European Commission's proposal for Pharmacovigilance

EU Regulatory Network

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Key steps

- 2004 – Commission launches call for proposals for independent study
- 2005 – Independent study conducted
- 2006 – Commission launches public consultation
- 2007 February – Vice-President Verheugen announces Commission strategy
- 2007 December – Launch of public consultation on draft proposals for changes to legislation

Stakeholder feedback

- 5 patient and consumer groups
- 16 healthcare professional groups / academics
- 26 regulators
- 29 from industry
- 6 others

General Feedback

- Strong support for the objectives pursued (stronger health protection, more rational, more robust PhV)
- Strong support for the draft proposals overall
- 2 / 82 responses not welcoming the proposals
- Strong support for clear legal provisions and better use of resources

Pharmacovigilance: main principles guiding the legal proposals

- Better risk identification
- Less paperwork
- Clear follow-up to identified risks
- More patient involvement
- Better communication

Main envisaged changes

- Clarifying responsibilities
- Strengthening transparency
- Simplification of the reporting obligations
- Monitoring of literature
- Scrutiny of PhV system
- Less routine requirements

Commission legislative strategy

- Changes to Directive 2001/83/EC
- Changes to Regulation (EC) No 726/2004
- These are adopted by the European Parliament and the Council, therefore:
  - Co-decision directive to change the Directive
  - Co-decision regulation to change the Regulation

Next steps

- Commission plans to adopt proposals for legislation in November 2008
- Submission to the European Parliament and to the Council
- Co-decision procedure will likely take two to three years

Thank you!