EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on lessons learnt from COVID-19

PCWP/HCPWP meeting with all eligible organisations on 15 November 2022

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An agency of the European Union

Outline

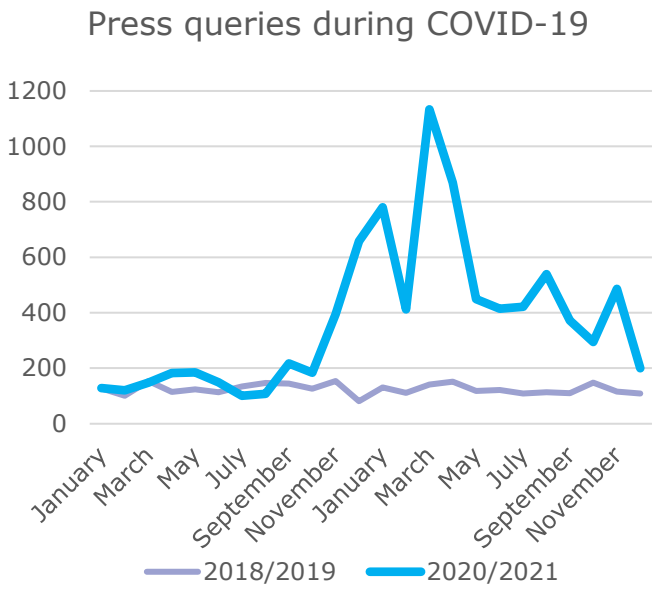
- Impact of the COVID-19
- Focus areas of lessons learnt
- Some preliminary conclusions
- Priority areas for future

Some of the impacts of COVID-19 on EMA

Need for new medicines

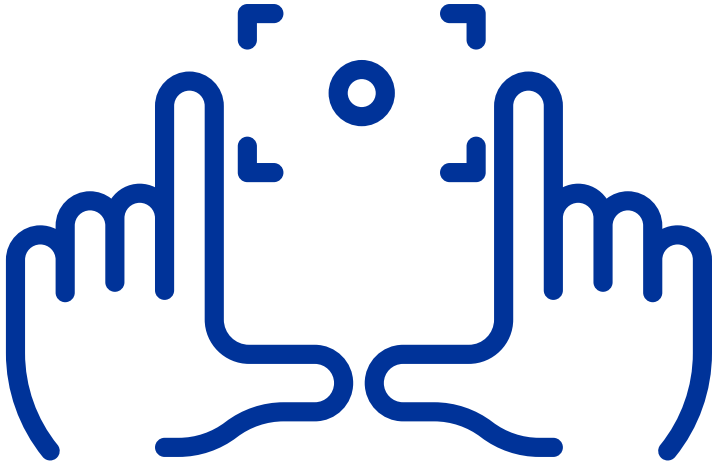
The lockdown

Interest in EMA's work



Main areas covered

- **COVID-19 products**: development, authorisation, monitoring and expanding supply, as well as related processes
- Managing **workload** and resourcing
- **Cooperation** within the network and with various partners and stakeholders
- Addressing important public health aspects **beyond core regulatory tasks**
- **Communication** and transparency



Some preliminary conclusions

Some preliminary conclusions – **what worked well** (1/2)

For **medicinal products** for prevention and treatment of COVID-19, EMA:

- Offered **enhanced presubmission dialogue**
- For promising candidates conducted agile assessments, leading to **prompt authorization and updates**
- Enabled rapid review of change for expansion of **supply capacity**
- Ensured close **safety monitoring**

Significant procedural **delays were avoided**, despite major workload and resourcing challenges

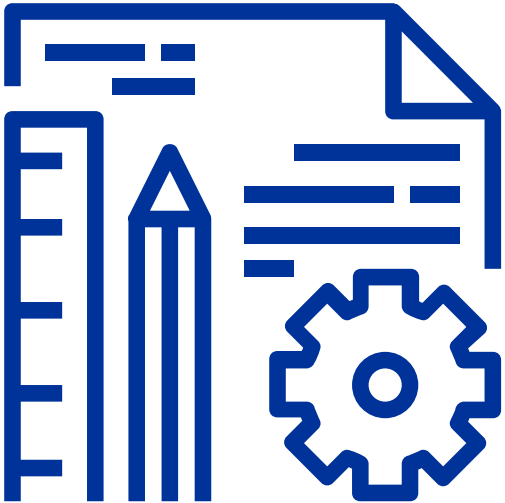
Some preliminary conclusions – **what worked well** (2/2)

- EMA had unprecedented visibility and was able to address the **communication** needs
- On basis of ETF work, EMA provided **public health advice** addressing pressing public health needs beyond the scope of core regulatory approval
- Close and strengthened **cooperation** and coordination with MS authorities, EC, ECDC and international partners
- EMA's role was recognized in a **formal extended mandate**, covering also medicine shortages and some medical device aspects

Some preliminary conclusions – **what we'd like to improve**

- Need for large **clinical studies** that can provide timely and meaningful results
- Need to extend available **sources of data** and improve IT systems for processing it
- Need to reserve resource-intensive measures to **most promising medicines**
- Need for a **capacity** 'reserve' and more streamlined **processes** to deal with increased workload, need to increase capacity in certain areas
- Need for **reinforced cooperation** with other partners, e.g. NITAGs
- Develop further elaborated approaches to **communication**

Selected priority areas for future



Medicinal product assessment

- Work on improving timely **availability of data post-authorization**, incl. DARWIN, EU Vaccine Monitoring Platform, reflection on studies requested from MAHs
- Improve **timely availability** of early (preliminary) data in an emergency situation
- Reflect on the role of **rolling reviews** and other flexibilities used during the pandemic, incl. prioritization of eligible products
- Improve the operation of **assessment related processes** – predictability and maturity of submissions, efficient ways to raise and clarify blocking issues, rationalize further the review process and documentation
- Tackle **resourcing** challenges – improved and more coordinated resource planning and allocation, strengthened training, extended use of multi-national assessment teams' approach, expand the pool of available experts

Engagement with partners and stakeholders & communication

- Strengthen cooperation with **NITAGs** (with engagement of ECDC)
- Strengthen engagement with developer and 'owners' of **repurposed products**
- Establish networks, processes and technical solutions for **enhanced data gathering from partners** *(see also medicinal product assessment)*
- Pursue work to ensure **common messages** with partners
- Reinforce the framework for ensuring **agile scientific assessment to underpin communication** messages addressing urgent public health needs (mainly through ETF)
- Strengthen **support to** enable **tailored communication** at national level
- **Leverage high public attention** to convey communication messages and sustain regular engagement with media
- Consider how to further strengthen **approach to communication**, incl. elaborated data visualization, user testing, best ways of counteracting misinformation
- Maintain and expand **increased transparency**

Any questions?

Further information

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