



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Forward

8 November 2012
Stakeholder meeting

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Forward.....

- Hope: objectives
- Achieve: looking back
- Survey: environment
- Continue: forward to 2013
- Plan: beyond 2013
- Improve: key success factors
- Perform: measures of impact
- Conclude: the best is yet to come



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Hope: objectives

- Clear roles and responsibilities
- Engage patients and healthcare professionals
- Science based - integrate benefit and risk
- Risk based and proportionate
- Increased proactivity and planning
- Reduced duplication/redundancy
- Robust and rapid EU decision-making
- Increase transparency and provide better information on medicines

Promote and protect public health by reducing burden of ADRs and optimising the use of medicines



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Achieve: looking back

A few highlights:

- Dialogue and consultation with stakeholders
- Technical regulation and guidance
- Established PRAC and started to assess and decide
- Driven up transparency
- Created new processes and improved established ones
- Trained
- Collected > 200,000 structured product entries, 4 million ADR reports
- 500 monthly signal analysis reports
- New public adverse reaction website for centrally authorised products
- EC consultation on fees for pharmacovigilance
- New directive 2012/26/EC and regulation (mediator stress test)



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Survey: environment

Consider:

- Change – pharmacovigilance legislation is biggest in a generation
- More change – falsified medicines, devices, clinical trials
- Economy – 'it's the economy stupid'
- Technology enhancement
- Social media
- Globalisation
- Expectations



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Continue: forward to 2013

Continue:

- New risk management process
- Periodic Safety Update Reports: list, centrally authorised product (CAP) assessment, joint CAP and nationally authorised product (NAP) single assessment
- Safety studies: oversight of protocols and results for CAPs and NAPs
- Adverse reaction reports: collection, training, data management
- Signal detection and management for CAPs/NAPs
- Committee: assessment and “decision-making”
- Publish adverse reaction data for CAPs
- New referral procedures
- Transparency: PRAC agendas and minutes
- Coordination of safety messages



New: forward to 2013

Subject to agreement by EMA Management Board / HMA:

- Efficacy study scientific workshop and guidance + consultation on grounds
- Legal proposal from the European Commission on fees for pharmacovigilance
- Medication error workshop 28 Feb/ 1 March + best practice document
- Structured product information: Maintenance + core validation + publication
- Collaboration procedure for joint industry safety studies
- Additional monitoring: list published + introduction of new symbol / wording
- Public Hearings for Urgent Union Procedure
- Further increase in transparency: CHMP + CMDh agendas and minutes for PV
- Revised process for PV inspections
- Integrated performance management
- 1st EudraVigilance annual report
- 1st EMA and National Competent Authority system audits
- Committees – strategy on best evidence



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Plan: beyond 2013

Plan, prepare, pray:

- Further IT development: EudraVigilance (EV) functionalities, PSUR repository
- EMA literature monitoring for adverse reactions and entry in EV
- Payments to rapporteurs
- PSUR single assessment for substances not included in CAPs
- Programme for monitoring effectiveness of risk minimisation
- Public hearings outside the scope of Urgent Union Procedures



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Improve: key success factors

Learning from implementation:

- Clarity of governance
- Careful impact analysis
- Strict planning and project management
- Detailed process mapping and process improvement / simplification
- Dialogue and consultation with stakeholders
- Manage expectations
- Remain focussed on the key objective: promotion and protection of public health



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Perform: measures of impact

Key performance indicators to improve and inform on impact:

- Approach (OECD):
 - Process / regulation implemented: e.g. guidance available, website launched
 - Behaviours changed: e.g. prescribing, dispensing, consumption
 - Outcomes: e.g. mortality, morbidity, quality of life, costs
- Method:
 - Qualitative vs quantitative
 - Descriptive vs comparative (temporal, geographical, medicine, population)
- Outputs:
 - Process improvement
 - Committee decision-making
 - Annual report (including peer-reviewed journal)
- Resources:
 - Leverage existing measurement and collaborate with stakeholders



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Conclusions

- Objective: promote and protect public health
- Change: biggest change for human medicines in a generation
- Achieve: major delivery over the last two years
- How: together
- Forward:

**For public health promotion and protection –
the best is yet to come!**