EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PCWP Workplan - 2012

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Meetings scheduled for 2012

- **27 & 28 February** 2012 - Joint meeting with Healthcare Professionals' Working Group
- (**07) 08 May** 2012 – PCWP Plenary meeting
- **(24) 25 September** 2012- Joint meeting with Healthcare Professionals' Working Group
- **29 November** 2012 - Training session
- **30 November** 2012 - Meeting with all eligible organisations

Introduction

- Previous focus for PCWP - implementation of the ‘Framework on the interaction between the Agency and PCOs
- Actions identified within framework now implemented and formal interaction established
- Further scope to broaden and streamline the involvement of PCOs in the Agency activities
- ‘Reflection paper on the further involvement of patients and consumers in EMA activities’; revise the current framework of interaction.

Introduction

During 2012, the PCWP will focus its work on this revision to address;

- The role of patients within the different scientific committees
- Their involvement in CHMP benefit/risk evaluations, and
- The development of a strategy for training and support

The revised framework will determine the involvement of patients and consumers in the work of the Agency in the coming years.

Introduction

- Continue to monitor patient participation in activities throughout the Agency (review of information, participation in SAG meetings, Committee/WP consultations, conferences and workshops, etc).
- The new pharmacovigilance legislation will also strengthen the interaction; PCWP will be directly involved in implementation of legislative provisions.
- Contribute to strengthening procedures for Agency interaction with appropriate organisations in a transparent manner.

Area of information on medicines

Quality review of the package leaflet (PL), EPAR summary and safety communications

Nominated experts will continue to be involved in the review of:

- Package Leaflets
- EPAR summaries
- Safety communications

Action: Monitor and report on the activities performed in 2011/2012.

Area of information on medicines

Review of information on herbal medicinal products

- Contribute to activities aimed at improving information for the public on herbal medicinal products.

Action 1: Explore and define key information on herbal medicines and appropriate vehicles for providing this information - (2/3Q2012).

Action 2: Investigate process by which PCOs representatives could contribute to the preparation of this information in lay language - (2/3Q2012).

Area of information on medicines

Benefit/risk communication

- Continue to support activities to optimise presentation of information on benefit/risk assessments

Action 1: Explore how to improve available benefit/risk information, through PL and EPAR summary, but also consider additional communication tools - (throughout 2012).

Action 2: Involvement in the preparation of upcoming EPAR summary revision - (throughout 2012).

Area of pharmacovigilance and Risk Management

Participation of patients and consumers in the activities of the PhVWP

- PCOs' representative/alternate continue to participate in the PhVWP meetings until new pharmacovigilance and risk assessment committee (PRAC) in July 2012.
  Patient representatives will be formal members of this new committee.

Action: "Analysis of experience" in the PhVWP to be presented at the joint meeting with PCWP and the HCPWG – (February 2012).

Area of pharmacovigilance and Risk Management

New pharmacovigilance legislation

- PCWP will provide input and support in the preparation of implementation of the new legislation.

Action 1: Participation in stakeholder meetings - (throughout 2012).

Action 2: Dedicated meeting and/or discussion, on specific legislative provisions regarding risk management plans (RMP), including the preparation of the “RMP summary” template – (1Q2012).

Area of pharmacovigilance and Risk Management

Action 3: Contribute to development of standard web-based reporting forms for patient-reporting of suspected ADRs - (2012).

Action 4: Additional monitoring of medicines - input on development of symbol and text for PL, incl. encouraging reporting of suspected ADRs – (2012).

Action 5: Contribute to the development of procedures for public hearings – (2012).

Area of pharmacovigilance and Risk Management

Implementation of EudraVigilance Access Policy

Action: PCWP members will continue to be part of "EudraVigilance Users Group" to provide input and support on presentation of adverse reactions data within the Eudravigilance database -(throughout 2012).

Area of pharmacovigilance and Risk Management

PhVWP/CMD(h) consultations on safety related issues

Action 1: Continue to respond to consultation requests from PhVWP and CMD(h) – (throughout 2012).

Action 2: Establish a system for consultation requests from new committee (PRAC) once established; ensuring that activities from PhVWP are transferred and adapted accordingly to PRAC - (2012).

Action 3: Explore possibilities for increasing scope of PCO involvement in work of the PRAC – (2012).

Area of transparency and dissemination of information

EMA awareness

- Explore ways of raising awareness of EMA activities;

Action 1: Raise public awareness of activities where PCWP/PCOs are involved within the Agency - (throughout 2012).

Action 2: Identify methods to increase awareness of EMA as a validated source of information on medicines for patients - (throughout 2012).

Area of transparency and dissemination of information

Agency's website

Action 1: Continue to provide feedback on the functionality and user-friendliness of the EMA website – (throughout 2012).

Action 2: Support wider dissemination of the Human medicines monthly highlights – (throughout 2012).

Action 3: The Agency is developing a social media strategy; where appropriate, PCWP will provide input and support to related activities – (throughout 2012).

Area of transparency and dissemination of information

EudraCT

Action: Continue to provide support to the development of the EU Clinical Trials Register; participation in EudraCT Joint Operational Group (e.g. input related to the user interface design and functionalities for future versions of the EU-CTR) – (throughout 2012).

Transparency

Action: Provide support to the implementation of different actions and measures in the Agency's transparency policy, currently under preparation - (throughout 2012).

Area of interaction between the agency and patients' and consumers' organisations

Revision of the framework of interaction

Action 1: EMA, together with PCWP, to prepare revised framework for adoption by the Agency's MB, taking into consideration; role of patients and consumers as members of committees, development of a training strategy and definition of PCO involvement in benefit/risk evaluations - (2012).

Action 2: Develop together with the CHMP and PRAC criteria to identify in which cases patients and consumers are to be involved in benefit/risk at the CHMP and PRAC - (2012).

Area of interaction between the agency and patients' and consumers' organisations

Participation in SAG meetings

- Patients and consumers participated in SAG meetings for a 1 year pilot phase (Oct 2010 – Oct 2011).

Action: Based on the experience acquired during the pilot phase, agree the "terms of reference" with the CHMP for the participation of patients in SAG meetings - (2012).

Area of interaction between the agency and patients' and consumers' organisations

Training

- In the context of the framework revision:

Action 1: Develop a training strategy to provide support to patient participation in the different EMA activities - (2012).

Action 2: Identify priorities to develop specific training modules (e.g. SAG meetings). Explore use of new tools (e.g. web-based tutorials) and identify situations where individual support is needed – (2012).

Action 3: Expand the scope and streamline in-house training sessions - (2012).

Action 4: Annual training session to be held at the Agency - (3Q2012).

Area of interaction between the agency and patients' and consumers' organisations

Annual meeting with all eligible organisations

Action: Annual meeting with all eligible organisations – (4Q2011).

Other areas of interest (throughout 2012)

Action 1: PCWP contribution to ENCePP (EMA and European Network of Centres for Pharmacoepidemiology & Pharmacovigilance) activities, through involvement of PCWP representative in ENCePP steering group (throughout 2012).

Action 2: Participation in the PROTECT project (Pharmacoepidemiological Research on Outcomes of Therapeutics by a European ConsorTium) (throughout 2012).

Area of interaction between the agency and patients' and consumers' organisations

Monitoring of the interaction

Action: To continue to monitor the involvement of PCOs in the Agency's activities (next update report - 2012).

Performance indicators

Action: Continue to monitor the degree of satisfaction (next analysis report - 2012).

Organisational matters

Eligibility criteria

Action 1: Finalisation and publication of SOP on process for (re-)evaluation of eligibility for PCOs – (1Q2012).

Interaction with healthcare professionals

Action 1: Two Joint meetings PCWP and HCP WG (increased meetings).

Action 2: Ensure adequate co-ordination on actions and issues of common interest. HCP WG representative to attend PCWP meetings and vice-versa – (throughout 2012).