



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PCWP/HCPWP workplan 2019-2022 and EMAN Strategy to 2025

Topic prioritisation for 2022

Presented by Ivana Silva on 22 September 2021
Public and Stakeholders Engagement

An agency of the European Union



Mandate 2019-2022 – overall objectives agreed in Sep 2019

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- Continue to engage in consultations where patients', consumers' and healthcare professionals' input can bring added value to **benefit-risk assessment and decision-making**
 - Contribute to EMA activities related to **information on medicines and communication with healthcare professionals and patients**
 - Support the continuous improvement of the operation of the **pharmacovigilance** system
 - Participate at key stages of **EMA policy development and implementation** as well as in other EMA initiatives aimed at supporting the **implementation of EU legislation**
 - Contribute to recommendations as identified within the **Regulatory Science Strategy to 2025**, as relevant



PCWP/HCPWP workplan 2019-2022

Shared areas of work

- Medicines development and evaluation
- Information on medicines
- Building trust and developing methodology
- Public health focus areas

PCWP

- Patient data generation
- Package leaflet
- ADR reporting

HCPWP

- Advances in clinical practice
- Education & research

EMAN Strategy to 2025

- Availability and accessibility of medicines
- Data analytics, digital tools and digital transformation
- Innovation
- Antimicrobial resistance and other emerging health threats
- Supply chain challenges
- Sustainability of the Network and operational excellence
- COVID-19 pandemic
- EMA extended mandate

EMA multiannual workplan for 2021-2024

Strategies (EMAN and RSS to 2025)

- Develop content strategy in key public health areas and hot topics, including evidence-based communication materials
- Develop and implement a stakeholder engagement and communication plan for crisis management and EMA's extended mandate

Public health activities – stakeholder interactions

- Identify suitable experts (patients and HCPs) and support their involvement in cross-agency procedures throughout the medicine's lifecycle
- Further develop external engagement and communications to raise awareness of EMA's work and promote trust and confidence in the EU regulatory system
- Maintain and foster PCWP and HCPWP as a platform for dialogue and exchange



- We need to **take stock of** mandate 2019-2022 and **prepare for** new mandate 22-25
 - Develop PCWP/HCPWP workplan 2022-2025
- **PCWP/HCPWP journey** since 2019
 - Topics for follow up
 - Emerging topics



Medicines development and evaluation



Areas for follow up: TBD

ICH E6 - organise dedicated discussion in 2022/2023 (public consultation phase)

ERNs; ATMPs; Personalised medicines

Big Data/RWD/Registries

Special populations strategies

Impact of PhV activities

Patient data generation

Medicines repurposing

New mandate 22-25

Planned workshops:

Patient data generation (June)

2022

Jun 21

Update on **Big Data**
Scientific advisory groups (patient satisfaction survey and open call for experts)

Nov 21

Discussion on workshop on **patient data generation?**

Mar 21

ICH guidance (GCP E6/E8; reflection paper on patient data)
ERNs in the European Health Data Space
Personalised medicines

Sep 20

Workshop on GDPR in **Secondary Use of Health Data** for Medicines
Workshop on benefit-risk of medicines used during **pregnancy and breastfeeding**

Mar 20

Introduction to review of **ICH guidelines** on general considerations for clinical trials and GCP

Sep 19

Impact of PhV activities – PRAC to work with WPs on where and how improvements can be made

Aspects related with **data sharing** to be further discussed

Early engagement on revision of GVP module XVI on **additional RMMs**

Input to draft guideline on **Registry-based studies**

ICH E6(R3) good clinical practice workshop with WPs

Update on HMA/EMA **Big data** task force recommendations and future actions

Big Data Steering Group to include WPs' representatives

Access to **ATMPs** – enhancing engagement with CAT

HMA/EMA **Big Data** Steering Group deliverables

DARWIN EU advisory board to include WPs' representatives

Update on GVP XVI on **additional RMMs**

Update on guideline on **Registry-based studies**

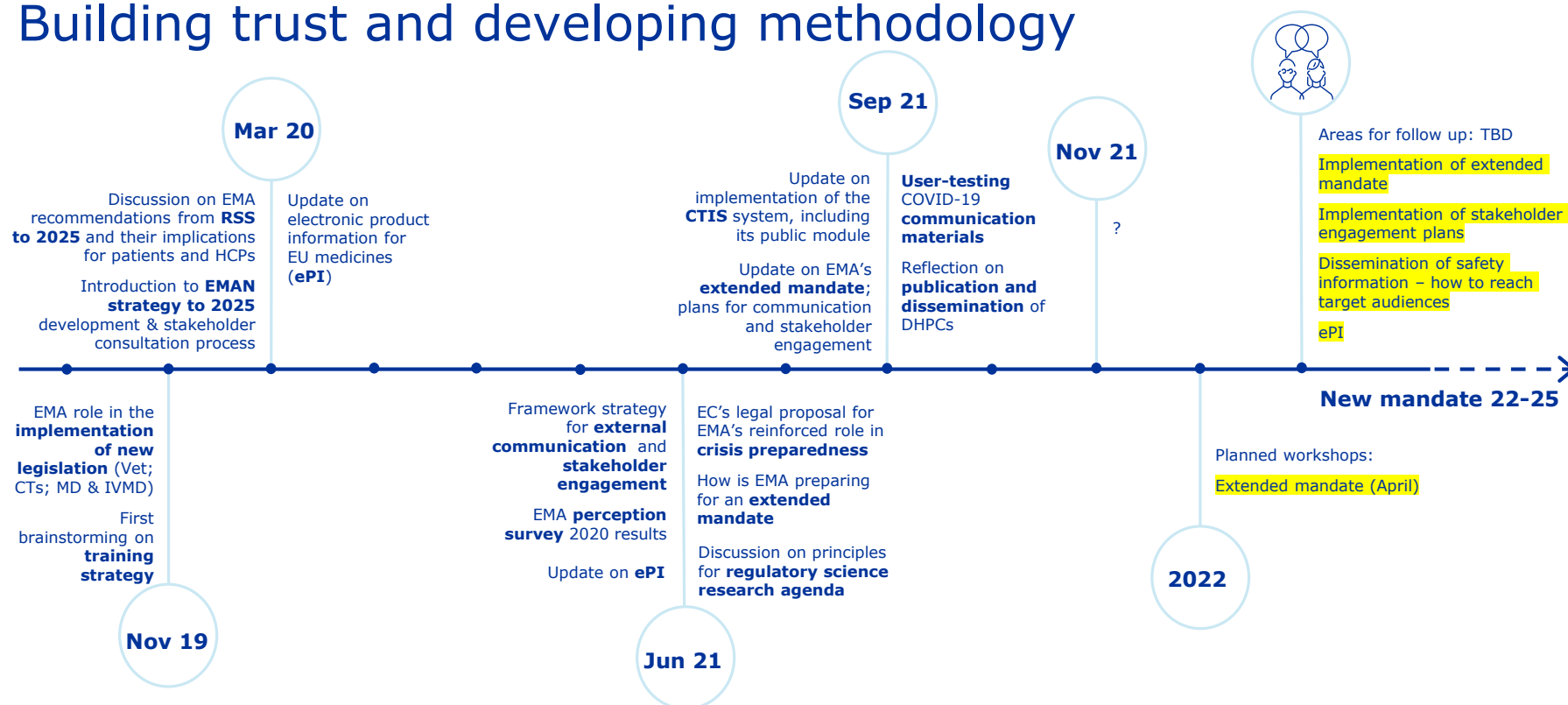
Sep 21

Jun 20



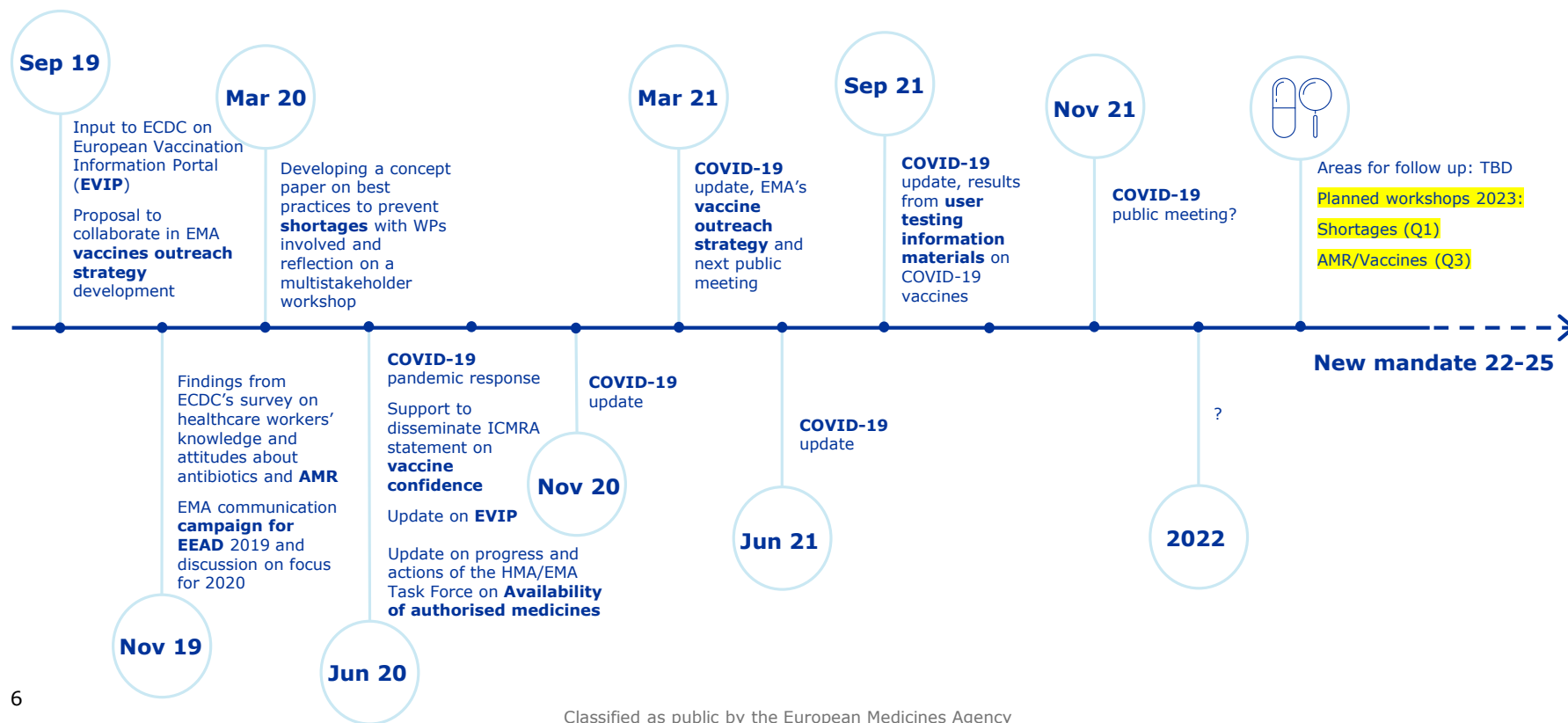
Information on medicines

Building trust and developing methodology





Public health focus areas





Any questions?

Further information

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