EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PCWP/HCPWP workplan 2022-2025: development and topic prioritisation

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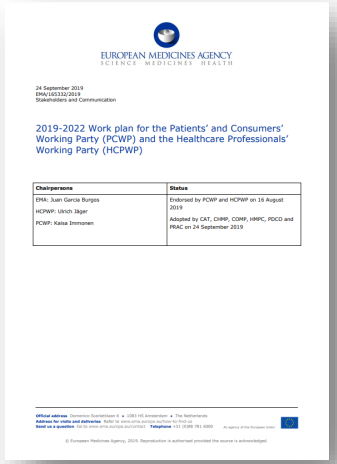
An agency of the European Union

Drafting the 2022-2025 Joint Work Plan



2019-2022 work plan

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EMAN and RSS

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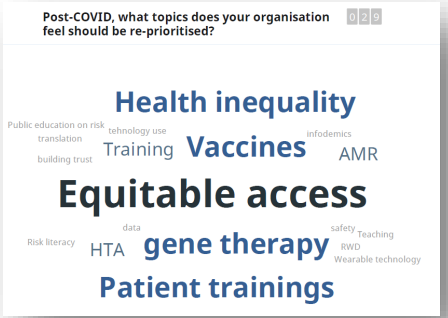
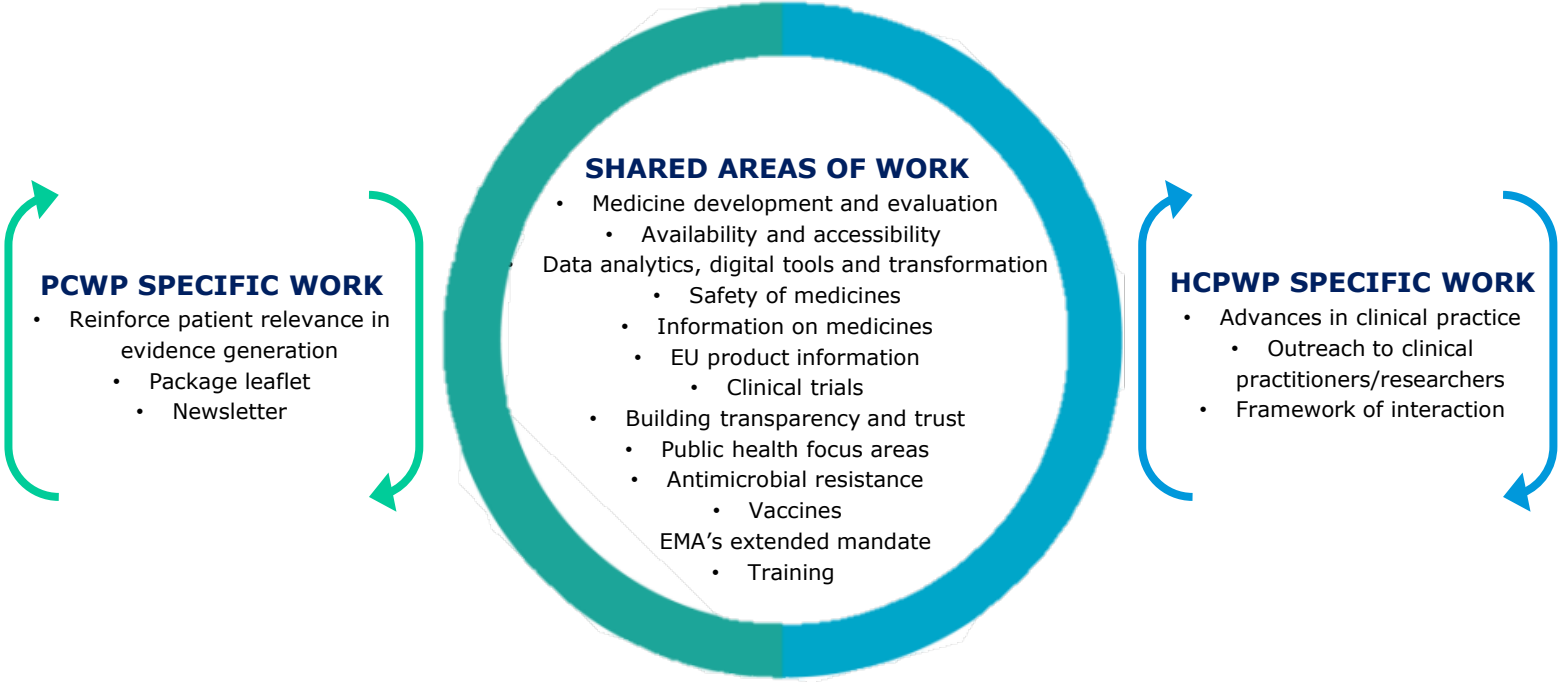


Slido feedback received

Work plan 2022-2025; structure



Overarching objectives for all actions

- Bring the patient, consumer and healthcare professional perspectives into EU/EMA initiatives and proposals
- Inform and reflect with EMA and WPs on advances in specific domains, initiatives and concerns of the respective stakeholder groups
- Raising awareness/communication – trust and transparency

Shared areas of work

Medicine development and evaluation

- Repurposing pilot, DARWIN EU, CTIS, ACT EU, CHMP pilot on early dialogue, patient experience data, pregnancy strategy, ICH PFDD guidance.

Availability and accessibility

- HMA/EMA task force on availability of medicines (TFAAM), multi-stakeholder workshop & webinar on shortages, collaboration with HTAs - EMA/EUnetHTA21, extended mandate: shortages steering group, monitoring platform.

Data analytics, digital tools and transformation

- Big Data initiatives: Big Data Steering Group, DARWIN EU Advisory Board, multi-stakeholder forum and workshops, data protection Q&A, ePI.

Safety of medicines

- PRAC points-to-consider on engagement, revision of GVP on risk minimisation measures (RMMs), enhance impact of safety communications

Information on medicines

- Implementation of EMA Action Plan to improve Product Information and user-testing, next phases of ePI project.

EMA communications for patients and HCPs

- Review and user-test EMA communication materials, disseminate EMA communications, identify needs and preferences for EMA communication materials

Shared areas of work

Clinical trials

- Implementation of the Clinical Trials Information (CTIS) system, workshop on ICH E6, consultations and training on ICH E8, ACT EU & its multi-stakeholder platform, policy on the publication of clinical data (policy 0070).

Public health focus areas

- Antimicrobial resistance: multi-stakeholder workshop, guidance on antimicrobial use and increase stakeholder understanding of new antimicrobials
- Vaccines: creation and user-testing of communication materials, combat misinformation & increase vaccine confidence, joint PCWP/HCPWP workshop on vaccines in 2024.

Crisis management & EMA's extended mandate

- Multi-stakeholder workshop on extended mandate, ETF, MSSG/ DSSG, implementation of communication and stakeholders' engagement plan on shortages.

Training

- Provide input to training materials supporting patient involvement in EMA activities, training strategy for engagement with patients, consumers, healthcare professionals and academia.

Building transparency and trust

- Communicate science behind EMA decisions, develop information materials and awareness raising campaigns for patients and HCPs, develop specific dialogue on topics of common interest.

Next steps:

Timeline	Action
End March	Working party members to comment on draft workplan
April	Share with CXMP for comments
May	Circulate final draft to working parties
June	Final presentation and adoption of workplan
July	Circulate to CXMP for adoption
August	Publication of 2022-2025 joint workplan

Any questions?