



Connecting dots – Can we collaborate better on digital health?

Andrzej Rys

**Director health systems, medical products and innovation
DG SANTE, European Commission**

EU activities in digitising medicines

- Authorisation
 - *Clinical trials*
 - *EMA Medicines portal*
- Monitoring
 - *Falsified medicines*
 - *Online pharmacies*
 - *Pharmacovigilance*
 - *Patient registries*
- Patient information
 - *Electronic leaflet*
 - *Electronic prescription*
 - *Self reporting*

EU Clinical Trials Portal and Database

- The Clinical Trial Regulation (EU) No 536/2014 aims at:
 - *creating an environment that is favourable for conducting CT, with the highest standards of patient safety*
 - *Fostering innovation through simplification of the CT application process, and to increase transparency and availability of information on CT and their results.*

EU Clinical Trials Portal and Database

- This will be achieved by means of an EU CT portal and database which is being developed by EMA in collaboration with the Commission and EU Member States
 - ✓ *A single set of documents via a single entry point*
 - ✓ *Harmonised procedure for assessment by MS*
 - ✓ *Facilitates communication between sponsor and MS*
 - ✓ *Facilitates access to information by public*
- This IT tool is essential for the functioning of the legislation: the application date of the CT Regulation is linked to the full functionality of the IT tool.

Article 57 Database

- Legal basis: Art. 57 of Regulation 726/2004
- The database shall include SmPC, package leaflet, labelling information and where appropriate references to data on clinical trials.
- To be developed in stages: priority to centrally authorised and MRP/DCP products, subsequently extended to cover any medicinal product placed on the EU market.

Article 57 Database

- Implementation of Article 57(2) requirements is a core project within EMA's Pharmacovigilance Programme
- Since October 2015 national competent authorities have continuous access to key Article 57 data for medicinal products with a valid marketing authorisation in the EEA.
- Since February 2016 MA holders no longer need to notify EMA or national authorities of changes in Qualified Person for Pharmacovigilance (QPPV) and the location of the Pharmacovigilance System Master File (PSMF) via variations. Instead the information submitted directly in the Article 57 database.



Electronic Package Leaflet

2015 NIVEL Study on the Package Leaflets and SmPC (commissioned by DG SANTE): "Electronic formats bring new opportunities for optimising patient information leaflets"

Explore possibilities to deploy new technologies for benefits of patients BUT

Need to **respect the existing legal framework**

⇒ Any potential future "electronic leaflet" would have to be complementary to the paper leaflet

The Commission Report on the Package Leaflet and SmPC (including the ePL) to be adopted in the autumn 2016

Safety features I

- The UI is carried by a 2D barcode (Data Matrix ECC200);
- Minimum printing quality;
- Human-readable format.
- For prescription medicines
- To be applicable by Feb 2019

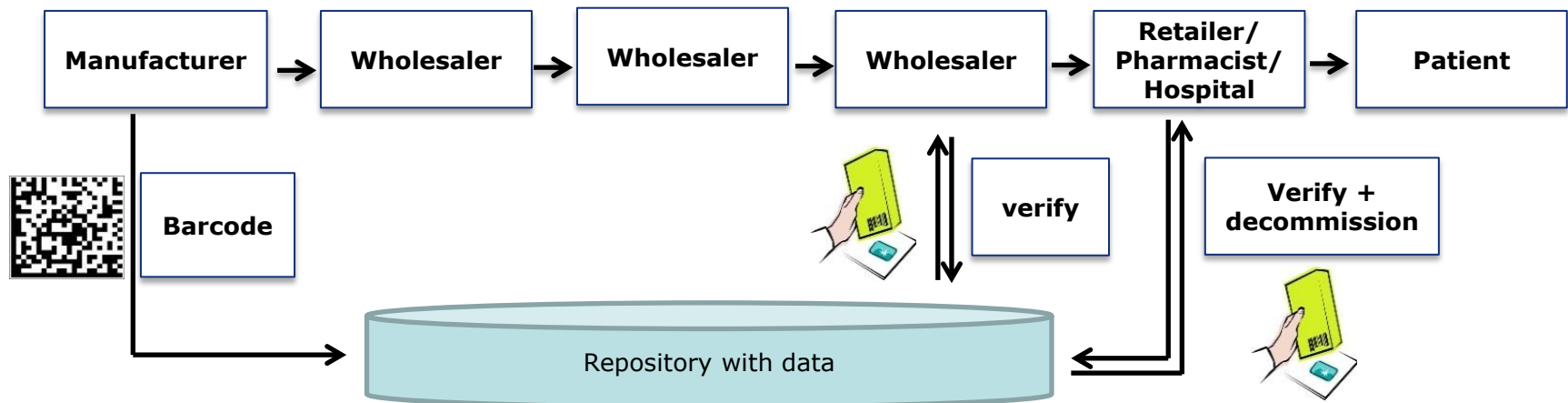
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Illustrative example – not binding

Verification of the safety features (II)

End-to-end verification system + risk based verifications





Common EU logo to identify legal operating on-line retailer

Commission Implementing Regulation (EU) 699/2014

on the design of the common logo to identify persons offering medicinal products for sale at a distance to the public and the technical, electronic and cryptographic requirements for verification of its authenticity



Click to verify
if this website
is operating
legally

General principles:

- *The logo will help consumers to identify the legally operating on-line retailer of medicinal products;*
- *The logo shall be displayed on every web page of the legally operating site offering medicinal products;*
- *One of the logo elements is the flag of the Member State where the online retailer is established;*
- *The logo is hyperlinked to the entry of the online retailer on the national list of legally operating online retailers;*
- *Hyperlink should be secured and the website with the list of national retailers accessible in a way so that public can be assured that it is a trusted site (e.g. on the .gov domains)*

Registries

General principle:

Serving needs for real world clinical evidence

PARENT joint action on registries (2012-2015)

- Methodological guidelines on registries (incl. interoperability and use of data in a cross-border setting)
- Online tool: "Registry of registries"

**Art. 14 on eHealth
Directive 2011/24/EU**

EUnetHTA 3 Joint Action (2016-2020)

- Activity on life cycle approach to improve evidence generation
- Testing of the PARENT registries guidelines through pilots

**Art. 15 on HTA
Directive 2011/24/EU**

The eHealth Digital Service Infrastructure

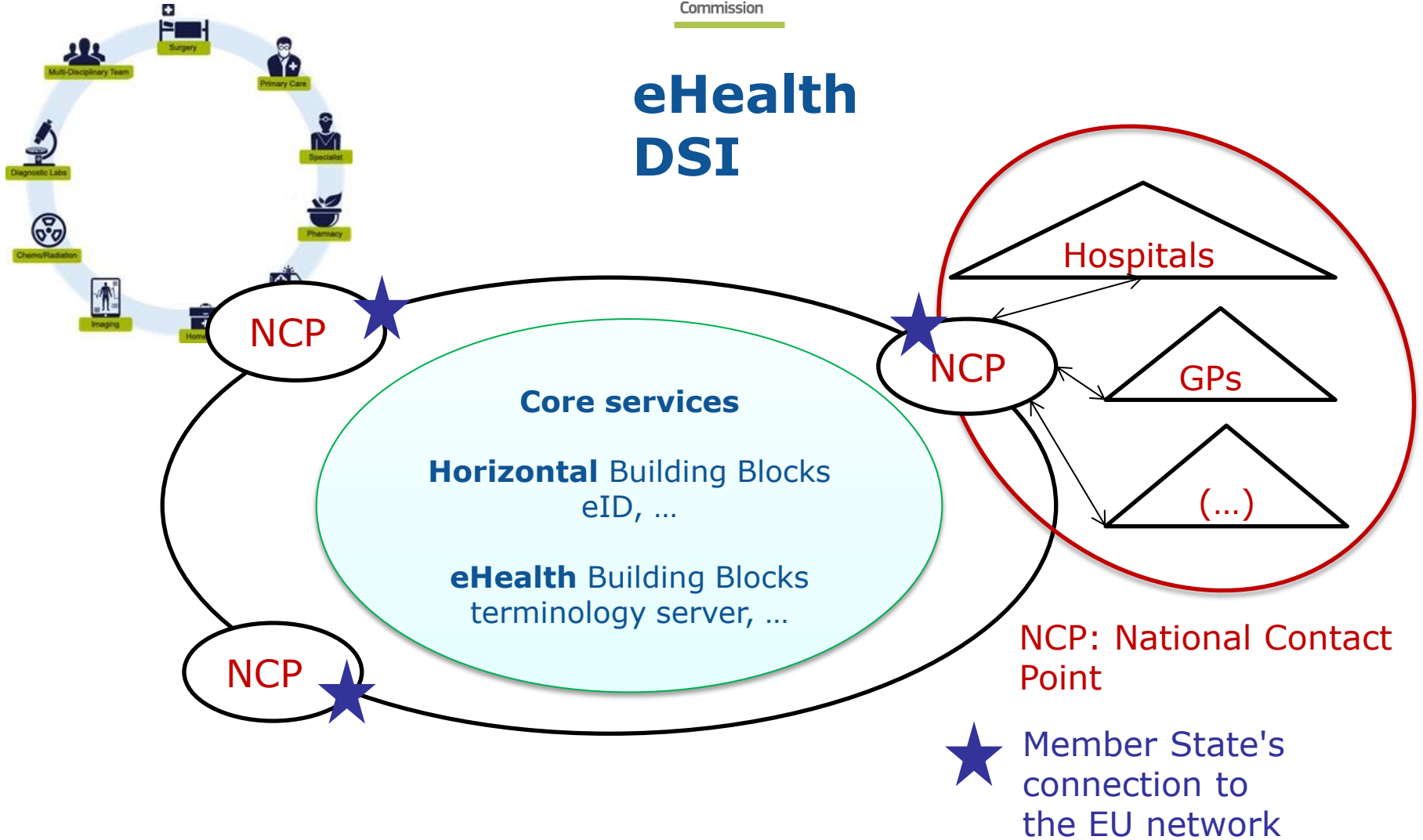
- Exchange of ePrescription and Patient Summary
- Funded under the Connecting Europe Facilities
- Call closed in March 2016, results published end of August
- 20 Member States applied,
 - *16 could be funded*





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NCP: National Contact Point

★ Member State's connection to the EU network



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So, can we connect dots??