15 December 2016
EMA/705066/2016
Stakeholders and Communication Division

Revised framework of interaction between EMA and healthcare professionals and their organisations

Annex I – Action plan

Actions	Estimated timeframes for completion
• Continue the mapping of relevant organisations and update information in the EMA's stakeholders database	On-going
• Maintain the network of European healthcare professionals' organisations	On-going
• Agree on working methods for the EMA Healthcare Professionals Working Party intended to: – Reinforce interaction with patients, academia and the EMA human scientific committees and working parties – Refine efforts in the domain of information on medicines to healthcare professionals – Share best practices on how healthcare professionals' organisations are creating awareness and understanding of EMA's mandate and work	Q2 2017
• Establish and maintain pools of experts as needed: – Maintain and expand the pool of experts on medication errors – continue to identify healthcare professionals (doctors, pharmacists, nurses) with relevant expertise who can make timely contributions to EMA scientific committees, working parties, scientific advisory groups, etc. – Maintain and further activate the pool of general practitioners/family physicians – identify concrete areas to pilot involvement and based on the outcome of the pilot phase develop a multi-annual action plan	On-going Q4 2017

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• Promote participation at key milestones during the lifecycle of medicines: – Review process to bring healthcare professionals' input into EMA scientific advice and qualification of novel methodologies for medicine development – Increase specific dialogue and interaction with healthcare professionals' organisations on development and implementation of risk management plans – Continue to identify suitable experts who can timely contribute to EMA benefit-risk assessment procedures – Consider the evolving roles of nurse practitioners/ nursing specialists and explore where nurses' input into EMA activities would be of mutual benefit	Q2 2018 Q4 2017 On going Q2 2018
• Develop specific dialogue and interaction with healthcare professionals' organisations on: – early access to medicines (i.e. use of real-world data and patient registries) – support to innovation (i.e. personalised medicine) – EMA guideline development process (blending science, clinical practice and regulation)	Q4 2018
• Stimulate reciprocal transfer of knowledge between healthcare professional organisations and EMA – Identify existing practices (e.g. jointly organised events; involvement in training programmes) – Discuss best practices and share learnings	Q4 2017 Q4 2018
• Monitor and increase transparency on the involvement of healthcare professionals and their organisations in the Agency's activities: – Establish a system for regular cross-Agency collection of quantitative and qualitative data for monitoring and reporting purposes – Acknowledge and promote visibility of input provided by healthcare professionals and their organisations in the context of the activities of scientific committees, working parties, scientific advisory groups and other expert groups	On going