The International Drug Safety Paradigm

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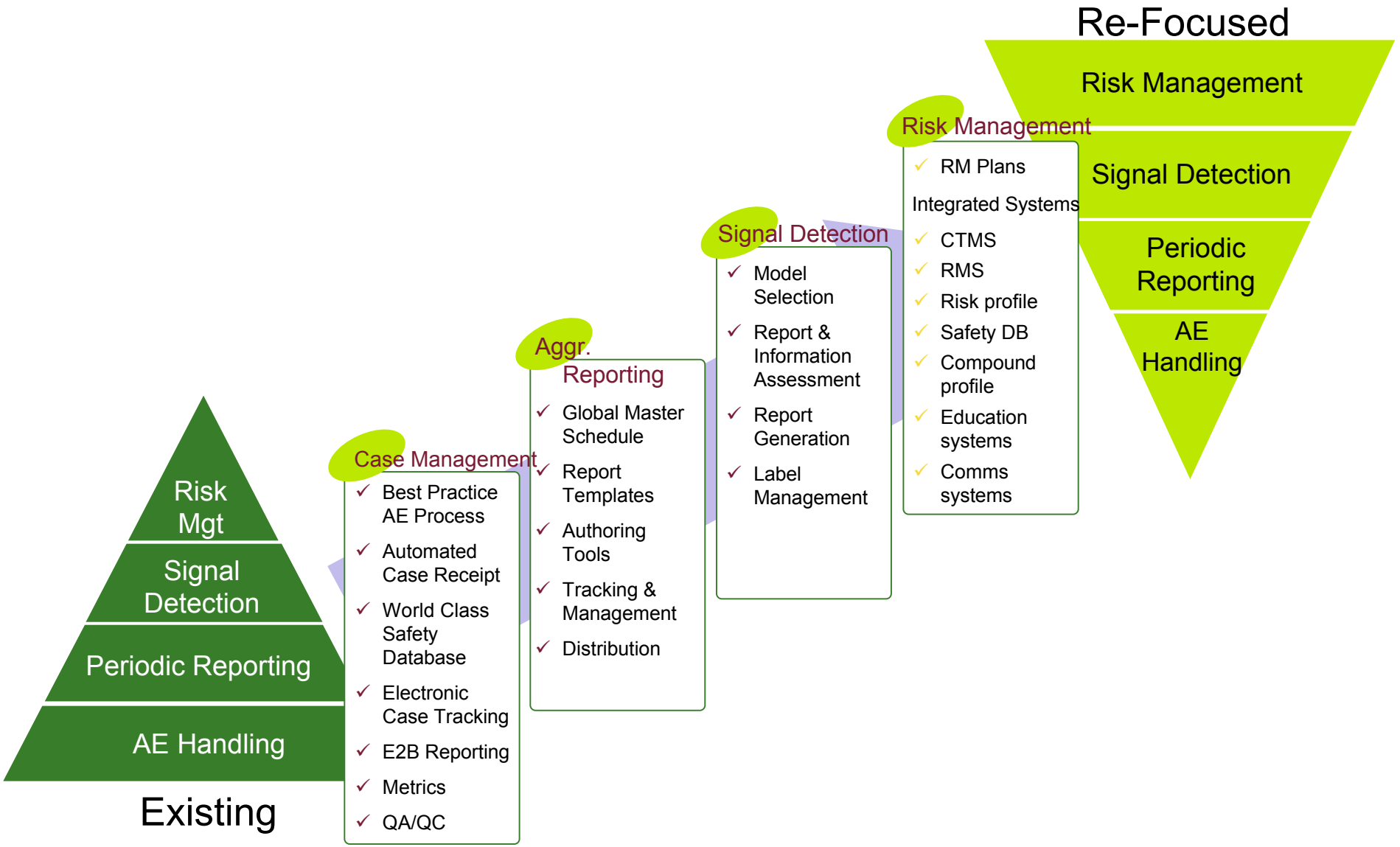
Global regulatory trends

- Safety has become a higher order concern within industry
- FDA move towards a risk-based approach
- US Congress increasing pressure on FDA post Vioxx
- EU Authorities increasing legislation

Drug Safety requirements

- Role is to protect patients who receive a company's products
- Traditionally focus has been to compliance with regulatory reporting requirements
- A pro-active approach needs to be fully established
  - Rapid identification, analysis, communication of safety signals
    - Define the Safety profile
    - Contribute to product labeling texts
    - Safety expertise to clinical development programmes
    - Facilitate risk management

How Drug Safety Processes must evolve to meet the new challenge



EU pharmacovigilance (PV) legislation – complex and confusing

- Spread over many documents
  - EU Council regulations applicable in all Member States
  - EU Directives not directly applicable
  - EU Commission guidelines have no input from legal services or Council and EU Parliament
- Legal issues arising from current EU-PV legislation
  - Ambiguous legislation (Eudralex Volume 9)
    - EU Qualified Person
    - Notification of PV ‘arrangements’ to Authorities

EU Pharmacovigilance regime needs to change to meet global challenges

- Current EU pharmacovigilance system across Members States is complex, and lacks legal certainty
- Potential burden on Pharma companies
  - Overlapping legal provisions
  - Duplication of effort
  - Confusion of responsibilities
  - Distortions in the marketplace
- Potential for increased product liability exposure

New approach required for the EU system of Pharmacovigilance

- Assessment of current EU-PV regime is underway
  - Results expected end 2005
- Improve clarity of regime through revision of Eudralex Volume 9
  - Increase legitimacy by consultation with other Commission services, EU Council and Parliament
- Adopt Pharmacovigilance Council Regulation
  - Detailed, clear, concise provisions
  - Applicable across Member States
  - Legally binding
  - Published in EU languages and Official Journal

New risk-based approach required by Industry

- Use risk-based inspection model, based on a risk-ranking and filtering method that is well recognized, objective, and rigorously systematic
  - FMEA* assessment
  - Risk profiling
  - Risk scoring and tracking
  - Assessment
  - Risk detection
  - Actions
  - Governance – roles, responsibilities
- Prioritizes and focuses activities
- Aligned with new regulatory approach (e.g. FDA)
- Creates a 'risk alert' culture

*FMEA: Failure Modes & Effects Analysis

Questions?

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