



# Medicines Master Data for Smarter Regulation

Annual Data Forum 2025

Aimad Torqui

Medicines Evaluation Board

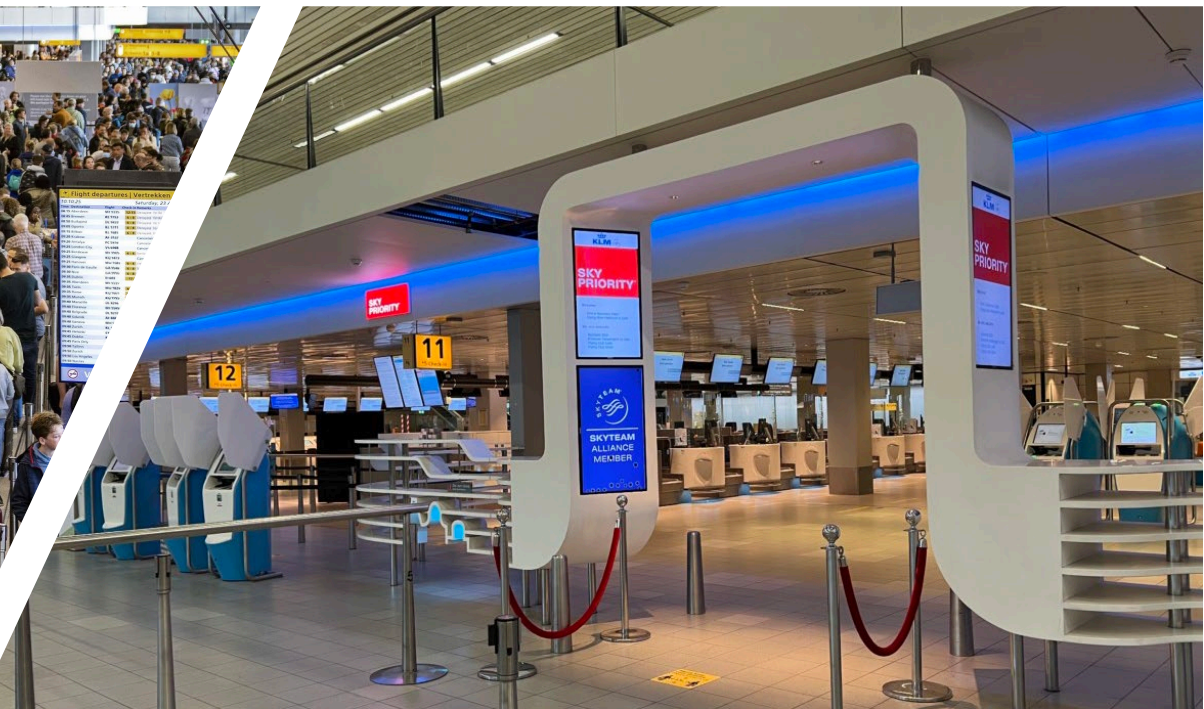


Maximise the generation, interoperability, use and exchange of data to support EU decision making in the context of key EU legislative initiatives ...

- EMANS 2028 leveraging data goal: *Seizing opportunities in a changing medicines landscape*

# A passport for every medicine: recognised everywhere, understood everywhere





With product master data, every medicine travels the regulatory and health system faster and with fewer errors ...

# Use cases and benefits: regulatory perspective

- Feed and improve regulatory business processes, supporting decision-making:
  - Integrate data flows and automate processes
  - Support regulatory obligations such as shortages and pharmacovigilance
- Support management of the lifecycle of medicinal products, from development to commercialisation, in one system to facilitate regulatory, safety, and clinical trial management activities



# Strategic recommendations for PMS implementation and data management

- PMS as the source of product master data for all products authorised in the EU as well as for products in development
- Transitional step enabling a single submission of product master data
- The need for an approach to data validation (alternatively referred to as data qualification) - one size will not fit all in terms of nationally authorized products

## Strategic goal:

*“Achieve a unique and shared repository of trusted product master data for all human medicinal products in the EU supporting the product data lifecycle (development and authorised) via a unified entry point for initial and subsequent product data submissions.”*

# Product data qualification: a feasibility study to move from concept to reality

## Challenge

- Aprox. 300k MRP/DCP/national products
- Consistent data in PMS and national databases

## The study aims

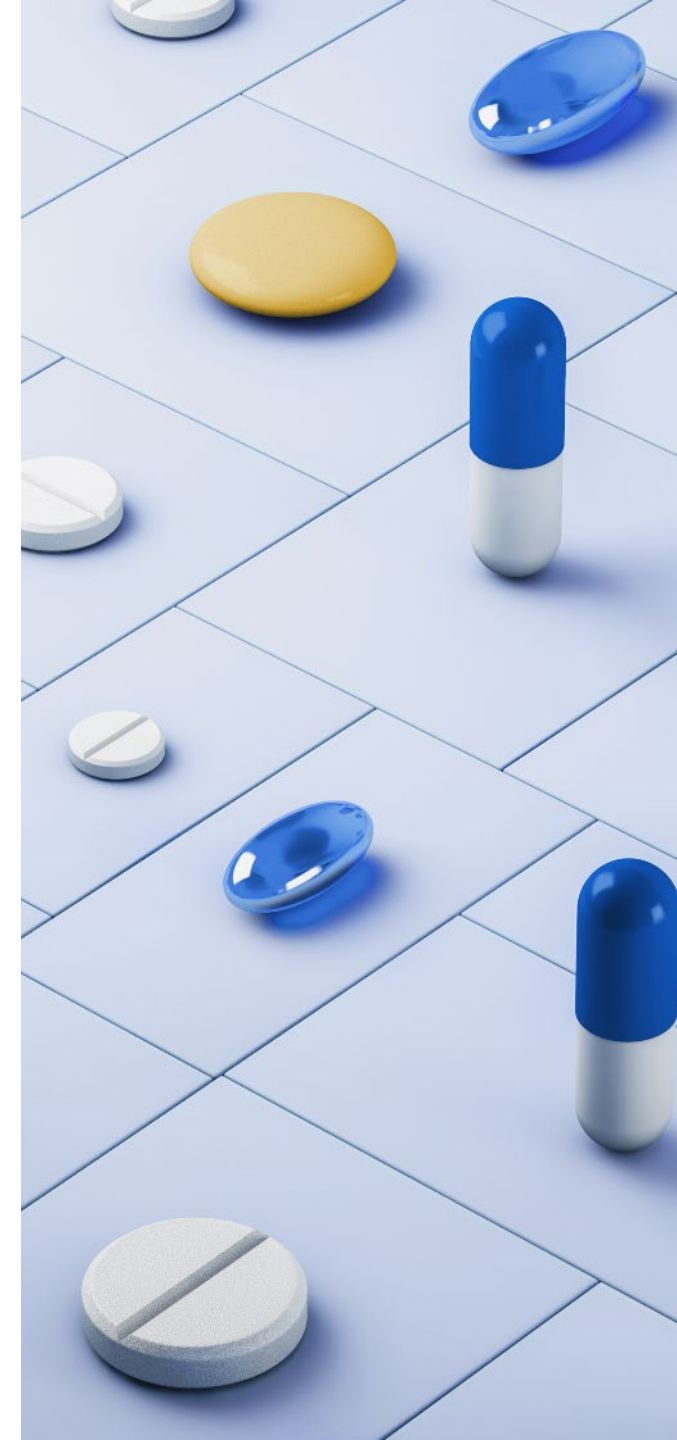
- to identify key challenges including an estimate of the required EMRN and Industry effort to qualify (and subsequently update) PMS data
- to propose actionable recommendations towards EU-wide implementation of the qualification process

## Planning

- Q1 feasibility study analyses report

# Use cases and benefits: health system perspective

- Public source of medicinal products providing clearer information to patients, supporting Medicines web Portal
- Enables safer, smoother, and more consistent digital prescribing and dispensing across the EU
- Supporting European Health Data Space (EHDS) regulation and its objectives



# EHDS in a nutshell

## **Primary use** = *delivery of healthcare*

- Improving patients' access to their health data;
- Ensuring seamless exchanges for continuity of healthcare.

## **Secondary use** = *research and public interest purposes*

- Making data available for research, innovation, policy-making and regulatory activities in a safe and secure way

## **Electronic health record (EHR) systems**

- Creating a single market for electronic health records systems, supporting both primary and secondary use

## What are we talking about?

### Primary use

- Patient summary
- e-Prescription
- Dispensation
- Medical images
- Medical test results
- Discharge reports

### Secondary use

- Exchange of data

### EHR systems

- compliance & interoperability

# D

## Deliver better care

For patients and healthcare delivery:

- Seamless access to personal health data
- Cross-border care and e-prescriptions
- Accurate, up-to-date medicine information

# A

## Accelerate innovation

For research, innovation & public interest

- High-quality, comparable EU-wide data
- Stronger evidence for research and policy
- Supporting cross-border research and public health comparisons

# T

## Trust in regulatory

For regulators and medicines oversight:

- Feed and improve regulatory business processes
- Fewer discrepancies between submissions and labels
- Correct propagation of safety alerts

# A

## Align health systems

For health systems infrastructure:

- Interoperable EHR market across the EU
- Reliable, secure cross-border data exchange
- Compliance with EU Interoperable Act

For decades we regulated medicines.

Now we must regulate the data behind them: as product master is no longer a filing cabinet, but a living system that shapes public confidence ...

# Thank you

Aimad Torqui

[a.torqui@cbg-meb.nl](mailto:a.torqui@cbg-meb.nl)

