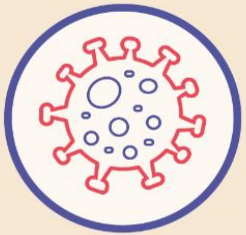
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA perspective: The EU Pharmaceutical Strategy and International Collaboration

DGRA Annual Congress, Bonn

Presented by Emer Cooke on 13 September 2021
Executive Director, European Medicines Agency

PHARMACEUTICAL STRATEGY FOR EUROPE



Learning from COVID-19, towards a crisis-resistant system

Ensuring accessibility and affordability of medicines

Supporting sustainable innovation, emerging science and digitalisation

Reducing medicines shortages and securing strategic autonomy

#EUPharmaStrategy

European Commission

EU Strategy to be send in context of multiple initiatives - e.g. European Medicines Agencies Network Strategy to 2025

Strategic focus areas

1. Availability and accessibility and of medicines
2. Data analytics, digital tools and digital transformation
3. Innovation
4. Antimicrobial resistance and other emerging health threats
5. Supply chain challenges
6. Sustainability of the Network and operational excellence

EMA priorities & Pharma Strategy for EU

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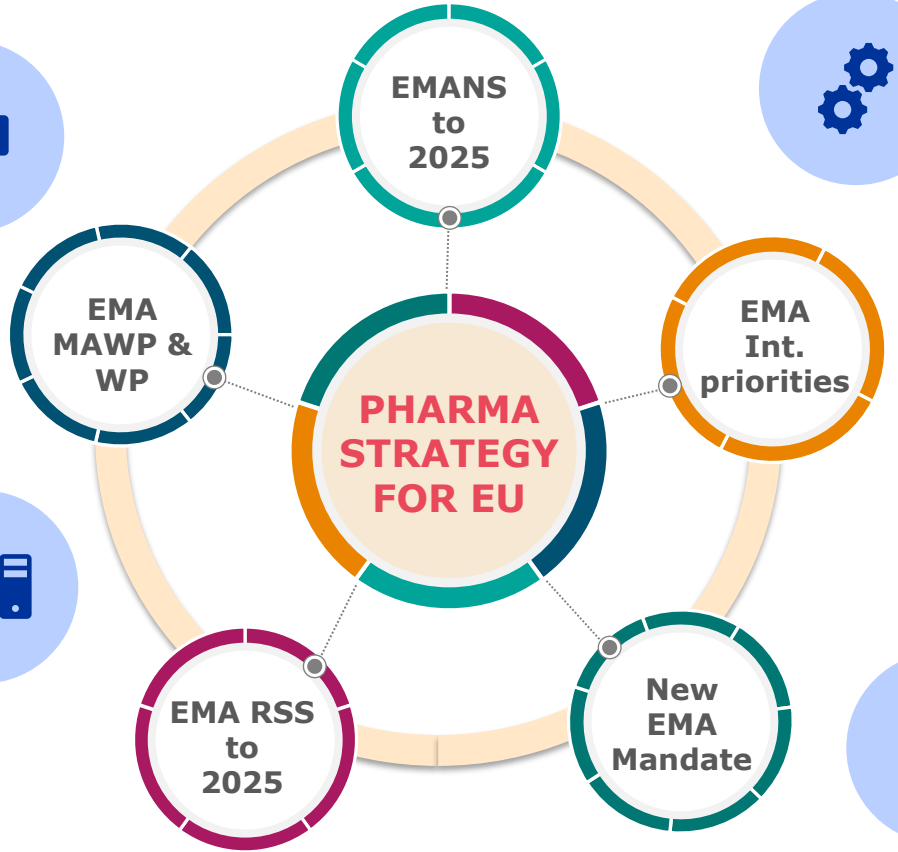


EFFECTIVE AND TRANSPARENT COMMUNICATION

AGILE, FLEXIBLE AND COLLABORATIVE AGENCY & NETWORK

HANDLING OF EMERGING HEALTH THREATS

DIGITALISATION AND DIGITAL TRANSFORMATION

SHORTAGES, ACCESSIBILITY, AND AVAILABILITY OF MEDICAL PRODUCTS

Towards a crisis resistant system (Pharma Strategy)
AMR and Emerging Health Threats (EMANS)

- EMA's role in the pandemic response is key – evaluating COVID-19 vaccines and therapeutics – managing the strain on EMA and the network's resources
- Multi-stakeholder approach and strong coordination and collaboration from all parties involved
- International collaboration, harmonisation of requirements and promotion of regulatory reliance is key for effective global response to the pandemic
- Information sharing, transparency and communication are essential to gain efficiency, avoid duplication and, importantly, to maintain public trust and confidence
- New mandate strengthens EMA preparedness role in crisis management learning from COVID-19
- Preparedness to tackle antimicrobial resistance also key

Ensuring Accessibility and Affordability of medicines, Reducing Medicines shortages (Pharma Strategy), Availability and Accessibility, Supply chain challenges (EMANS)

- EMA's role on Shortages in COVID-19 Pandemic – EU steering group and iSPOC system
- Increasing focus on and speed of authorisation of new product sites, filling lines, adapted formulations, remote inspections
- New EMA mandate gives EMA legal underpinning to managing and mitigation of shortages and additional role in medical devices shortage management
- Pharma strategy includes initiatives on Orphans, Paediatrics, AMR, interactions with HTA bodies

Enablers: Better integration and fostering sustainability

- Shape the future role of medicines regulation as part of the Pharmaceutical Strategy, and enhance the partnership approaches that we need to face large scale health issues
- Need for increased collaboration and engagement with all stakeholders including downstream decision makers such as HTA bodies and payers
- Build on the initiatives and achievements of EMA and EMRN on availability and shortages of medicines, before and during the ongoing pandemic, through the new EMA mandate and extend also to cover medical devices.
- Further progress in the veterinary medicine area and on environmental issues
- Opportunity of Clinical Trials Regulation – ensure competitiveness of EU for the conduct of clinical trials supporting innovation and digitalisation in clinical trials
- Build up expertise in the network (EU-NTC) and maximise the use of available resources while maintaining the high-quality scientific work of the scientific committee (e.g. MNAT).

Enablers: Digitalisation and digital transformation

- Provide stronger telematics systems to operate efficiently as dependency on IT services constantly increases and is a prerequisite for the sustainability of the Network.
- Modernise EMA’s processes and create a supporting digital infrastructure as a core part of EMA’s digital transformation process.
- Exploit digital technology and artificial intelligence in decision making.
- Integrate fully digitalised platforms, such as IRIS and SPOR, to support the Network activities.
- Provide the most up-to-date IT tools and centralised systems to support the assessment on the risks associated with the manufacturing of medicinal products.

Enablers: Agile, flexible and collaborative Agency

- Ensure the Agency is agile, receptive and science-based to react quickly to new information and development for both novel and repurposed medicinal products.
- Adapt EMA's processes to be flexible and pragmatic while still ensuring protection of our populations.
- Create an integrated evaluation pathway for the assessment of medical devices, in vitro diagnostics and borderline products
- Work closely with regulators across the world, ensure aligned approaches to accelerate innovation and support the development of safe and effective medicines.

International collaboration – deep dive

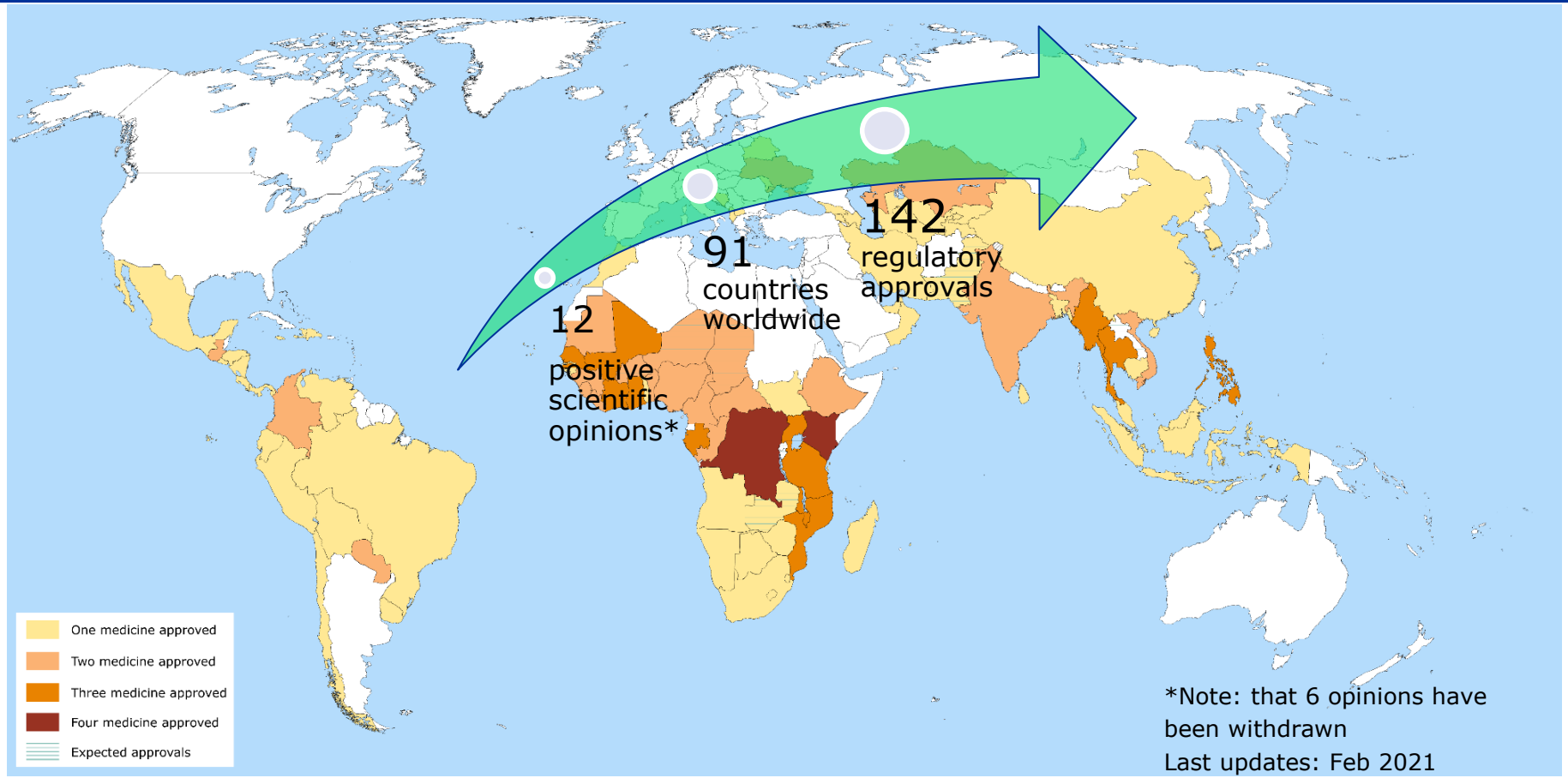
- Delivering on the promises of the EU Pharmaceutical Strategy – and the EU Network Strategy – will need efficient (and sustainable) use of **resources** and **knowledge**
- Complexity of global supply chains, companies, etc. mean we need a forward-looking approach to international cooperation
- COVID-19 has shown benefit of international alignment and cooperation, applies also to AMR, supply chain challenges, innovation challenges, etc.
- Need to increase international **collaboration** and **reliance**
- Some examples…

#1 EMA OPEN Pilot: collaborative assessment in action

- OPEN lets WHO and medicines regulators from outside the EU take part in EMA scientific evaluations – currently just for COVID-19 Tx and Vx
- Drivers: sharing scientific expertise, tackling common challenges, enhancing transparency on regulatory decisions
- Pilot launched December 2020 with TGA Australia, Health Canada, MHLW/PMDA Japan, Swissmedic and WHO
- Participate in CHMP assessments and COVID-19 EMA pandemic Task Force
- Experts keep full scientific and regulatory independence; participate under existing confidentiality arrangements; have no role in CHMP B/R decision
- What does success look like – authorization in 100 countries following EU decision

#2 Reliance in action: 'EU-Medicines4all' (Article 58)

- EMA assessment of innovative or generic medicines, including vaccines, that address unmet medical needs; medicines intended for use outside the EU
- WHO and non-EU regulatory authorities collaborate in assessment
- Benefit-risk evaluation targeted at intended non-EU populations, and conditions for use; leading to a scientific opinion
- Same standards as for medicines reviewed and approved in the EU
- Licensing decision taken independently by non-EU regulators in their countries (reliance principle)
- **NEW IN 2021**: Parallel centralised + EU-M4all applications launched



*Note: that 6 opinions have been withdrawn
Last updates: Feb 2021

#2 Parallel submission EU-M4all – Centralised

Vaccines/medici… health priority d…

- Active substanc… comparable
- Medicines may h… routes of adminis…

Submission of two …

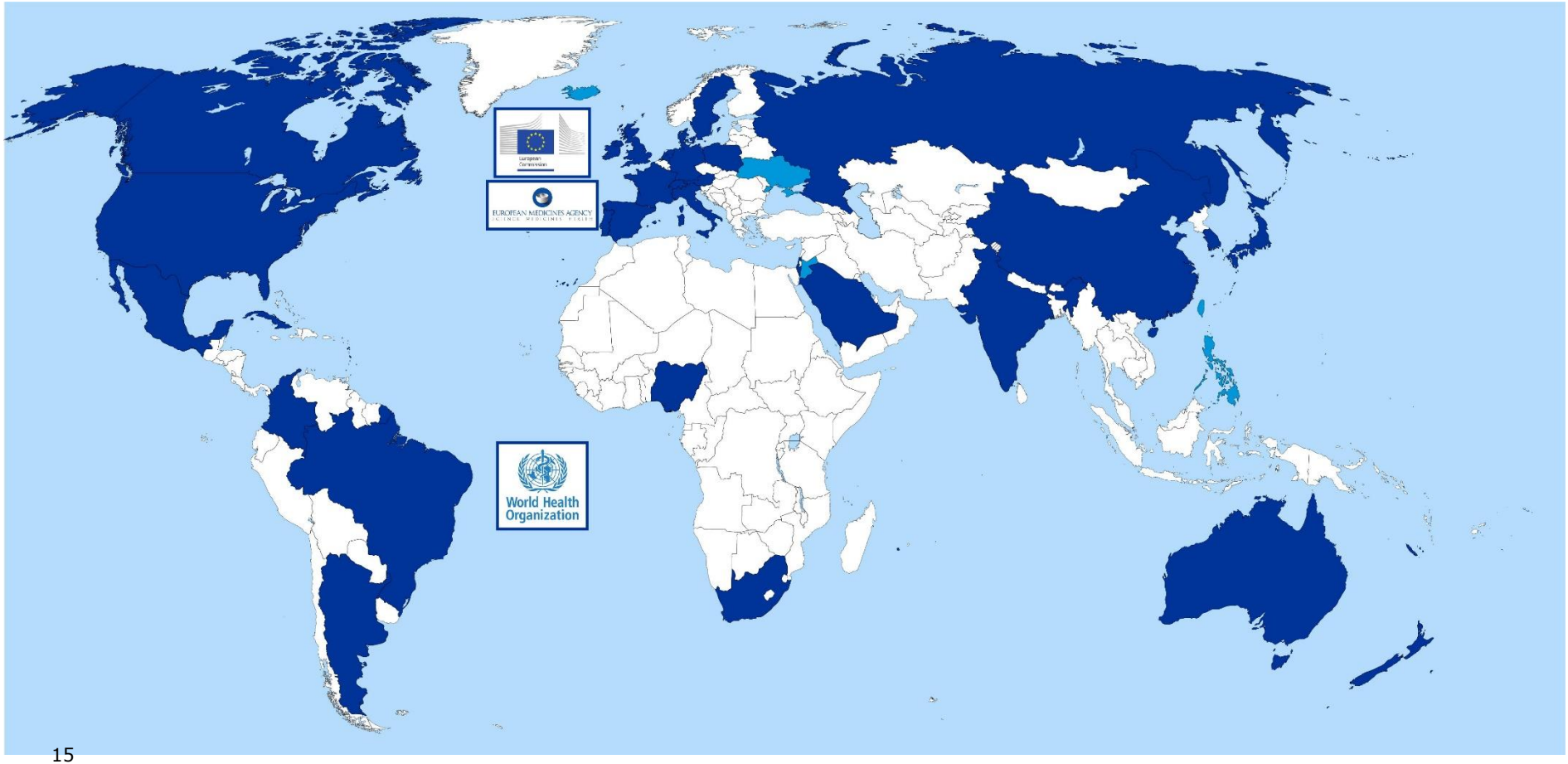
- CHMP carries out t… experts and non-E…
- EMA publishes two …

#3 International collaboration – ICMRA

International Coalition of Medicines Regulatory Authorities

- Informal group of leaders of medicines regulatory authorities that provides strategic directions for enhanced collaboration, improved communication and approaches to jointly address common challenges
- 34 participating authorities, plus WHO as Observer (with more applicants coming)
- Representation from across all continents and regions
- Big focus on aligning and harmonizing the COVID-19 pandemic response
- Collaborating on other shared regulatory issues and challenges e.g. Track & Trace interoperability, AMR, AI, Big Data/RWE, etc.

ICMRA
International Coalition of Medicines Regulatory Authorities



#3 International collaboration – ICMRA
Collaborating in the global COVID-19 response

- Regular Policy TCs ensure sharing of information and promote convergence
- Vaccine Pharmacovigilance Network, including work on vaccine confidence
- Regulatory agility and flexibilities (with future work on sustainability)
- Digital transformation of GCP and GMP inspections and clinical trials
- Convergence on trial design for scientific and regulatory robust (actionable) results
- Workshops to promote convergence in regulatory approaches
  e.g. responding to virus variants; inclusion of pregnant and lactating women in trials; reinforcing pharmacovigilance collaboration; manufacturing PACs
- Targeted communications and statements - Biosimilars, Transparency, Vaccine confidence

http://www.icmra.info/drupal/

Making reliance and collaboration work

- COVID-19 has shown that international collaboration is needed more than ever
- Spectrum across which regulators cooperate (reliance, work-sharing, reliance, etc.)
- Transparency, with openness to dialogue and sharing, are key
- ICMRA works – the coalition of willing partners has been agile, collaborated to align approaches
- International collaboration makes parallel applications attractive regulatory strategy
- Reliance, work-sharing and recognition are 21st century collaboration models for all regulators, whether high- or low-resource settings
- Challenge is practical implementation and maintenance beyond Covid

Take Away Messages

- Unprecedented opportunity to move forward in a strategic manner
- Important to build on the learnings of Covid and maintain focussed agility to enable innovation and embrace new thinking
- Invest in EMA and the network to strengthen scientific excellence and reduce administrative burden – increasing use of digitalisation as well as training and capacity building
- Use the increased visibility of medicines regulation to break-down silo working and improve communication and interactions with new and old stakeholders (e.g. patients, health care professionals, health policy makers
- If not now, when?

Any questions?

Further information

[Insert relevant information sources or contact details as applicable.]

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