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Regulators' response to consultation on EU legislative proposals for pharmacovigilance : common themes

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Christine Bendall

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Regulators' response to consultation on EU legislative proposals for pharmacovigilance

- See: http://ec.europa.eu/enterprise/pharmaceuticals/pharmacovigilance/cps.htm
- In excess of 80 responses divided by the Commission in to:
  - Patients and consumers
  - Healthcare professionals and academics
  - Regulators
  - Industry
  - Others

Regulators' response to consultation on EU legislative proposals for pharmacovigilance

- Review of EMEA, PfVWP, CHMP, MHRA, Spanish Agency for Medicines and Healthcare, French Agency, German Federal Ministry of Health, Medicines Evaluation Board Netherlands, National Pharmacovigilance Committee Italy, Medical Products Agency Sweden
- Common themes
- Commission Analysis of results April 2008

Regulators' response to consultation on EU legislative proposals for pharmacovigilance

Regulators' perspective considers:

- who does what in the EU
- how there will be increased co-ordination across MS
- how new processes and responsibilities are to be resourced
- how Eudravigilance will manage the data

Regulators' response to consultation on EU legislative proposals for pharmacovigilance : common themes

- Procedural
  - clarity eg referrals
  - public hearings
- Resourcing
- Roles and relationships
  - Relationship CHMP and new Committee on Pharmacovigilance
  - EMEA and national agencies: allocation of roles and responsibility for centrally and non centrally authorised products
- Inspections and Enforcement

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- Specifics of the proposals:
  - ADR reporting: simplification and definitions
  - Consumer/patient reporting routes
  - Product information and updating
  - Balancing risk and benefit
  - MAH responsibility for referring changes in risk/benefit

Regulators' response to consultation on EU legislative proposals for pharmacovigilance : common themes

- Exceptional circumstances and intensive monitoring
- RM
- PSURs
- PAS (non-interventional)
- Communication of safety information to HCPs and the public
- GVP

Response to consultation on EU legislative proposals for pharmacovigilance: Commission analysis

Commission's overview highlighted 13 aspects:

- General feed back :"very strong support for the objectives"
- Legislative Strategy: "relatively few stakeholders commented"
- Rationalisation of EU decision-making on safety issues: "strong endorsement" for "automatic" referrals (q. detail/public hearings); support for new Committee ("almost unanimously supported"), but issues on remit and composition

Response to consultation on EU legislative proposals for pharmacovigilance: Commission analysis

- Rationalisation of roles and responsibilities; for R/B change notification- “generally welcomed”, also support for updating product information, signal detection, MS delegation of tasks, GVP, MS penalties
- MAH PV systems and inspections; oversight by MS, suggested EMEA data base for reports, responsibility for central MAH inspection linked to site of main PV activity, not QPPV residence
- Risk management: “unanimous agreement” re making key measures in RMPs legally binding, broad support for intensive monitoring, but not for removal of exceptional circumstances (“strong objection”), terms (risk management plan/system)

Response to consultation on new EU legislative proposals for pharmacovigilance

- Legal basis for PASS: “unanimous support”, and for inclusion in MA, definition
- PASS: principles and oversight: strong support for guiding principles and oversight of a subset (Non-Interventional Studies), query interface with RMPs
- Rationalisation of ICS reporting: “very strong support”, support for use of Eudravigilance (but access and technical issues), electronic reporting for MAHs, legal basis for/ recipient of patient reports, and a core, but delineated, role for EMEA in literature monitoring. Medication errors. Definitions issues.

Response to consultation on new EU legislative proposals for pharmacovigilance

- Rationalisation of PSURs: “strong support”; clarification of link to RMP, publication of and assessment of PSURs by Pharmacovigilance Committee
- Transparency and communication: “unanimous support”, but balance presentation of R/B. Availability of ADR data to the public “welcome”. EU co-ordination of safety messages
- Strengthening of product information: “strongly supportive”, contextualisation of risk against benefit
- Other “diverse” issues

Response to consultation on new EU legislative proposals for pharmacovigilance

When will we know what impact has the consultation has had on the proposals?