “by secure means”, however, no binding technological specification has been laid out how the transmission has to take place.
- Serianet does **neither** handle **nor** host **personal health data**. Serial-numbers are only identifiers to verify the origin of a medicinal product. They do not bear any relation to personal health data. Thus, referring national regulations, like for instance the French **“Hébergeurs de Données de Santé (HDS)”**, do not apply to Serianet as no personal health data are processed.

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