Up-scaling the global univocal identification of medicines

Best practise / knowledge sharing workshop
Procedural Change with IDMP
WP 04
INFARMED - National Authority of Medicines and Health Products, I.P.
2024-04-02
Rui Vilar

This project has received funding from the European Union's
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INFARMED

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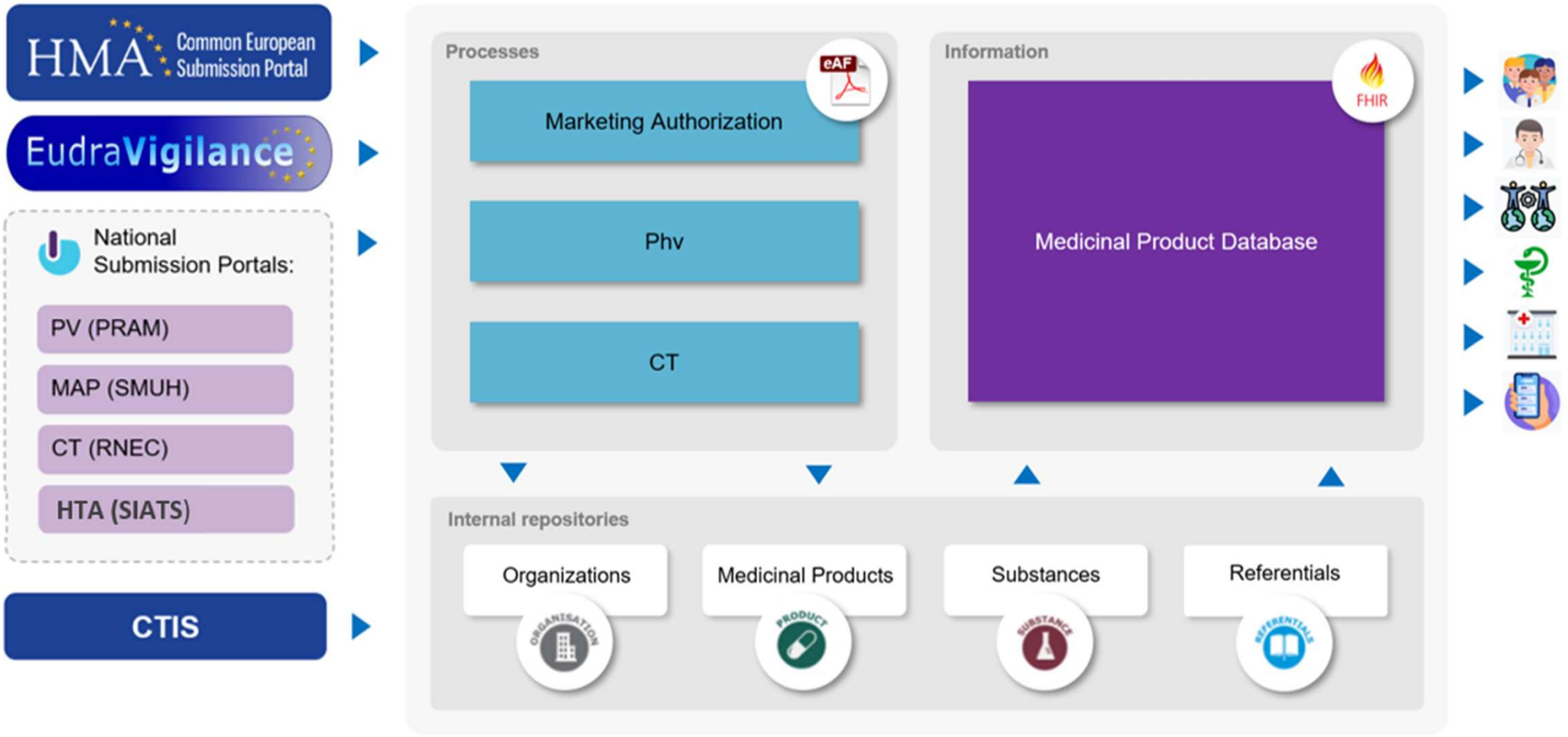
Future system



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Dataflow

Cross-border e-prescription system

In all these dataflows, there is an aim to move to **ISO IDMP** structure to facilitate the data exchange.

Product Masterdata System (PMS)

Work ongoing at EMA to make PMS the place for all published validated product data in EU in IDMP structure.

The application is assessed and the product data for all products centrally authorised by the EC is validated by EMA before upload.

Product data for nationally authorised products are provided by industry directly to PMS and are checked/validated by EMA (e.g. compliance to the current SmPC) but is not checked by the national authorities authorising these products.*

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Data provided to the "Article 57-database" for all authorised products in accordance with EC 726/2004 art.57(2) and then onwards to the PMS database (in IDMP format).

CP

SPMS EPE
Serviços Partilhados do Ministério da Saúde

National eHealth agency

Wholesalers

Hospitals

Marketing Authorisation Applications (eAF) within **centralised procedures**.

(eAF)

Product data on all products authorised for marketing in Portugal is checked/validated by PT INFARMED.

Infarmed
Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.

National Database: GiMED

Data on medical products including package info, prince info, reimbursement.

Pharmaceutical companies

(National portal (SMUH)+CESP)

NAC, MPR, DCP

Pharmacies

Healthcare

Marketing Authorisation Applications (SMUH + CESP) within **national, decentralised and mutual recognition procedures** (for national authorisation).

*) For PMS, there are ongoing discussions on if and how the data for products authorised within national procedures could be validated by the NCAs in the future, but no decisions are taken yet. Until then, the national product databases are the only place to find published validated product data for nationally authorised products.

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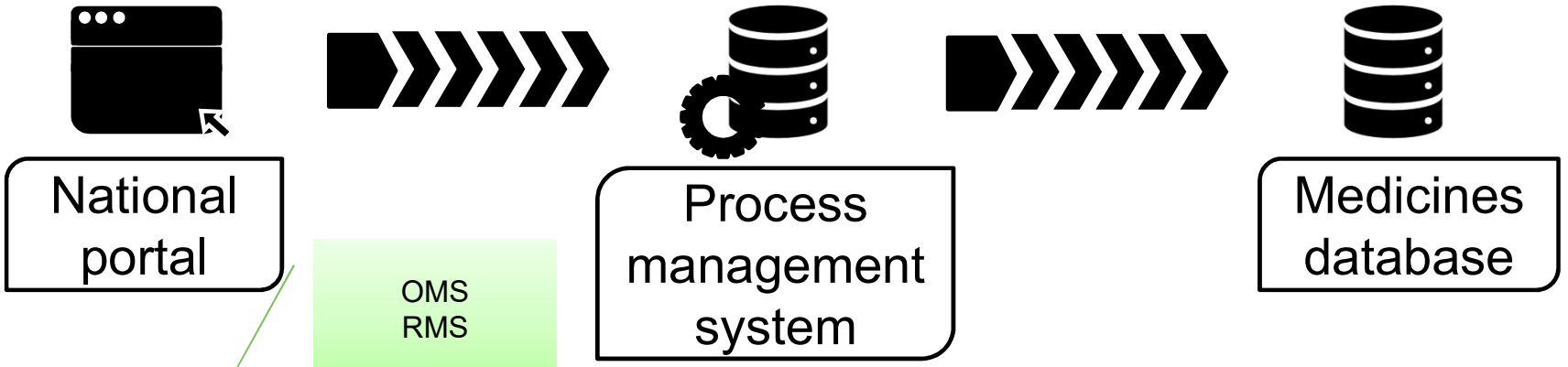
Working data – New marketing authorisations



OMS
RMS

- **Manufacturers**
- **Active substances and excipients**
- Packages
- Pharmaceutical form
- Product name
- Shelf life
- Special precautions for storage
- …

SMS
RMS

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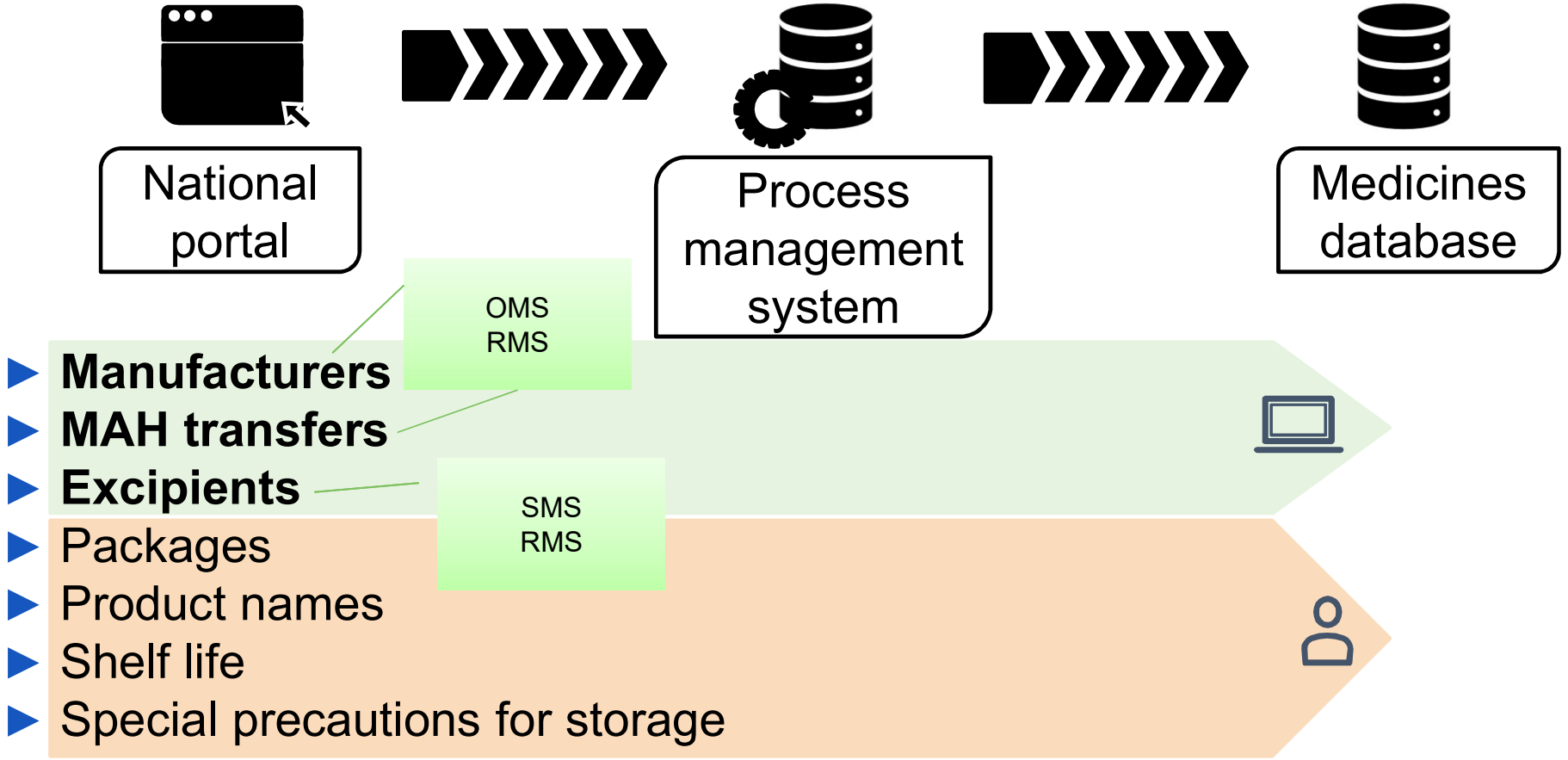
Working data - Variations



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Working data - Organisations

Entity	Address	Version	Additional Info.	Start Date	End Date
Bayer Bitterfeld GmbH (Fab. Bitterfeld - Wolfen)	Ortsteil Greppin, Salegaster Chaussee 1 - 06803 - Bitterfeld - Wolfen - Bitterfeld - Wolfen - DE	100		28-07-2010	
Bayer Bitterfeld GmbH (Fab. Greppin)	Salegaster Chausse, 1 - D-06803 - Greppin - Greppin - DE	100		14-07-1995	28-07-2010

- Historical data on organisations – Start Date and End Date
- National submission portal: currently approved
- Variations: automatic update of medicines database

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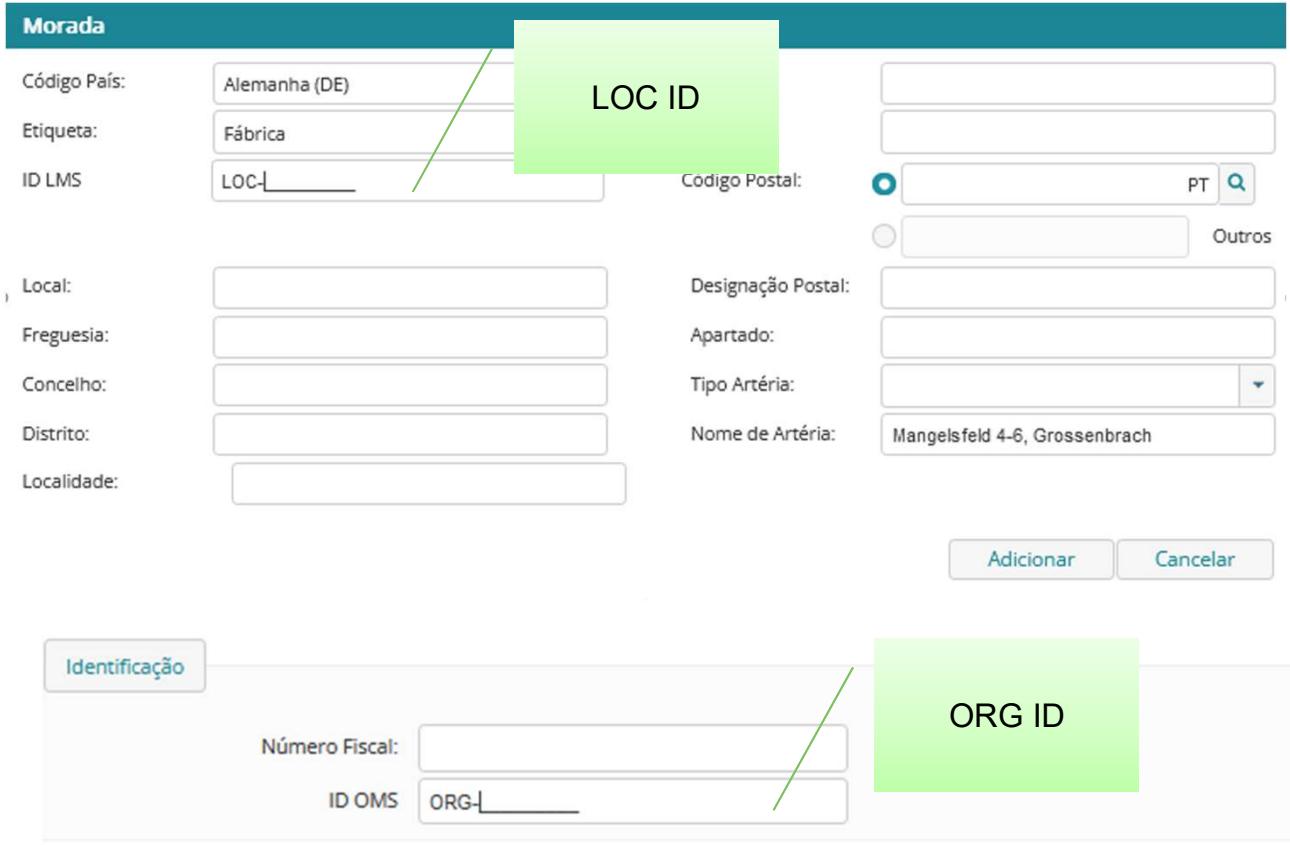
Working data - Organisations

National organisations database



Organisations SOP

- New/changes also validated against OMS
- ORG ID and LOC ID in database
- Data quality

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Working data - Substances

Substance	Function	Operator	Quant. 1
Starch maize	Excipient		10
Microcrystalline cellulose	Excipient		10

- National submission portal: currently approved formula
- Variations: automatic update of medicines database

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Working data - Substances

National substances database

Substances SOP

- New/changes
- SMS ID
- Data quality

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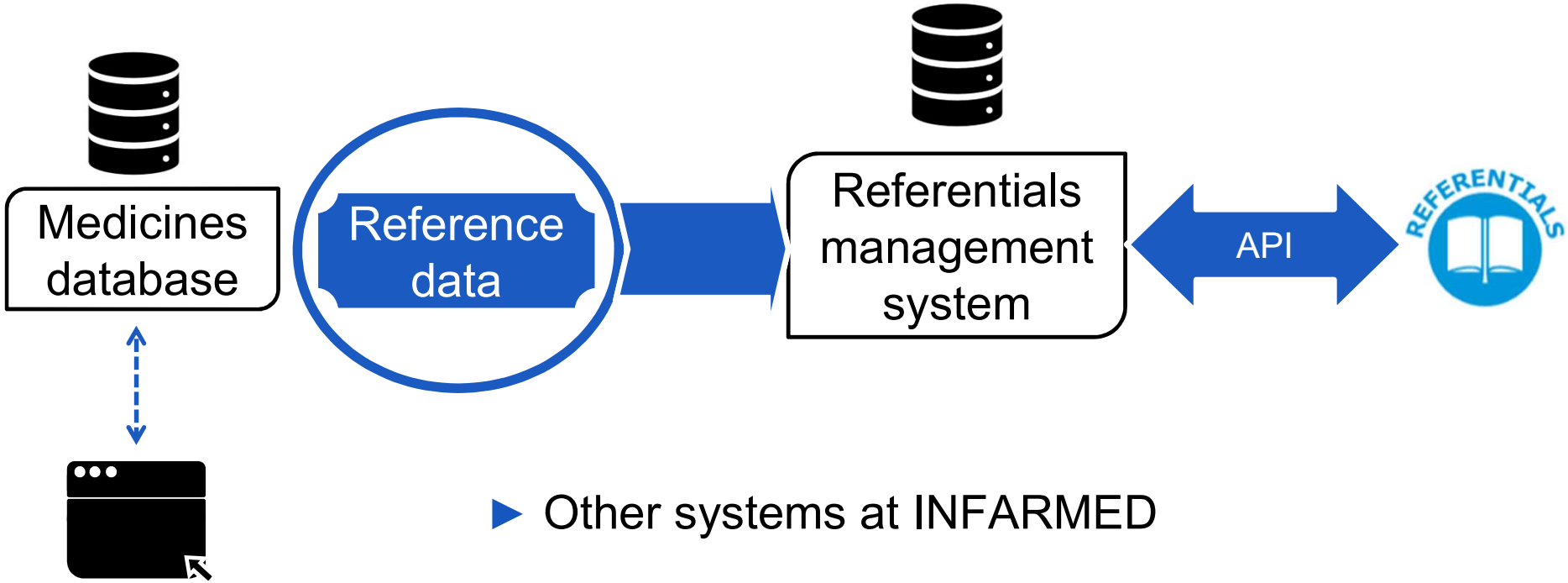
Working data - Referentials

- New system for referentials



- Other systems at INFARMED

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Working data - referentials

- Ingredient Role list

Medicines database

Active
Excipient
Flavor
Preservative
Propellant
Solvent
Coating
Reagent
Printing ink
…

Active
Excipient
Solvent / Diluent
Adjuvant
Starting material for excipient
Raw materials used in the manufacture of the product
Starting material for active substance
Overage

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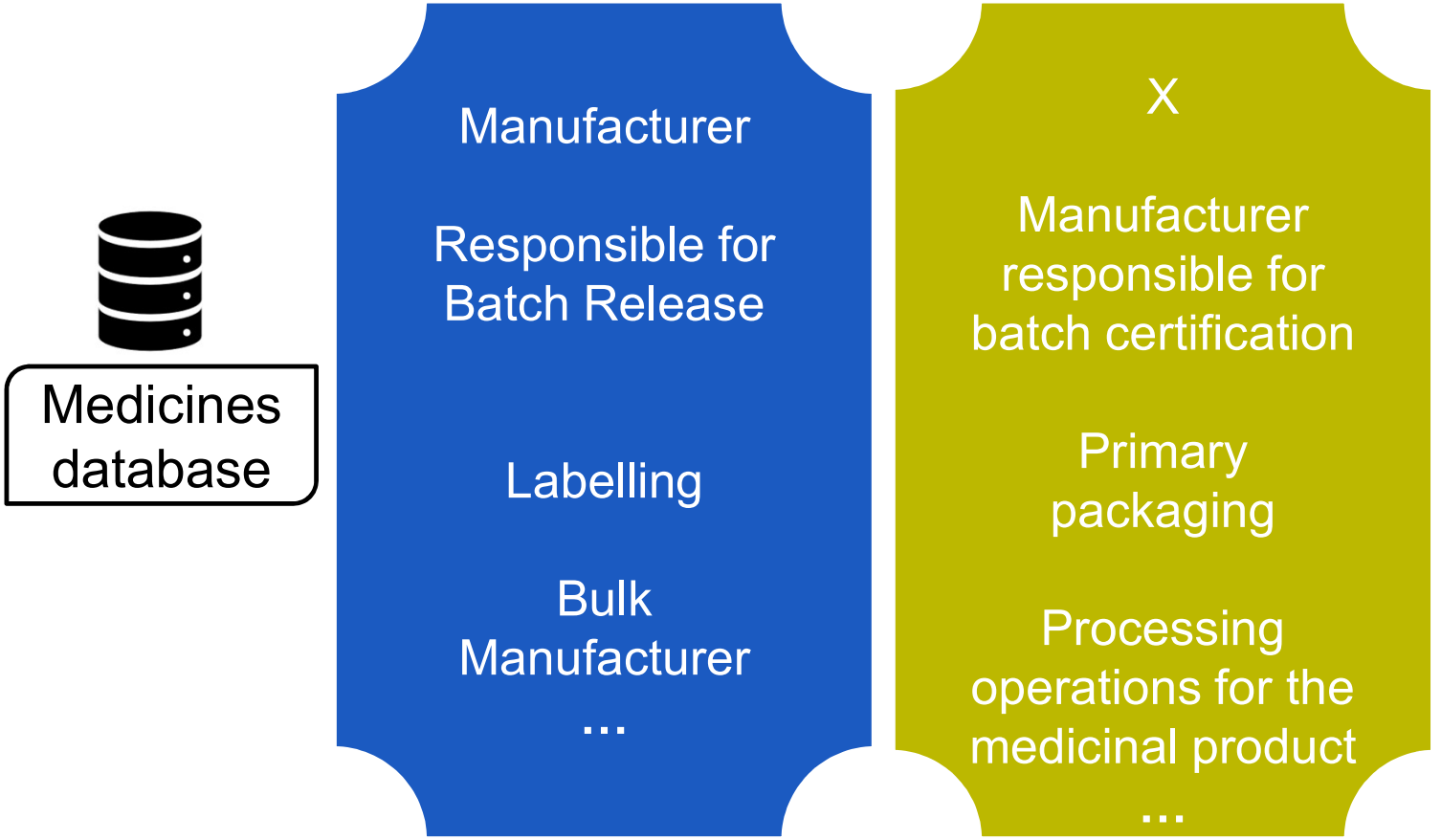
Working data - referentials

- Manufacturing Activity list



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Working data - referentials

- Legal Status for the Supply list

Medicines database

Medicines database	Referentials
Medicinal product subject to restricted medical prescription – a), b), c)	Medicinal product subject to restricted medical prescription
Medicinal product not subject to medical prescription - pharmacy only	X
X	Medicinal product on medical prescription renewable delivery / non-renewable delivery / renewable or non-renewable delivery / exempt for some presentations

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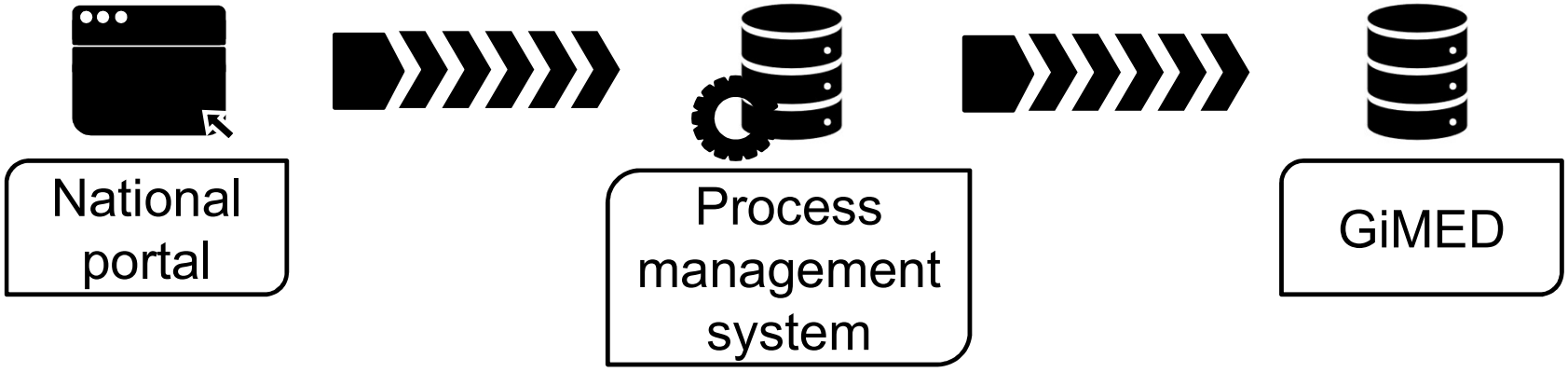
Working data - PMS



- Packages
- Product names
- Shelf life
- Special precautions for storage

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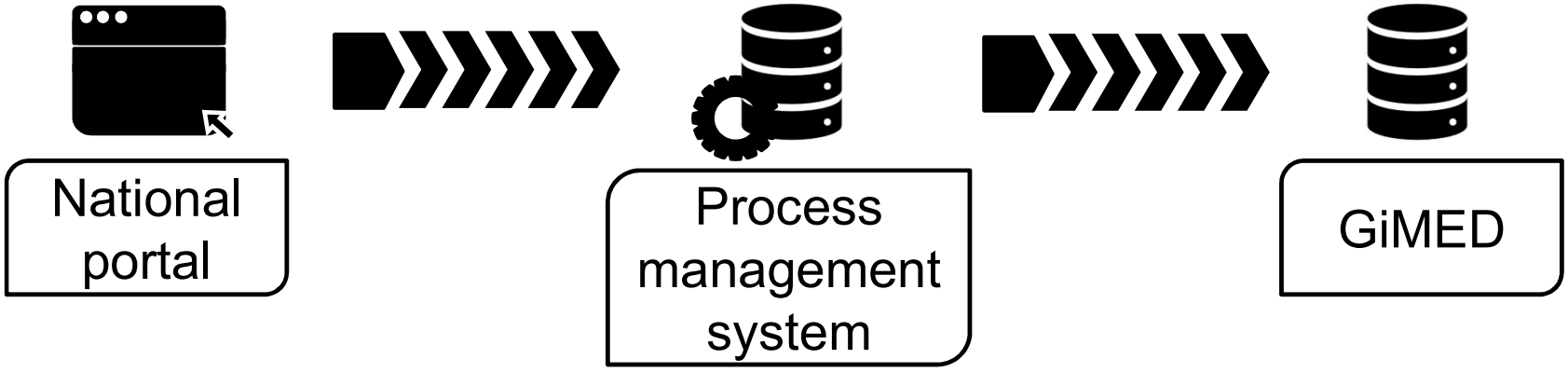
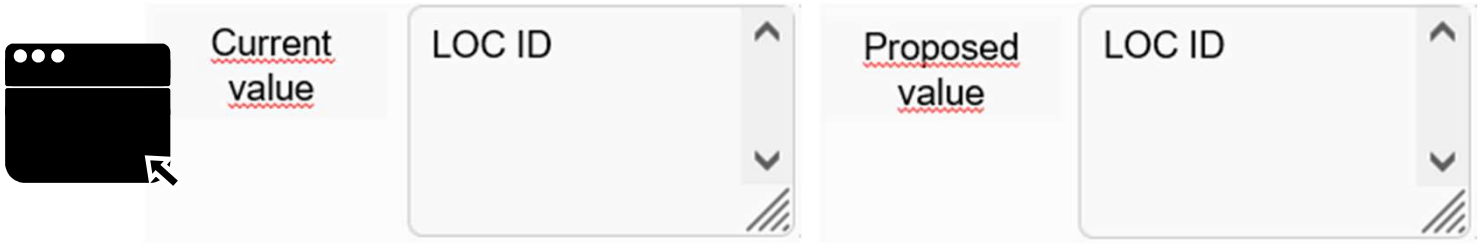
Working data - PMS



- MAH transfers

- Approx. 2900 between 2019-2023



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Procedural Change with IDMP

- As IDMP implementation spreads more in INFARMED, different departments will have to include IDMP in their procedures
- National specificity: submission portals
- Where in the flow is data being entered manually – IDMP an opportunity to automate
- Where and how to introduce right now procedural changes to start progressing as much as possible in SPOR and IDMP without having to wait for major changes in the systems or databases
- Substances, organisations and some RMS lists seem to be the best candidates
- Cultural change

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UNICOM

Up-scaling the global univocal identification of medicines

Thank you for your attention.

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