5. COVID-19 Lessons Learned

Joint report on the response to the Public Health Emergency

8th Industry Stranding Group, 25 March 2024

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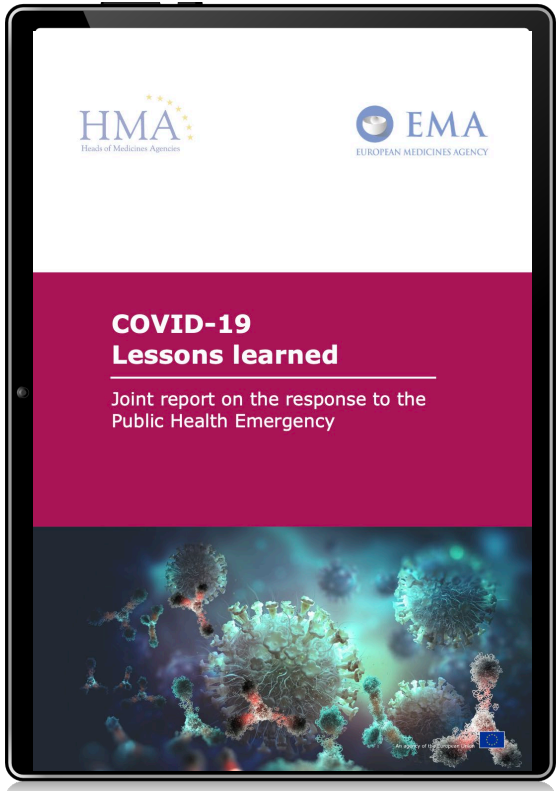
Outline

1. The EMRN’s response to COVID-19: context and milestones
2. Methodology for analysis of lessons learned
3. Areas where lessons learned have been identified
4. Lessons learned per area (*selection*)
5. Conclusions

EMA-HMA lessons learned from the COVID-19 Public Health Emergency (PHE)

- Report prepared on the basis of HMA-EMA analysis
- Describes key EMRN's activities in response to COVID-19
    - Includes tables with numbers of procedures and key activities
- Includes analysis of the lessons learned
- Endorsed by HMA and by EMA Management Board
- Published in December 2023



The EMRN's response to COVID-19: context & milestones

Scientific & regulatory mobilisation

- COVID-19 Task Force
- EU Network
- International

Development & evaluation

- Guidance to developers
- Early scientific advice
- Regulatory flexibility

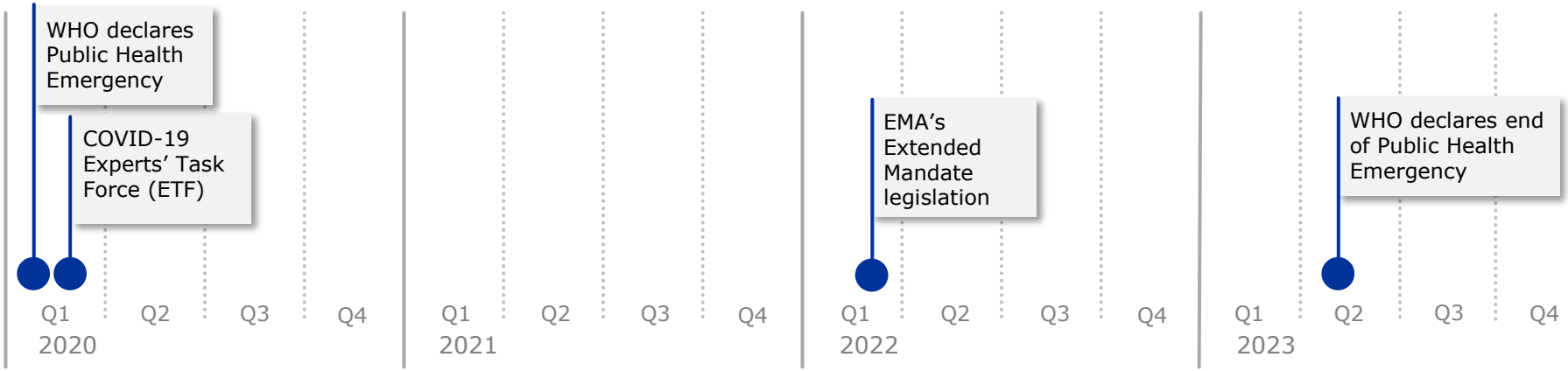
Essential medicines' supplies

- EU coordination
- Preventing shortages

Transparency & outreach

- Public engagement
- Communication

COVID-19 Public Health Emergency Jan 2020 - May 2023



HMA Heads of Medicines Agencies

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Inputs for analysis of lessons learned

Variety of methods for the collection and analysis of data and information on the response to the public health emergency

- **Internal analysis**
- Dedicated **workshops between EMA and HMA**
- Discussions with EMA's **Management Board**
- Discussions with the **Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)**
- EMA's contribution to the **EC's lessons learned** exercise - basis for the new regulation on EMA's reinforced role
- Interaction with **ECDC**
- Informal **EMA-HMA Strategic Resource Oversight Group**
- Discussion of early learnings and lessons learned exercise with civil society representatives, including **patients, citizens, healthcare professionals and industry stakeholders**

Areas where lessons learned have been identified

Crisis preparedness	Support to the development and approval of medicines	Regulatory framework and procedures	Scientific recommendations and public health activities beyond EMA's core remit	Clinical trials and Real-World Evidence
Safety monitoring	Medicines' supply and shortages	Network coordination and resourcing	Global collaboration	Transparency, stakeholder engagement and communication

Discussed today

Not discussed today

LESSONS LEARNED PER AREA

Support to development and approval of medicines

- Obtaining **comprehensive and systematic information** relevant to medicines development is key to provide support efficiently
  ETF working on preparedness in cooperation with partners
- Provide **agile feedback** and engage in regular dialogue with medicines developers
  now formalised in EMA's extended mandate
- **Prioritise the rapid assessment of the most promising candidate medicines**, taking into account the public health urgency
  role for ETF & EMA committees
- Ensure **review approach takes into account level of maturity of products and any major blocking factor(s)**, to avoid premature applications detracting resources from other assessments
  opportunity in Pharma Review
- Plan work **beyond the emergency period, to address long-term effects**, e.g. the need for medicines for Long COVID
  Ongoing

LESSONS LEARNED PER AREA

Regulatory framework and procedures

- Consideration of an EU level mechanism such an **emergency use authorisation**, which would provide more flexibility and complement the CMA Temporary Emergency Marketing Authorisation (TEMA) proposal in Pharma Review
- **Rolling review** is a key tool enabling prompt assessment outcomes to be maintained in future crises, with more selective criteria to determine pace of review for different products
- A similar stepwise **early review may also be considered for some high priority products for unmet patient needs** (e.g., PRIME) outside of the crisis setting proposal in Pharma Review
- A further **update of EMA's health threats plan** is planned to update process for rolling review and other accelerated procedures in a crisis context based on COVID-19 experience

LESSONS LEARNED PER AREA

Network coordination and resourcing

- Maintain a **common executive level forum for EMA, HMA and EC**, as well as a **dedicated scientific forum** for preparedness and crises formalised in MSSG and ETF
- Ensure **close coordination with scientific committees** and obtain their early strategic input into crisis response foreseen through ETF and scientific committees' Chairs
- **Prioritise products requiring resource-intensive rapid procedures** and additional support and identify the **procedures that need to be safeguarded** to avoid delays and ensure business continuity ongoing
- **Raise and maintain awareness of the EMRN's resourcing issues** and work with other partners to ensure long term resourcing and expertise ongoing through EMA-HMA strategic and operational groups on resourcing

Actions taken to address resourcing challenges

RESOURCING

- Informal EMA – HMA/NCA groups:
  - Strategic Resource Oversight Group
  - Operational Resource Planning Group
- Expanding the involvement of experts, e.g. through European Specialised Expert Communities (ESECs)
- Reinforcing training for the network
- Joint Action IncreaseNET

EFFICIENCY

- Foster use of multinational assessment teams (MNATs)
- Streamlining of the templates and documents
- Focus Group on Streamlining Lists of Questions
- Re-discussion of the approach to clock-stops
- Improving pre-submission interactions
- Tackling predictability and maturity of submissions – work ongoing with industry

LESSONS LEARNED PER AREA

Transparency, stakeholder engagement and communication

- **Apply extraordinary transparency measures** introduced during COVID-19 in future for future crises
- Monitor **public concerns and mis-disinformation** ongoing to strengthen our response to mis-disinformation
- Maintain **urgent communications underpinned by agile assessment by ETF/Committees** in future crises ongoing
- **Joint communications with the ECDC** were crucial for providing a complete perspective for future crises
- Set up a **crisis communication structure for rapid decision and update crisis communication plan** ongoing
- Maintain **regular press briefings and public stakeholder meetings** in crisis situations and explore more targeted way of reaching out to media and stakeholders ongoing
- Continue **research and user-testing activities** to develop optimised tools for communicating on benefit-risk, including data visualisation ongoing
- **Improve knowledge among communication officers** within the EMRN with trainings on crisis communication, tools and actions to increase transparency planned

Conclusions

Areas performing well

- **Regulatory** work and support to developers
  - **8 new vaccines** and 8 new therapeutics
  - Numerous procedures completed (SAs, EoIs)
- **Close cooperation** with MSs and partners
- Public health **advice beyond regulatory procedures**
- **Prompt identification of safety signals**
- **Enhanced transparency, communication and engagement**
- **Recognition** of the EMRN work during pandemic

Areas needing improvement

- **Larger** and more methodologically sound **clinical studies**
- Improve availability of **RWD sources**
- **EU level mechanism** for early availability of medicines
- **Ensure sustainability** for future crisis situations
- **Improve resourcing**, prioritisation and more streamlined processes to deal with the increased workload
- **Further strengthening of collaborations**, incl. for infodemic management

Access the report on our website

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Supplementary slides

LESSONS LEARNED PER AREA

Crisis preparedness

In preparation for future crisis, based on COVID LL and EMA's extended mandate, there is a need to:

- Update **crisis management processes, escalation routes and structures** Ongoing
- Further strengthen **horizon scanning of potential health threats** and relevant medical countermeasures
  Ongoing at level of ETF
- Have in place a leading structure to **centralise the relevant expertise for agile scientific and regulatory work**
  ETF now formalised
- Coordination and **information exchange with partners** remains key
  established with other EU bodies, international regulators and public health authorities (e.g., EC, ECDC, WHO)
- Ensure the EU Network has the **capacity to ensure a sustainable response** to an extensive crisis
  EMA-HMA Strategic Resource Oversight Group set up

LESSONS LEARNED PER AREA

Scientific recommendations and public health activities beyond EMA's core remit

- Continue **issuing scientific positions on urgent matters** not subject to formal regulatory procedures — role of ETF
- Engage in **activities beyond EMA's core regulatory mandate** when dictated by public health needs, with increased interaction with academia, governmental bodies and NGOs — to be applied in future crises
- Further strengthen **cooperation with the EC, ECDC, and national bodies, including NITAGs**, as well as HTAs — ongoing

LESSONS LEARNED PER AREA

Clinical trials and Real World Evidence

- Need to conduct **large clinical trials that are sufficiently powered and methodologically sound**
  ongoing in cooperation with partners (e.g., ACT EU)
- Establish regular interactions with **clinical trial networks in the EU and globally** planned for inter-PHE periods
- Proactively **put infrastructure in place for RWE studies** and identify early the need for such studies ongoing
- Continue developing the **framework for obtaining EU data from sources beyond companies** (**e.g., healthcare data)**
  ongoing through DARWIN EU and the Vaccine Monitoring Platform
- Obtain **data post-authorisation** in a timely manner, especially in **populations where evidence generation was challenging** pre-authorisation
- Continue **increasing expertise on RWD and RWE** in the EMRN, including investing in human resources ongoing
- Pursue ongoing efforts to develop capacity to analyse **individual patients' data from clinical trials** ongoing

LESSONS LEARNED PER AREA

Safety monitoring

- The **EU pharmacovigilance system is robust, fit for purpose** and has been particularly efficient promptly spotting and dealing with emerging issues
- **Spontaneous safety reports were crucial for early detection** of emerging safety concerns
- Reinforce **access to high quality and fit-for-purpose RWD** (e.g., healthcare systems) in a timely manner in various EU countries to complement safety monitoring, risk contextualisation and rapid evaluation of the risk-benefit balance ongoing
- Continue to operate a **robust yet flexible signal management process**, from data analysis to committee discussion and communication on a particular signal ongoing
- Further modernise **EU Pharmacovigilance IT tools for increased data integration** to support advanced analytics, group risk assessment, data visualisation and communication ongoing
- Ensure **networks of data sources** for preparedness and in crisis (e.g., Vaccines Monitoring Platform) ongoing with collaboration of stakeholders and public health bodies
- Conduct **studies into pathophysiological mechanisms leading of adverse events of special interest (AESIs)** to provide adequate management and mitigation strategies planned

LESSONS LEARNED PER AREA

Supply and shortages

- Continue key role as **central EU coordinator on medicines availability and shortages**, which has been formalised in EMA's extended mandate ongoing
- Maintain **measures for extending supply capacity and additional regulatory flexibility** tools (e.g. labelling flexibilities) to be agreed by the MSSG
- **Balance resource capacity with the expected public health impact** when prioritising resources for additional support to increase supply capacity ongoing
- **Improve efficiency of GMP compliance assessment**, with stronger reliance on inspections conducted by trusted international partners ongoing

LESSONS LEARNED PER AREA

Global collaboration

- Maintain efforts to **facilitate global alignment on regulatory requirements**
  ongoing through cluster collaboration with partners and global discussion such as ICMRA or COVAX
- **Strengthen international cooperation** ongoing through ICMRA, continuation of OPEN, etc.
- Develop **IT tools to share information more efficiently** and foster reciprocity of information exchange planned
- **Strengthen expertise** e.g. by real-time exchanges with partner regulators