



Reports from
parallel work stream:
REGULATORS

Rapporteur: Birka Lehmann, BfArM

Chair: Nicola Bedlington, EPF



Report from Regulators Work Stream

Case study 1 presentation and questions: Partnership of EUPATI and **AIFA**; patient involvement in regulatory processes in Italy

Silvia Cammarat

- 2012 - Involvement of patients proactive: ADRs, SmPC & PL. transparent communication, personalized medicine;
- 2014 MoU with EUPATI and national platform: 112 month training course in IT language
 - Collaboration with patients organisation all vs selected

Case study 2 presentation and questions: **MHRA** patient involvement

Mike Dykes

- 2014 Patients Group Consultation Forum – informal group to support all MHRA

Composition: 30 health issues

Rules: ,real' patients and organisations impute on: ADRs, views on packing, accelerated acces review,

Multi stakeholder meetings on selected issues

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Case study 3 presentation and questions: **Swissmedic** Pilot patient involvement

Cordula Landgraf

2014 EUPATI and national platform: no involvement of product related question; difficulties to reach out for all/right organisations/patients,

Training has to be adapted to Swiss legislation,

Discussion on topics for patients involvement

Case study 4 presentation and questions: Medical Products Agency **MPA**: Swedish experience

Lena Ring

Expierence 2009 – 2011 patients dropping

New approach: implizit

Involvement of pat org. - in principle following the EMA concept : advisory council for overall topics and on product specific

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■ SUMMARY

- Which kind of patients to be involved? Given advice as individuals?
- Selection of patients as experts/organisation vs patients
- Membership duration?

- Building common knowledge – training on national level for patients
- & training for regulators to interact with patients



- Where to fit in the med prod & med devices products

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■ SUMMARY

- Compensation of patients/patients involvement? Like other experts - harmonised (EU) – standardised approach needed
- Matrix (out- come measurments) - flagged to be further defined

Many Member States improving the interactions with patients/patientsorganisation:

- Mostly on informal request/requirement  to go for a legal basis
- Exchange of experiences and needs for improvement  EMA & HMA & observers - net working to be implemented