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EU Regulatory Network: Lessons learned from the Pandemic

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Early lessons learnt from the pandemic

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- Weak or suboptimal preparedness plans and modelling
- Vulnerabilities in global supply chain
- Insufficient oversight of manufacturing capacities and research priorities
- Responsibilities partly unclear, especially for medical devices
- Concentration of resources on Covid 19 procedures, bottlenecks in other procedures

BUT

- We reached a lot and the Network did - and is doing – a great job!

- AND we worked closely together!

Virtual meetings – some we will keep

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- Webex, Teams, Zoom, ….
  - Hybrid meetings
- Adapted rules of procedure
  - MB-Meetings, HMA meetings
  - Committee meetings
  - Stakeholder meetings
    - Election of the executive director of the EMA
    - 25 years celebration
  - …..
- Mid Oct 2021 – again start of F2F meetings (if possible)

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EMRN – European Medicines Regulatory Network

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- A strong network between all HMA, EMA and EC, co-chaired by HMA and EMA.
- EMRN - absolutely essential to handle all the challenges and tasks in the regulatory pharmaceutical field.
- EMRN meetings on technical aspects related to the scientific assessment of COVID-19 treatments (vaccines and therapeutics)
  - on a weekly basis
  - facilitate the preparedness for and implementation of the EC Decisions at national level
    - Handling of the pandemic made clear that the differences in the health systems across the EEA result in challenges
    - They require action at political level
    - Challenges particularly when the EMA conclusions are implemented differently by the MSs in the context of their national vaccination strategies

Increase in Workload for the Network

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Rapid formal review procedures related to COVID-19

Speed!

Necessary to adapt processes to ensure a rapid response to the COVID-19 pandemic whilst maintaining core regulatory activities to protect public and animal health in the EU

- 1.Rapid scientific advice
- 2.Rapid agreement of a paediatric investigation plan and rapid compliance
- 3.Rolling review
- 4.Marketing authorization
- 5.Extension of indication and extension of MA

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↑ Formation of Multi National Assessment Teams

COVID-19 guidance: evaluation and marketing authorisation

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- Experts assessed applications for COVID-19 medicines under the **minimum timeframe** necessary to allow for a **thorough evaluation of the medicine's benefits and risks.**

- The rapid procedures can accelerate every step of the regulatory pathway while ensuring that **robust evidence** on **Q/S/E** is generated to support scientific and regulatory decisions.

- They are available for **initial marketing-authorisation applications** for the treatment or prevention of COVID-19, as well as for applications to 'repurpose' medicines already authorised for other conditions, by extending their indication to include COVID-19.

Rolling Review (1/2)

For Covid19 therapeutics and vaccines

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- The review takes place while development is still ongoing
- Several rolling review (RR) cycles can be carried out during the evaluation of one product while data continue to emerge.
- Each cycle is pre-agreed between EMA and the applicant; when the data package is complete - the applicant can submit a formal MAA - shortened timetable

Rolling Review (2/2)

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- Don´t submit pre-mature dossiers!
- RR won´t be possible for all applications in the centralized procedure

EU: Conditional Marketing Authorisation (CMA)

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Until Covid 19 – CMA not granted for vaccines, but

CHMP may issue a positive opinion for a CMA, if all of the following **criteria** are met:

- the **benefit-risk balance** of the medicine is **positive**;
- it is likely that the applicant can provide comprehensive data post-authorisation
- the medicine fulfils an unmet medical need;
- the benefit of the medicine's immediate availability to patients is greater than the risk inherent in the fact that additional data are still required.

➢ CMAs are **valid for one year** and can be renewed annually.

➢ Once a CMA has been granted, the MAH must fulfil **specific obligations** within defined timelines - completing ongoing or new studies

⟹ Post-marketing activities are very resource intensive for the network!

Ressources in the EU-network are limited

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EMRN - COVID-19 Business Continuity Plan, Additional measures to allow experts to focus on COVID-19 activities (11 May 2021)

- Principles:

Resources are highly focused on the review of COVID-19 vaccines and therapeutics, and the rigorous safety monitoring of these medicines

Always maintaining the robustness of its scientific evaluations (Q/S/E)

Maximum flexibility with timetables or temporary changes of Rapporteurs for non-COVID-19 procedures

Importance of the EU pharmacovigilance system

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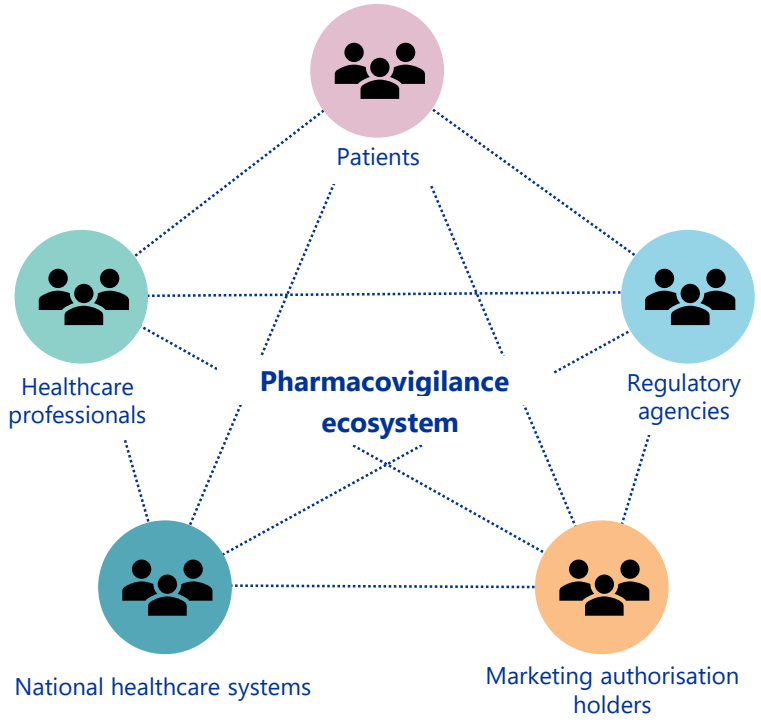

- All medicines, including vaccines, have **benefits and risks**
- **At the time of approval:** evidence comes mainly from controlled, randomised clinical trials
- **After approval:** medicines will be used in real conditions by a far larger population
- **Safety monitoring** after approval is important **to identify** any new or changing risk as quickly as possible, and **take action**
- Due to large number of people vaccinated in a short time we need to ensure safety monitoring **reacts quickly**

- ➢ Reporting suspected side effects following vaccination is critical
- ➢ All reports are sent finally to EudraVigilance
- ➢ Evaluation by the PRAC – recommendations published

EU Executive Steering Group on Shortages of Medicines Caused by Major Events

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- Regular meetings (HMA, EMA & EC) and open meetings with industry
- Monitoring shortages
- Forecasting demand for medicinal products in the EU/EEA

  - **Reflection paper / Pilot phase**
    - A pilot phase of demand forecasting was restricted to 5 ICU medicines
    - Forecast to cover a **6-month** period (November 2020 to April 2021)
    - To report: total demand forecast:
      - *COVID-19 patient needs,*
      - *non-COVID-19 patient needs.*
    - On 3 June 2021 EMA published recommendations to forecast demand of medicines,
    - The reflection paper summarises best practices that can help develop accurate forecasting of demand for human medicinal products across the EU and at national level for emergencies which require to forecast demand for medicines

Joint procurement procedures

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- **For the first time in the EU!**
- **Important: separation between assessment and procurement**
  - Not within the same unit!
  - Different responsibilities
- **Goal:** to secure a certain amount of specific medicinal products for Europe
- 1 st joint procurement of a Covid 19 medicinal product:
  - Veklury (Remdesivir)
  - Pros and cons
- Vaccines
- MABs

EMA (& ECDC) extended mandate

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The Commission has also learned its lessons from the crises

EC legal proposal (for EMA):

- Key areas:
  - Monitoring and mitigating shortages of critical Medicinal Products (MPs) and management of major events
  - Monitoring and mitigating shortages of critical medical Devices (MDs)
  - MPs with the potential to address Public Health Emergencies
    - Emergency Task Force (ETF)
    - Legal bases for DARWIN (Data Analysis & Real World Interrogation Network)
    - Vaccine monitoring Platform
  - MDs Expert panels

DARWIN EU - Importance of data!

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- DARWIN EU vision:
  - Establish a **network of data, expertise, and services**, that supports better decision-making throughout the product lifecycle with reliable evidence from real world healthcare data.
- DARWIN EU: Benefits
  - DARWIN EU will significantly **increase the capacity** of the Network to undertake high-quality observational studies based on real-world data**.**

National and EU **regulation of medicines**:

Drug development – disease epidemiology, unmet need, historical controls, planning

Authorisation – contribution to BR, controls, extrapolation to general and/or special populations

Post-authorisation – benefit-risk monitoring, extension of indication, risk minimisation measures

Conclusion

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- The pandemic situation has made us aware of all the problems and challenges we face.
- We have all moved closer together - despite social distancing - because only together within the network, we can face these challenges
  - and it is not over yet

- But we have to make sure that the good cooperation across borders is maintained, even if we don't see each other regularly F2F. We have to be careful that this cooperation between experts, EMA, member states and stakeholders doesn't deteriorate
- Learning from this experience presents an opportunity to shape the future role of medicines regulation nationally and at the EU level

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