



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Interaction with healthcare professionals





Involvement of healthcare professionals (HCPs) in the Agency's activities

- **HCPs** are an integral part of the work of the Agency (e.g. as experts in scientific committees, working parties, working groups, etc)
- The Agency has worked with **HCPs' organisations** since its creation
- The Pharmaceutical legislation calls for the Agency to:
 - **implement specific interactions with HCPs**
 - **provide clear and useful information to HCPs**
- New pharmacovigilance and anti-falsification legislation further expand the areas in which HCPs will be involved



How HCPs can participate in the Agency's activities

Based on legal provisions and experience so far, HCPs can participate as:

- Members (and alternates)
- MB; PDCO; CAT; *PRAC*
- Experts
- SAGs; product related consultations
- Observers
- PCWP; ENCePP
- Representatives
- HCP WG; conferences/ workshops; EudraCT; EudraVigilance



Health Professionals Working Group (HCP WG)

WHO?	WHAT?	HOW?
Members: 20 European NFP associations (associations of clinicians/ practitioners, research-related organisations and learned societies) - CHMP members Observers: HMPC, CMD(h), PCWP, MB	Initial focus - Recommendations & proposals for action (Ref: EMA/18506/2008) - Project 'Information on B/R of medicines' (Ref: EMA/40926/2009) Current focus - Develop the framework for interactions between the Agency and HCPs organisations - Input to consultations (e.g. CT in 3rd countries; guidelines; EudraCT; new website) - Better understanding of EMA activities	- Meetings (3x) - PCWP/HCP WG annual joint meeting - Monitoring/facilitating - Written contributions to EMA consultations - Consultation by EMA committees and WPs - Identification of experts (e.g. SAGs) - Participation in EMA workshops



Framework on the interaction between the Agency and healthcare professionals - Objectives

1. Enhance the participation of healthcare professionals' organisations in certain Agency activities, ensuring that their views can be taken into account in benefit/risk decision making;
2. Provide clear and useful information on medicines to healthcare professionals' organisations, to support their role in the safe and rational use of medicines;
3. Optimise and further develop appropriate communication tools (content and delivery) that support the provision of information to and the collection of feedback from healthcare professionals;
4. Enhance healthcare professionals' organisations understanding of the mandate and work of the Agency;
5. Facilitate and encourage the cascade of information to the constituencies of healthcare professionals' organisations (i.e. to reach out to healthcare professionals at national level).



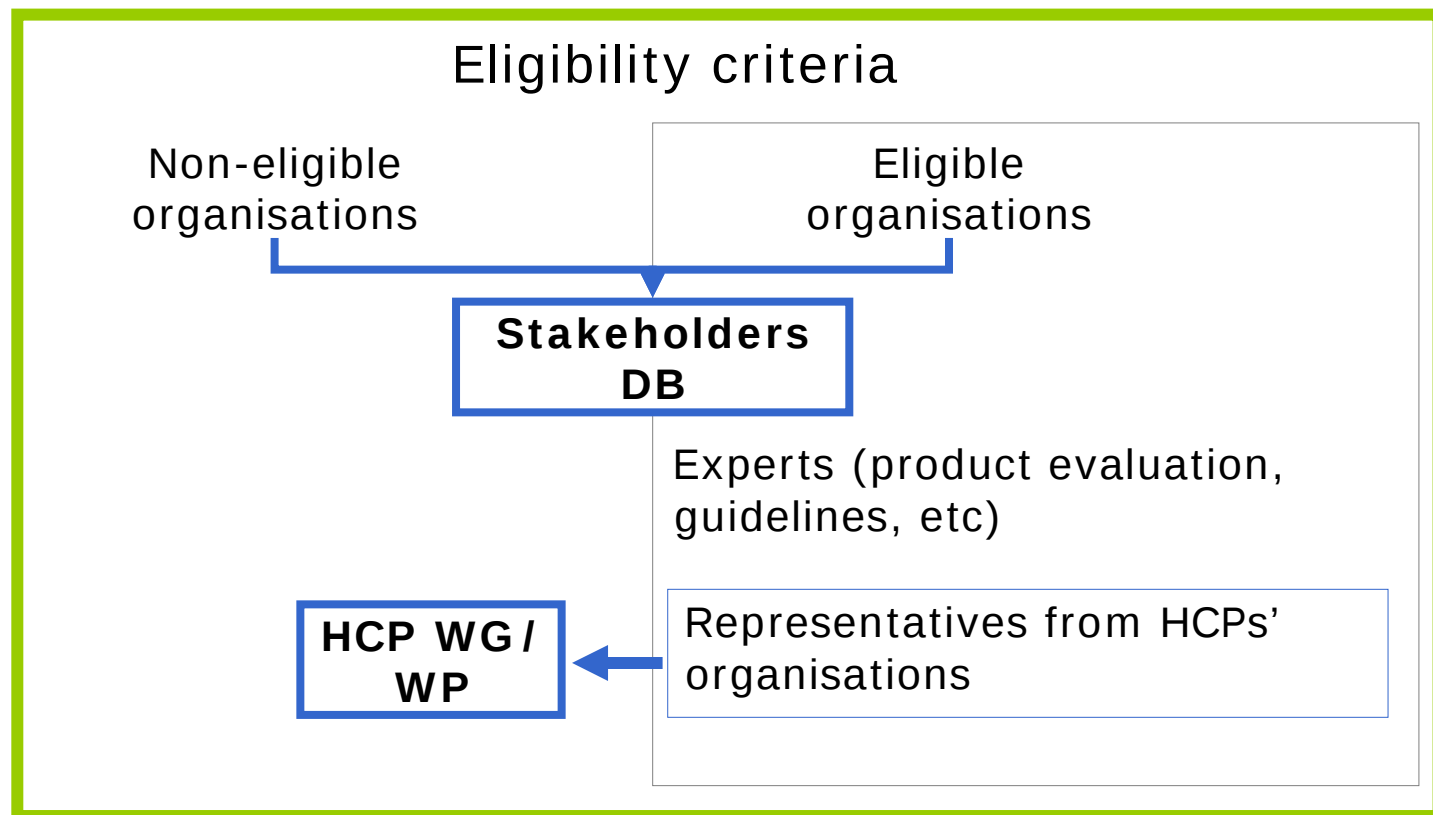
Framework on the interaction between the Agency and healthcare professionals – Areas covered

1. Establishment of a network of European healthcare professionals' organisations;
2. Interaction with the Agency's Management Board;
3. Interaction with Scientific Committees, working parties, scientific advisory groups and other expert groups;
4. Interaction related to pharmacovigilance and risk management;
5. Interaction related to the provision of information on medicines to healthcare professionals;
6. Interaction related to clinical trials;
7. Interaction related to awareness raising on the Agency's activities.



Framework on the interaction between the Agency and healthcare professionals

Network of European HCPs' organisations is currently under development





PCWP/HCP WP Interaction

- Continue to organise the annual joint meetings between the PCWP and HCP WG/HCP WP
- Identify observers from the HCPWG/HCP WP to participate in the PCWP meetings (and vice-versa)
- Strengthen the links between the PCWP and the HCP WG/HCP WP, by identifying topics of common interest and ensure discussion in both forums