Reform of the pharmaceutical legislation: 1993 – 2023

31st Anniversary of INFARMED

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The EU-network of the National Competent Authorities (NCAs)

- HMA (Heads of Medicines Agencies) – volunteer cooperation
- How it all began ….

1995 – club of few member states, few topics on the agenda

Enlargement of the EU (Pan European Forum), numbers of topics increasing

2004: Foundation of the HMA-MG and a permanent secretariat, to be able to manage all the upcoming tasks for NCAs at EU level

2010: first common strategy HMA + EMA

Joint HMA – EMA strategy 2021 - 2025, Multi Annual Work Plan

EMA and HMA are functioning in partnership in close involvement with EC.

Many important topics for a harmonised efficient cooperation within the HMA network to safeguard public health

- Legal basis for HMA in the pharmaceutical legislation?

Digital transformation
Digitalising of Submissions

CTD
Common Technical Document

DVDs - digital but still a lot of administration

Separate Portas with multiples registrations

Tons of paper

- Single delivery system for submissions
- Mandatory e-submissions in the legislation

Paper

2016-2018 Transition phase to mandatory usage of eCTD

2019 Mandatory usage of eCTD

Digitalising data exchange in regulatory activities

Reuse of data

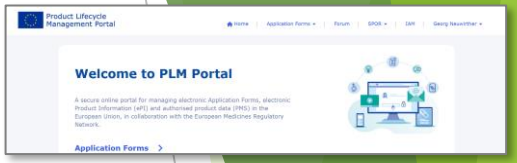
Word Files contain
medicinal
Product data

2016

Data contained in PDF-based forms

DATA BACKBONE
Support automatic
Data import into case management
tools

2022



Online tool enriching digital opportunities

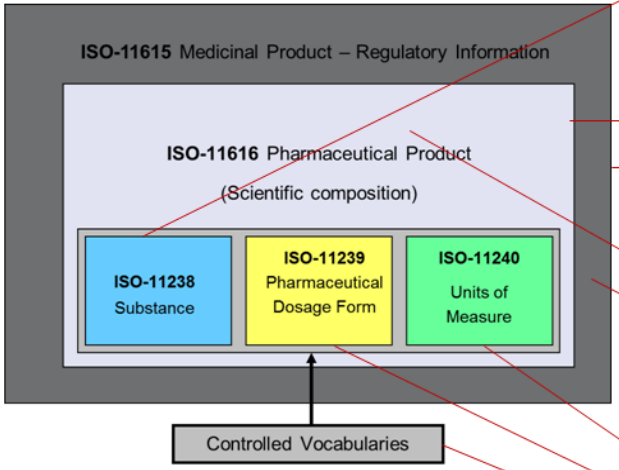
Full Support of SPOR integration and electronic processing

Stepwise compliance to international representation of medicinal product data

ISO IDMP HL7 FHIR

IDMP Identification of Medicinal Prodcuts
HL7 Health level 7
FHIR Fast Healthcare Interoperability Recources

IDMP & SPOR



IDentification of **M**edicinal **P**roducts

Substance

Single source of substance information for the network

Product

EU database of products for human and vet. medicines

Organisation

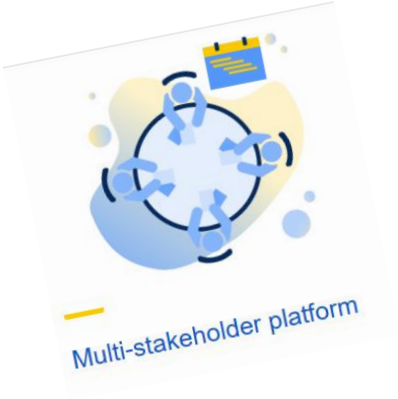
Unique EU identifier for organisations, e.g. MAH, manufacturer,…..

Referential

Common terminologies, building blocks for product & substance data set

Clinical Trials Regulation

Better, faster, optimised clinical trials
Improving the clinical trials environment in the European Union through harmonisation, innovation and collaboration with stakeholders.



CTIS
Clinical Trial Information System

- The Regulation was **adopted in April 2014** by the European Parliament and published in May 2014 (EU 536/2014).
- To make Europe **attractive for clinical trials** considering the decline in CTs and number of patients the past years
- Increased **harmonization** of a robust and agile approval process for clinical trials and close **coordination** between Member States for multi-country trials
- **Transparency** of clinical trial data to allow adequate public scrutiny and support improved clinical research efficiency
- To ensure the production of reliable and robust, **high-level scientific data**, ensuring high standards in **patient safety**

Optimisation of available human resources

The EU-network has limited human resources for all the regulatory activities at centralised and decentralised level

- Feb 2006 – HMA started „Resource Planning WG“
  - increased workload due to new legislation: Paed Reg., ATMP, CT Dir implementation, …
- Brexit – EU Referendum June 2016 – loss of UK expertise
- Corona Pandemic situation **- Increase in Workload for the Network**
  - Rapid formal review procedures related to COVID-19
  - Speed!
  - Necessary to adapt processes to ensure a rapid response to the COVID-19 pandemic whilst maintaining core regulatory activities to protect public and animal health in the EU
- Currently
  - HMA/EMA - Tactical Group on resourcing
    - MNAT (Multi National Assessment Teams) – assessment work cross border
  - EC – Joint action „Capacity building of the EU medicines regulatory network – addressing ressource challenges
    - Mapping available resources, Identify future needs and Training needs

Training

Within the EU Network - **EU Network Training Centre** (EU-NTC)

- EU NTC is a **joint initiative of EMA and the national competent authorities** (HMA) to address the training needs of the **EU medicines regulatory network** with respect to both human and veterinary medicines.
  - *Avoid duplication of efforts across the network regarding the development and management of training;*
  - *Improve collaboration between NCAs towards knowledge harmonisation and sharing*
  - *Provide a single platform with all training events organized by the EU Network accessible to EMA and NCAs*
  - *Establish a structured way for delivering scientific, regulatory and telematics training through curricula framework*

Shortages

Availability – Accessibility - Affordability

- **Shortages of medicines:** global problem and on the rise in Europe
- **Reasons for shortages - causes are varied:**
  - Economic causes
    - Price reductions, low manufacturing costs in China and India
    - Parallel import/export
  - Corporate reasons
    - market changes - "merger" - product cleansing
    - Low prices - low production costs
    - Quantities produced according to orders
  - Production and supply chain problems
    - Quality problem
    - Production and supply chain problems
    - No stocks pilling any more - "demand planning"
    - Increased demand
- Improving the **availability of medicines** authorised in the European Union (EU) is a **strategic Focus Area** to be featured in the EU Medicines Agencies Network Strategy to **2025**. Mrs Stella Kyriakides, asks …*"look at ways to help ensure Europe has the **supply of affordable medicines** to meet its needs…"*

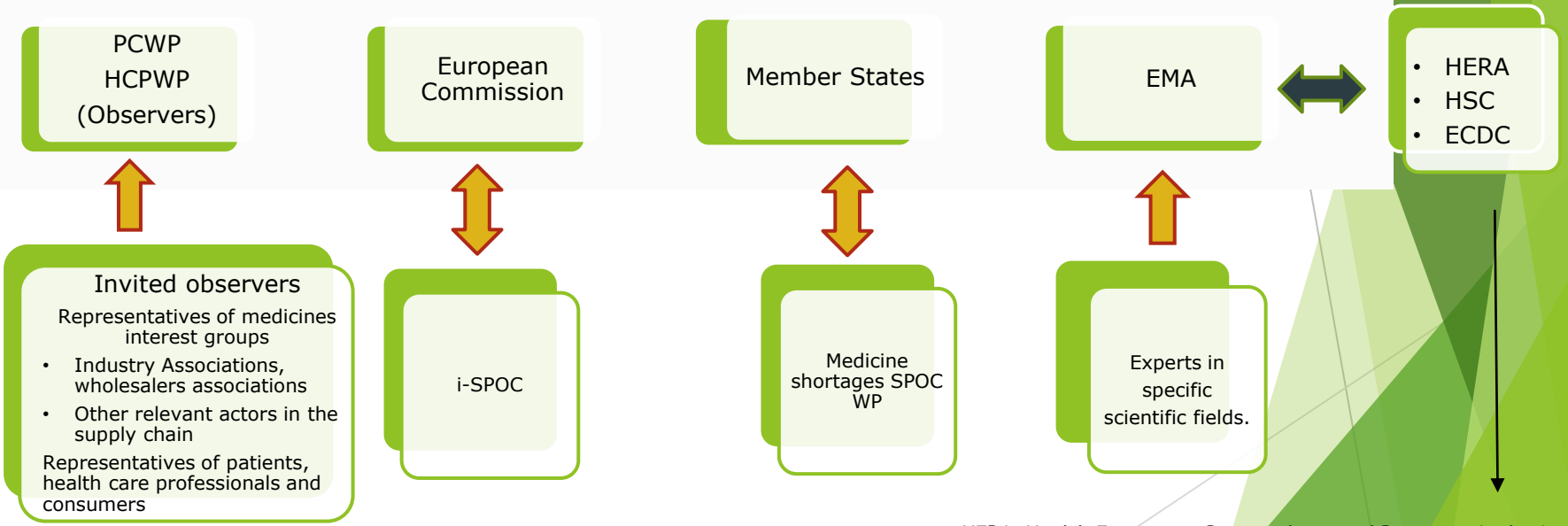
EMA extended mandate

Regulation (EU) 2022/123

- Monitoring and mitigating shortages of critical medicinal products and management of Major Events
  - Implementation date: 1 March 2022
  - Building on initiatives and achievements of EMA during the coronavirus pandemic
- A “Medicines Shortages Steering Group” to be established as part of the EMA,
  - Members: EC, EMA and 1 representative per MS
  - Steering Group to be supported by a Working Party of Single Points of Contacts in the MSs (current EU SPOC Network) and by a sub-network of contact points from the concerned MAHs (current i-SPOC)
- Preparedness role: EMA, together with MSs, to continuously monitor any events which may lead to a major event or a public health emergency, and which may affect the supply, quality, safety and efficacy of medicinal products.

Executive Steering Group on Shortages and Safety of Medicines

MSSG



HERA Health Emergency Preparedness and Response Authority
HSC Health Security Committee
ECDC European Centre for Disease Prevention and Control

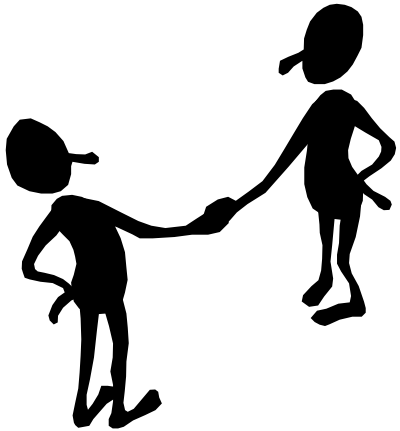
MAIN NEW TASKS OF THE AGENCY TO FACILITATE A COORDINATED EU-LEVEL RESPONSE TO HEALTH CRISES:

- **Monitoring and mitigating the risk of shortages of medicinal products and medical devices**, in particular for those on critical lists during major events and public health emergencies
- Setting up an interoperable **IT platform** at EU level to enable monitoring and reporting of shortages of medicinal products
- **Providing scientific advice on medicinal products** that may have the potential to treat, prevent or diagnose the diseases causing public health emergencies
- **Coordinating studies to monitor the effectiveness and safety of medicinal products** intended to treat, prevent or diagnose diseases related to the public health emergencies
- **Coordinating clinical trials for medicinal products** intended to treat, prevent or diagnose diseases related to the public health emergencies
- **Providing support for the expert panels** of the Medical Device Regulation

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Competitivness of EU compared to other regions

- Have we reached the goal with the Clinical Trial Regulation?
- Are there attractive provisions in the proposal of the Pharma legislation?
- Reduce administrative burden of EU marketing authorization procures (new proposal: eg. shorten timeline, update of Var. Reg., use of real world data)
- Innovation – is Big Pharma still interested to perform Research and Development in EU? New provisions in the Pharma legislation:
  - Data protection?
  - Regulatory sandboxes – future proof legislation - to adapt to scientific and technological development



Thank you for your attention!

Questions?

Christa Wirthumer-Hoche