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SCIENCE MEDICINES HEALTH

Healthcare data in medicines regulation

European Data Protection Supervisor Seminar
25 January 2021

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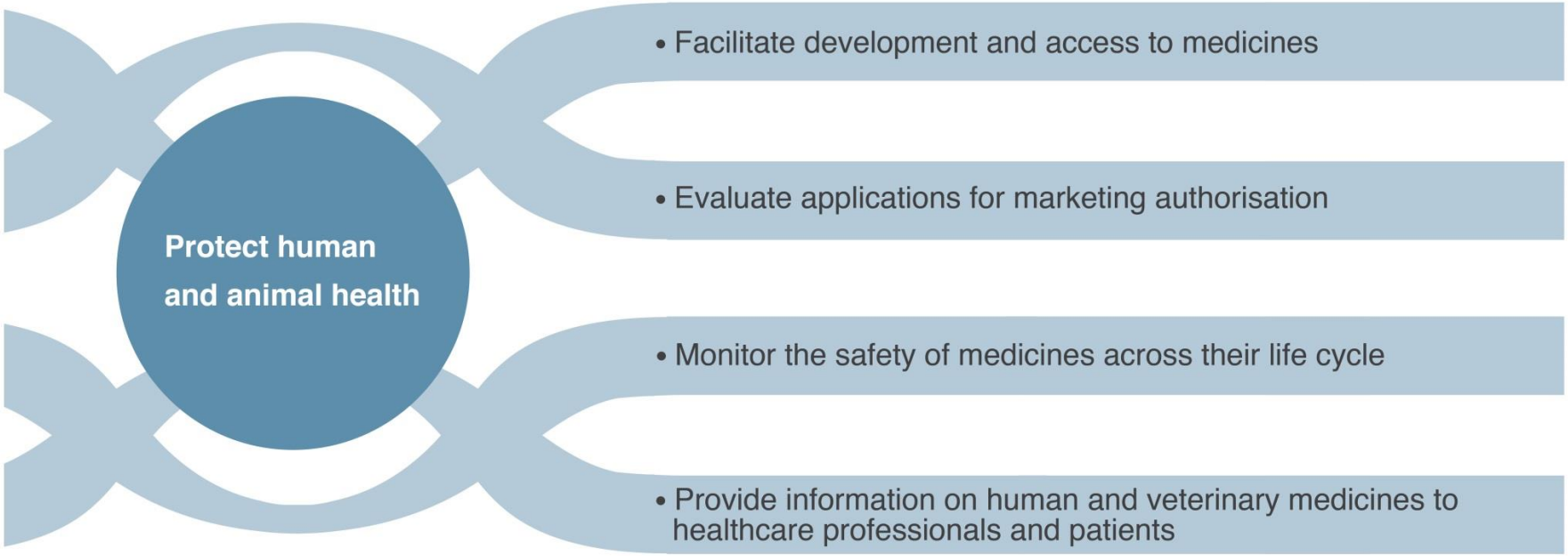
European Medicines Agency

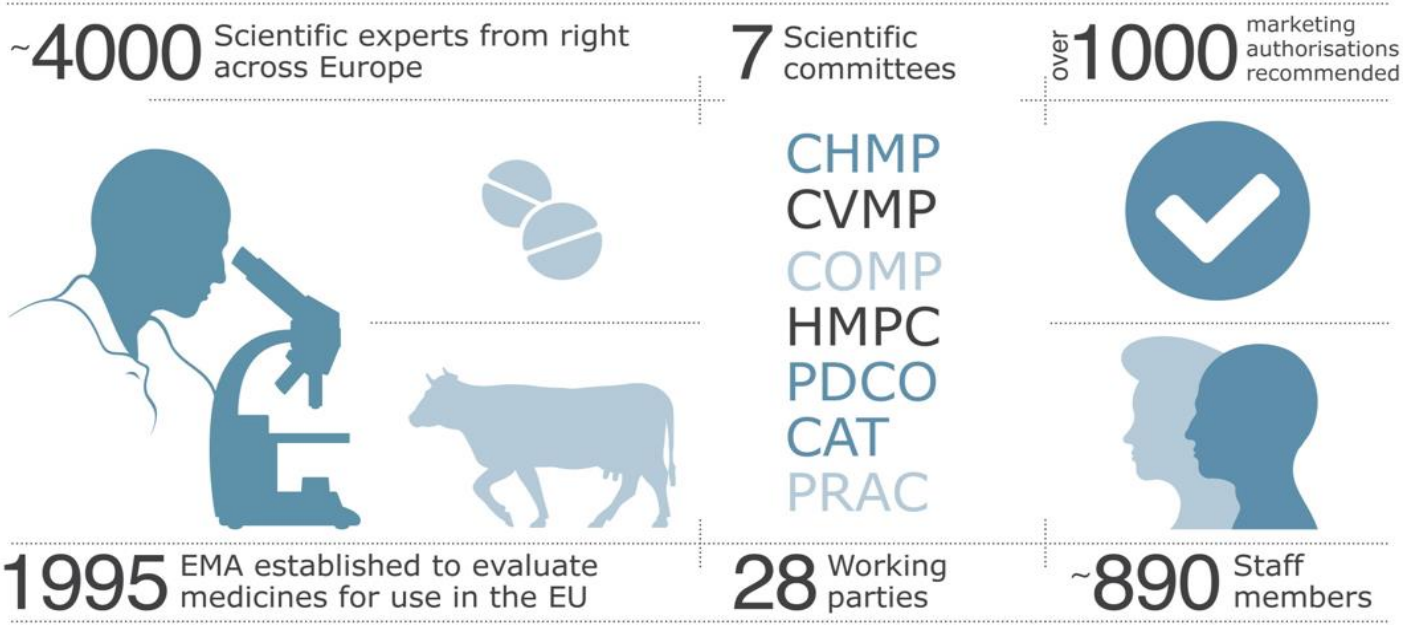
Healthcare data in medicines regulation – Overview

- Brief introduction to EMA and medicines regulation
- Healthcare data in medicines regulation
- COVID-19 pandemic response as an example
- Strengthening data governance
- Conclusions

What do we do?


Protect human and animal health
• Facilitate development and access to medicines
• Evaluate applications for marketing authorisation
• Monitor the safety of medicines across their life cycle
• Provide information on human and veterinary medicines to healthcare professionals and patients

Who are we?



European Medicines Agency

European Commission

EEA National Competent Authorities

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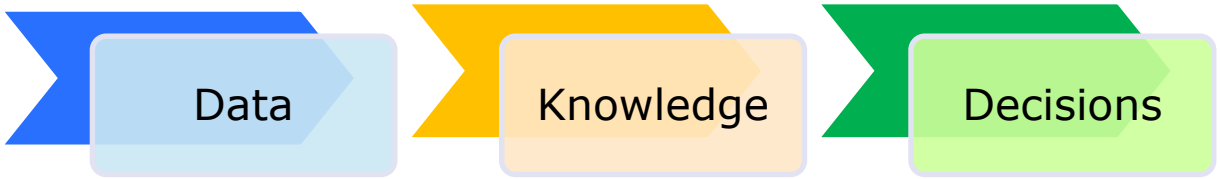
Healthcare data in medicines regulation

We transform 

on medicines for the promotion and protection of public health

Three main pillars:

- Randomised controlled trials (RCTs): may be conducted within or outside EU, submitted in Marketing Authorisation Application.
- Reports of suspected adverse reactions of medicines: EudraVigilance
- Real world data: covering safety, effectiveness, medicine utilisation and others

Randomised controlled trials: the foundation of evidence in medicines regulation

R	C	T
Randomisation the most important design techniques for **avoiding bias** in clinical trials are blinding and randomisation	**Controlled** to allow discrimination of patient outcomes caused by the test treatment from outcomes caused by other factors	**Trial** to ensure that groups are treated similarly in the course of the study to estimate effects **attributable to treatment**

Safety Monitoring of development and authorised medicines

1,821,211 individual case reports processed in 2020

- ✓ 812,760 (45%) reports originated from EEA
- ✓ 143,958 reports submitted by patients/consumers

EudraVigilance as a data hub: 2020

- ✓ 251,558 ICSRs were rerouted to NCAs following receipt of the reports from MAHs
- ✓ 1,212,939 ICSRs were forwarded to WHO
- ✓ 8,073,849 ICSRs downloaded by companies

But the data landscape is changing….

Clinical databases
(Prescriptions, EHRs and registries)

'Omic data
(Genetic, proteomic, metabolomic)

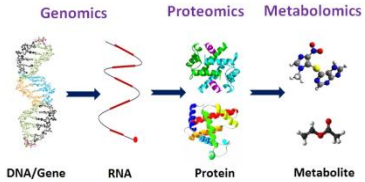
Published literature

Post authorisation data
(ADR, sales, Safety updates, PASS, PAES)

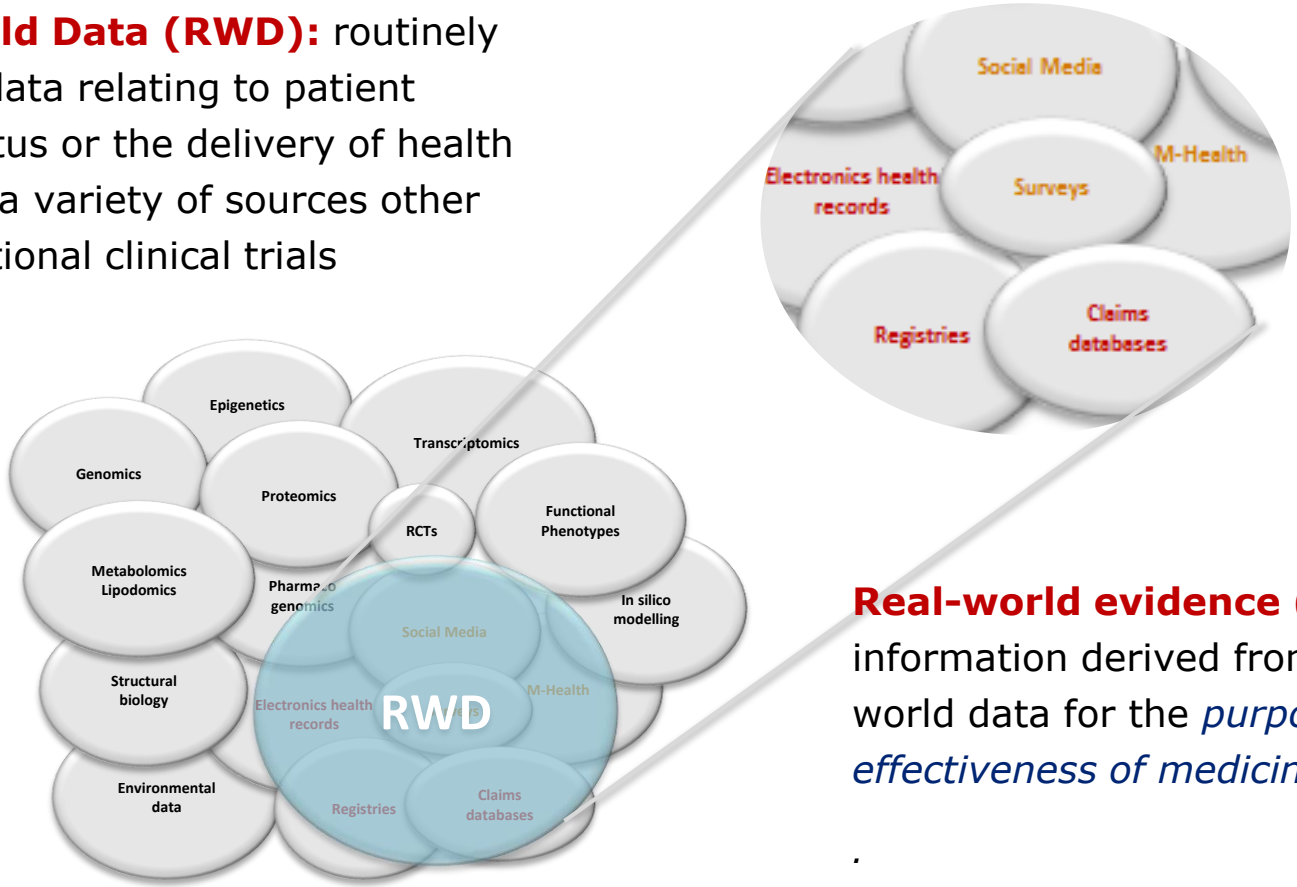
Clinical trial data

Imaging data

Social media data/m-health



Real-World Data (RWD): routinely collected data relating to patient health status or the delivery of health care from a variety of sources other than traditional clinical trials



Real-world evidence (RWE): information derived from analysis of real-world data for the *purpose of safety and effectiveness of medicines*.

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Development, authorisation and supervision of medicines

Regulatory use cases for healthcare data

Relevance of clinical trial data versus clinical practice	Safety monitoring and evaluation	Drug utilisation studies such as use in different age groups (children) and off-label use
Extrapolation of adult data to children or elderly	Identification of unmet medical need	Assessing disease incidence/prevalence

Data-driven regulation: HMA-EMA Big Data Task Force

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HMA
Heads of Medicines Agencies

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HMA-EMA Joint Big Data Taskforce
Phase II report:
'Evolving Data-Driven Regulation'

Big Data Task Force Priority recommendations

1	•Deliver a sustainable platform to access and analyse healthcare data from across the EU (Data Analysis and Real World Interrogation Network: DARWIN EU)
2	•Establish an EU framework for data quality and representativeness
3	•Enable data discoverability
4	•Develop EU Network skills in Big Data
5	•Strengthen EU Network processes for Big Data submissions
6	•Build EU Network capability to analyse Big Data (technology / analytics)
7	•Modernise the delivery of expert advice
8	•Ensure data are managed and analysed within a secure and ethical governance framework
9	•Engage with international initiatives on Big Data
10	•Establish an EU Big Data 'stakeholder implementation forum'
11	•Veterinary recommendations

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EMA activities in support of drug development

- **COVID19 EMA pandemic task force (ETF):**

  EMA scientific committee and working party members expert in vaccines, infectious diseases, preclinical and clinical trial design, paediatric aspects, quality of biological medicinal products

- Support to the development, authorisation and supervision of medicines and vaccines


COVID-19

COVID-19: latest updates Share

The latest updates on the COVID-19 pandemic from the European Medicines Agency (EMA) are available below.

What's new

Show 25 entries Search:

DATE	TOPIC	UPDATE	MORE INFORMATION
15/01/2021	Transparency: exceptional measures for COVID-19 medicines	EMA extended its target timeframe for publishing European public assessment reports for COVID-19 medicines.	

Inventory of rapid procedures

Development support

- Rapid scientific advice
- Rapid agreement of a paediatric investigation plan and rapid compliance check

Evaluation (initial authorisation & post-authorisation)

- Rolling review
- accelerated assessment for Marketing authorisation, Extension of indication

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4 May 2020
EMA/213341/2020

EMA initiatives for acceleration of development support and evaluation procedures for COVID-19 treatments and vaccines

The European Medicines Agency (EMA) together with the responsible scientific committees and their working parties, and in collaboration with the European Commission, operates rapid procedures to support the development and evaluation of treatments and vaccines for COVID-19. The EMA emerging health threats plan foresees that detailed procedures are set-up to adapt different types of review activities to the needs of the health threat/crisis situation. Whilst respecting the regulatory requirements and established review principles (e.g. independence of experts), these procedures aim, within timelines that are appropriate for the public health emergency situation, to provide most efficient management of product-review activities leading to scientifically sound and robust outcomes.

EMA initiatives for acceleration of development support and evaluation procedures for COVID-19 treatments and vaccines

EMA, RWE and COVID-19

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EMA review of study results

- **Daily triage** of published studies
- **Rolling reviews** e.g. Hydroxychloroquine to support ETF

EMA-funded projects

- Infrastructure for COVID-19 **vaccine monitoring** and specific studies
- Framework for **multicentres collaboration** for multicentre observational studies
- **Pregnancy study** on effects of COVID-19 infection and treatments

International collaboration (ICMRA)

- Preparation for **vaccine safety monitoring** (lead MHRA)
- Building **international cohorts** facilitating multicentre observational studies (lead Health Canada)
- **Pregnancy research** to support regulatory decision-making (lead EMA)

ENCePP

- **Strengthened mandate** in the context of the COVID-19: ENCePP COVID Response Group
- Guidance on **COVID-19** for the ENCePP Method Guide

Vaccines Monitoring Preparedness

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Lessons Learned H1N1

Lessons learned from A/H1N1 pandemic adapted to current emergency situation

Signal Detection Methods

- Rapid **detection**, **exchange**, **prioritisation** and **assessment** of safety **signals**
- Testing of **new methodologies** specific for COVID-19

COVID-19 Vaccines Monitoring Preparedness Plan

Enhanced monitoring activities to be carried out in the EU for COVID-19 vaccines, including **roles**, **responsibilities** and **interactions** of stakeholders involved

- Active surveillance of **vulnerable populations**:
- Active data collection on **rare** and **severe** risks
- **ACCESS**, **ICMRA**, **pregnancy studies**, **int. cohorts**

International And Research Centres Collaboration

- **Engage** and **communicate** with public, patients and HCP.
- **Enhanced communication** and **transparency** measures

Transparency & Communication

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EMA Stakeholder Engagement and Data Protection

In September 2020, stakeholders discussed the application of the General Data Protection Regulation (GDPR) in the area of health with focus on *Secondary Use of Data for Medicines and Public Health Purposes*

This followed a targeted stakeholder consultation by EMA

https://www.ema.europa.eu/en/events/workshop-application-general-data-protection-regulation-gdpr-area-health-secondary-use-data

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2 December 2020
EMA/532436/2020

GDPR and the secondary use of health data

Report from EMA workshop held with the EMA Patients' and Consumers' Working Party (PCWP) and Healthcare Professionals' Working Party (HCPWP) on 23 September 2020

Introduction

The introduction of the General Data Protection Regulation (GDPR) in 2018 has created a new framework for the protection of personal data in the European Union. It is particularly relevant to healthcare, where technological advances and the increasing availability of data from a range of sources offer many opportunities for the further processing (or secondary use) of data in scientific research, medicine development and policy making. However, with these opportunities come legal, technological and digital skills challenges.

This workshop was set up to discuss these challenges and opportunities with patients, consumers, and healthcare professionals and to present the development of an EU-wide governance framework and a future code of conduct on processing personal data in the health sector. These and other initiatives such as EMA's Questions and Answers (Q&A) on the GDPR in secondary use of health data will ensure the full potential of big data in the health arena can be harnessed in a way that benefits EU citizens, while at the same time protecting their privacy. This report offers a high-level summary of the output from the workshop.

'Healthcare professionals have long been advocating the use of big data in the interest of our patients', Ulrich Jaeger, Co-Chair of HCPWP

Development of set of Question & Answers Q&As

- Clarify compliance with data protection legislation
- Ensure rights and freedoms of patients & consumers
- Facilitate secondary use of health data for medicines & public health purposes

In consultation with EC & EDPS based on EDPS and EDPB guidance

Q4 2021

- Clarify the concept of **secondary use of data** within the GDPR/EUDPR
- Clarify the concept of **scientific research** within the GDPR/EUDPR
- Clarify the **specific rules** applicable to scientific research and secondary use, e.g. legal basis (consent or other), data erasure and retention period, transparency

Key issues to be addressed

- *Need for a clear and harmonised interpretation of scientific research and the "further processing" of health and medical data for medicines and public health purposes in the context of the of the EU DPR/GDPR*
- *Develop a practical data protection framework that offers high levels of protection for individuals and high-quality data access for EMA, researchers and healthcare providers*
- *Provide transparency on data use for all purposes with focus on public health benefit*
- *Need for a pseudo/anonymization strategy that ensures that the health data remain of sufficient granularity for scientific research*
- *Establish minimum security requirements to ensure an equivalent level of protection of personal data shared by patients across the EU and to facilitate cross-border healthcare and scientific research*
- *Simplify data sharing in the context of international collaboration of regulators and researchers*

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Healthcare data in medicines regulation: Key messages

- EMA regulates the development, authorisation and supervision of medicines
- EMA turns data to knowledge to decisions for public health
- Analysis of healthcare data is critical to public health including health crisis planning and response
- Need for common interpretation of data protection rules to help stakeholders to comply – EMA is engaging with EDPS to share operational experience and challenges
- EMA is working with stakeholders to increase the utility of healthcare data and with EC to build the European Health Data Space

Thank you

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