



European
AIDS Treatment
Group

EATG, 2012
6th Stakeholder Forum on the implementation of the new
Pharmacovigilance legislation, 08/11/2012, EMA London
1/12

6th Stakeholders forum on the implementation of the new Pharmacovigilance legislation

Patient Organisations' Considerations

David H.-U. Haerry, European AIDS Treatment Group



Communication

- Extensive communication by EMA on legislation and implementation
- Detailed work plans, tables
- Very good example of transparency, proactive and professional



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PCO consultation

- Consulted & involved since very beginning
- Very useful stakeholder forums
- Good public consultations on vigilance practices, public hearings etc



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National implementation

- Unsatisfactory



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Italy

- Academic researchers concerned about patient data privacy due to additional safety reporting requirements due to new legislation



France: Additional monitoring

Inverted triangle ▼

In all package leaflets of medicines with “additional monitoring”

French regulatory authority published list of all medicines with additional monitoring

- But with no explanation
- Objective: transparency
- Outcome: confusion



Art. 102 of Directive 2010/84

The Member States shall:





- (a) take all appropriate measures to encourage patients, doctors, pharmacists and other healthcare professionals to report suspected ADRs to the NCA; for these tasks, organisations representing consumers, patients and healthcare professionals may be involved as appropriate;
- (b) facilitate patient reporting through the provision of alternative reporting formats in addition to web-based formats;



A large experience already

1978	Kilen (S)	www.kilen.org	Consumer group
1993	FDA (USA)	www.fda.gov/medwatch	Government
2003	Medicines Agency (DK)	www.dkma.dk	Government
2003	Lareb (NL)	www.lareb.nl	Government
2003	Therapeutic good administration (AU)	www.tga.gov.au	Government
2003	Health Canada		Government
2004	Meldpunt Medicijnen (NL)	www.meldpuntmedicijnen.nl	Consumer group
2005	MHRA (UK)	www.mhra.gov.uk	Government
2006	Test Aankoop (BE) Test Achat	www.contactmedicaments.be www.meldpuntgeneesmiddelen.be	Consumer group
2008	Afssaps	www.afssaps.fr	Regulatory agency and patients' groups

Reporting tools, July 2012

-  On-line reporting form
-  Printed form
-  No information available
-  Non-EU/EEA





Belgium – direct reporting

- Launched by press release from public authorities
- **Encouraging patients to report to doctors & pharmacies!**
- NCA concerned about work load?



Summary

- Big changes = big challenges
- We feel missing budget on implementation
- No patients in PRAC, foreseen is only one
- Patients joining PRAC expected to work for free
- Future looks bright, remember Bill Gates 1981:
"640K ought to be enough for anybody."



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12/12

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