



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

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



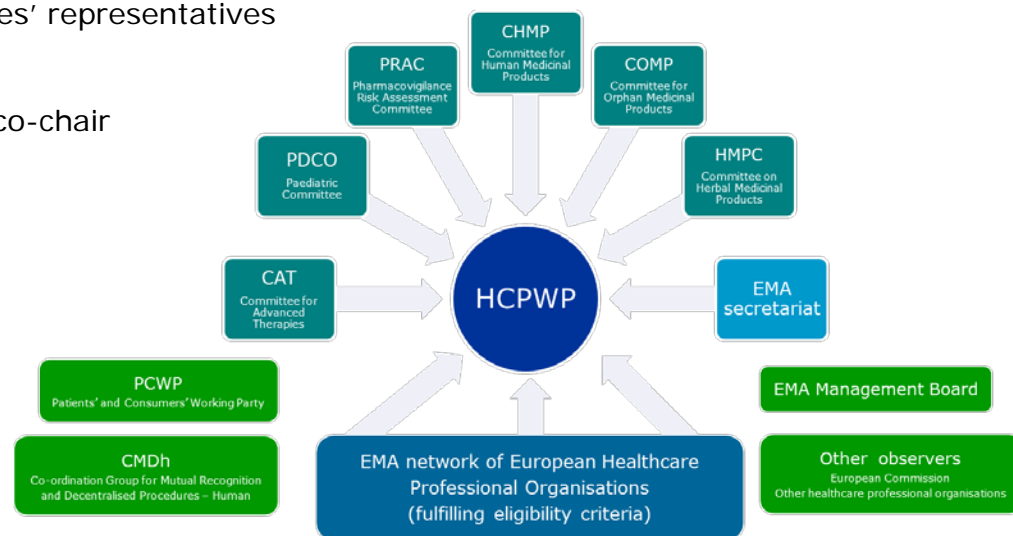
Enhance healthcare professional organisations' **understanding** of the role of the EU medicines Regulatory Network

Network of European healthcare professional organisations



Achievements in 2013

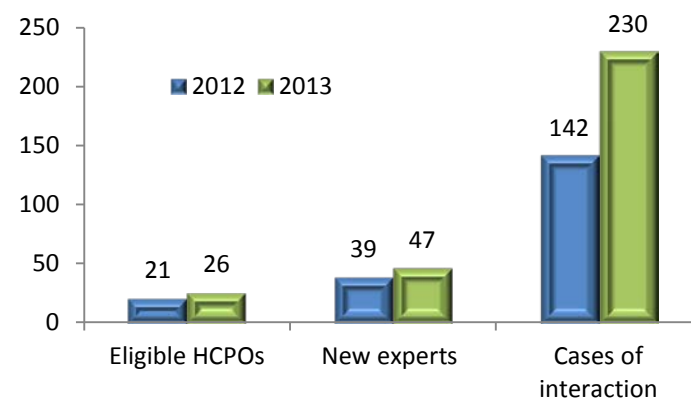
- Establishment of the EMA Healthcare Professionals Working Party (HCPWP)
 - ✓ Mandate and rules of procedure discussed and endorsed February-May
 - ✓ Executive Director's Decision on 31 May 2013
 - ✓ Appointment of organisations' and committees' representatives
 - ✓ Appointment of Isabelle Moulon as 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





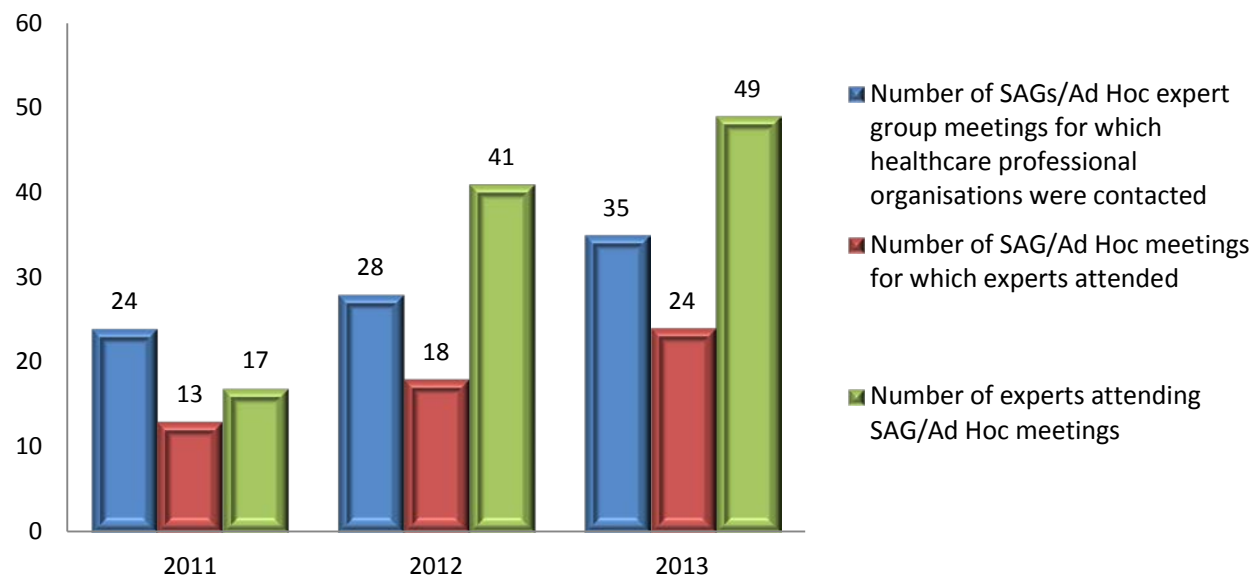
Achievements in 2013

- 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; infectiologists; 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 use it 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 September 2013 - input from doctors and pharmacists on the impact of the legislation in clinical practice
 - Survey on additional monitoring awareness campaign in October 2013

Healthcare professionals' perspective on implementation

Geriatrician's perspective on implementation of the new pharmacovigilance legislation.

J.P. Baeyens
Healthcare Professional Representative : EUGMS
European Union Geriatric Medicine Society

Smooth Stakeholders forum
Healthcare professionals' perspective on implementation
Jean-Philippe Baeyens, EUGMS

What does the black triangle mean?

The European Union (EU) has introduced a new way of identifying medicines that are being monitored particularly closely. These medicines have a black inverted triangle displayed in their package leaflet, together with a short sentence that reads:

▼ "This medicinal product is subject to additional monitoring."

All medicines are carefully monitored after they are placed on the EU market. However, medicines with the black triangle are being monitored even more closely than others. This is generally because there is less information available about them compared with other medicines, for example because they are new on the market. It does not mean that the medicine is unsafe.

How to report side effects

You should report any suspected side effects with a medicine you are taking, particularly if it displays the black triangle. You can report side effects to your doctor, pharmacist or nurse. You can also report side effects directly to your national medicines regulator, using the reporting system in your country. Information on how to do this can be found in the package leaflet of your medicine or on your national medicines regulator's website. By reporting side effects, you can help medicines regulators assess whether the benefits of a medicine remain greater than its risks.

Healthcare professionals' perspective on implementation
Jean-Philippe Baeyens

PGEU GPUE



Pharmaceutical Group of the E
Groupement Pharmaceutique d

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68° CONGRESSO NAZIONALE

La tecnologia nello studio medico del Medico di Famiglia:
coniugare approccio olistico e high-tech



4-9 novembre 2013
Roma - Ergife Palace Hotel



2° Congresso Nazionale Corte di Giustizia Popolare per il Diritto della
Salute

IN EVIDENZA

04
NOV
2013

Telemedicina: oltre 70% mmg
interessato.
Ma il 52% dice sì se si migliora
l'organizzazione della
professione.

04
NOV
2013

Al via oggi il 68° Congresso
Nazionale della Fimmg
La tecnologia nello studio del
medico di famiglia al centro
dell'appuntamento annuale

FIMMG NOTIZIE

08
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2013
L'osservatorio- la più grande fonte di dati medici
di studio non è condizione
sufficiente per essere assoggettati
all'Irap
18
OTT
2013
Petrone: nuova aggressione a
medico di controllo Inps, serve
Osservatorio su sicurezza
Irap, nuova sentenza a favore mmg
14
OTT

am
AVVENIRE MEDICO
è online il numero 3/2013

AL VIA LA CAMPAGNA
DI COMUNICAZIONE EMA

«Stacca quel
per saperne di più»



Advice on black triangle

Adding the ne
cians and
Does the
angle mean?

re) has introduced a new EU-wide
ed and serious adverse reactions to
g, including supported by a list of
ly for products that are new, or have had
concerns have been raised.

duct
ring of
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a Union
ack triangle.

erted black triangle symbol have been
see the [factsheet](#) and video below and the [EMA Press](#)

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, eribulin mesylate, axitinib, ruxolitinib, cabazitaxel,
pertuzumab, pixantrone, tegafur/gimeracil/oteracil, lapatinib, panitumumab, everolimus,
anagrelide, crizotinib, denosumab, ipilimumab, trabectedine, aflibercept, vemurafenib,

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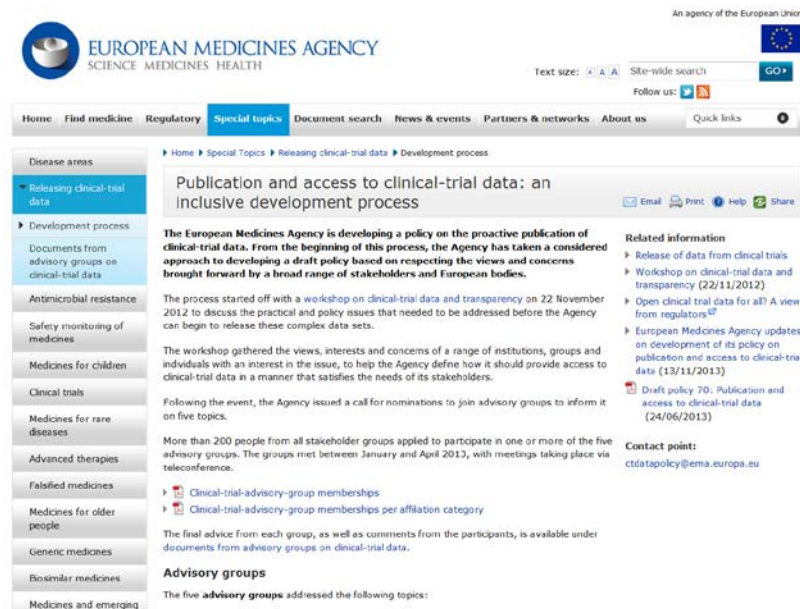
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Input into EMA transparency initiatives

- February 2013

Clinical trials advisory groups



- September 2013

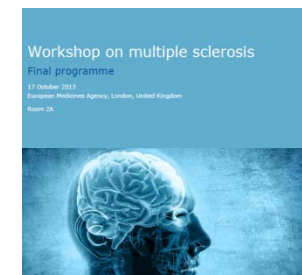
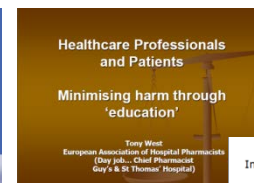
ColS workshop





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.

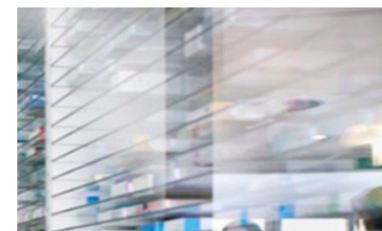
Unlike the paediatric case (regulation (EC) No 1901/2006), there is no specific legal requirement for the development of medicines for geriatric use. Yet EMA acknowledge a need for the pharmaceutical development of medicines to take into consideration that:

- 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

and the specific needs of the

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Gynecology**[Home](#)[The ESG](#)[Sitemap](#)**EFSD****49th EASD
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#	Article Title	Hits
1	European Medicines Agency starts safety review of Combined hormonal contraceptives	712
2	European Medicines Agency starts safety review of Diane 35 and its generics	750
3	EMA Consultation: Concept paper on the need for revision of the guideline on the evaluation of medicinal products for the treatment of primary osteoporosis	993
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
6	La dernière mise en garde de l'EMEA	1929
7	Warning of EMEA: Avastin use in metastatic breast cancer	3535

This website was last updated on Friday 21 February 2014



Raising awareness

- Participation in conferences organised by HCPOs



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SCIENCE MEDICINES HEALTH



Working with
healthcare
professionals

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Pharmacovigilance in Europe: where
are we and how can we improve?

UEG symposium, Berlin, 14 October 2013

Presented by: Isabelle Moulon
Head of patients and healthcare professionals



Sharing Our Vision?

A view from the European Medicines Agency

PGEU Symposium, 27 June 2013, Rome

Presented by: Guido Rasi
Executive Director – European Medicines Agency

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EUROPEAN MEDICINES AGENCY
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Role of regulators in providing information to healthcare
professionals

Juan García Burgos
Stakeholders and Communication
European Medicines Agency

An agency of the European Union





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!