EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The New Mandate of EMA and its consequences

24th DGRA Annual Congress

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An agency of the European Union

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COVID-19 Pandemic – some highlights

March 2020

- COVID-19 declared a public health emergency
- Restrictions put in place
- Full use of EMA Health Threats plan

End of 2020

- Acceleration and flexibilities lead to authorization of first COVID-19 vaccine
- Work continues to expand supply and authorise other vaccines and therapeutics

Summer 2022

- 5 vaccines and 8 treatments authorised
- 72% of EU population have received primary vaccination
- Face-to-face activities restarted

Special measures for dealing with COVID-19

Acceleration

- Scientific discussions and meetings organised ad hoc, as needed
- Rolling review
- Shortening of procedure timelines
- Frequent updates for national regulators at an executive level
- Non-stop engagement with international partners

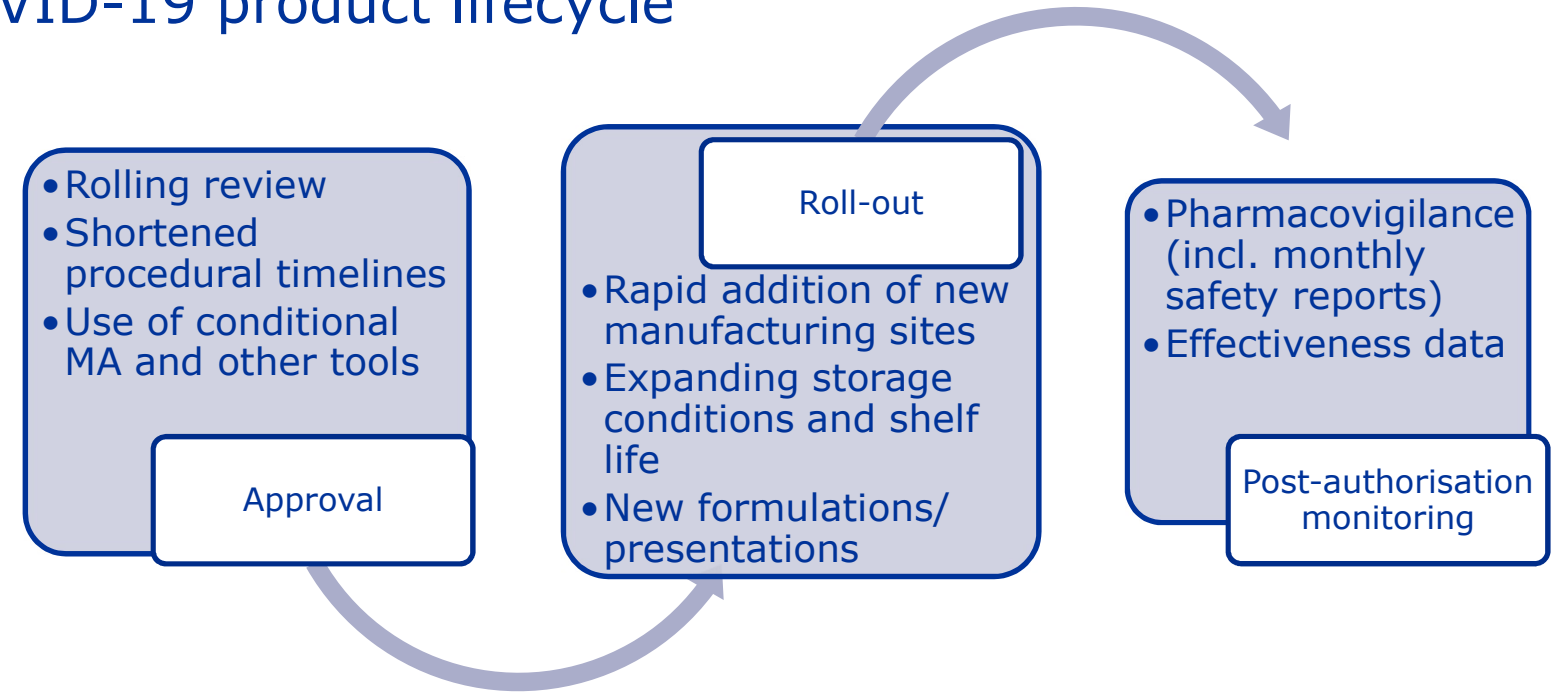
EMA initiatives for acceleration of development support and evaluation procedures for COVID-19 treatments and vaccines

Flexibilities

- Distant assessment for inspections
- Exceptional change management process possible for crucial medicines
- Electronic certificates
- Extension of GMP certificates
- GMP flexibilities (e.g. post-ponement of certain testing)
- …

Regulatory Expectations for Medicinal Products for Human Use During the COVID-19 Pandemic

COVID-19 product lifecycle



Outside regulatory procedures: public health communications based on ETF scientific position (e.g. on vaccination, jointly with ECDC)

Tackling (ICU) medicine shortages

Challenges	• Lockdowns • Transport issues • Export bans • Increased demand
Products affected	• Anaesthetics • Antibiotics • Miorelaxants • Anti-inflammatory medicines and immunomodulators
Actions taken	• EMA as a central coordinator • Executive Steering Group on Shortages caused by major events • List of crucial medicines • Single Points of Contact for regulators and manufacturers

EMA Extended Mandate

Regulation (EU) 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices

- Adopted on 25/01/2022
- Entered into force on 1/02/2022
- Applicable from 1 March 2022*

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English edition

Legislation

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1 *Legislative acts*

REGULATIONS

★ Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (1) 1

* - some parts become applicable later

EMA Extended Mandate – direct consequences - already in place (1/2)

MSSG	Executive Steering Group on Shortages and Safety of Medicinal Products
	Most members are heads of national competent authorities
	Monitoring of events, lists of critical medicines, recommendations for and coordination of EU harmonised action
Medicine shortages *	Working Party of Single Points of Contact (SPOCs) from national competent authorities
	Tackling critical shortages, monitoring of shortages that can lead to a 'major event' (i.e. a crisis)
	During crisis: sub-network of industry SPOCs activated; reporting and tackling of shortages (incl. reporting of expected demand and supply)

*Note: medicine shortages also addressed in complementary initiatives, e.g. EU Joint Action on Shortages, Pharma and EMRN strategies

EMA Extended Mandate – direct consequences - already in place (2/2)

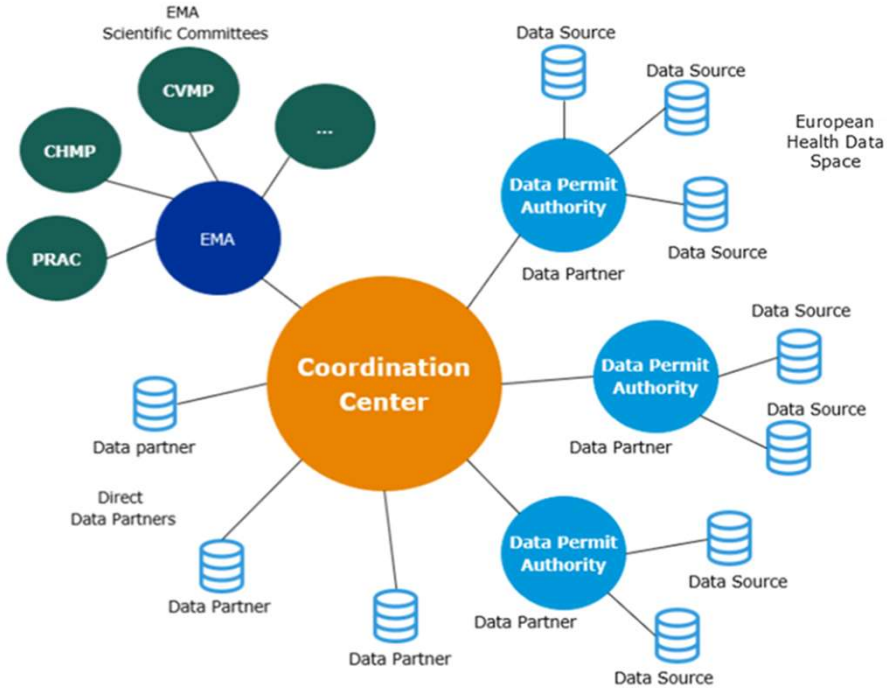
ETF	EMA's Emergency Task Force
	Representation from various scientific bodies, best available expertise
	Leading role for provision of advice and agile scientific input during a public health emergency
Medical device expert panels	Established under medical devices' legislation, secretariat role transferred from the European Commission
	Provide opinions to notified bodies on assessment clinical and performance evaluations
	In future will also provide advice to the Commission, Member States and industry

EMA Extended Mandate – Consequences -implementation work ongoing

Device shortages	From February 2023
	Only during a declared public health emergency or major event
	Medical Device Shortage Steering Group (MDSSG)
	Respective SPOC networks
ESMP	European Shortages Monitoring Platform
	From February 2025
	IT platform for collection and analysis of shortage related data
	Medicines only
Real world data	Pan-European network of real-world data, DARWIN EU established
	Aim – to integrate Big Data into the assessment and decision making

DARWIN EU

*«DARWIN EU® is a federated **network** of **data**, **expertise** and **services** that supports better decision-making throughout the product lifecycle by generating reliable **evidence from real-world healthcare data**»*



FEDERATED NETWORK PRINCIPLES

- Data stays **local**
- **Use of Common Data Model** (where applicable) to perform studies in a timely manner and increase consistency of results

Other consequences – Enhanced cooperation with other EU bodies

European Centre for Disease Prevention and Control (ECDC)

- Observational studies
  - Vaccine monitoring platform
  - Joint Advisory Board (JAB)
- Monitoring of major events and preparedness for public health emergencies

EU Health Emergency Preparedness and Response Authority (HERA)

- Created recently to strengthen EU's capabilities to prepare for and respond to health crisis situations
- EMA-HERA Memorandum of Understanding in preparation
- Cooperation already takes place to support availability of medical countermeasures

International cooperation

International Coalition of Medicines Regulatory Authorities (**ICMRA**)

- Aims to achieve greater cooperation and provides support for regulatory convergence globally
- During COVID-19 common positions achieved on start of first-in-man studies, principles for confirmatory clinical studies, transparency on vaccine assessments and adaptation of vaccines to address variants of concern
- Pharmacovigilance, real-world evidence, clinical trials in crisis settings

OPEN is an international collaboration framework of near-concurrent review among international regulators

- EMA conducts full review of applications but shares and discusses assessments with OPEN experts
- OPEN experts have similar requirements as for EU experts (e.g., confidentiality, absence of conflict of interests)
- OPEN experts participate actively in ETF and CHMP meetings
- OPEN experts exchange comments and reviews with EMA
- All regulators keep full scientific and regulatory independence
- Direct consequence – registations in less than 2 weeks for EMA decision in more than 100 countries
- Proposal to extend to products with potential to address AMR

TGA Health Canada Swissmedic MHLW/PMDA WHO EMA

All participate under the terms of their Confidentiality Arrangement with the EU

Conclusions

- The European Medicines Regulatory Network (EMRN) has shown it can deliver with great agility and flexibility in a crisis
- World of medicines regulation is now in the public eye
- The EMRN and the extended European community has worked with unprecedented agility to meet the needs of European citizens for medicines supplies, new vaccines, new and adapted therapeutics
- Delivery and coordination have been phenomenal
- Direct consequence - Informal measures translated into the new legislation
- Challenge now to use the momentum and energy to translate learnings into sustainable systems and processes which will serve all stakeholders both in peacetime and crisis
- The new legislation and other initiatives (e.g., EU Pharma strategy and the Agencies Network Strategy to 2025) provide us with the tools needed – we must use them well

Any questions?

Further information

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