



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Interaction with healthcare professionals

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Overview of involvement in EMA activities during 2015

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# Framework for interaction between the EMA and healthcare professionals



Support the Agency in order to access the best possible **independent expertise** and obtain information on the current use of medicines in **real clinical practice**



Contribute to a more efficient and targeted **communication** to healthcare professionals, to support their role in the safe and rational use of medicines



Enhance healthcare professional organisations' **understanding** of the role of the EU medicines Regulatory Network

Network of European healthcare professional organisations



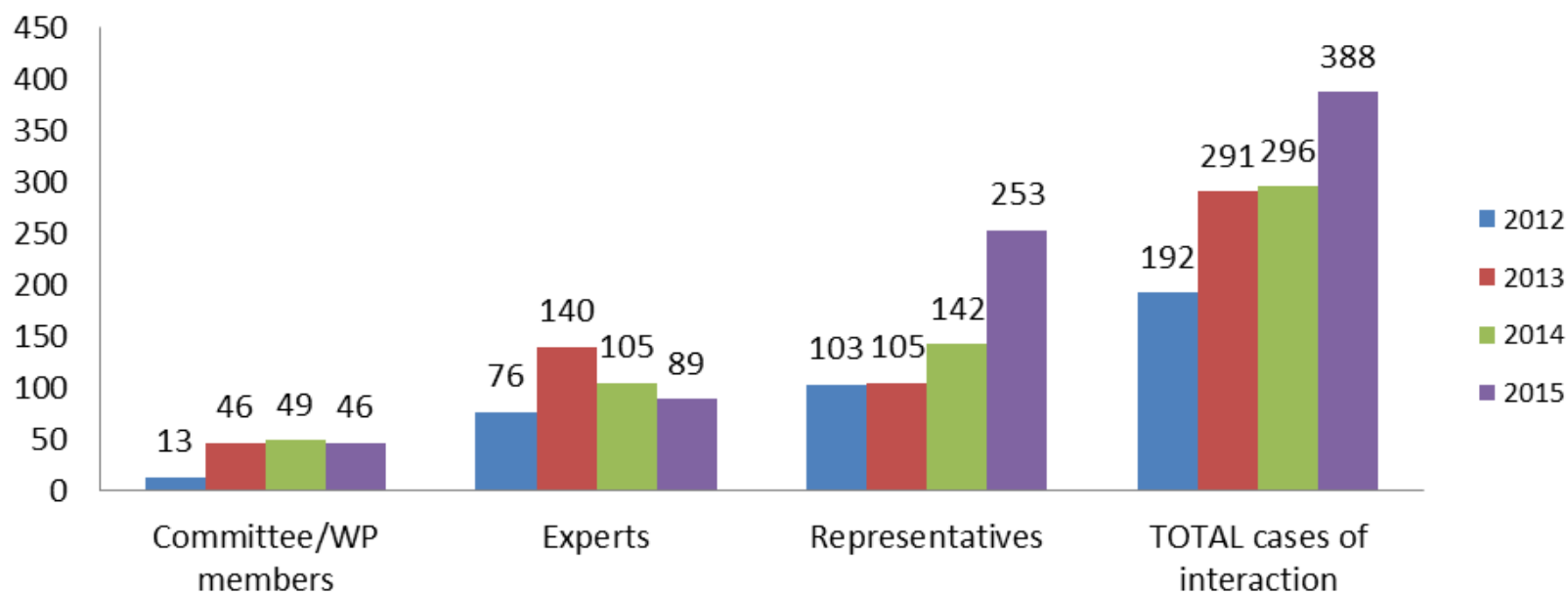
# Maintenance of the Network of European healthcare professional organisations (HCPOs)



- 29 eligible organisations by Dec 2015
- Transition into revised eligibility criteria

## Sustained involvement in core activities (I)

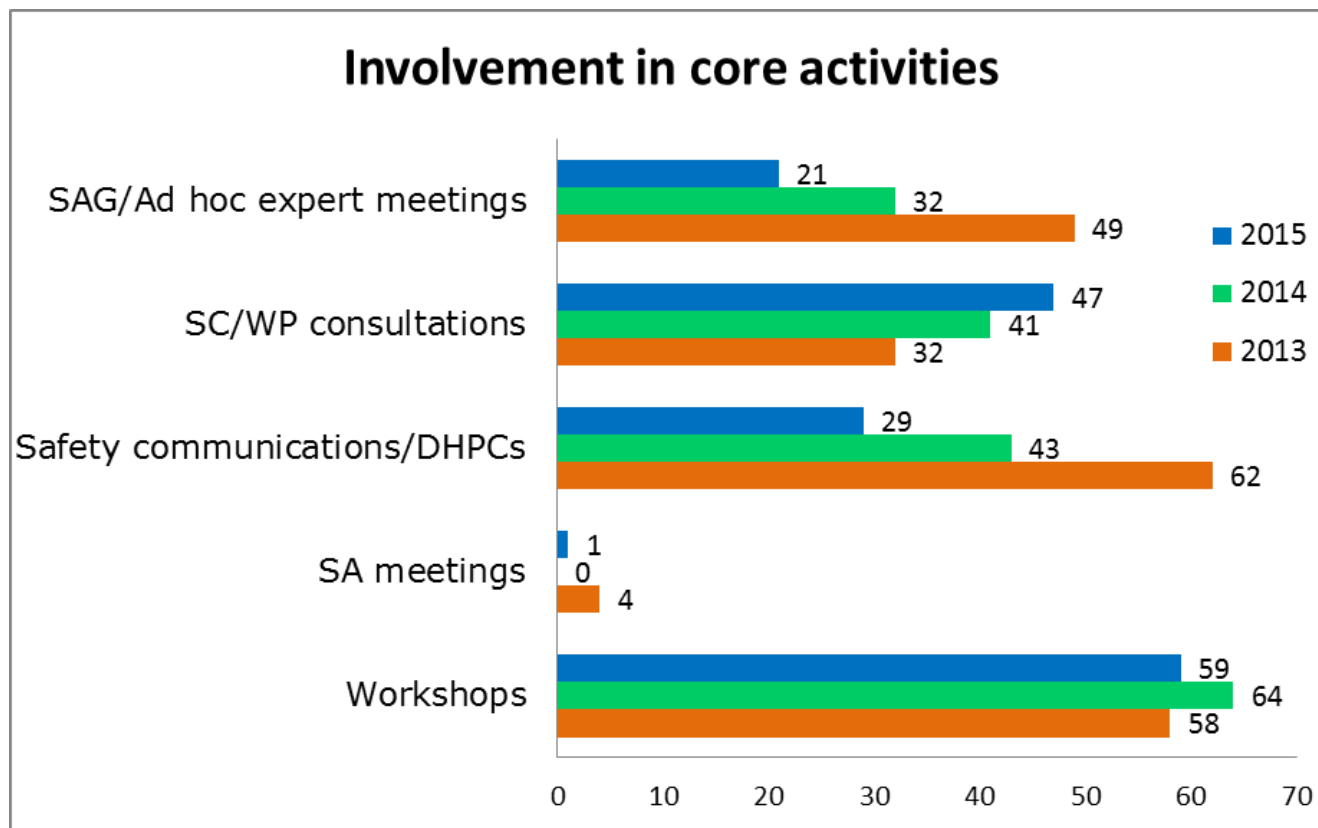
**Comparison of involvement as committee / WP members, experts and representatives of organisations**



- Big increase in representatives → explained by introduction topic groups and contributions to surveys



## Sustained involvement in core activities (I)



Support the Agency in order to access the best possible **independent expertise** and obtain information on the current use of medicines in **real clinical practice**

- Input and participation continued to be spread-out by various core activities
- Cases of interaction with previous years differ, due to the nature of the Agency's activities



## Sustained involvement in core activities (II)

### Input in SAG/Ad-hoc expert group meetings from a wide range of clinicians:

- Allergology; pulmonology; hepatology; psychiatry; neurology; immunology; virology; paediatrics

### Review of safety communications and DHPCs

- 4 DHPCs with feedback/comments
- 25 safety communications with feedback/comments
- 13 reviewers (including 1 GP; 1 pharmacist; 3 experts in medication errors)



Support the Agency in order to access the best possible **independent expertise** and obtain information on the current use of medicines in **real clinical practice**



# Sustained involvement in core activities (III)

## SCs/WPs consultations

- PDCO - Publication of the PDCO public summaries of the evaluation of PIPs
- PRAC - With regards to codeine containing medicinal products for the treatment of cough and/or cold in paediatric patients
- PRAC - Good Practice Guide on Risk Minimisation and Prevention of Medication Errors - Addendum on Risk minimisation strategies for high strength and fixed combination insulin products
- EMA/QRD – Expression of strength of an ophthalmic formulation
- EMA/QRD – Expression of strength for a medicine used in paediatric-onset hypophosphatasia
- EMA/QRD – Pharmaceutical form and instructions for use for two antineoplastic medicines
- EMA/QRD – Expression of strength for a fixed-dose combination used in heart failure



Support the Agency in order to access the best possible **independent expertise** and obtain information on the current use of medicines in **real clinical practice**



## Sustained involvement in core activities (IV)

### Participation in EMA workshops (examples)

- Information session on biosimilars
- EMA 20th anniversary conference: Science, Medicines, Health: Patients at the heart of future innovation conference
- Workshop on chordoma as a model for very rare cancers
- Bacteriophage therapy workshop
- Webinar: Implementation of EMA policy on publication of clinical data
- EMA workshop on the development of new medicines for the treatment of ulcerative colitis and Crohn's disease
- IMI ADVANCE project
- Anticoagulants workshop
- EMA workshop on shortages
- 9th Stakeholder Forum on PhV legislation
- Workshop to clarify concept/demonstrating of significant benefit of orphan medicines
- EMA 20th anniversary event - The view from the sharp end: what patients and healthcare professionals



Enhance healthcare  
professional  
organisations'  
**understanding** of the  
role of the EU  
medicines Regulatory  
Network



## HCPWP expanded discussions

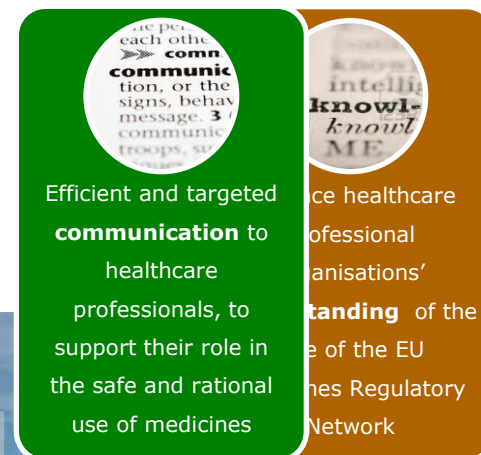
- Input through topic groups
- Brainstorming on healthcare professionals/learned societies interests in EMA collaboration with Academia





## Continued to raise awareness

- Participation in conferences organised by HCPOs



- Continued targeted dissemination of safety communications



## The challenges

- Maintaining interest and levels of participation in meetings, surveys, working groups
- Ensuring consistency in the implementation of transparency requirements
- Providing contextualised information of EMA activities
- Finding the balance between clinical practice and academic/research interests

## Work in progress

- Revision of framework of interaction
- Follow up on topic groups
- Longer term planning



## Achievements in 2015

- Maintenance of network and transition to new transparency requirements
- Sustained involvement in core activities
- HCPWP expanded discussions:
  - Expanded discussion/input through topic groups
  - Gaining better understanding of healthcare professionals/learned societies interests in EMA collaboration with Academia
- Continued awareness raising



# Collaboration of EMA with healthcare professionals

