EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Interaction with healthcare professionals

Overview of involvement in EMA activities during 2014

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An agency of the European Union

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

Expanded network and HCPWP fully operational

- Maintenance and expansion of the Network of European healthcare professional organisations (HCPOs)
  - ✓ 29 eligible organisations by Dec 2014 (3 new: UEMO; EAACI, HCWH)
  - ✓ Re-evaluations for 25 eligible organisations completed

- EMA Healthcare Professionals Working Party (HCPWP) in full operation

Increased transparency

- Publication of the first report on EMA interaction with HCPs
- Revised eligibility criteria
- Policy statement on the evaluation of financial information

Annual reports

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Document(s)	Language	Status	First published	Last updated	Effective Date
Annual report on European Medicines Agency's interaction with patients, consumers, healthcare professionals and their organisations (2013)	(English only)	adopted	08/10/2014		

Guidance for involvement

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Document(s)	Language	Status	First published	Last updated	Effective Date
Criteria to be fulfilled by healthcare professionals' organisations involved in European Medicines Agency activities	(English only)		19/12/2011	19/06/2014	
Evaluation of financial information from patients' consumers' and healthcare professionals' organisations for assessment of EMA 'eligibility'	(English only)		19/06/2014	24/09/2014	
Rules of involvement of members of patients' and/or consumers' and healthcare professionals' organisations in committee related activities	(English only)	adopted	12/02/2009		


ESN
EUROPEAN SPECIALIST NURSES ORGANISATIONS
ESNO Summit 2015
Thursday 5 - Friday 6 November
HOME MISSION MEETINGS MEMBERS ACTIVITIES SUMMIT 2015 CONTACT
European Specialist Nurses Organisations
The goal of European Specialist Nurses Organisations (ESNO) is to facilitate and provide an effective framework for communication and co-operation between the European Specialist Nurses Organisation and its constituent members in order to represent the mutual interests and benefits of these organisations to the wider European community, for the interest of the public health.
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Renal and transplant
Oncology
Critical care
Education
Diabetes
Urology
Psychiatry
Directors
Operating
Anesthetists
ESNO members - click to enlarge
ESNO
European Specialist Nurses Organisations (ESNO) is the recognized and unified voice of specialist nurses in Europe. Members of ESNO consist of individual European specialist nurses organizations.
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20-6-2013
ESNO / EMA-HCPWP
Last week the ESNO received the formal Confirmation of membership in the Healthcare Professionals Working Party. We are officially member of the European Medicines Agency Human Scientific Committees Working Party with Healthcare Professionals' Organisations (HCPWP). At the EMA website the is a online PowerPoint with goals and structure.


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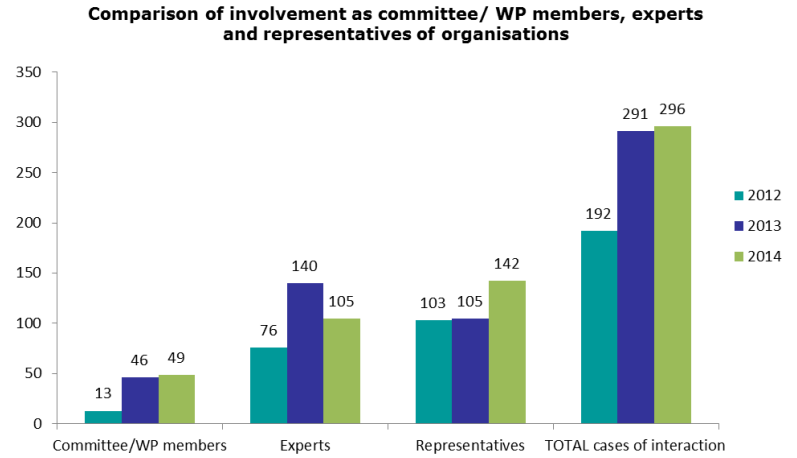
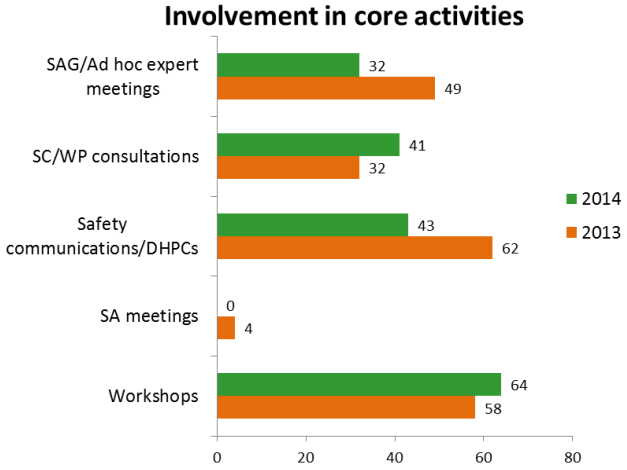
PGEU is a member of the European Medicines Agency Human Scientific Committees' Working Party with Healthcare Professionals' Organisations (more commonly known as the Healthcare Professionals' Working Party or HCPWP).


UNITED EUROPEAN GASTROENTEROLOGY
ueg
EMA
For more than five years, UEG has regularly been represented at meetings of the Healthcare Professionals Working Party of the European Medicines Agency (EMA). Since 2012, UEG is officially considered as a healthcare professional organisation eligible to be involved in EMA activities, and has since then provided scientific expertise to public consultations on various topics, such as chronic constipation and Crohn's disease. On occasion of UEG Week Berlin in October 2013, a symposium on "Drug issues in Gastroenterology: A European perspective" was organised in close cooperation with EMA.
Annual Report
2013/2014

Sustained involvement in core activities (I)





- Volume of interaction similar to previous year
- Input and participation continued to be spread-out by various core activities
- Cases of interaction with slightly different distribution compared to 2013 (related to Agency activities' offer/demand)

Sustained involvement in core activities (II)

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

- Experts in erythropoietic protoporphyria; paediatricians; psychiatrists; diabetologists; cardiologists; ophthalmologists; radiologists; oncologists; nephrologists; neurologists; pharmacists (particular expertise in methadone formulations and in medication errors)

Review of safety communications and DHPCs

- 6 DHPCs with feedback/comments
- 28 safety communications with feedback/comments
- 23 reviewers (including 2 GPs; 5 pharmacists)

Sustained involvement in core activities (III)

SCs/WPs consultations

- CAT - Design and conduct of clinical trials concerning autologous chondrocyte implantation: information on the current European standard of care
- CHMP - Adrenaline auto-injectors: input on route of administration
- PRAC - Valproate and related substances: input on how information on risks associated with the use of valproate is provided to women with child bearing potential and pregnant women; and input on education materials
- CHMP/CVMP QWP - Survey regarding in-use shelf-life of reconstituted/ compounded parenteral products
- EMA/QRD Medication errors-related consultations - focus on high strength insulins; instructions for dilution for an anticancer medicine (including input from doctors; nurses and pharmacists)

One concrete example – valproate

- Review of new information on risk of long-term developmental problems in children whose mothers took Valproate – referral started in Oct 2013
- PRAC Meeting with patients - need to consult with HCPs was much emphasised by patients – April 2014
- PRAC consultation with HCPOs – where input on how information on risks associated with the use of valproate is provided to women with child bearing potential and pregnant women is requested - July
- PRAC written consultation on education materials for Valproate – September
- Ad hoc expert group meeting – October
- Review of draft public health communication – November
- Discussion with learned society on impact of recommendations in clinical practice – December

Sustained involvement in core activities (IV)

Participation in EMA workshops

- Workshop on B/R (PCWP/HCPWP)
- Targeted TC - input to EMA policy on proactive publication of and access to clinical-trial data
- 8th Stakeholder Forum PhV leg
- Workshop on Risk Communication (PCWP/HCPWP)
- WEBRADR IMI project – Webinar
- Workshop on Alzheimer's Disease
- Workshop on Guideline on pharmaceutical development of medicines for paediatric use
- WEB RADR (IMI project) - Workshop

Continued support to EMA groups and networks

- EU CT Information System Expert Group and Stakeholders
- Enpr-EMA
- Cross Committee Task Force on Registries
- Ad-hoc core group of patients, consumers and healthcare professionals' organisations for pandemic preparedness activities

Involvement in new initiatives/projects

- **IMI/WEB-RADR project**

  Recognising adverse drug reactions – improve pharmacovigilance through new technology

WORK PACKAGE 1 – GOVERNANCE AND POLICY

Led by the **European Medicines Agency (EMA)**, the objective of this work package is to develop a policy framework on the use of mobile devices and social media for the purpose of reporting ADRs, surveillance and communication in the context of EU medicines and pharmacovigilance legislation. This aims to support further development of Good Pharmacovigilance Practices (GVP) and other guidance in this area.

EMA will ensure compatibility of WEB-RADR deliverables with EU law, EU systems and GVP modules. This will also ensure consistency with ongoing work in other European forums and facilitate consultation with EMA's Health Care Professionals Working Party (HCPWP), the Patients and Consumer Working Party (PCWP) and the EudraVigilance Expert Working Group (EV-EWG). Further, technical expertise will ensure compatibility of Individual Case Safety Report (ICSR) reporting standards, and associated product dictionaries.

WEB-RADR

Continued to raise awareness (I)

- Participation in conferences organised by HCPOs

Continued to raise awareness (II)

- Dissemination of information and reference to EMA

The challenges

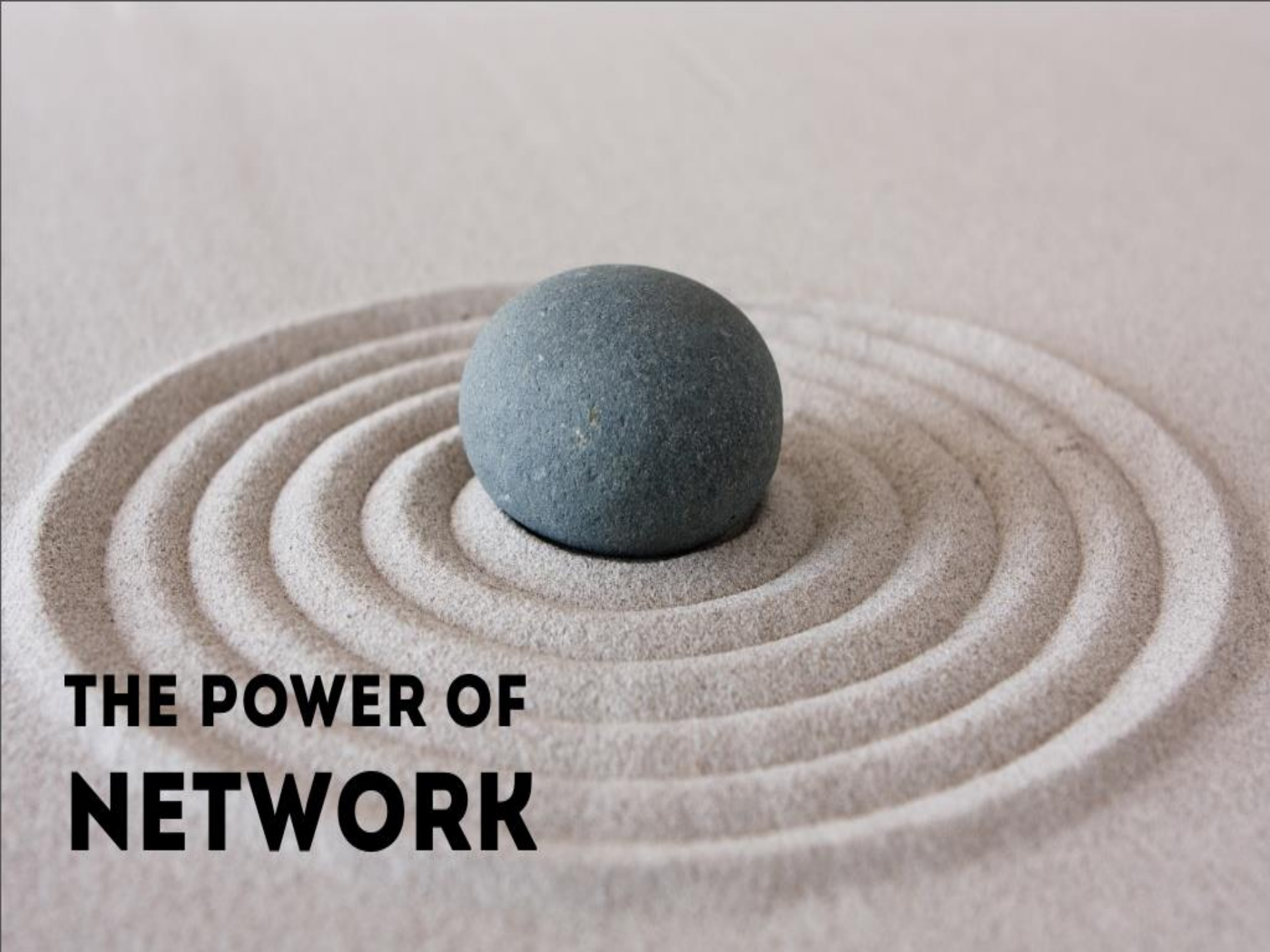
- Optimising the use of limited resources in the organisations
- Responding within short timelines
- Finding suitable and available experts
- Handling conflicts of interest

Focus for next years

- Assess current practices and identify room for improvement
- Continue to increase transparency on the involvement of HCPOs in the Agency's activities
- Explore ways to further recognise individual experts involved in EMA activities

Achievements in 2014

- Expanded network and HCPWP fully operational
- Increased transparency
- Sustained involvement in core activities
- Continued support to established EMA groups and networks
- Involvement in new initiatives/projects
- Continued to raise awareness


THE POWER OF
NETWORK