European Medicines Agency
Post-authorisation Evaluation of Medicines for Human Use

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2009 WORK PLAN FOR THE EMEA HUMAN SCIENTIFIC COMMITTEES' WORKING PARTY WITH PATIENTS' AND CONSUMERS' ORGANISATIONS

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1. MEETINGS SCHEDULED FOR 2009

5th March	Plenary meeting
9th June	Joint meeting with HCP WG
29th September	Training session on the quality review of Package Leaflets and EPAR summaries
30th September	Plenary meeting
8th December	Meeting with all eligible patients' and consumers' organisations

2. INTRODUCTION

The EMEA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) has focused in previous years on the implementation of the 'Final Recommendations and Proposals for Action' (EMEA/149479/2004/Final), adopted by the CHMP and subsequently published on the EMEA website. For 2009, while ensuring that implementation of the "Recommendations" is concluded, the PCWP will move towards a further development and monitoring of activities already in place, in particular its contribution to the preparation of EMEA information adapted and oriented to patients and consumers.

The PCWP will work in the development of a more systematic interaction and involvement of patients and consumers at different levels of the Agency work, and particularly at the level of the different scientific committees and its working parties. The PCWP will examine whether this could be achieved within the current 'Framework on the interaction between the EMEA and patients' and consumers' organisations' (EMEA/354515/2005/Final) or whether there is any need to review it.

3. AREA OF PRODUCT INFORMATION

3.1 Quality Review of the Package Leaflet (PL)

Patients' and consumers' organisations have been involved on the review of the PL of centrally authorised medicines at the time of the renewal of marketing authorisation since 2007. Since September 2008, the procedure covers the PL at the time of the initial evaluation of marketing authorisation.

Action: report on the activity performed in 2008 and monitoring of the involvement of PCOs during 2009.

3.2 Quality Review of the EPAR summaries

Patients' and consumers' organisations have been involved on the review of the EPAR summaries for new authorised medicines since 2007.

Action: report on the activity performed in 2008 and monitoring of PCOs involvement in the review of EPAR summaries during 2009.

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3.3 Review of Q&A documents

Patients' and consumers' organisations have been involved occasionally in the review of the Q&A documents regarding safety issues.

Action: proposal for a more systematic involvement in the preparation of the Q&A documents to be considered on the basis of the experience gained in 2/3Q2009.

3.4 Training of patients and consumers experts involved on the Quality Review of PLs and EPAR summaries

Every year a training session is offered to experts from patients' and consumers' organisation to be involved in the review.

Action: annual training session co-organised between the EMEA and the PCWP to be held at the EMEA in 3Q2009.

4. AREA OF PHARMACOVIGILANCE

4.1 Finalisation of the recommendations from the EMEA/CHMP Working Group with Patients' Organisations on Pharmacovigilance

4.1.2 PhV education module

The objective is to develop a training programme based on already existing experiences in PCOs, and which can be used afterwards for training of patients in the context of their respective organisations. The training will focus on pharmacovigilance, surveillance and risk communication.

Action: the group has started some reflection and work for defining content of the training programme (headlines, objectives, main messages and definitions) – Finalisation is expected for 1/2Q2009.

4.1.3 Risk/benefit communication

Standardisation of quantitative measures for communicating benefit/risk of medicines in EMEA documents. Consideration of their ability to convey the most appropriate message to the public.

Action: a joint exercise involving patients, consumers, healthcare professionals and regulators has been undertaken during 2008. Outcome and any recommendation coming from this exercise will be considered. The opportunity to develop a glossary of effective words in communicating risks and benefits will be explored 1/2Q2009.

4.2 Other initiatives

4.2.1 European Risk Management Strategy (Work Programme for 2009)

Action: to provide input in various areas which requires interaction with patients' and consumers' organisations, such as:

- access to EudraVigilance database, including user requirements and technical specifications of the public interface (website)
- improved transparency on safety issues

4.2.2 Safety communication

Maximise involvement of patients and consumers in safety communication aspects.

Action: proposal for a more systematic involvement of PCOs in safety communication will be considered in 2/3Q2009.

4.2.3 Participation of patients and consumers in the activities of the PhVWP

During a first pilot phase to be implemented in 2009, experts from patients' and consumers' organisations will participate as observers at the meetings of the PhVWP.

Action: monitoring of the implementation of the above mentioned initiative. Based on experience of the initial pilot phase, a report is to be prepared by 3/4Q2009.

5. AREA OF TRANSPARENCY AND DISSEMINATION

5.1 EU Telematics

5.1.1 European Database on Medicines

Action: to provide support to the EudraPharm project throughout 2009.

5.1.2 EudraCT website

Action: to provide support to the project throughout 2009.

5.1.3 EudraVigilance website

Action: to provide support to the project throughout 2009.

5.2 EMEA website

Action: to provide input and support to the restructure of the EMEA website and the EMEA public-facing online project throughout 2009.

5.3 EMEA transparency

Action: to provide support on further measures and initiatives to be developed by EMEA on this area throughout 2009.

5.4 EMEA awareness

Action I: continue exploring how to increase awareness at the level of patients' and consumers' organisations (e.g. distribution of EMEA information leaflets in different EU languages) - 2/3Q2008.

Action II: further promotion of "criteria to be fulfilled by PCOs involved in EMEA activities" to improve transparency in the process of selecting groups.

Action III: explore measures for dissemination of EMEA information in medicines specifically adapted to patients.

6. AREA OF INTERACTION BETWEEN THE EMEA AND PATIENTS' AND CONSUMERS' ORGANISATIONS

6.1 Involvement of member(s) of patients' and consumers' organisations in EMEA activities.

Action I: further to the conclusions coming from the first 'Report on the progress of the interaction with patients' and consumers' organisations and analysis of the degree of satisfaction of patients and consumers involved in EMEA activities' (EMEA/478814/2007), published in June 2008, the PCWP will contribute to develop a "Reflection Paper" with specific proposals for a more systematic interaction and involvement of patients and consumers at different levels of the Agency work, and particularly at the level of the different scientific committees and its working parties - 4Q2009. The "Reflection Paper" will explore if this interaction can be achieved within the current 'Framework on the interaction between the EMEA and patients' and consumers' organisations' (EMEA/354515/2005/Final) or whether there is any need to review it.

Action II: continue to monitor the involvement of PCOs in EMEA activities and to prepare a report in 4Q2009.

6.2 Eligibility criteria - EMEA interaction with patients' and consumers' organisations

Action I: monitoring of compliance with "EMEA eligibility criteria" by eligible PCOs. Status report to be presented to PCWP in 4Q2009.

Action II: all eligible patients' organisations with interest in regulatory activities but not represented in the PCWP, will be invited to a plenary meeting for 2009, to be held in 3Q2009.

Action III: based on expressed interest from PCOs fulfilling the criteria, enlargement of PCWP membership to cover areas currently not represented will be considered by 2/3Q2009.

6.3 Framework of interaction – performance indicators

Continuing implementation and monitoring of specific performances indicators. Conclusions and results will be analysed, and adequate measures will be put in place accordingly. Indicators for 2009 will monitor degree of satisfaction of measures already identified and put in place following analyses of performance indicators in 2007.

Action: Implementation throughout 2009 - Analyses report to be prepared by 4Q2009.

7. ORGANISATIONAL MATTERS

7.1 Interaction with healthcare professionals

Continue ensuring adequate level of interaction with representatives of healthcare professionals' organisations.

Action: annual joint meeting between PCWP and Healthcare Professionals' Working Group (HCP WG) to be held in 2Q2009.