EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PCWP/HCPWP workplan 2022-2025

Mid-point implementation report

PCWP/HCPWP joint meeting

Presented by Ivana Silva on 27 February 2024
Public and Stakeholder Engagement Department

An agency of the European Union

PCWP/HCPWP shared workplan

57 actions across 10 strategic areas

- Completed/ achieved – 24/57;
  - Mostly under strategic areas 'Data analytics, digital tools and digital transformation' and 'Availability and accessibility of medicines'
- Ongoing/ work in progress – 23/57
- Clarification on action to be provided – 3/57
- More information needed to progress action – 4/57
- Not yet started/ requires more attention – 3/57
  - Mostly under strategic area 'Safety of medicines'

82% completed or in progress

Key topics addressed (1)

Medicines development and evaluation

- Biosimilars
- Patient Experience data
- Nitrosamines
- Scientific Committees updates

Clinical Trials

- ACT EU; multistakeholder platform
- Good clinical practice ICH E6(R3)
- ICH 21
- Decentralised CTs

Safety of medicines

- Reflection paper on digital support for risk minimisation
- PRISMA
- Pharmacovigilance report 2019-2022

Data analytics and digital tools

- Big Data workplan 2021-2023
- RWE activities and DARWIN EU
- Pilot on raw data analysis

Availability and access to medicines

- Task Force on Availability
- Reporting of shortages by organisations
- Workshop on shortages
- Guidance on prevention and communication
- Preparedness activities for autumn/winter
- EU list of critical medicines
- HTA related activities

Key topics addressed (2)

Information on medicines

- ePI
- Use of EMA communications
- Revision of QRD template for package leaflet (PL) improvement
- Mis- and disinformation

Crisis management and extended mandate

- Lessons learnt from COVID-19
- Medical devices
- Monitoring of events and preparedness for Public Health Emergencies/Major Events
- Clinical trials in emergency situation

Public health focus areas

- COVID-19 updates
- AMR

Transparency and trust

- Perception survey
- Stakeholder Engagement report
- Social media strategy
- Corporate website
- Involvement of patient and HCP representatives in various EMA groups
- EMA Working Party reorganisation

Training and support

- Feedback from the ATMPs dedicated webinar

Steering needed from PCWP/HCPWP

- What strategic areas to focus on after February 2024
  - Mandate ends in May 2025
  - Actions to be transferred to next mandate
- How to address (keep, remove, reword)
  - Clarification on action to be provided
  - More information needed to progress action
- Are there new emerging strategic areas/actions
- Feedback by 15 March

Medicines development and evaluation

Action	Status
WPs kept regularly updated and provide input on current and emerging concepts and methodologies used in the development and evaluation of medicines	∞
WPs consulted throughout development and implementation of EMA initiatives, proposals and guidance	∞
Members representing scientific committees to share highlights/ relevant committee initiatives	✓
WPs involved in ICH guideline development and updates specifically dealing with good clinical practice (GCP) and patient-focused drug development (PFDD)	✓
WPs are involved in scientific guideline development and updates	∞
Relevant topics identified by WP members will be included as agenda items for information and discussion in plenary meetings	✓
WPs to identify knowledge gaps and awareness-raising needs to inform on current and emerging concepts and methodologies used in the development and evaluation of medicines	∞
WPs to participate in EMA's Cancer Medicines Forum	i
WPs to be kept informed of relevant EMA actions that might arise in relation to the Healthier Together EU Non-Communicable Diseases Initiative	?

Clinical trials

Action	Status
WPs updated on implementation of the Clinical Trials Information (CTIS) system in context of Clinical Trials (CT) Regulation; WPs involved in the development and update of recommendations on reporting clinical trials	✓
WPs to identify and discuss issues around CT in a dedicated session (e.g. continued access to trial medicines, lay summaries for publication, informed consent and ethical requirements, ensuring representative patient samples, comparison against standard treatment, selection of endpoints and surrogate validation)	✓
WPs participation in workshop on ICH GCP E6 (R3) and follow up actions	✓
WPs informed of and involved in ACT EU multi-stakeholder platform	∞
WPs updated on progress of relaunch of EMA's policy on the publication of clinical data	!

Safety of medicines

Action	Status
WPs contribute to *EMA/Pharmacovigilance Risk Assessment Committee (PRAC) strategy on impact of pharmacovigilance activities* and continue enhancement of patient and healthcare professional involvement in PRAC activities, in particular the Engagement Workstream on risk minimisation measures and the points-to-consider on engagement	∞
WPs to further support engagement of patients and healthcare professionals in regulatory pharmacovigilance by: • Providing input in the finalisation of the revision of EMA GVP Module XVI on risk minimisation measures (RMMs)	∞
• Discussing any case studies related to safety concerns and possible RMMs implementation	∞
• Contributing to a reflection on how to enhance impact of safety communications	!
• Identifying knowledge and awareness gaps and providing relevant information to WPs	?
• Continuing to increase awareness on adverse drug reactions (ADR) reporting by healthcare professionals and patients/consumers	!

Data analytics, digital tools and digital transformation

Action	Status
Continue WP collaborations on Big Data initiatives: • representatives on the Big Data Steering Group and the DARWIN EU Advisory Board	✓
• participation in the annual multi-stakeholder forum and in relevant workshops (e.g. data quality, RWE analytics)	✓
• consultation on data protection Q&A	✓
WPs to be kept informed of progress and to provide input into next phases of electronic product information (ePI) set-up project	✓
WPs to promote awareness and provide input on the use of public interface of Clinical Trials Information System (CTIS)	✓
WPs to contribute to discussions on collection of real-world data from healthcare professionals and patients	∞

Availability and accessibility of medicines

Action	Status
WPs to be informed of progress and provide input, as needed, to the Heads of Medicines Agencies (HMA)/EMA task force on availability of medicines (TFAAM), with a particular focus on: • deliverables to improve prevention, management and reporting of shortages and their causes	✓
• multi-stakeholder workshop and webinar on shortages, public communication and transparency (e.g. workshop report and recommendations, shortages catalogue	✓
• use of 'Good practice guidance for patient and healthcare professional organisations on the prevention of shortages'	✓
WPs to contribute to the implementation of the Communication and Stakeholders' Engagement Plan on EMA's extended mandate for medicines and medical device shortages: • Observers on the Medicines/Medical Devices shortages steering group (MSSG/ MDSSG)	✓
• Provide input to development of the EU shortages monitoring platform and the lists of critical medicines and medical devices	∞
WPs to be kept informed and discuss progress of ongoing initiatives, such as biosimilars, repurposing of medicines, compassionate use and expanded access programmes, aimed at facilitating access to medicines	✓
WPs regularly updated on EMA's collaboration with HTA bodies	✓
WPs to identify knowledge and awareness gaps on HTA bodies' and EMA's practices and provide relevant information to WPs	∞

Information on medicines

Action	Status
WPs continue to support EMA in the implementation of EMA Action Plan to improve Product Information and user-testing	∞
WP to be kept informed of progress and to provide input into next phases of electronic product information (ePI) set-up project	✓
WP to help identify volunteers through their organisations to review and user-test EMA communication materials and advise on contextualisation of information to support health literacy	∞
WPs to disseminate EMA communications through their organisations' websites and other channels	∞
WPs to advise on organisations' needs and preferences for EMA communication materials	✓

Crisis management and EMA's Extended Mandate

Action	Status
WPs to be regularly kept informed of implementation of EMA's extended mandate	∞
WPs updated about the work of the expert panels on medical devices	∞
WPs to contribute to the implementation of the Communication and Stakeholders' Engagement Plan on EMA's extended mandate including: • WPs to participate in multi-stakeholder workshop on extended mandate	✓
• Members of EMA's Emergency Task Force (ETF)	✓
• Observers on the Medicines/Devices shortages steering group (MSSG/ MDSSG)	✓
• Provide input to development of the EU shortages monitoring platform	∞

Public health focus areas

Action	Status
WPs to promote guidance on antimicrobial use and the Agency's approach to antimicrobial resistance in the environment and increase stakeholder understanding of new antimicrobials	
WPs to participate in multi-stakeholder workshop on AMR and contribute to any discussions on alternative models for the development of new antibiotics	
WPs to contribute to any activities related to European Antibiotic Awareness Day (EAAD)	
WPs to continue to contribute to the creation and user-testing of materials and combatting misinformation to increase vaccine confidence	
WPs to participate in joint PCWP/HCPWP workshop on vaccines in 2024	

Building transparency and trust

Action	Status
WPs informed and provide input to: • initiatives intended to communicate the science behind EMA decisions, particularly on areas of high public health priority (e.g. vaccines)	∞
• development of information materials and awareness raising campaigns targeting patients, consumers and healthcare professionals	∞
WPs to stimulate reciprocal transfer of knowledge between member organisations, EMA and international partners to develop specific dialogue on topics of common interest	∞
WPs to promote awareness of EMA's stakeholder database and benefits of registration (e.g. targeted communications, invitations for workshops)	?
WPs to continue to create awareness of EMA's Regulatory science research needs	?

Training and support

Action	Status	Comments
WPs to be updated and to provide input to training materials supporting involvement in EMA activities, considering the training strategy for patients, consumers, healthcare professionals and academia	∞	
Induction training for new PCWP/HCPWP members	✓	

Any questions?

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