EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Implementation of the new pharmacovigilance legislation:

Key achievements and status of prioritised implementation

Sixth Stakeholders forum
European Medicines Agency

8 November 2012

Franck Diafouka,
Project Manager,
Pharmacovigilance and Risk Management Sector, EMA

Content

- High level objectives
- Key achievements
- Prioritised implementation - status

High level objectives

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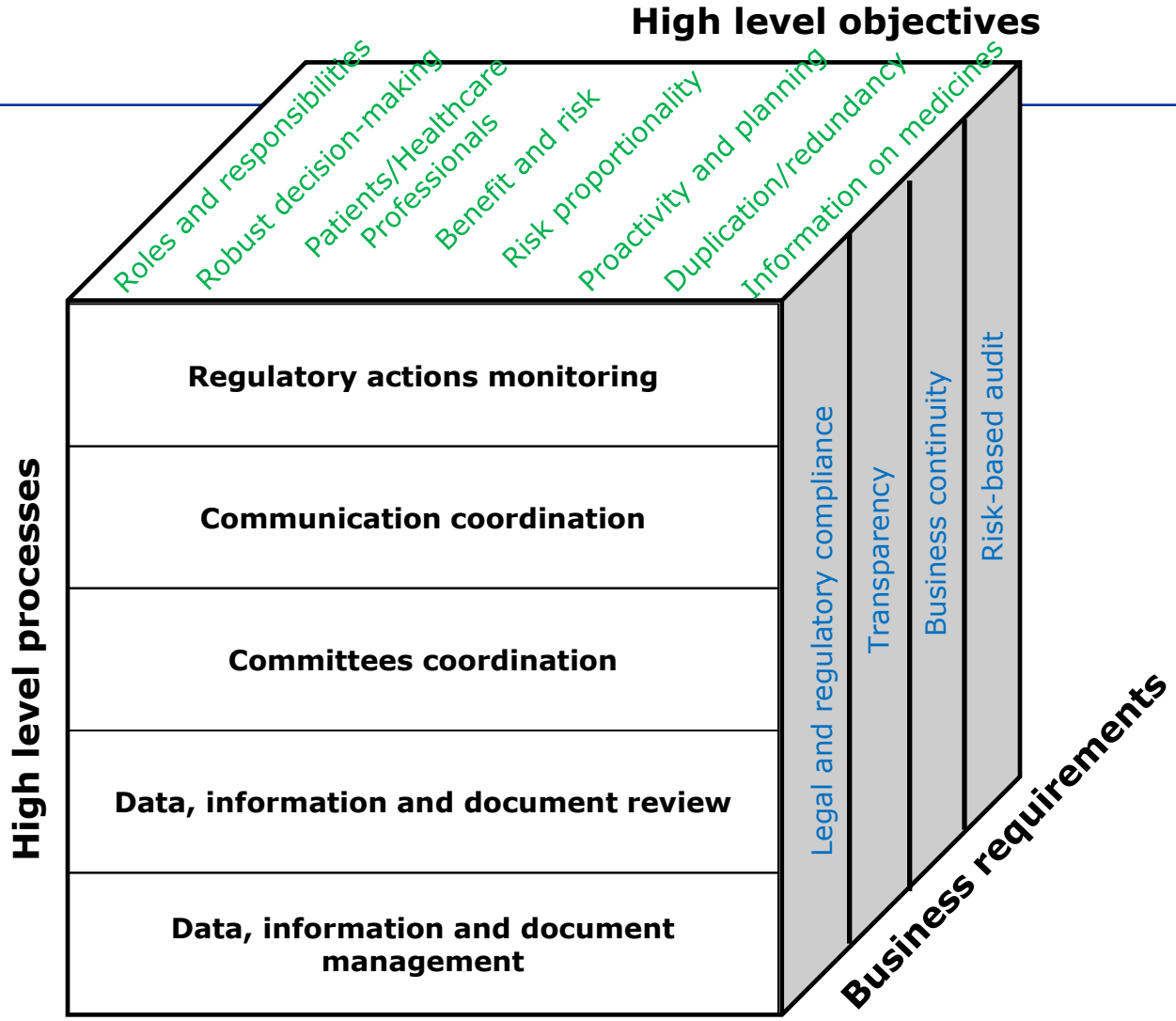

Key achievements

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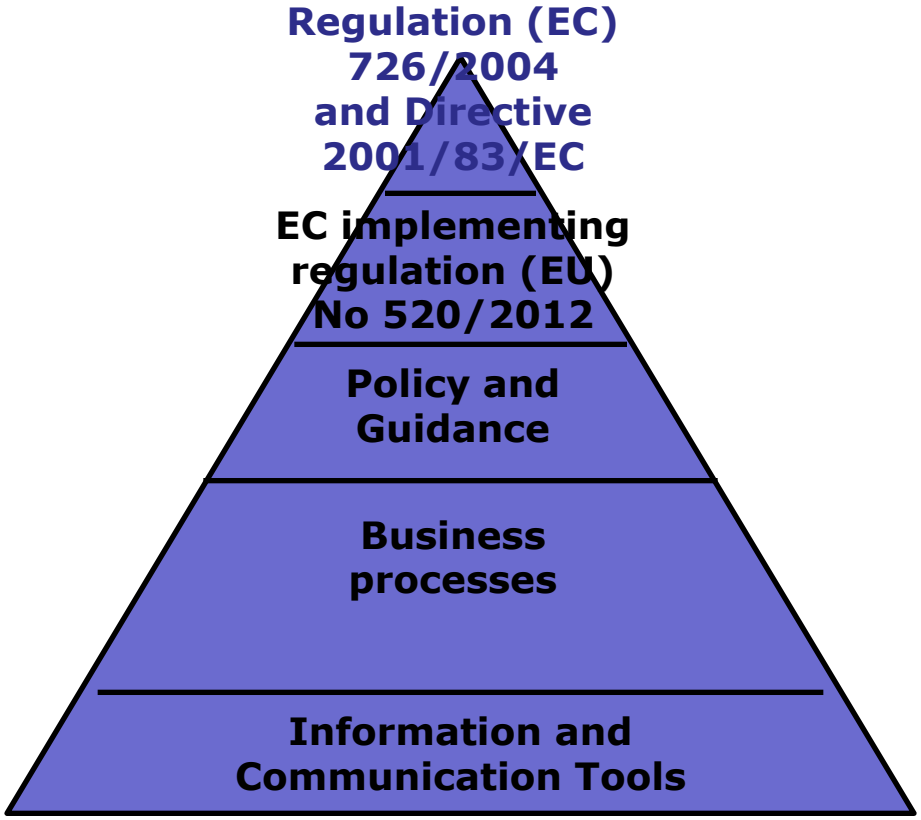

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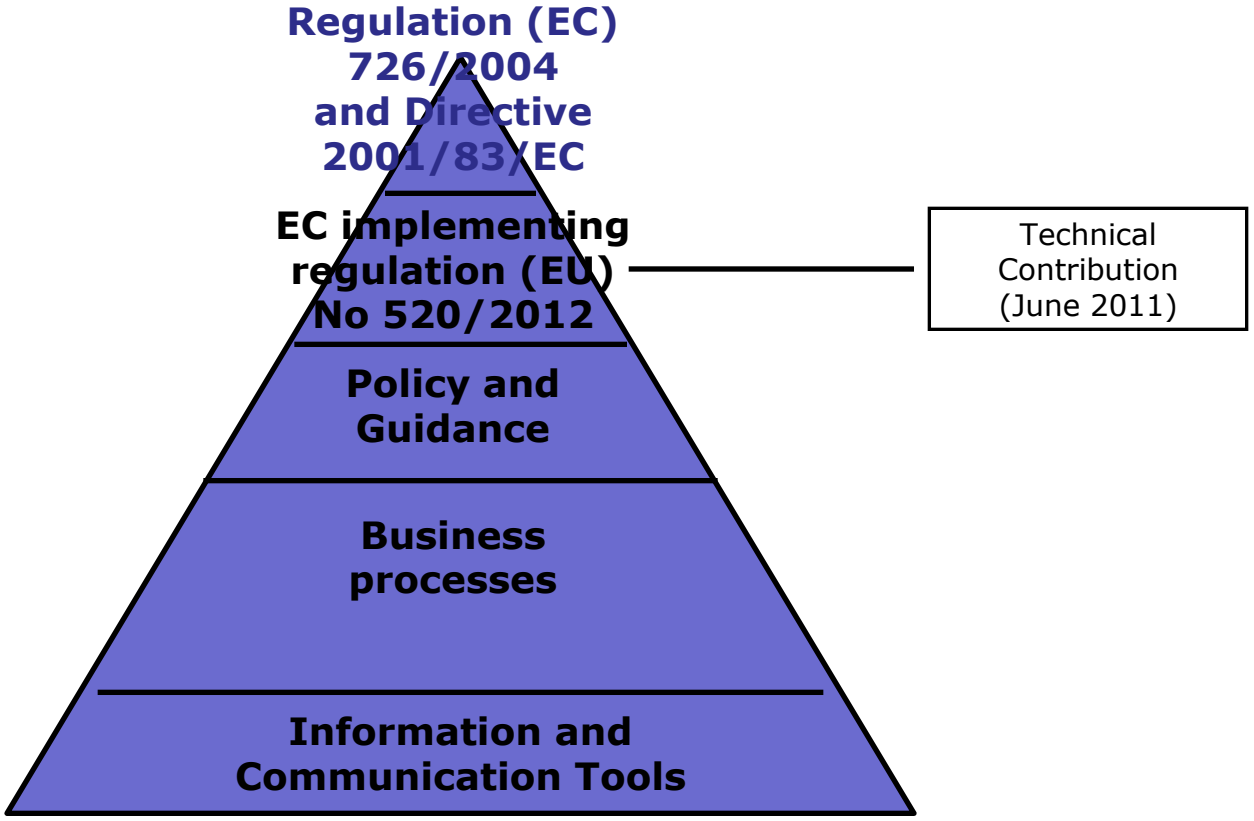

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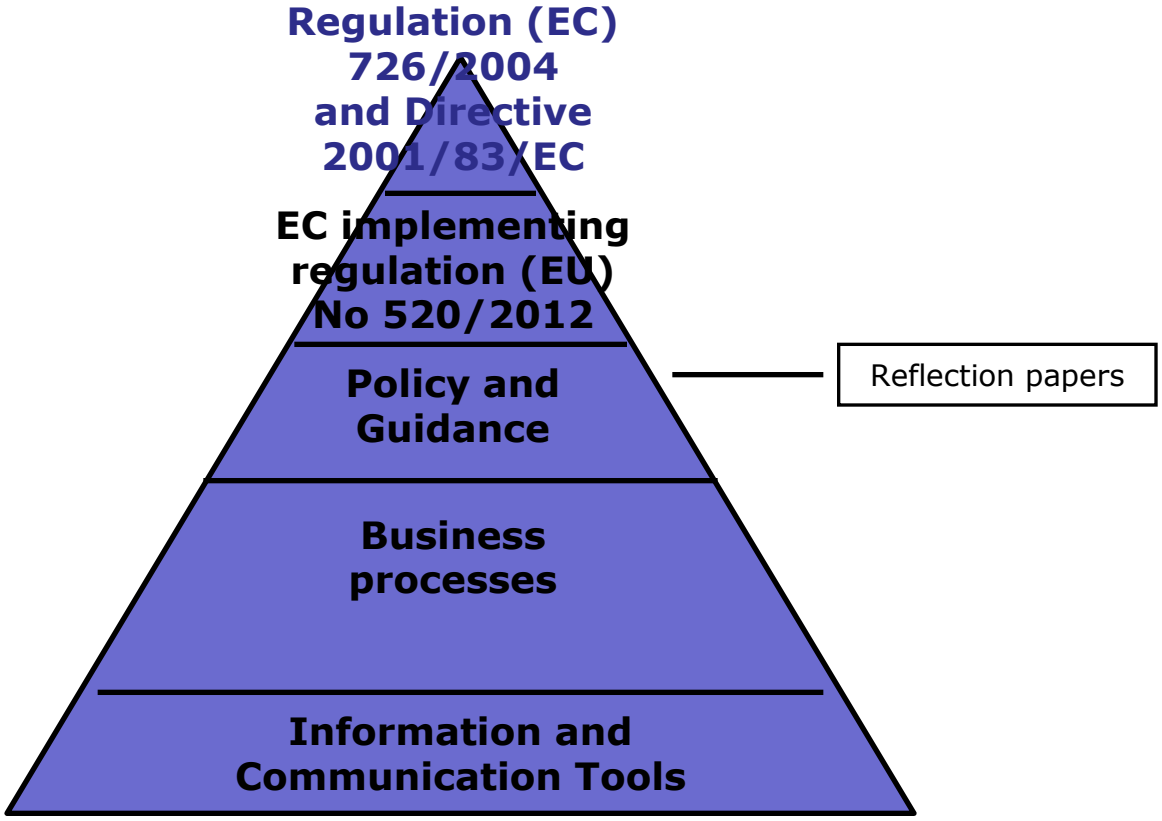

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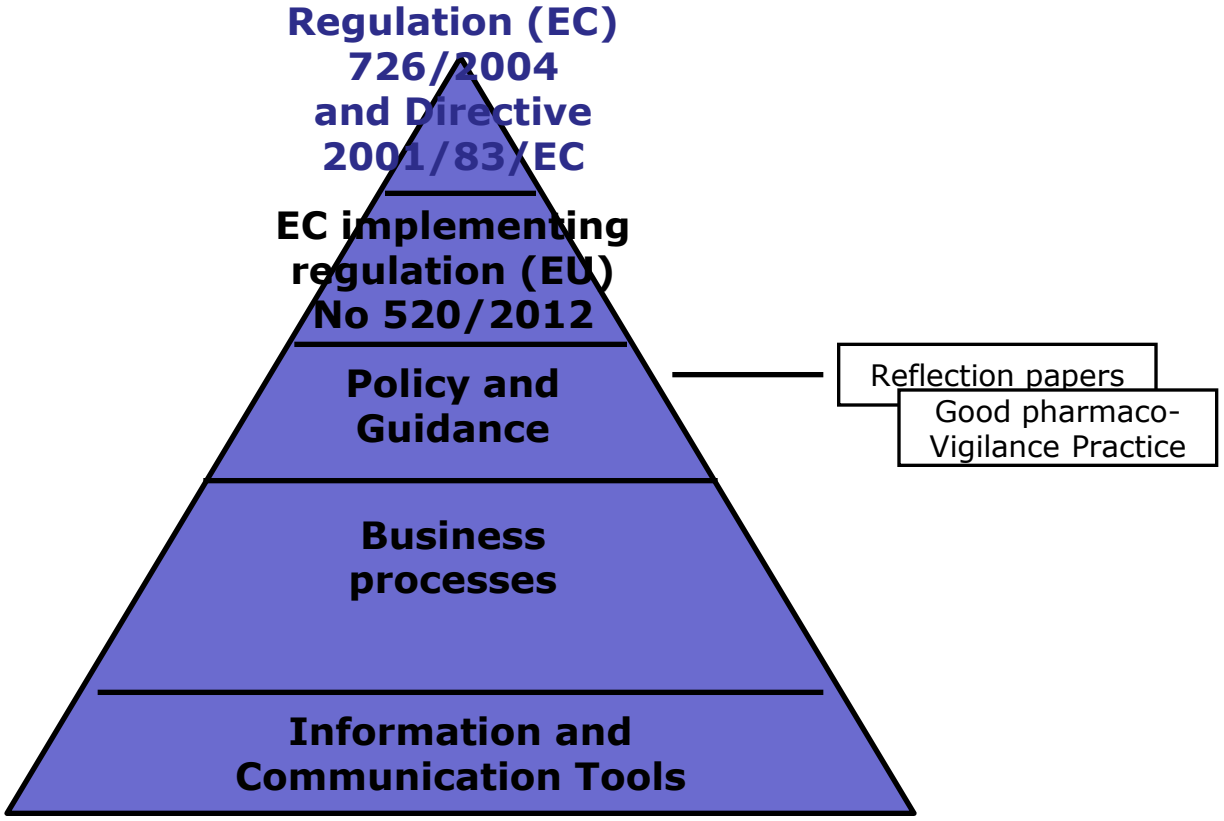


First wave of GVP Modules: (finalised in June 2012)

- **Module I -** Pharmacovigilance Systems and their Quality Systems
- **Module II -** Pharmacovigilance System Master File
- **Module V -** Risk Management Systems
- **Module VI -** Individual Case Safety Reports
- **Module VII -** Periodic Safety Update Reports
- **Module VIII -** Post-Authorisation Safety Studies
- **Module IX -** Signals

Second wave of GVP Modules: (post-public consultation)

- **Module III** – Inspections: Publication scheduled for **December 2012**
- **Module IV** – Pharmacovigilance Audits: Publication scheduled for **December 2012**
- **Module XV -** Safety communication: Publication scheduled for **December 2012**

- **Module X -** Additional monitoring: Public consultation closed, **Finalisation scheduled for Q1/Q2 2013** (new legislation)

Second wave of GVP Modules: (on-going)

- **Module XI -** Public participation: Public consultation scheduled for **Q2 2013**
- **Module XII -** Continuous pharmacovigilance, benefit-risk evaluation, communication planning and decision-making for regulatory action: Public consultation scheduled for **Q1 2013**
- **Module XIII** - Incident management **UNDER DISCUSSION** (maybe to be included in M XII)
- **Module XIV -** International collaboration: Public consultation scheduled for **Q2 2013**
- **Module XVI -** Risk minimisation measures: Public consultation scheduled for **December 2012/Q1 2013**

GVP Product- and Population-Specific Considerations

P I - Vaccines (revision of previous guideline) **Public consultation scheduled for Q1 2013**

More planned:

- Biological medicinal products
- Pregnancy
- Elderly
- …

GVP Annexes

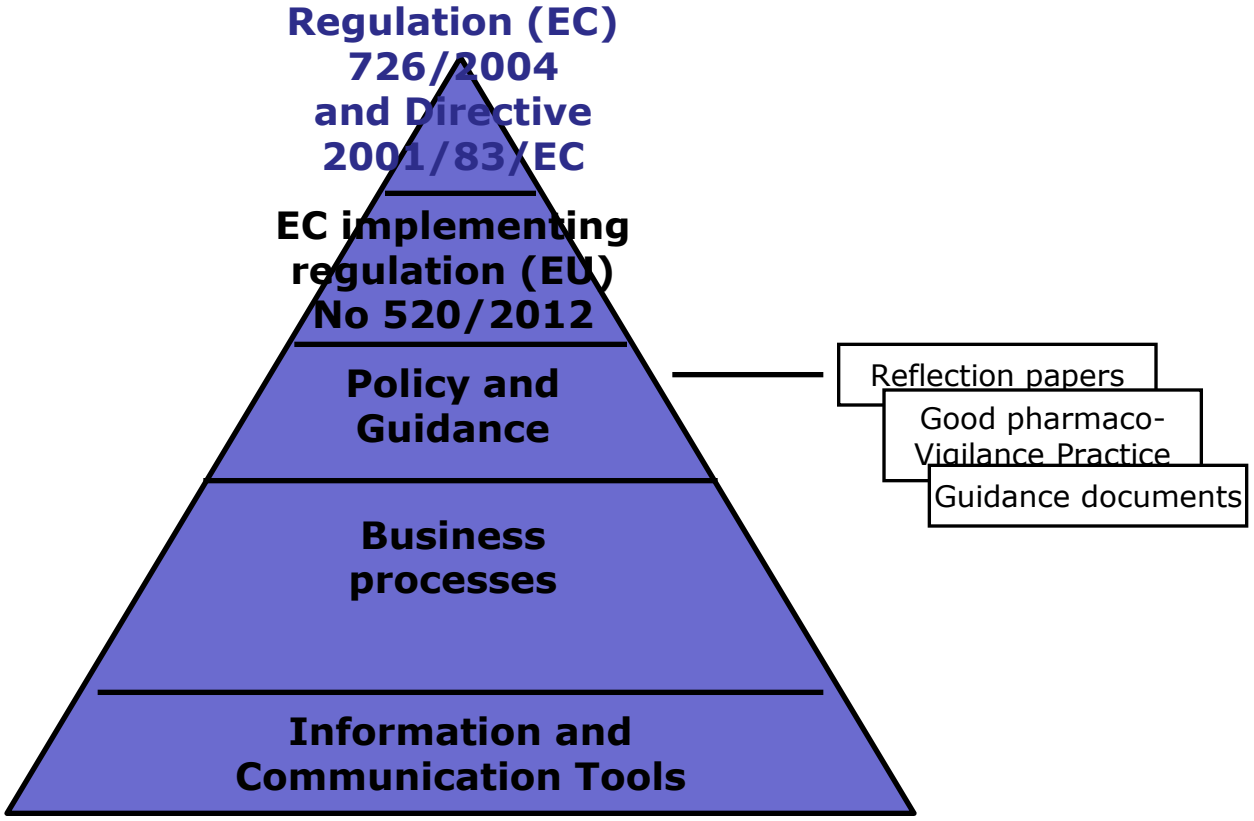
- **A I** – Definitions: for first wave of GVP modules,
  - First revision scheduled for December 2012 (M III, IV, XV),
  - Second revision scheduled for 2013.
- **A II -** Templates: **scheduled for 2013**
- **A III -** List of other guidelines: **scheduled for 2013**
- **A IV -** List of ICH Guidelines: **scheduled for 2013**

GVP updates and maintenance

- Overall maintenance process is being established
- Pharmacovigilance helpdesk for further advice:

p-pv-helpdesk@ema.europa.eu

Key achievements



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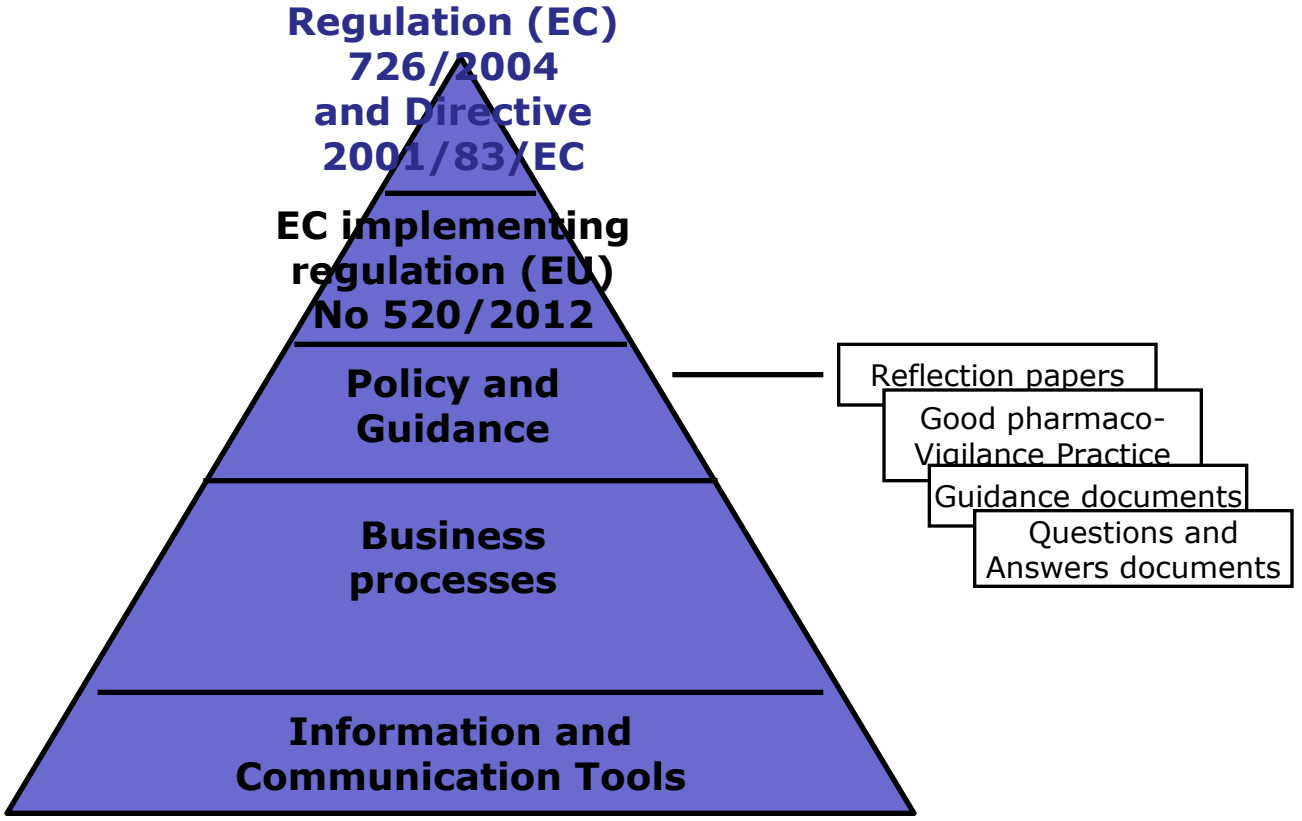

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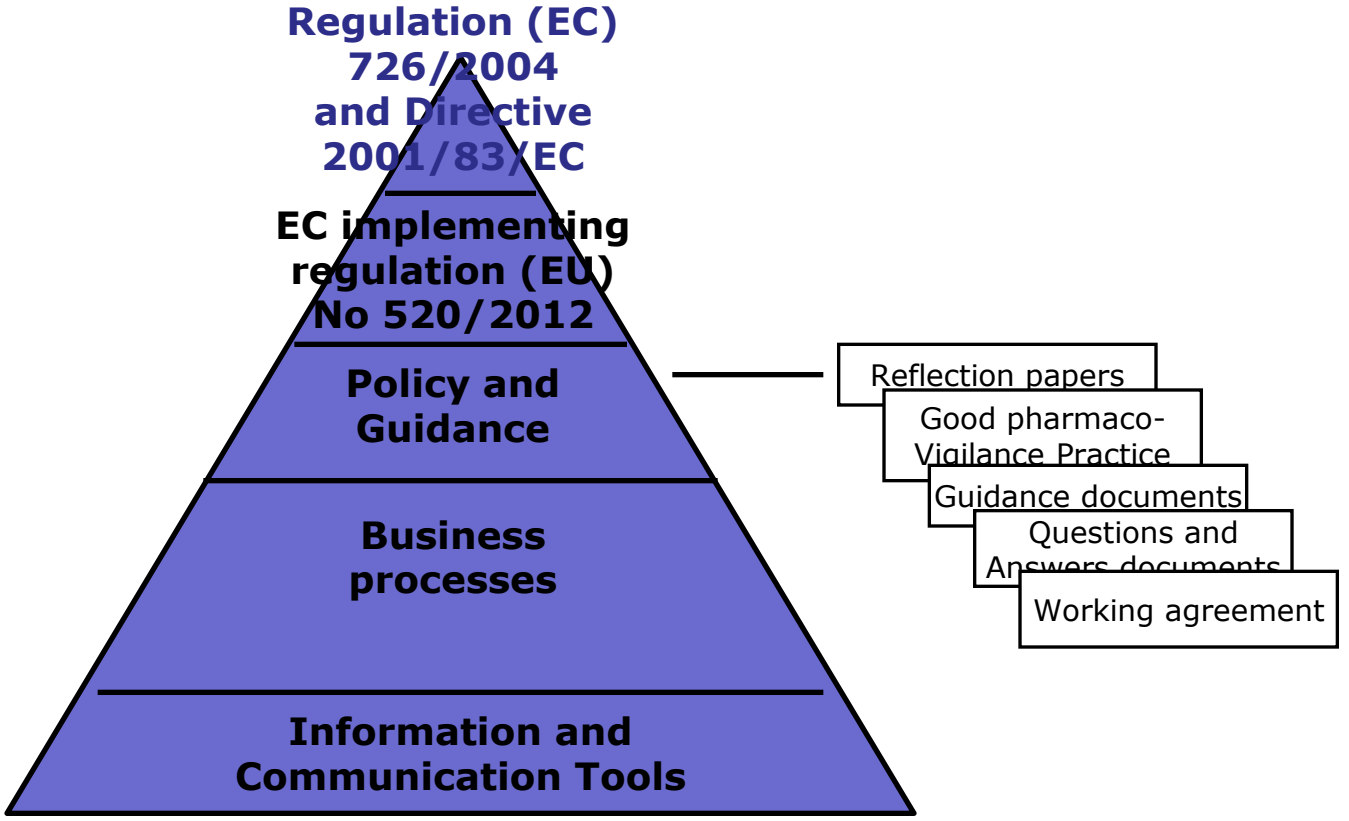
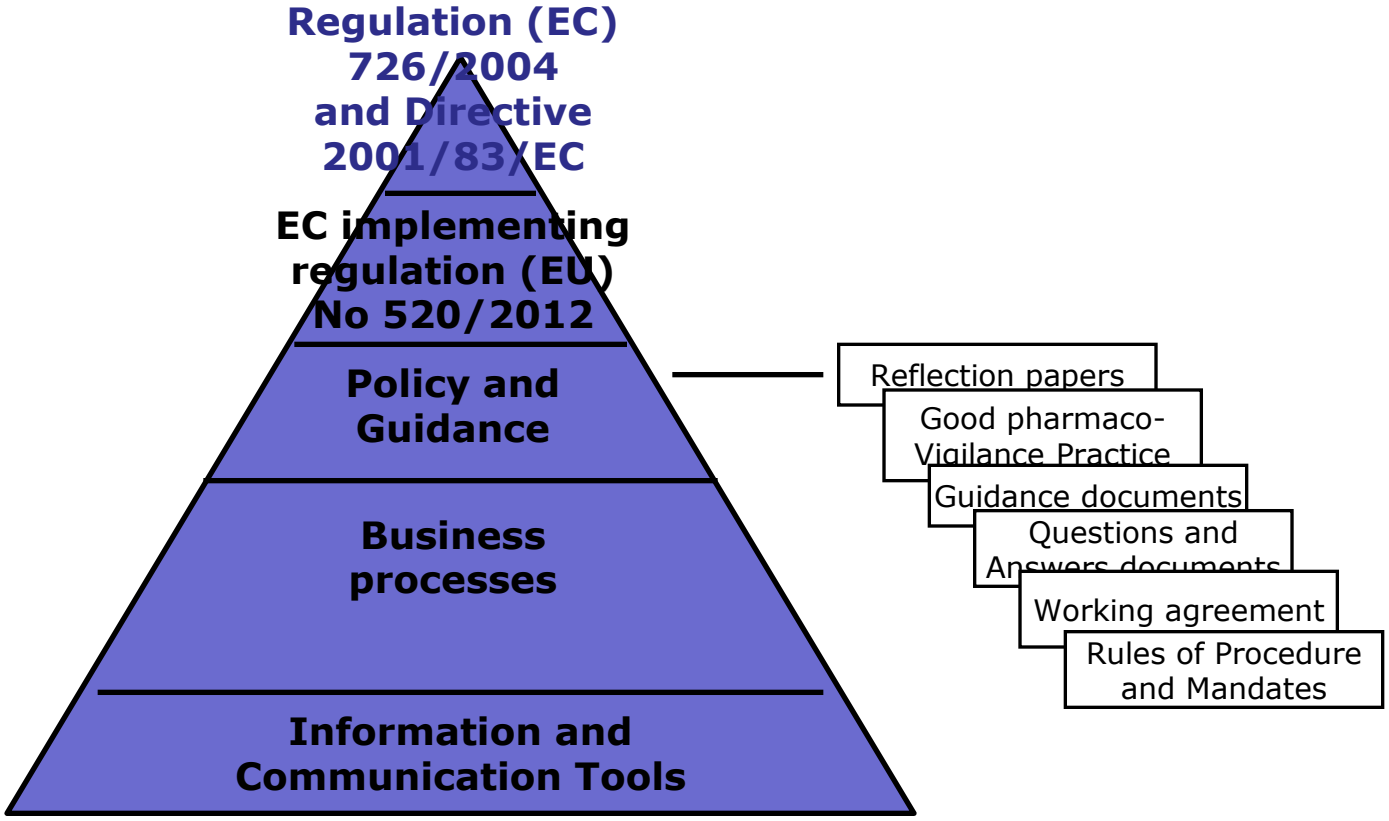


Working agreement to enhance cooperation with EMCDDA*

- Article 28c(2): 'The Agency and the EMCDDA shall exchange information that they receive on the abuse of medicinal products including information related to illicit drugs'.
- Working arrangement (first signed in 2010) amended by EMA and EMCDDA Directors to strengthen information-exchange practices.
- More timely response to potential public health threats

*EMCDDA: European Monitoring Centre for Drugs and Drug Addiction

Key achievements



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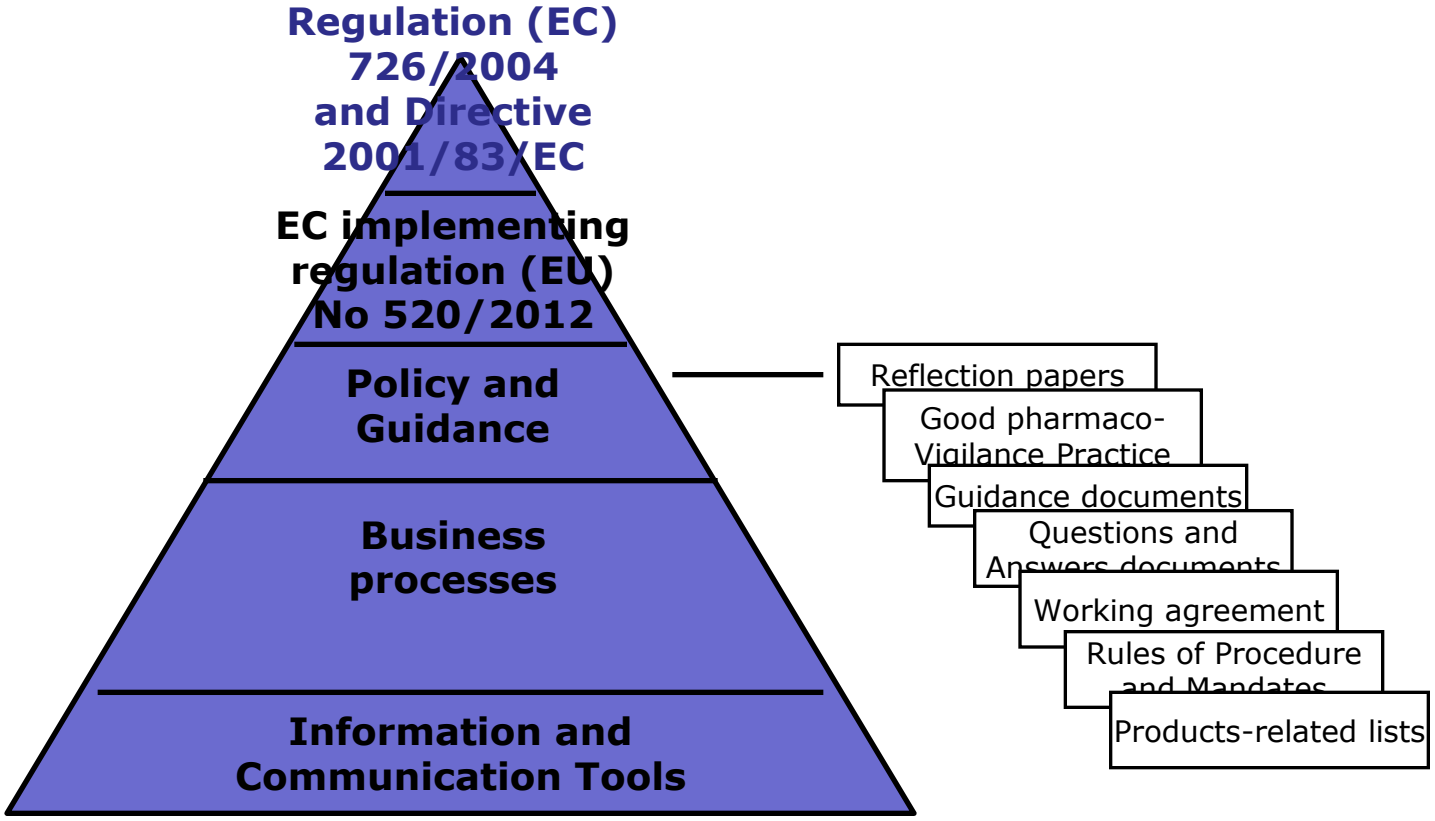

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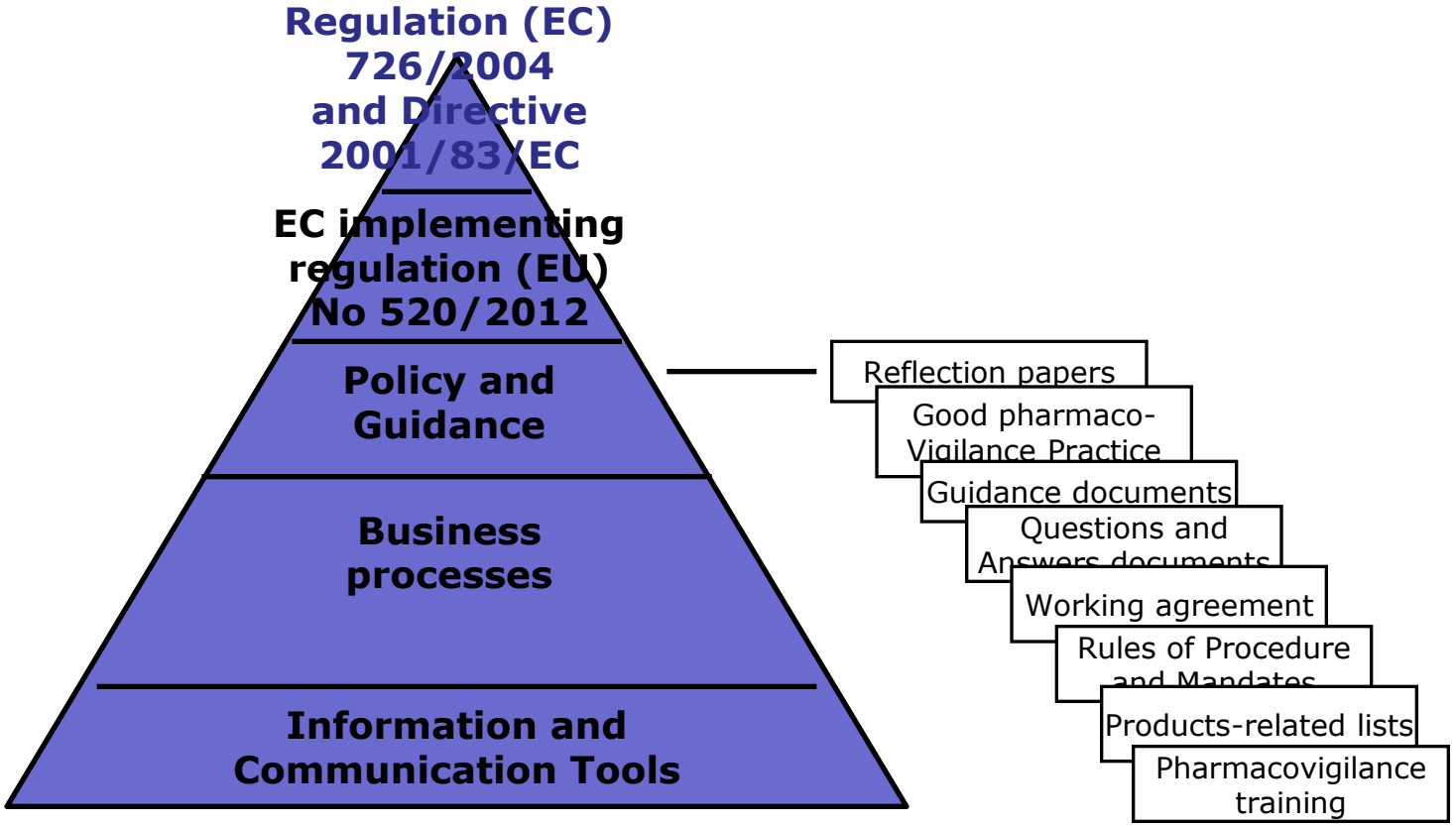

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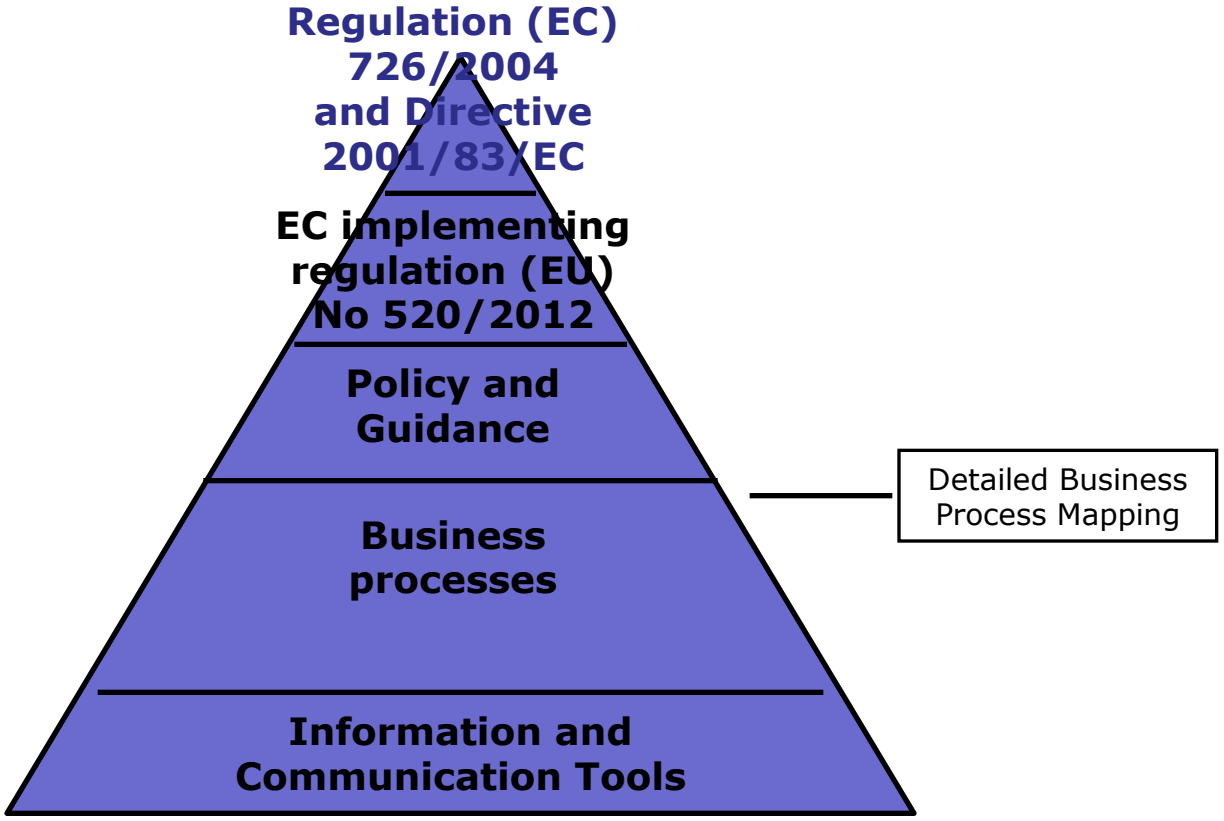

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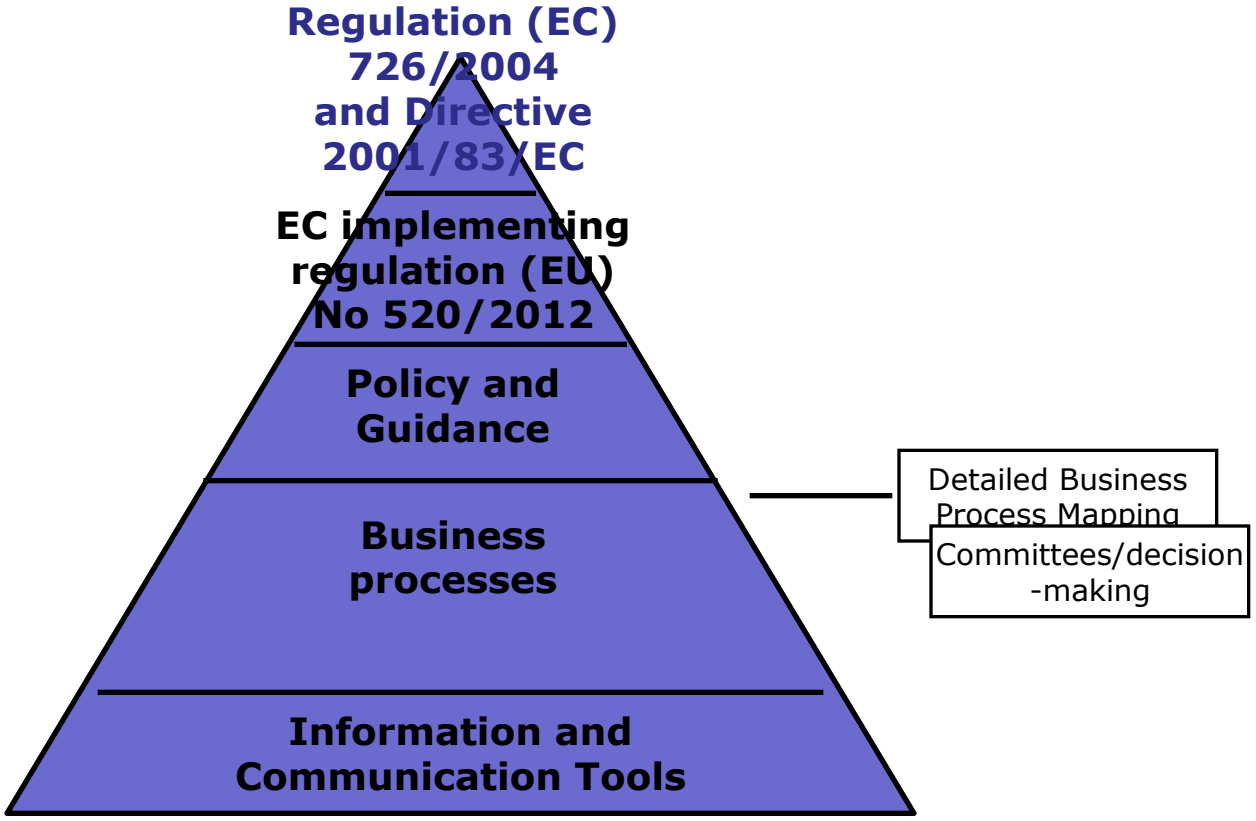

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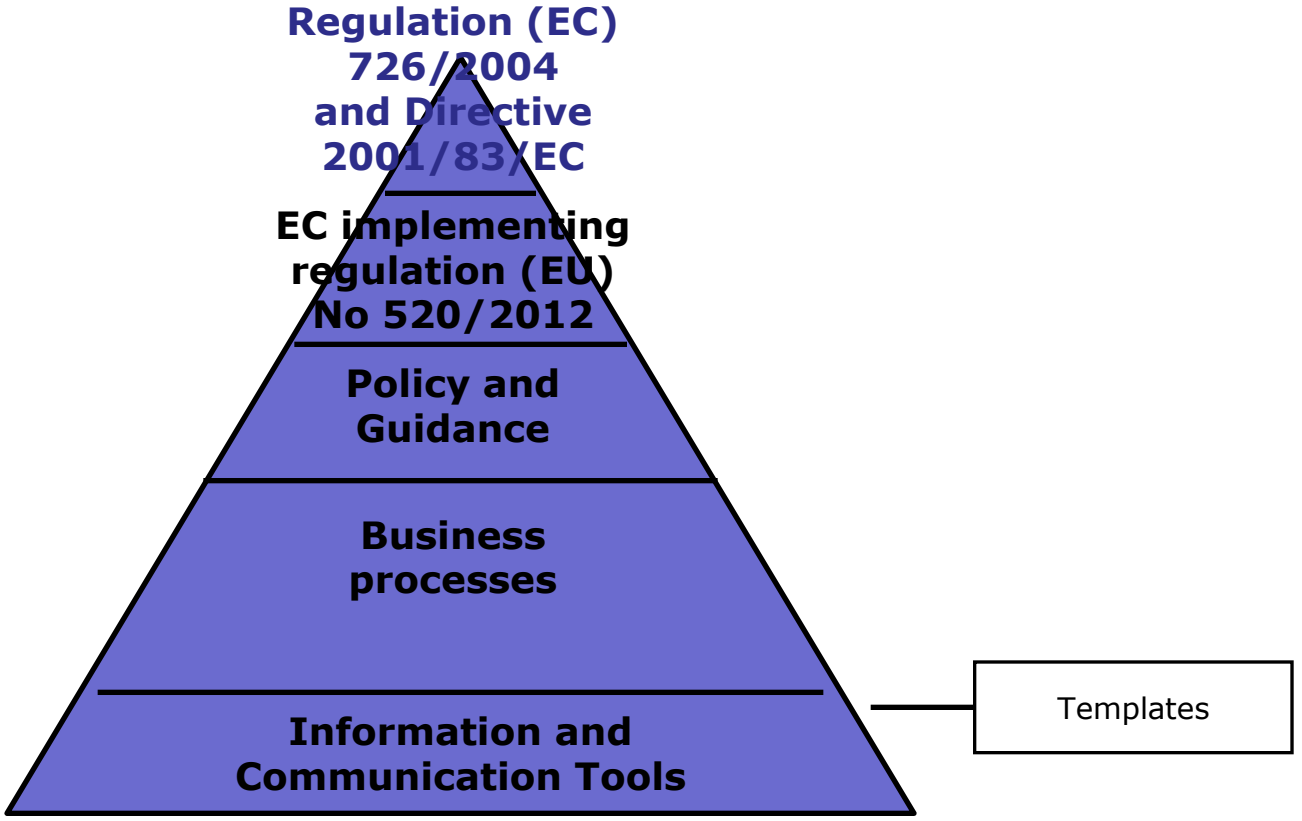

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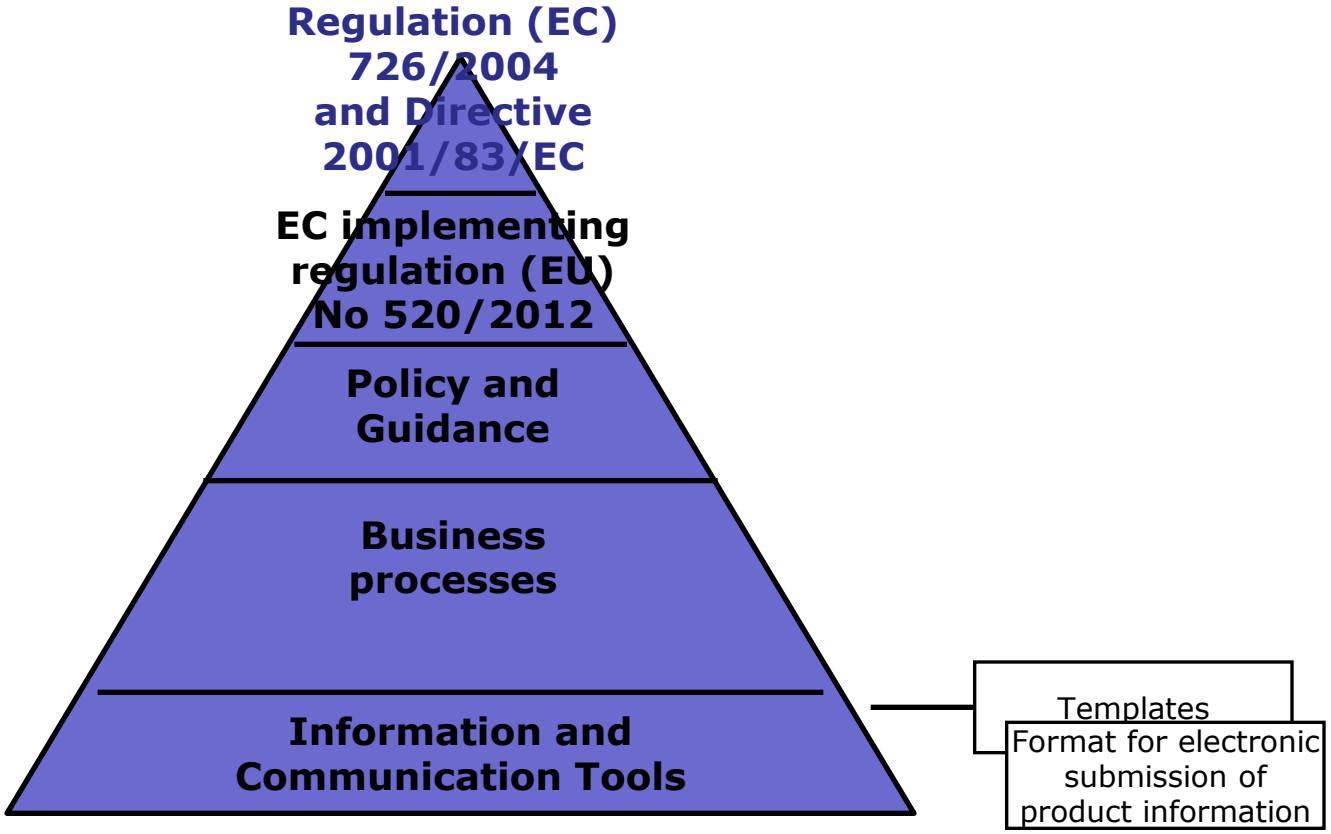


Format for electronic submission of product information

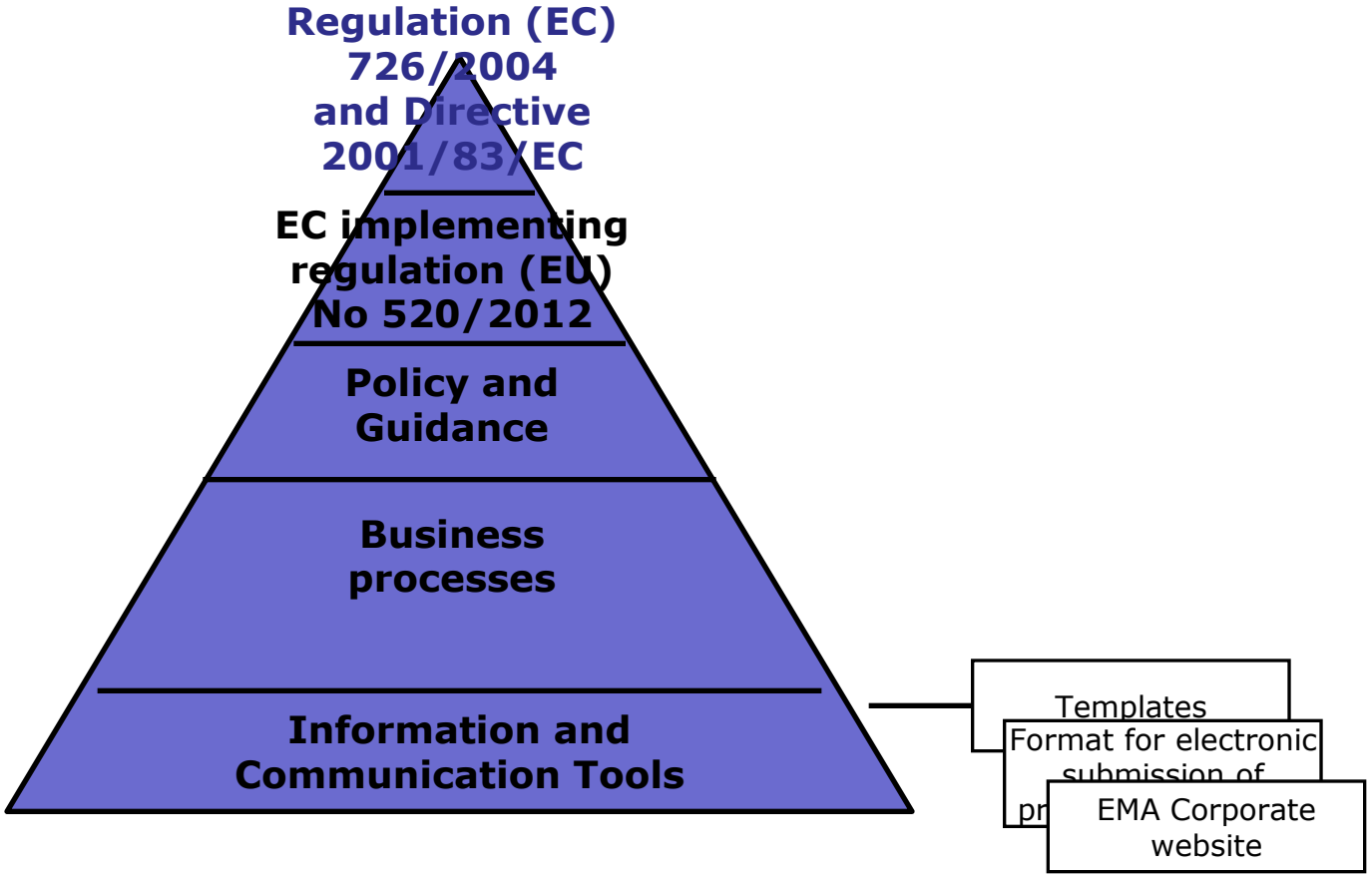
- Format for electronic submission of product information ('Article 57') released in June 2011, together with relevant information (i.e. Legal Notice, XEVPRM schema, Detailed Guidance)
- The XEVMPD web application (EVWEB data entry tool – released on March 2012))
- Questions & Answers documents
- XEVPRM Terminologies and Controlled Vocabularies
- Dedicated helpdesks:

art57@ema.europa.eu and eudravigilance@ema.europa.eu

Format for electronic submission of product information

- Organisation of several (>40) XEVMPD face-to-face training sessions
- New XEVMPD e-learning modules (released in May 2012)
- Workshops with EU Industry associations
- Establishment of a joint implementation group involving representatives from EU Industry associations
- One dedicated DIA Infoday in February 2012 and presentation during DIA IDMP Infoday in May 2012.

Key achievements



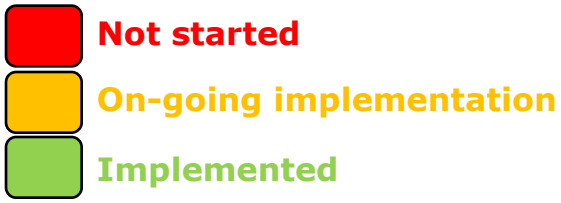
EMA Corporate website

- Legal notice: EMA website will serve as the EU Medicines Web-portal
- Upgrade of EMA corporate website
  - New page for general public on pharmacovigilance implementation, including 'video'.
  - Updated template for safety referrals
  - New search function for all referrals,
  - New page for industry on pharmacovigilance implementation
- Publication of plan for prioritised implementation

Prioritised implementation agreed by EMA Management Board in December 2011

Prioritised implementation agreed by EMA Management Board in December 2011

- **Criteria for prioritisation:**
  - Firstly, public health activities
  - Secondly, transparency and communication activities
  - Thirdly, simplification activities (primarily for pharmaceutical industry)
- **Activities grouped into four main topic areas:**
  - Collection of key information on medicines
  - Better analysis and understanding of data and information
  - Regulatory action to safeguard public health
  - Communication with stakeholders
- **Traffic light:**



Implementation of the pharmacovigilance legislation by the EMA in 2012:

Collection of key information on medicines (1/2)

1. Risk Management Plans:		
Establishment and operation of new procedure for requesting and assessing RMP		• Started July 2012 • Templates for industry (Oct) • Format compulsory (Jan 2013)
2. Periodic Safety Update Reports:		
Operation of new procedures related to PSURs for CAPs		• Started July 2012
Development and publication of harmonised birthdates to support PSUR submission		• First list published in Oct 2012 (monthly update)

Implementation of the pharmacovigilance legislation by the EMA in 2012:

Collection of key information on medicines (2/2)

3. Post-Authorisation Safety and Efficacy Studies:		
Implementation of the PASS procedure for protocols approval and results management for CAPs		• Started July 2012
Consultation on scientific guidance for PAES		• Awaited
4. Electronic submission of core medicine information by MAHs ('Article 57'):		
Start validation of received information		• Joint implementation group (Oct 2012)
5. Reporting by patients:		
Cooperation with Member States to provide information to patients on direct reporting		• Core data fields agreed by Member States (June 2012)

Implementation of the pharmacovigilance legislation by the EMA in 2012:

Better analysis/understanding of data and information (1/2)

1. EudraVigilance and signal detection		
Operation of revised signal detection process for CAPs		• Started July 2012
Support Member States to operate the new EU signal detection processes for NAPs		• Started July 2012 • Signal work-sharing list published (Oct 2012)
Start of signal management through the Pharmacovigilance and Risk Assessment Committee (PRAC)		• Started Sept 2012
Continuation of maintenance work for the current EV system including data quality		• As planned
Implementation of web-publishing of adverse reaction data (further to the EV Access Policy)		• Delivered in May 2012

Implementation of the pharmacovigilance legislation by the EMA in 2012:

Better analysis/understanding of data and information (2/2)

2. Additional monitoring:		
Develop and publish the list of medicines with additional monitoring status		• Initial list likely to be published in March/April 2013
3. IT systems to support processing and analysis of data:		
Finalisation of business requirements for enhanced IT systems		• On-going

Implementation of the pharmacovigilance legislation by the EMA in 2012:

Regulatory action to safeguard public health

1. Scientific committees and decision-making:		
Establishment of new committee (PRAC) and new responsibilities for CMD(h)		• Established July 2012
2. Strengthening referral procedures:		
Operation of new referral procedure (Urgent Union Procedure)		• First referral launched in Oct 2012

Implementation of the pharmacovigilance legislation by the EMA in 2012:

Communication with stakeholders

1. Online publishing of information:		
Publication (on EMA website) of agendas, minutes, assessments, approvals, recommendations, opinions and decisions of PRAC, CMD(h) and CHMP.		• Started July 2012 for PRAC agendas and minutes
2. Coordination of safety messages:		
Operation of the coordination of Member States' safety announcements for non-CAPs.		• Started July 2012
3. Public hearings:		
Introduction of public hearings in the context of Urgent Union Procedure		• Definition of public hearings on-going

Conclusion

- Prioritised implementation 2012 – on target
- Work on-going taking into new amendment to the 2010 legislation and remaining deliverables
- Strong and continued collaboration, cooperation and Stakeholders liaison to focus on promotion and protection of public health

Thank you!