



PGEU GPUE

Pharmaceutical Group of European Union
Groupement Pharmaceutique de l'Union Européenne

REFLECTIONS AND EXPERIENCES OF HEALTHCARE PROFESSIONALS ON THE IMPLEMENTATION OF THE DIRECTIVE SO FAR...



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Jurate Svarcaite, PGEU

Pharmaceutical Group of European Union

Members: Professional Bodies & Pharmacists' Associations



2012: 31 Countries

	Austria		Netherlands
	Belgium		Poland
	Bulgaria		Portugal
	Cyprus		Romania
	Czech Rep		Slovakia
	Denmark		Slovenia
	Estonia		Spain
	Finland		Sweden
	France		United Kingdom
	Germany		Croatia
	Greece		FYR Macedonia
	Hungary		Norway
	Ireland		Serbia
	Italy		Switzerland
	Luxembourg		Turkey
	Malta		

Healthcare Professionals Working Group (HCPWG)

The **European Medicines Agency/Committee for Medicinal Products for Human Use Working Group with Healthcare Professionals' Organisations** is a platform for dialogue and exchange of information with healthcare professionals' organisations.

Three **priority areas** for its work:

- information on medicines;
- **pharmacovigilance activities;**
- involvement of healthcare professionals' organisations in the work of the Agency's scientific committees.

Expectations

- Clear tasks and responsibilities for all Member States, EMA, industry.
- Improved decision-making procedures at the Community level and efficient use of resources in the network.
- Proactive and proportionate risk management.
- Stronger link between safety assessments and regulatory action.
- Strengthened transparency, healthcare professionals involvement.

Key points of the Directive for HCPs (I)

- **New medicines** and specific products subjected to additional monitoring will need to be **identified** through a **black symbol** in the **summary of product characteristics (SMPC)** and **patient information leaflet(PIL)**.
- **Patient direct reporting** is enabled.
- **EU** and **MSs** will need to set up linked **pharmacovigilance websites**. Those websites will include **assessment reports, summaries of product characteristics and patient information leaflets**.
- **Eudravigilance** database becomes the single point of receipt of pharmacovigilance information for medicinal products authorised in the EU.
- MSs may impose **specific obligations for healthcare professionals in the reporting system**.

Key points of the Directive for HCPs (II)

- **HCPOs** may be **involved in the consultation** regarding the tasks assigned to HCPs in the **pharmacovigilance system**.
- **HCPOs will need to be consulted** in the future **eventual revision** on the **PIL and SmPC content**.
- New scientific committee at the EMA: “**the Pharmacovigilance Risk Advisory Committee**” („PRAC”) responsible for providing advice on pharmacovigilance **will have a representative of healthcare professionals**.
- Competent authorities may **grant exceptions to the labelling and packaging requirements** in cases of severe problems in respect of the availability of the medicinal product.



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Communication by the Agency

- 5th Stakeholder Forums took place since in 2011-2012,
- 3 HCPWG meetings,
- 2 joint meetings with PCWP,
- Regular updates by e-mails and in a form of press releases.

Overall communication by the Agency is outstanding



Involvement of HCPs

- Numerous presentations by HCPs during Pharmacovigilance Stakeholder Forum's,
- Consultation on Good Vigilance Practice (GVP) modules,
- Consultation on the Eudrovigilance data presentation,
- Usability testing of the EMA adverse drug reaction website,
- Consultation on the design of web-reporting forms for Healthcare professional reporting of adverse drug reactions,
- Consultation on black symbol and accompanying test,
- Etc.



Some reflections...

- “Some HCPOs are more involved than others in the implementation of the directive. Pharmacists are on the frontline , while nurses are more focusing on consequences of the implementation in their clinical activities. The requests for comments from the Agency were then not adapted for some HCPOs.” (*ESNO*)
- “From now on there is a long way and hard work to do to disseminate the information and to implement the knowledge and the applicability of the new legislation for professionals (Task of the PRACC, when, how, what type, ethical issues about the clinical trials that will be required or not post-authorization).

In this context there is a strong need of join workshop within EMA and specific HCPOs (in my cases, specifically the European Society of Cardiology) in order to understand the future practicalities of the legislation.” (*ESC*)



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National reflections...

- “In Finland the EMA has been quite invisible, but the national (medicines agency) FIMEA has keenly worked according to the EMA and directive mainstream...” (*CPME*)



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Patient Safety

maximizing patient safety in Europe
through the safe use of medicines



PGEU EXPERIENCE

Communication

- Regular updates to Members during face to face meetings of dedicated working groups and General Assemblies,
- Written updates in the monthly reports of the Secretariat, Work Programme, Annual report,
- Dedicated sessions during Annual Symposium,
- E-mail communication.

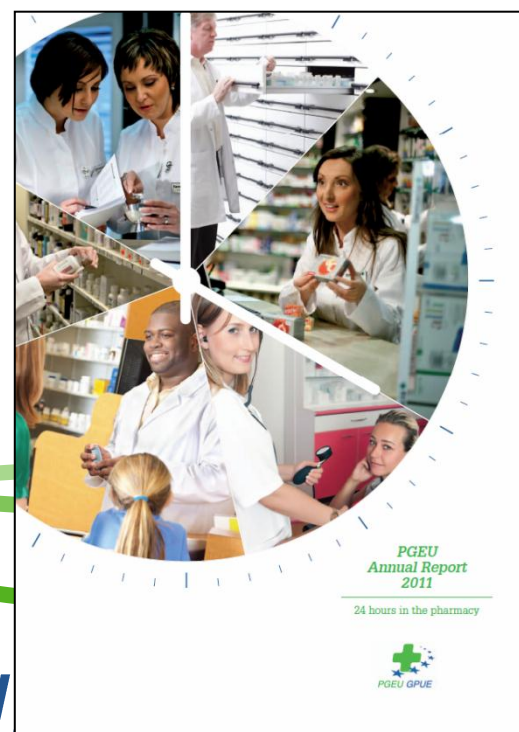


Table of Contents	
1. NEWS FROM THE SECRETARIAT	4
PGEU attended the Platform on Ethics and Transparency meeting	4
PGEU met BEUC on Patient access to health data	4
PGEU attended the EFPIA patients advisory board	4
PGEU attended the EUROPEAN Medical Devices UDI Ad Hoc WG MEETING	4
PGEU in Nottingham	4
PGEU met Tiedje	4
PGEU met DG Sanco	4
PGEU met Eucomed meeting	5
PGEU met Pfizer	5
PGEU attended the European Stakeholder Model meeting	5
PGEU addresses Board of Swedish Pharmacy Association	5
PGEU attended the CoT Advisory Board Meeting	5
2. NEWS FROM THE EU	5
Cyprus Presidency of the EU	5
New rules on importing active pharmaceutical ingredients into EU	6
EMA consults on risk-based auditing of pharmacovigilance systems, communicating safety info and guideline on the evaluation of medicinal products indicated for treatment of bacterial infections	6
Public Health: Panel of independent experts to work on the improvement of health care systems	7
ENVI adopted health for growth Report	8
3. ONGOING DOSSIERS OF INTEREST TO PGEU	8
New Pharmacovigilance Legislation Comes into Operation	8
Recognition of Professional Qualifications Directive	9
European Standardisation Directive	9
Working Time Directive: Commission agrees to extend time for social partners' negotiations	9
EFSA further assesses health claims and publishes guidance	10
EP calls for stricter and simpler rules on food intended for vulnerable populations	10
A clean and open internet: Public consultation on procedures for notifying and acting on illegal content hosted by online intermediaries	11
Conclusions of Working Group on E-Commerce	11
Commission boosts clinical research in Europe by simplifying the rules for conducting clinical trials	11
4. NEWS FROM MEMBER STATES and beyond	12
France: self-selection study finds need for information	12
Greece: ePrescription	13
Germany: switch committee rejects paracetamol reverse	13
PGEU Monthly Activities Report - July-August 2012	Page 2 of 17



Participation in Consultations

- Consultation on the Eudrovigilance data presentation,
- Usability testing of the EMA adverse drug reaction website,
- Consultation on the design of web-reporting forms for Healthcare professional reporting of adverse drug reactions,
- Consultation on black symbol and accompanying test,
- Etc.

Expectations of Pharmacists

17/06/2011

- Cases like Mediator to be detected earlier using Eudravigilance!
- 'Dear health professional' instead of 'Dear doctor' letter.
- To be consulted in the future eventual revision on the PIL and SmPC content.
- Instant overview of medicines safety issues when using public interface of Eudravigilance.
- Feed back → Individual follow up of reports + safety info feed into pharmacy ICT support tools.

Outstanding issues

- Improve spontaneous ADRs reporting by pharmacists,
- Participation in awareness campaigns on black symbol and a
- Prom **‘Pharmacovigilance: more a responsibility than a role!’** rs,
- Feed *Kelly B. Pharmacovigilance: more a responsibility* report tools *than a role. Austr Pharm 2001;20:128.*
- Involvement in the risk assessment of pharmacy practitioners,
- Medicine shortages.





THANK YOU

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