



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Framework on the interaction between the EMA and healthcare professionals

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An agency of the European Union





# Rationale

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- The Pharmaceutical legislation calls for the Agency to implement specific interactions with HCPs
  - Many have already been implemented
- Recent review of current practices:
  - HCPs are already integrated in the Agency's work
  - There is still a gap in relation to interactions with HCPs' organisations that calls for a structured framework
  - Need to establish regular **monitoring and reporting**
- The Agency's Road Map to 2015 identifies the importance of involving and facilitating participation of civil society (patients/users of medicines and healthcare professionals) in the Agency's activities.



## Creation of a network of European HCPs' organisations

- Can help the Agency to access the best possible **independent expertise** in any matter related to medicines;
- Can help the EMA to gain a better understanding on **real clinical practice**: with the aim of obtaining information on the current use of medicines in clinical practice and their therapeutic environment, for the purposes of benefit/risk decision-making;
- Can support a more efficient and targeted **communication**, especially in relation to the benefit and risks of medicines and its rationale use.

*Criteria to be fulfilled by HCPs' organisations involved in EMA activities*



# Next steps

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1. 29 February 2012
  - Launch the call for expression of interest to become an eligible organisation (permanent open call)
2. Organisations to express their interest by submitting their application form and the necessary supporting documents
  - First wave of applications expected throughout March 2012
3. Evaluation committee to assess applications
  - First assessment during April 2012
4. Publication of first list of eligible organisations
  - May/June 2012



## Establishment of the Healthcare Professionals WP

- **Formalisation of the current CHMP working group with healthcare professionals**, which will become a Working Party (HCP WP) with links to all human scientific committees.
  - Platform for dialogue and exchange with HCPs' organisations on relevant issues concerning medicines for human use; it will be mandated to monitor the progress of the interaction and will help to further identify gaps and priorities in the overall interaction.



# Next steps

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1. Establish the EMA Healthcare Professionals Working Party (HCP WP) – 3/4Q 2012
  - Balanced representation of **different types of HCPs** will be seek. 15 to 20 organisations (depending on available budget for 2013)
  - Launch call for expression of interest to become a member of the HCP WG (Members of the HCP WP are expected to be **selected from the list of eligible HCPs' organisations**)
  - Ensure a representative of each SC is nominated as a member of the HCP WP
  - Observers from MB, CMDh, and PCWP
  
2. First meeting of the HCP WP foreseen for 2013
  - Mandate and Rules of procedure
  - Election of co-chair