EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Interaction with healthcare professionals

Overview of involvement in EMA activities during 2013

Presented by: Ivana Silva
Stakeholders and Communication Division

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

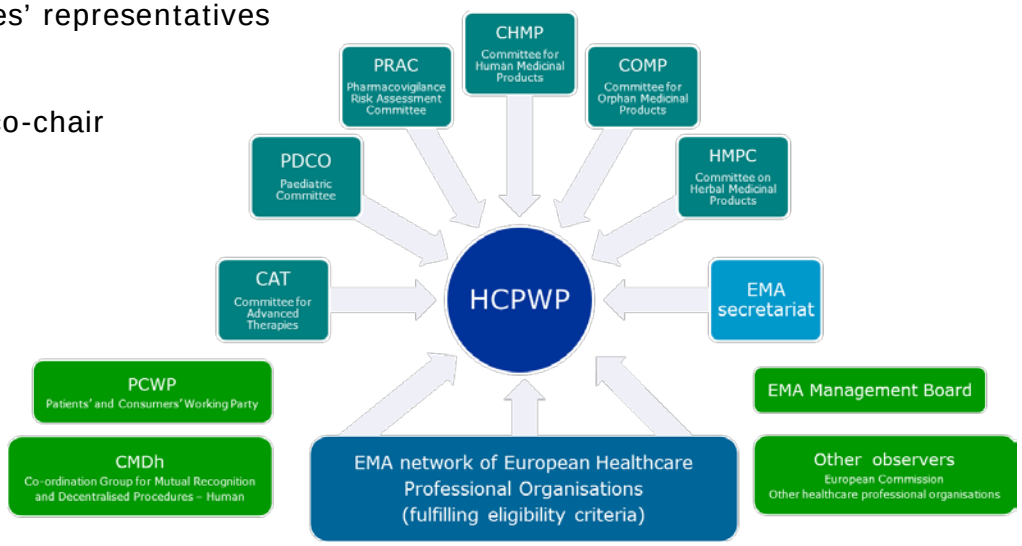
Enhance healthcare professional organisations' **understanding** of the role of the EU medicines Regulatory Network

Network of European healthcare professional organisations

Achievements in 2013

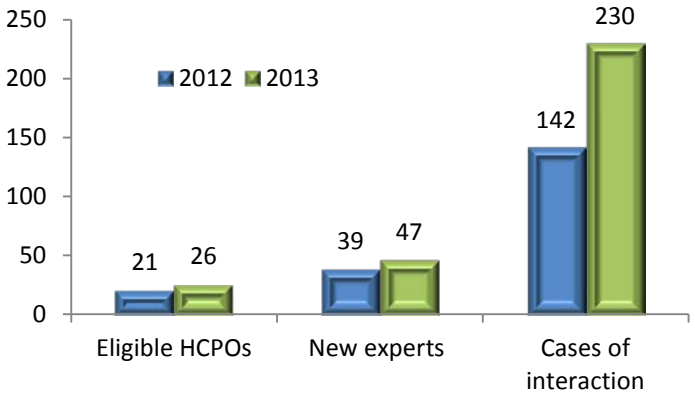
- Establishment of the EMA Healthcare Professionals Working Party (HCPWP)

  - ✓ Mandate and rules of procedure discussed and endorsed February-May
  - ✓ Executive Director's Decision on 31 May 2013
  - ✓ Appointment of organisations' and committees' representatives
  - ✓ Appointment of Isabelle Moulon as the EMA co-chair
  - ✓ First meeting of the working party in June and election of Gonzalo Calvo as co-chair
  - ✓ Nomination of observers to PCWP, ENCePP and EnprEMA



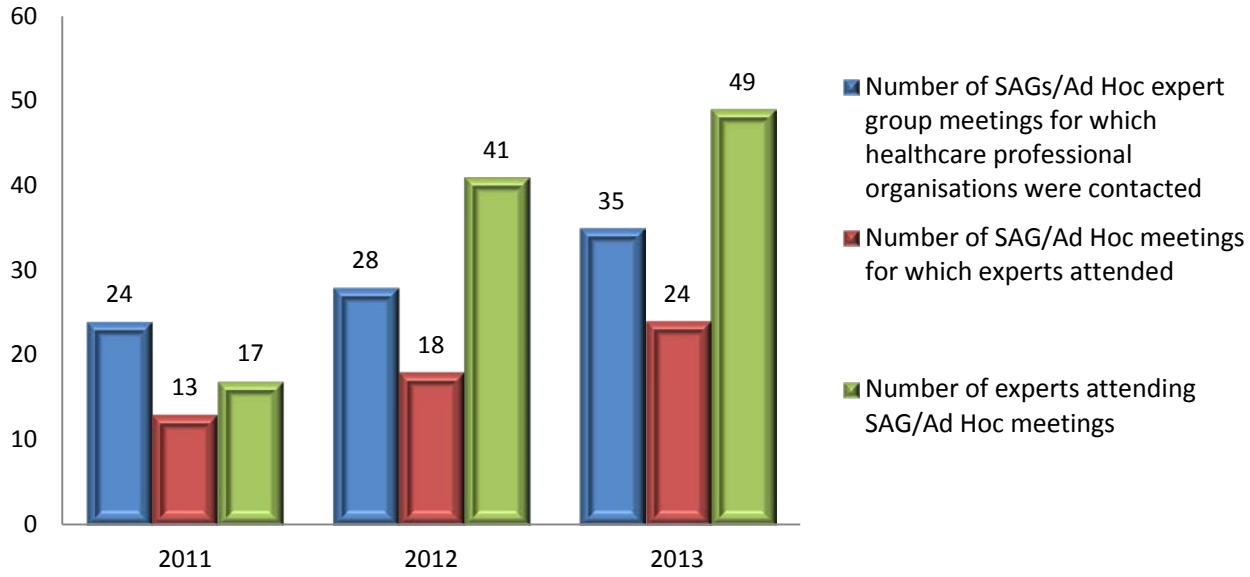
Achievements in 2013

- Maintenance and expansion of the Network of European healthcare professional organisations (HCPOs)
  - ✓ 6 new eligible organisations joined;
  - ✓ 26 eligible organisations by the end of 2013;
  - ✓ Financial re-evaluation for 20 eligible organisations completed.



- Use of the network of HCPOs as a valuable source of independent expertise

Participation in SAG/Ad-hoc expert group meetings



- ✓ Clinical expertise in specific conditions (e.g.): Duchene's muscular dystrophy; severe primary insulin-like-growth-factor-1 deficiency; transfusion-dependent anaemia due to low- or intermediate-1-risk myelodysplastic syndromes; multidrug-resistant tuberculosis; sepsis; cognitive impairment no dementia

- ✓ Input from diabetologists; cardiologists; infecciologists; haematologists; oncologists; neurologists; endocrinologists; gynaecologists; rheumatologists; hepatologists; nephrologists; vascular surgeons; intensivists

Interaction throughout the year

- Scientific Advice – involvement of nephrologists in two Qualification Teams for biomarkers to be used in polycystic kidney disease and drug-induced kidney injury
- Product-specific written consultations associated with potential medication errors
  - Expertise in psychiatry and oncology (including specialists; nurse and pharmacist specialised in oncology; and experts in medication errors)
- Review of safety communications and DHPCs
  - 19 DHPCs with feedback/comments
  - 27 safety communications with feedback/comments
  - 20 reviewers (15 physicians, including a general practitioner; 2 nurses; 3 pharmacists)

Example of input reflected in a Public Health Communication following comments from General Practitioner and Community Pharmacist

Example of input reflected in a Public Health Communication following comments from nephrologist

One concrete example – combined hormonal contraceptives

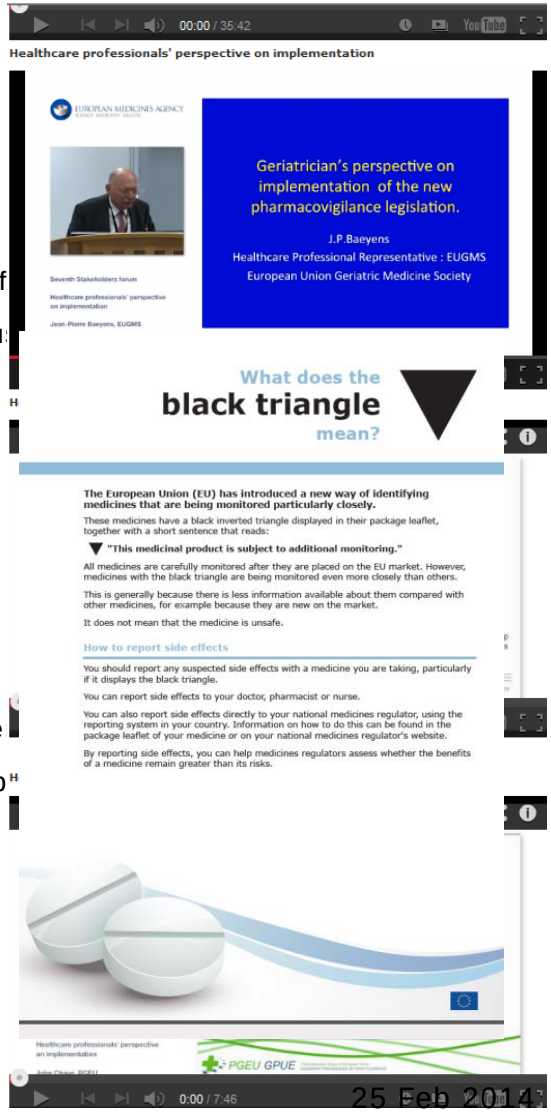
- Start of referral – February
- Ad hoc expert group meeting – July
- Consultation on best presentation of risk in the proposed changes of Section 4.4 of the SmPC and on the proposed table for inclusion in DHPC – October
- Consultation on the draft DHPC - October
- Review of draft public health communication - November

Benefits of combined hormonal contraceptives (CHCs) continue to outweigh risks – CHMP endorses PRAC recommendation

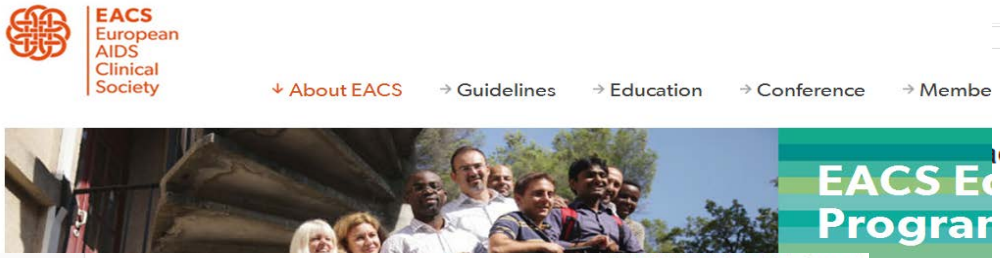
Facilitate HCPOs input and contribution to the implementation of new legislation

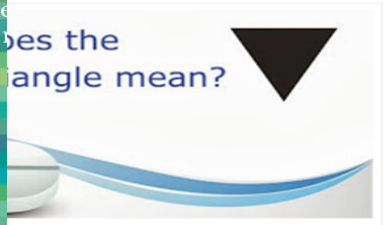
- Falsified medicines
  - Joint PCWP/HCPWP discussion in February 2013 strengthening the importance of
    both on the purpose of the common logo as well as how legally operating sites u
    and kept trust worthy

- Pharmacovigilance
  - Feedback on initial communication following publication of first list of medicines
    under additional monitoring in April 2013
  - Presentations from EUGMS, CPME, and PGEU at 7th Stakeholders Forum in Septe
    - input from doctors and pharmacists on the impact of the legislation in clinical p
  - Survey on additional monitoring awareness campaign in October 2013



News from the EACPT





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basal cell carcinoma or locally advanced basal cell carcinoma inappropriate for surgery or radiotherapy. More...

4. New European system for medicines under additional monitoring
Next anticancer medicines and biologics subject to additional monitoring in the EU are: brentuximab vedotin, ofatumumab, nelarabine, bosutinib, vandetanib, decitabine, clofarabine, eribuline mesylate, axitinib, ruxolitinib, cabazitaxel, pertuzumab, pixantrone, tegafur/gimeracil/oteracil, lapatinib, panitumumab, everolimus, anagrelide, crizotinib, denosumab, ipilimumab, trabectedine, aflibercept, vemurafenib,

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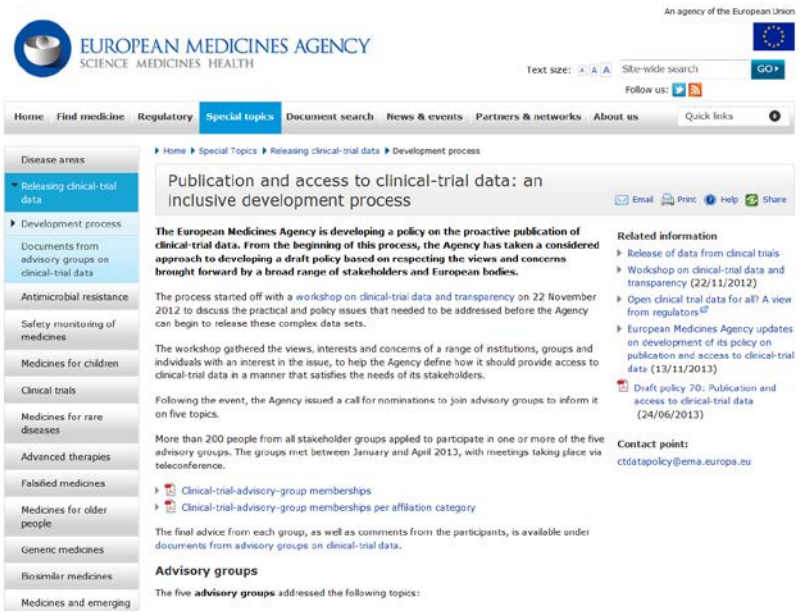
Input into EMA transparency initiatives

- February 2013

  Clinical trials advisory groups

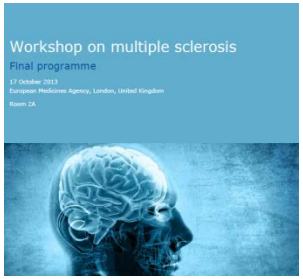


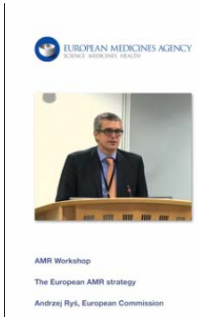
- September 2013

  CoIs workshop

Increased participation in EMA workshops

- 28/02/13 – Medication Errors
- 07/06/13 – Patient-support programmes (PSPs) and market-research programmes (MSPs)
- 26/09/13 – Patient's voice in the evaluation of medicines
- 14/10/13 – Product shortages due to manufacturing and quality problems
- 17/10/13 – Clinical investigation of new medicines for the treatment of multiple sclerosis
- 31/10/13 – Biosimilars
- 08/11/13 – Best use of medicines legislation to bring new antibiotics to patients and combat the resistance problem
- 26/11/13 – EMA/HTA-body workshop on parallel scientific advice in drug development





Systematic dissemination of information produced by EMA

- 83 draft guidelines, concept papers, herbal monographs disseminated
  - Comments on draft guidelines/ concept papers from HCPOs
    - April - Concept paper on the need for a reflection paper on quality aspects of medicines for older people (EUGMS)
    - August - Draft qualification opinion of a novel data-driven model of disease progression and trial evaluation in mild and moderate Alzheimer's disease (EUGMS)
    - October - Concept paper on the need to revise condition–specific guidance, appendix 4 to the guideline on the evaluation of anticancer medicinal products in man (ESMO)
- 46 safety communications, shortages, batch recalls disseminated
- Increased feedback from HCPOs on further dissemination of EMA information among their networks

EMA seeks views on needs of the elderly in medicines quality and development

The European Medicines Agency (EMA) is seeking stakeholder views on the best ways to ensure the specific needs of the elderly are integrated during the development, approval and use of medicines, especially in relation to quality issues.

Unlike the paediatric case (regulation (EC) No 1901/2006), there is no specific legal requirement for the development of medicines for geriatric use. Yet EMA acknowledge a need for the pharmaceutical development of medicines to take into consideration that:

- elderly patients may face physical and cognitive impairment and hence they may have difficulties in taking their medicines e.g. swallowing tablets, opening packagings or reading the user instruction and patient information leaflet;

assistance of caregivers than the overall

, renal impairment or altered

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News from the EMA

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4	EMEA:Give your opinion concerning a draft reflection paper on risk based quality management in clinical trials	2579
5	The EU Clinical Trials Register is launched today	5145
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Raising awareness

- Participation in conferences organised by HCPOs

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

ALL POSSIBLE

BECAUSE OF YOU

AND WITH YOU!

THANK YOU!