EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PCWP/HCPWP workplan 2022-2025

Mid-point implementation report – follow up actions

PCWP and HCPWP plenary meetings

Presented by Ivana Silva on 2 and 3 July 2024
Public and Stakeholder Engagement Department

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

PCWP/HCPWP feedback sought via survey

- 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

34% of all members replied
(8 PCWP and 7 HCPWP)

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	?

Majority agrees to reword to 'WPs to be kept updated on the activities of EMA's Cancer medicines Forum'

Focus on lessons learned relevant across disease areas; sufficient attention to diversity in patient characteristics during pathfinder project (including multimorbidity, frailty, etc.)

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	?

Majority agrees to keep action as is

Consider a general presentation on the initiative and concrete outcomes

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	!

Suggestions for progressing on this action:

Updates on progress of implementation, including challenges/barriers and backlog; any actions planned to encourage/ensure compliance; attention to clinical data about multimorbility (related to polypharmacy, physical performance and frailty)

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	!

Safety of medicines

Suggestions for addressing identified actions:

General

- regular session where these topics are covered and make more use of the HMH newsletter

Safety communications

- discussion on process: how to reach the right people with the right safety information
- short report highlighting how safety communications have contributed to public health

Increase awareness of ADR reporting

- presentation on progression of spontaneous ADR reporting in last years, overview of awareness raising activities by NCAs and stakeholders, discussion on remaining challenges and best practices
- reflection on how to increase usability of data (quality; training; apps) and what can organisations do to raise awareness of ADR reporting (e.g. co-create campaign; factsheet)

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	!

Majority suggests including it as part of overall identification of training needs

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	ⓘ

Split views on whether to keep action as is or reword to 'WPs to be kept updated on activities related with EMA's OneHealth strategy and Vaccines outreach strategy'

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	?

Majority agrees to keep action as is and inform EMA of how they are addressing this action

Majority considers the high-level presentation given in November 2023 sufficiently addressed this action

New emerging strategic areas/actions

- EMA actions to implement relevant provisions of new pharmaceutical legislation once adopted
- Medical misinformation and disinformation
- Herbal medicines: understand the science behind monographs on how to make the information easier to use
- Polypharmacy
- Non-clinical development topics

Other comments:

- Continue to have a dedicated space for WP members to raise concerns in advance
- Health economics
- Study of safety of treating myopia lenses
- Balance between regulatory control, security and bureaucracy and impact in research projects and funding opportunities

PCWP specific work

Completed

- CHMP pilot on early dialogue: report published and extension to all medicines
- Input to ICH guidelines
- Revamped newsletter

In progress

- PED work developed and progressed
- ePI
- QRD template for package leaflet

3. PCWP specific work

3.1. Reinforce patient relevance in evidence generation

Actions:

- WP to review analysis of outcome of CHMP pilot on early dialogue with patient organisations
- WP to review pilot proposal for disease-specific focus groups
- WP to participate in workshop on enhancing the patient voice in the development and authorisation of medicines; Q2 2022
- WP informed of potential use of patient preferences in decision making
- WP involved in ICH guideline development and updates specifically dealing with good clinical practice (GCP) and patient-focused drug development (PFDD) (see 2.1.)
- WP to explore complementary methodologies for the collection and use of patient data (e.g. real world evidence, patient-reported outcomes (PROs), patient preferences) for medicine's development, assessment and monitoring
- WP to provide input on best ways to communicate on benefit-risk assessments, and the various marketing authorisation options (e.g. conditional, exceptional circumstances).

3.2. Package leaflet

Actions:

- WP to provide input to support implementation of EMA's action plan to improve the product information (PI)
- WP to be kept updated on progress of implementation, in particular ePI

3.3. Exchange with international stakeholders

- WP to join annual meeting with FDA's CTTI/Patient Engagement Collaborative and identify topics for discussion

3.4. Newsletter

- WPs to review and contribute to proposed enhancements of current newsletter (HMH) with patient-relevant information

Any questions?

Further information

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Telephone +31 (0)88 781 6000
Send us a question Go to www.ema.europa.eu/contact

Follow us on **@EMA_News**