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EU network vaccine monitoring strategy

ENCePP in the Time of Covid 19 - **20/11/2020**

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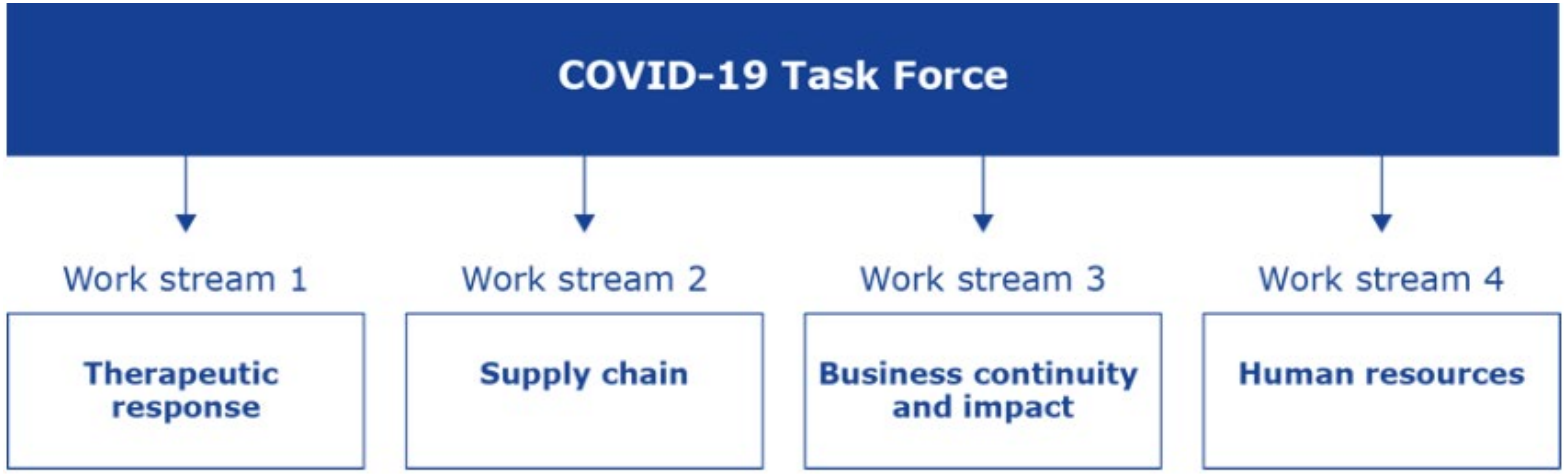
Presentation Outline

- EMA Approach to the Pandemic
- Enhanced EU Safety Activities in the context of COVID-19
- COVID-19 Vaccines Monitoring Preparedness

EMA Approach to the Pandemic

COVID-19 EMA pandemic task force (COVID-ETF):

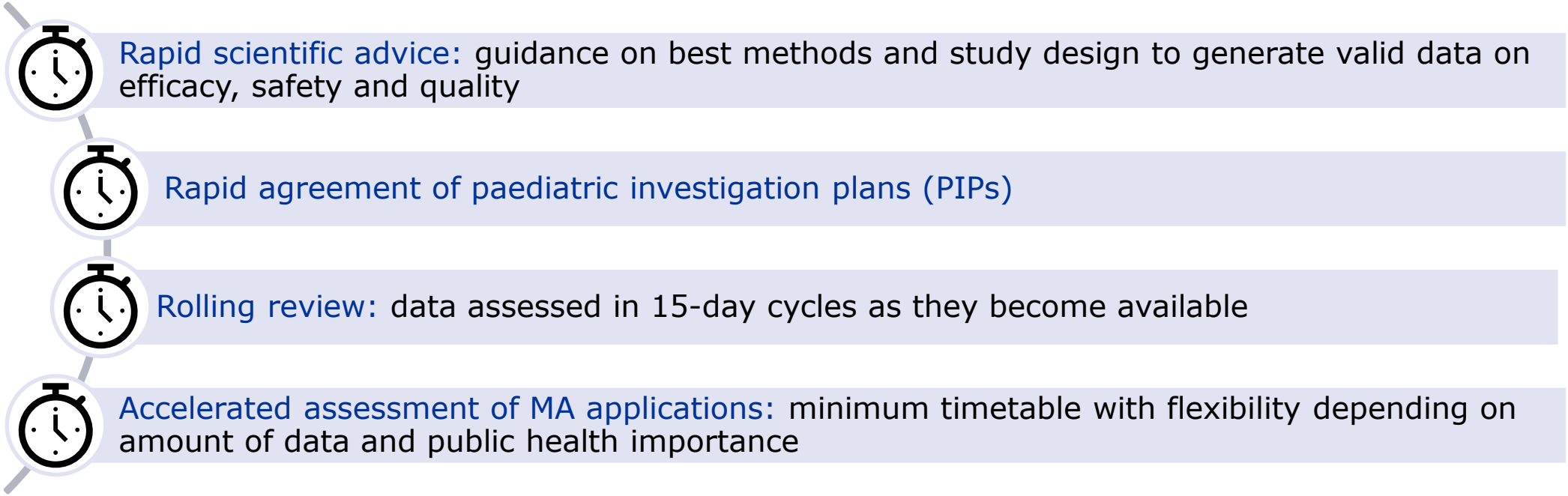
- EMA scientific committee and working party members expert in vaccines, infectious diseases, preclinical and clinical trial design, paediatric aspects, quality of biological medicinal products
- Support to the development, authorisation and supervision of medicines and vaccines
- Deal with the scientific, regulatory and operational challenges created by the COVID-19 pandemic



EMA Approach to the Pandemic

- Regulatory procedures adapted to grant marketing authorisation (MA) of safe, effective and high-quality COVID-19 vaccines and therapeutics as soon as possible

- Fast reviews supported by COVID-ETF coordinates and enables fast regulatory actions on development, authorisation and safety monitoring of treatments and vaccines intended for COVID-19:



COVID-19 Vaccines Monitoring Preparedness

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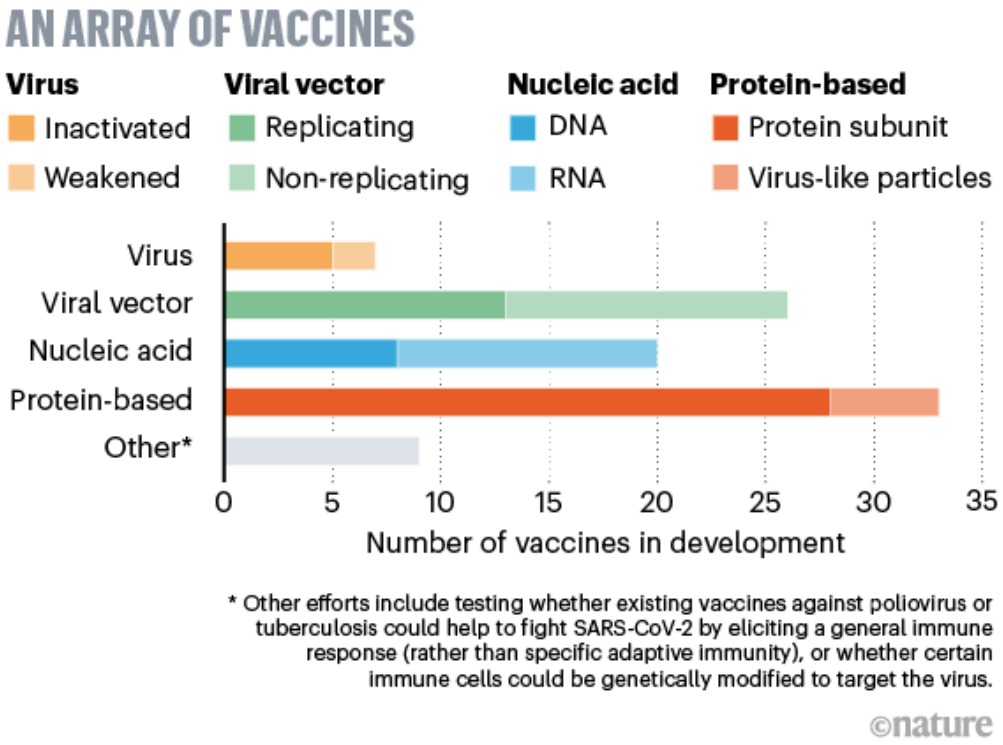
- Potentially many different vaccines, **new technologies**
- **Accelerated** development and approval
- **Rapid vaccination** to occur in millions or billions
- **Safety critical**: Unexpected or rare serious ADRs could negatively affect vaccination campaigns and increase vaccine hesitancy
- Regulators need to demonstrate to have systems in place to rapidly **detect** and **minimise** serious risks to patients
- **Transparency** and **communication** will be key

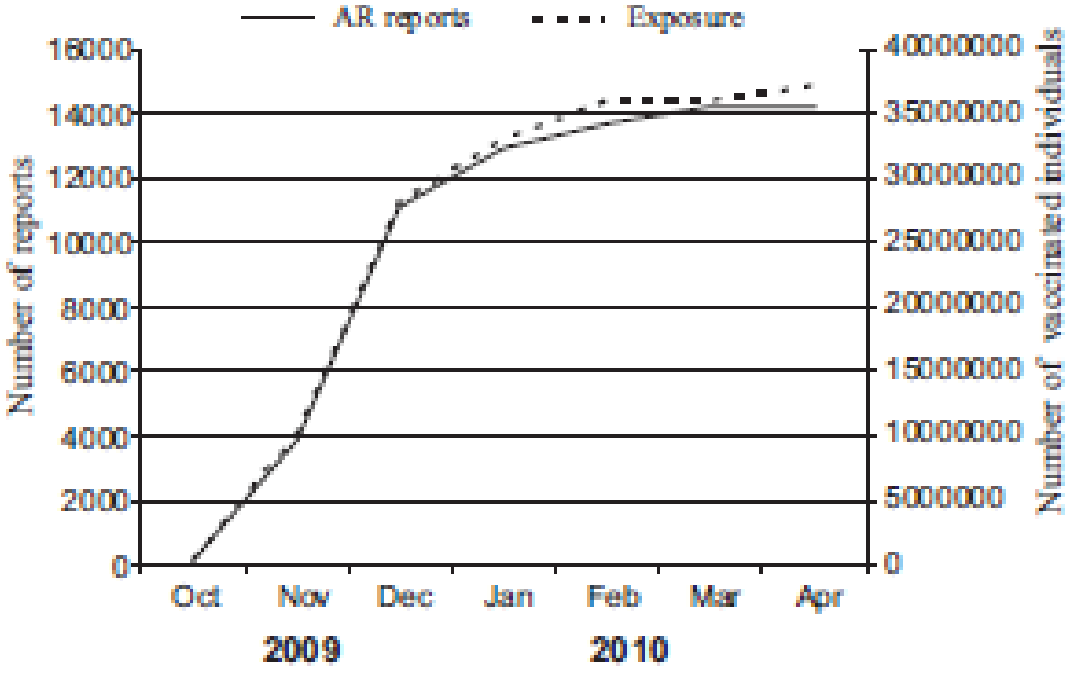


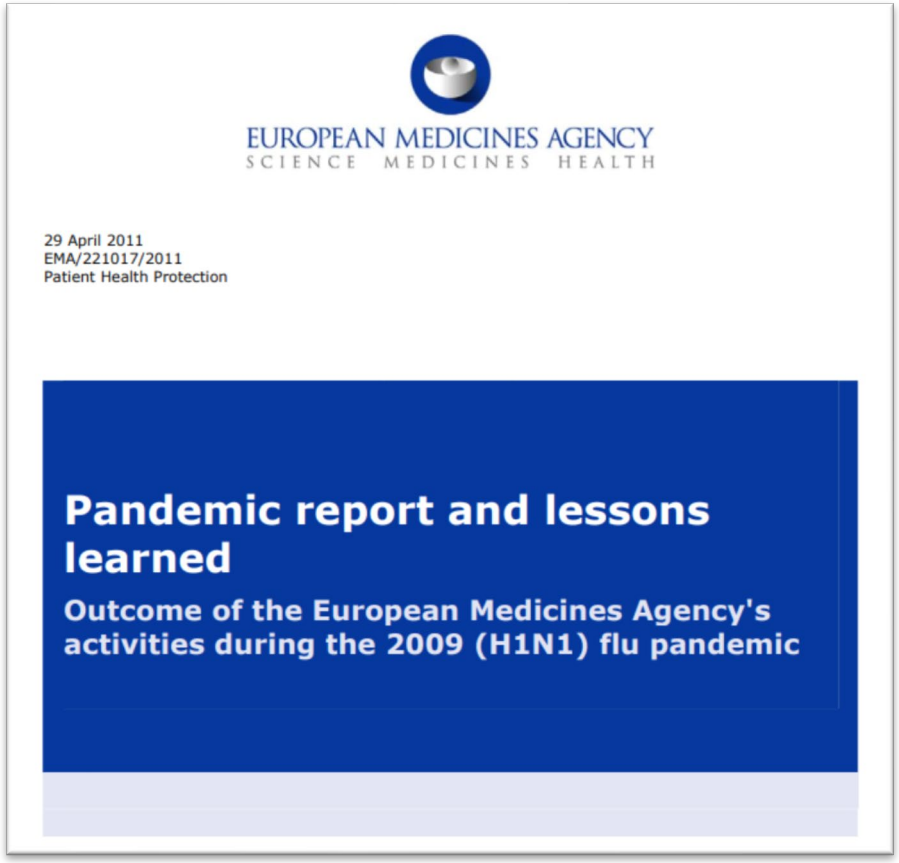
Enhanced Safety Monitoring of Medicines Used In Treatment of COVID-19

A range of pharmacovigilance measures have been put in place:

- ✓ Detailed guidance on individual case safety reports (ICSRs) in the context of COVID-19
- ✓ Call for ADR reporting to HCP and patients
- ✓ Updated guidance on conduct of clinical trials during pandemic to stimulate SUSAR reporting in EV
- ✓ Stimulate reporting in EudraCT: reminders sent to NCAs, sponsors reminded to include "COVID-19" in titles
- ✓ Encouraged registration of observational studies related to the pandemic in EU-PAS Register
- ✓ Dedicated eRMRs (EudraVigilance safety monitoring reports) with increased frequency
- ✓ Close monitoring of ongoing observational studies and sharing information to network on a weekly basis
- ✓ Reduced timeframe for confirming urgent COVID-19 related signals
- ✓ CoreRMP19
- ✓ Monthly summary safety reports from manufacturers post approval (in addition to 6 monthly PSUR)

Lessons have been learned from A/H1N1 pandemic vaccination campaign, but more uncertainties and fast introduction of COVID-19 vaccines after approval

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29 April 2011
EMA/221017/2011
Patient Health Protection

Pandemic report and lessons learned

Outcome of the European Medicines Agency's activities during the 2009 (H1N1) flu pandemic

COVID-19 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 existing and new **methodologies** specific for COVID-19

COVID-19 Vaccines Monitoring 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

Pharmacovigilance Plan of the EU Regulatory Network for COVID-19 Vaccines

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- Uses the established pharmacovigilance system of the EU regulatory network
- Adapts pharmacovigilance activities to the pandemic situation

- Content:
  - Risk management plans, safety update reports, exposure data
  - Observational research
  - Spontaneous reporting of suspected adverse reactions
  - Signal management
  - Information exchange, communication and transparency
  - Capacity building

- Published 13/11/2020; To be kept up to date with evolving knowledge and experience

https://www.ema.europa.eu/en/documents/other/pharmacovigilance-plan-eu-regulatory-network-covid-19-vaccines_en.pdf

Real-World Monitoring of COVID-19 Treatments and Vaccines

EMA review of study results

- **Daily triage** of published studies
- **Reviews** e.g. ACEi/ARBs and HCQ to support regulatory decision making
- Use of **EU PAS Register** to support collaborations and quality of studies

EMA-funded projects

- Framework for COVID-19 **vaccine monitoring**
- Framework for **multi-centres collaboration** for observational studies
- **Pregnancy** study on effects of COVID-19 infection and treatments
- Nov. 2020. Launch of study: **Early safety monitoring of SARS-Cov-2 vaccines in the EU MS**

International Collaboration (ICMRA, WHO)

- Preparation for **vaccine safety monitoring** (lead MHRA/TGA)
- Building **international cohorts** facilitating multicentre observational studies (lead Health Canada)
- **Pregnancy research** to support regulatory decision-making (lead EMA)
- WHO: Focus Group 4: Vaccine Authorization and Safety Monitoring

Core Risk Management Plan for COVID-19 Vaccines – Guidance for vaccine developers and marketing authorisation applicants/holders

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- Guidance for planning pharmacovigilance activities and risk minimisation measures
- Add-on to the requirements in the good pharmacovigilance practices (EU-GVP)

- Content:
  - COVID-19 specific-topics in the safety specification, including missing information and adverse events of special interest (AESI)
  - Content and periodicity (monthly at the beginning) of summary safety reports
  - Specific elements for designing post-authorisation safety studies (PASS) for rapid data generation, also using results of ongoing EU efforts
  - Signal detection adapted to pandemic use of the vaccine
  - Stickers for product and batch traceability – additional electronic methods to be considered

- Published 13/11/2020; To be kept up to date with evolving knowledge and experience

https://www.ema.europa.eu/en/documents/other/consideration-core-requirements-rmps-covid-19-vaccines_en.pdf

Transparency and Communication

- **Timely communication** and high level of **transparency** critical to ensure public trust in vaccines and protect public health
- Engage and communicate with **public**, **patients** and **HCP**
- **Exceptional transparency measures**
- **Regular public safety updates**

Regulatory procedure	Standard practice	COVID-19 medicines
Compassionate use opinion	Published in Compassionate use after CHMP opinion	News announcement published within 1 day of CHMP opinion
Start of rolling review	Not applicable	News announcement published within 1 day of start of review
Marketing authorisation application	Active substance and therapeutic area listed in Medicines under evaluation	News announcement published within 1 day of application
Application for extension of indication	Not announced	News announcement published within 1 day of application
Publication of European public assessment report (EPAR)	Published at least 2 weeks after marketing authorisation	Published within 3 days of marketing authorisation
Product information	Published in all EU languages with EPAR	Published (in English) within 1 day of positive CHMP opinion; published in other EU languages with EPAR
Risk management plan (RMP)	Summary of RMP published	Full RMP published
Clinical trial data	Publication suspended until further notice	Published on Clinical data website after marketing authorisation

Key Messages

- COVID-19 pandemic presents a major public health challenge – we need to be prepared and we are all committed to a common goal
- Unprecedented collaboration and unprecedented interest and scrutiny
- Regulators need to rise to the challenge and demonstrate to have systems in place to rapidly detect any safety issues and minimise serious risks to patients
- Timely exchange of information, transparency and communication are critical

Any questions?

Thank you for your attention

Further information

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