Building a unified Network data strategy for operational excellence

28 November 2024

Session 4 of the EU Big Data Stakeholder Forum 2024: Unlocking the value of data with the EMRN data strategy

Presented by: Georg Neuwirther, Head of IT - Austrian Medicines and Medical Devices Agency

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The content reflects the personal view of the presenter.

Content

- Introduction, Motivation
- Data Value Chain
- Drivers and Enablers
- Example in the Austrian Medicines and Medical Devices Agency
- Next steps and hand-over-to speakers

Introduction

Source: ADragan/Shutterstock.com

After this session, we might have a better overview of the value of medicinal product data and how we will maintain this asset more efficiently.

Hypotheses:

Organisational and technical opportunities are available for realising this value of Medicinal Products Data while reducing data management effort

Where are we coming from?

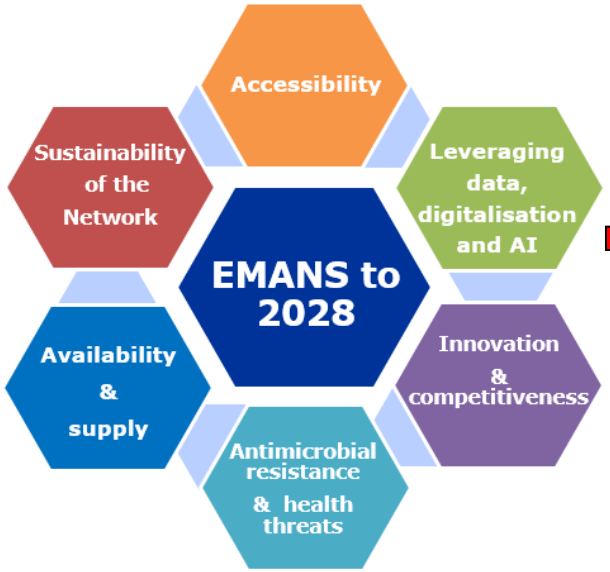
… from paper-oriented submissions of medicinal product data

… heading towards to a data-driven eco-system

See also: EMANS to 2028: Leverage **data**, digitalisation and AI - DRAFT

Source: EMANS 2028

Draft EMANS to 2028
Leverage **data**, digitalisation and AI



Goal 1: Maximise the **interoperability, use and exchange of data** across the EU network as well as the **generation of evidence from data on safety, quality and efficacy of medicines**, to support EU regulatory decision-making.

Goal 2: **Leverage digitalisation, experimentation and innovation** as an opportunity to deliver optimised regulatory processes, data-driven ways of working and a connected user-journey for EMRN and its wider stakeholders

Goal 3: **Realise the EMRN vision on AI for a regulatory system** harnessing the capabilities of AI for personal productivity, process automation and systems efficiency, increased insights into data and strengthened decision-support for the benefit of public and animal health.

Motivation

- High demand for structured medicinal product data for national and European Use-Cases
- Administrative effort to handle the hight number of data elements needs to be reduced

European Shortages Monitoring Platform

Share

The European Medicines Agency (EMA) is setting up the European Shortages Monitoring Platform (ESMP) to gather information about medicine supply and demand in order to prevent, detect, and manage human medicine shortages in the European Union (EU) and European Economic Area (EEA).

New platform for collection of sales and use data of antimicrobials in animals

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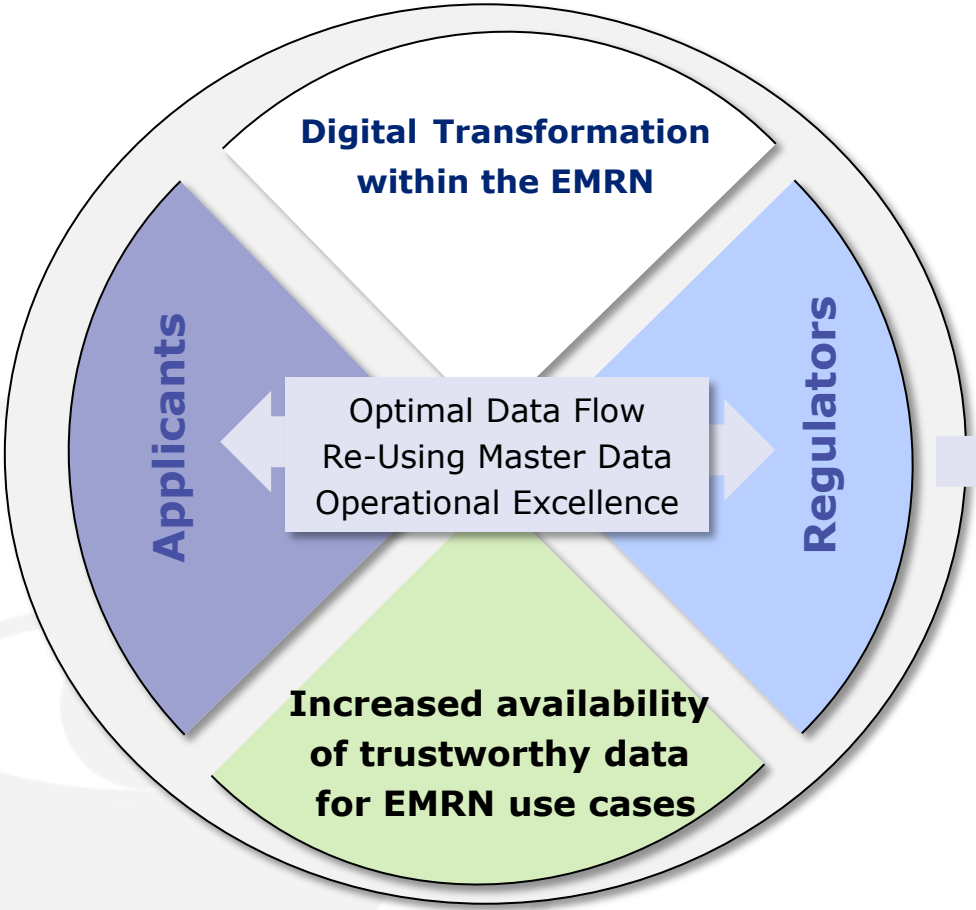
29 January 2024

EMA has just launched the new Antimicrobial Sales and Use (ASU) Platform to support the collection of data by Member States on the sales and use of antimicrobials in animals.

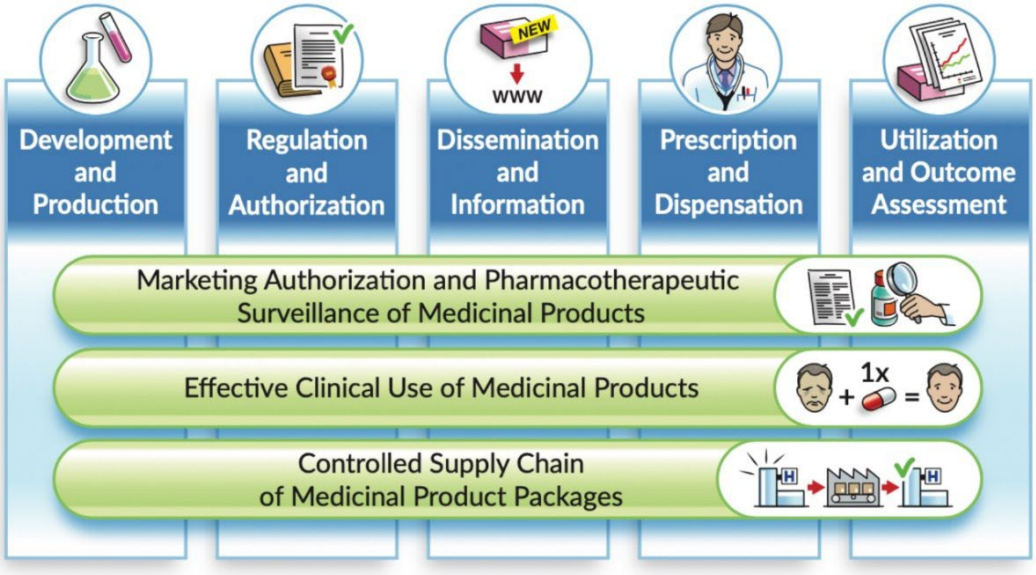
Pharmacovigilance

National ePrescribing projects



Additional and new "external" use cases urge and require trustworthy medicinal product data.

Data Value Chain



Source: UNICOM, https://unicom-project.eu/

- Pharmaceutical companies applying for marketing authorisation of medicinal products
- National medicinal products authorities
- Providers of medicinal product dictionaries
- Clinical software producers
- Healthcare professionals (incl. pharmacists)
- Patients
- Start-ups developing intelligent apps for patient empowerment
- Cross-border digital health services (patient summaries, ePrescriptions, and beyond)
- Medical research
- Public Health

(Source: UNICOM project)

Challenges

Source: VonaUA/Shutterstock.com

Veterinary Domain **46.372***
Human Doman: > **737,000 valid authorisations and 22,500 substances** **

** Source 11/2024: https://medicines.health.europa.eu/veterinary/de/search-medicines?keys=*&sort_by=search_upd_product_name*
*** Source 11/2024: Article 57 database*

approx. **300 potential data elements per Medicinal Product** were identified while working on
the new eAF creation tool

Challenges

Working in “Data - Silos”

Source: paulaphoto/Shutterstock.com

We still love typing ☺

Source: paulaphoto/Shutterstock.com

Problem statements on data:

- Data not findable, accessible nor reusable
  What data do we have? Where is it? What standards apply? Who owns the data? Who can access? Who can I ask for data? Is this data the same as that data?
- Data quality monitoring & fix not systematic/ standardised
  How should data quality be monitored? What's the leading system for certain elements? Who should monitor? Who is responsible for fixing it? What is adequate data quality?
- Roles, responsibilities & definitions in data management vary and are not formalised
  Who works on what data? Who is responsible for what? What does a data owner do? What does "data asset" mean?
- Difficulties to solve issues on data matters between systems
  Who should be addressed? Who can decide - when, where and how? How can it be fixed?
- Different working standards & structures, unclear processes
  What working agreements apply? How can we understand the process?
- Manual processing/ use of data is time-consuming, risk for errors, inconsistent outcomes

The EU network is not yet fully realising the full value from data to benefit public/animal health and its business processes

Drivers and supporters

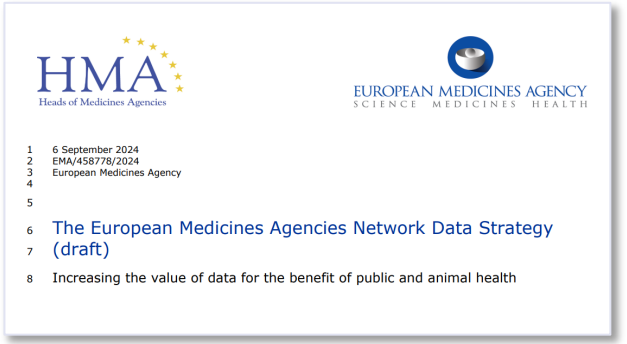
- **Need of data**
  - EMRN use cases need trustworthy data
  - External stakeholder demand availability of trustworthy data
- **EU network mandate:**
  - The European medicines agencies network strategy 2028 – NEW draft under public consultation in 2024
  - HMA EMA Big Data Task Force recommendations, Big data steering group workplan 2023-2025, Veterinary big data strategy 2022-2027, AI workplan 2023-2028
  - Draft EMRN Data Strategy – draft under public consultation until end of December 2024
- **Changing policy environment:**
  - EHDS (European Health Data Space) Proposal
  - Pharmaceutical Strategy for Europe
  - EU Interoperability Act and EU Interoperable Framework
  - AI act
  - EU Data Act and EU Data Governance Act - Regulation (EU) 2022/868
- **Changing technological environment:**
  - Importance of AI to the work of EU network has increased significantly

Source: EMA

Data Strategy of EMRN managed data

Goals

- Data are fit for purpose: of good quality, representative, protected, safe and secure
- Consistent data management, data governance and practical use of data
- FAIR (Findable-Accessible-Interoperable-Reusable)
- Traceable data
- Contribute to the creation and use of international data standards and international initiatives
- Improve Data analytics, self-service analytics



Under publication until end of 2024

Final version to be published in early 2025

Increasing the value of data for the benefit of public and animal health

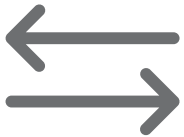
Key benefits from investing in data

Regulatory compliance

Trusted decisions

Better future preparedness

Analytics enabled



Improved interoperability

Improved efficiencies

EMRN Data Strategy content

Strategic objectives

1. Data Governance	**2. Data Quality Management**	**3. Interoperability**
4. Data Cataloguing and Metadata Management	**5. Knowledge & change management**	**6. Value of data through analysis and use of tools**

Underpinning the data strategy…

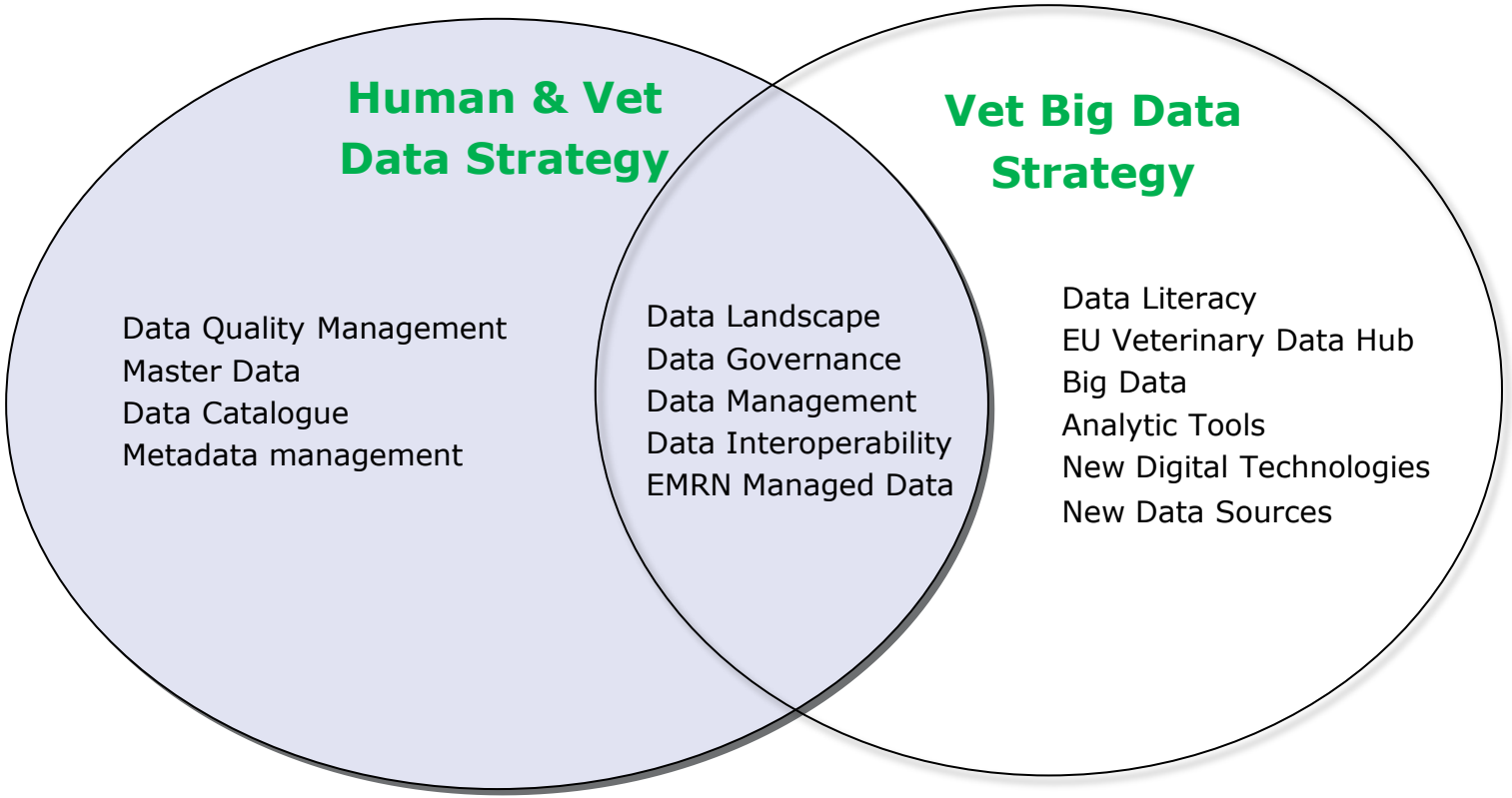
Personal Data Protection

Data principles:

1. **Data are an asset**
2. **Data are accessible**
3. **Data are shared**
4. **Data are managed**
5. **Common Vocabulary and Definitions**
6. **Data are safe and secure**

Ethical use of data

EMRN Data strategy & Vet Big Data Strategy



Joint HMA/EMA Network Data Steering Group

One Network Strategy, one Network Data Strategy work plan → one governance group to oversee the implementation

Source: ronstik/Shutterstock.com

Big Data Steering Group

BDSG workplan & AI workplan

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Network Data Board

Focus on Interoperability incl. adoption of ISO IDMP

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Network Data Steering Group

Network Data Strategy & workplan

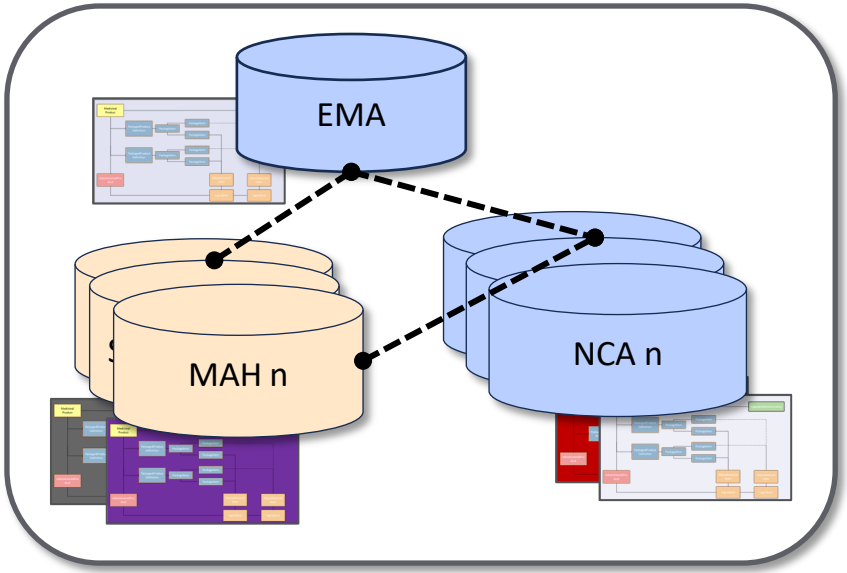
A unified Network data governance

Interoperability

Enabling effective management and use of high quality data;
Enabling high levels of interoperability and exchange of data through the use of standards, terminologies and master data

Semantical Interoperability

Ensures that information is interpreted consistently by all parties involved.



Information Landscape

Technical Interoperability

Focuses on the technical interfaces and protocols that enable data and information exchange.

Interoperability initiatives

- ISO-IDMP standards and annexes
- **plus European IDMP Implementation guide**

ISO IDMP

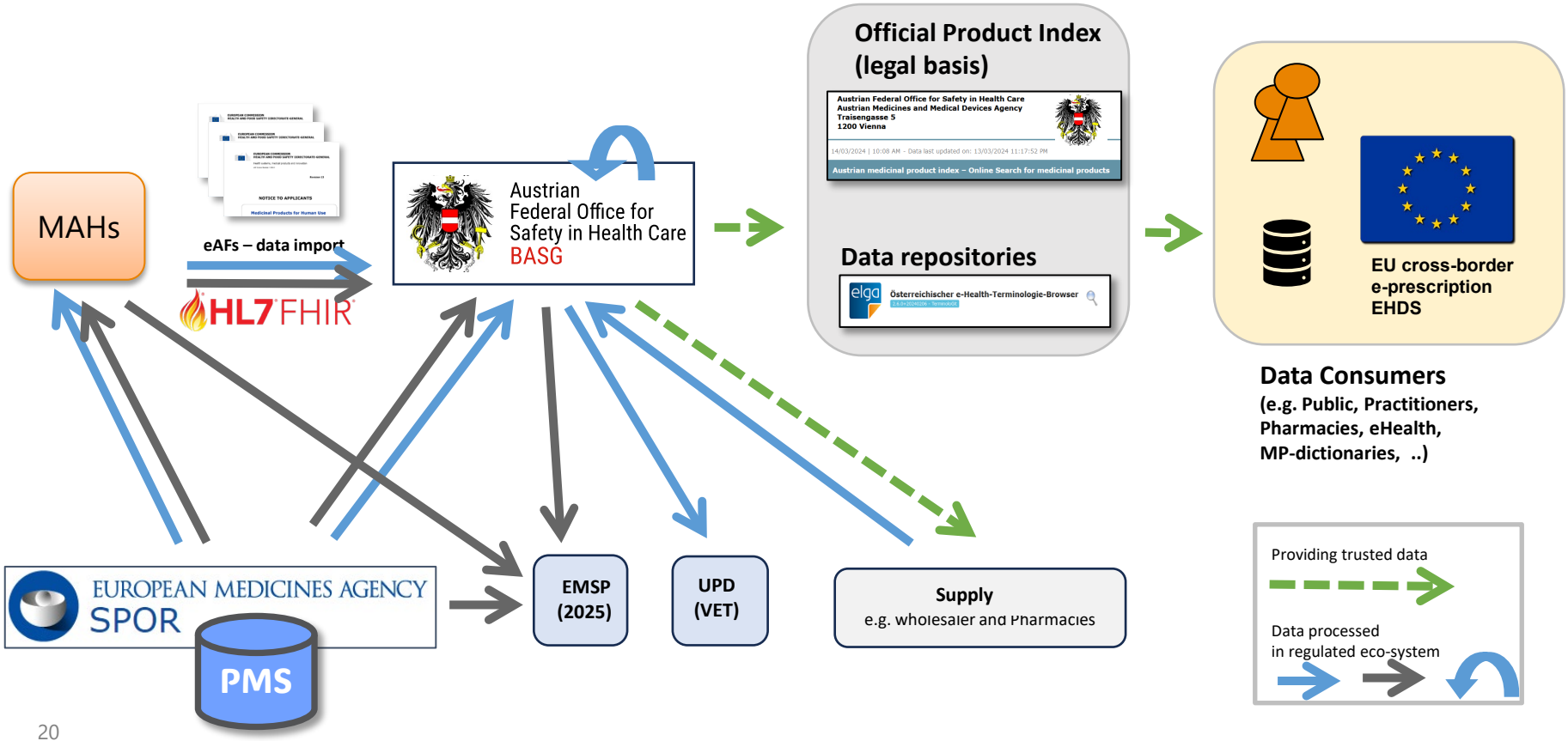
- FHIR definitions
- FHIR implementation guides and profiles

HL7 FHIR

- Shared common dictionaries
- SPOR interface (API)

S(P)OR

Medicinal Products – Data Flow



Introducing Speakers

Hans-Joachim Bigalke

(EDQM, NDB member)

Isabel Chicharo

(EMA, NDB member)

Kristine Aasen

(NOMA, NDB member)

Contacts

Bundesamt für Sicherheit im Gesundheitswesen
BASG

Georg Neuwirther

Head of IT AGES - Austrian Medicines and Medical Devices Agency

Email

Georg.Neuwirther@ages.at

LinkedIn

Hilmar Hamann

Head of Informatin Management – European Medicine Agency

Email

hilmar.hamann@ema.europa.eu

Thank you for listening

Further information

See websites for contact details

Heads of Medicines Agencies www.hma.eu
European Medicines Agency www.ema.europa.eu

The European Medicines Agency is an agency of the European Union