EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Pharmacovigilance legislation:

Our implementation journey…

Training session on the new pharmaceutical legislation,
European Medicines Agency

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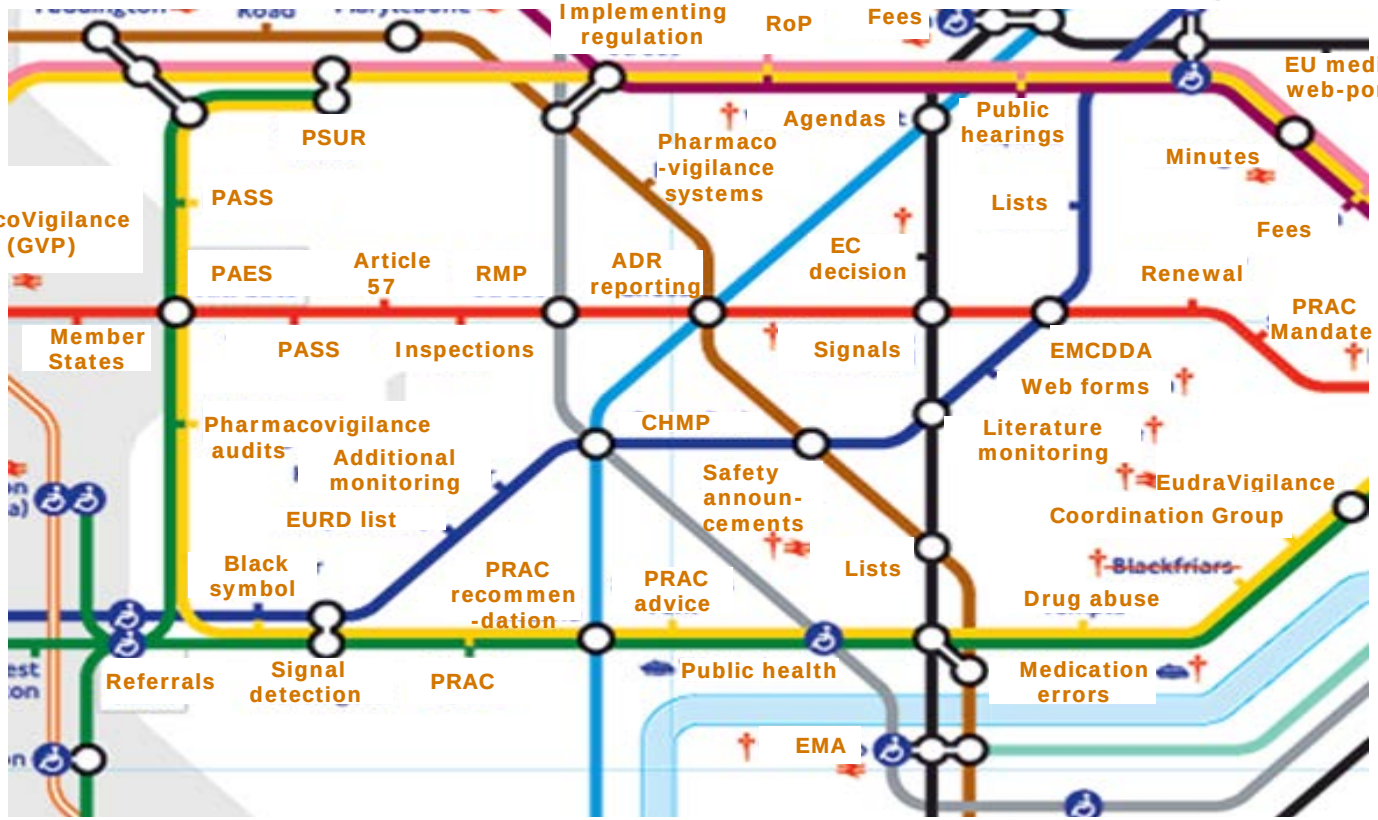
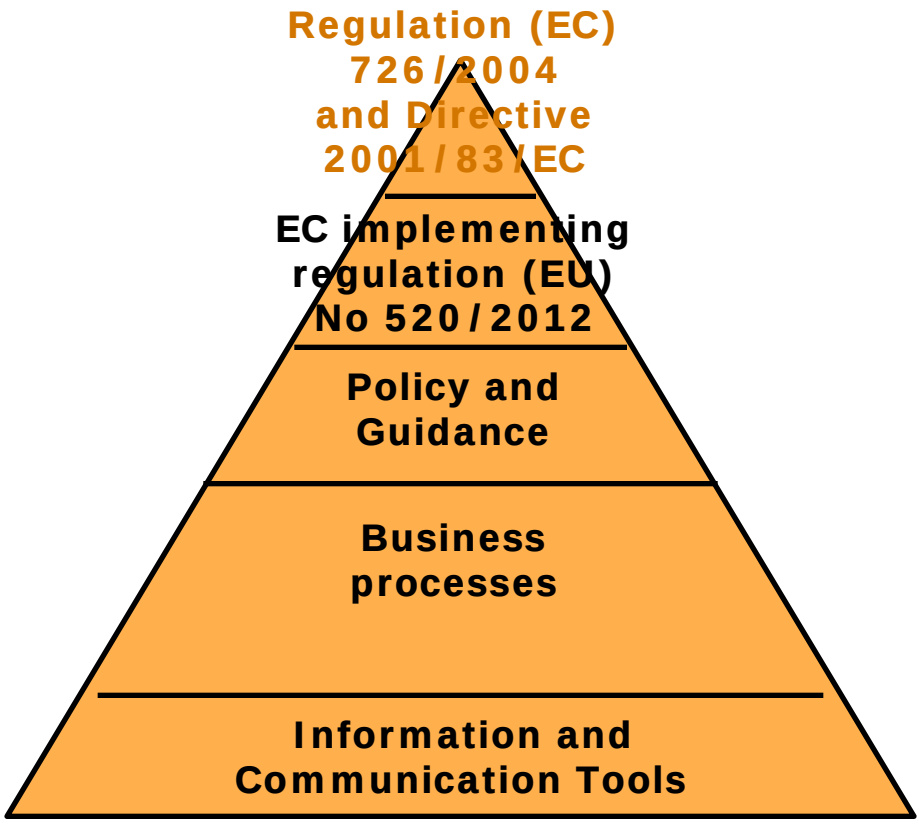
- Our implementation journey: where are we going?
- Conclusion

Implementation journey....

PHARMACOVIGILANCE



Key achievements



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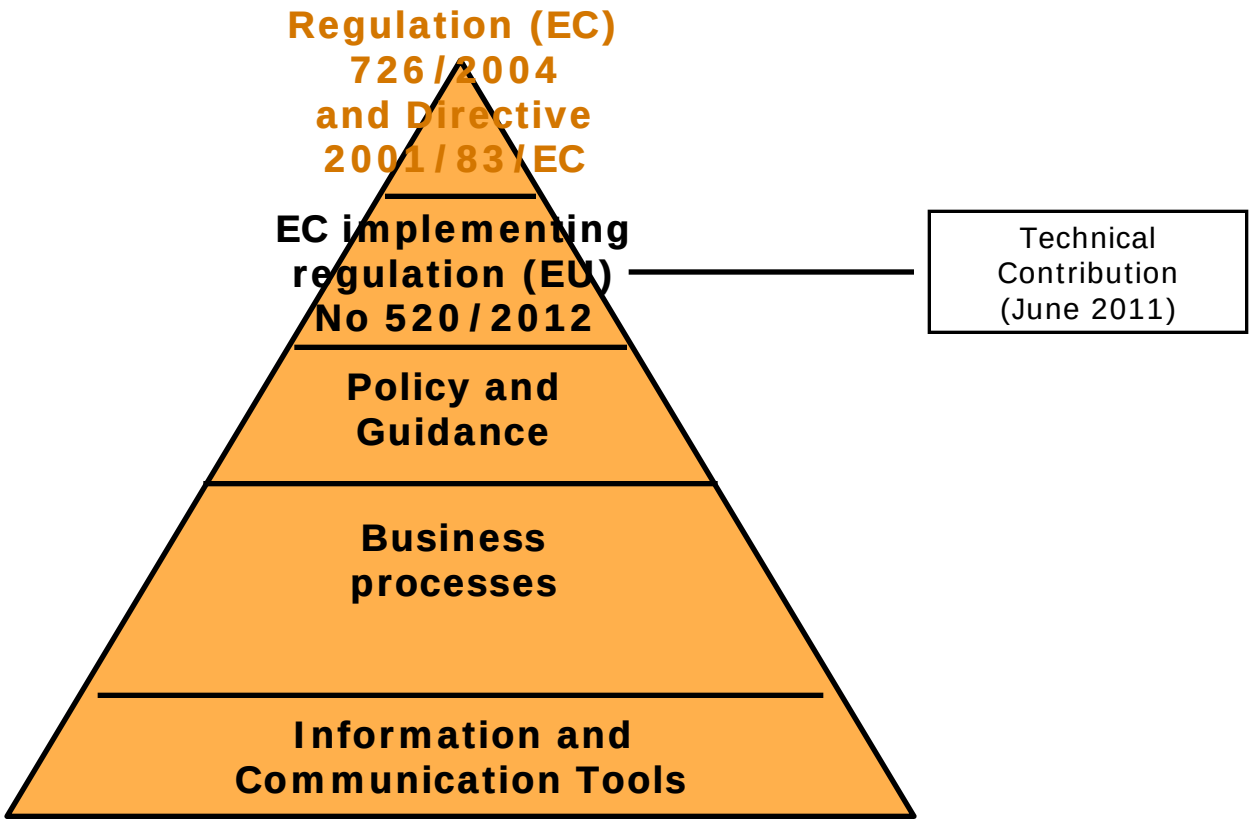

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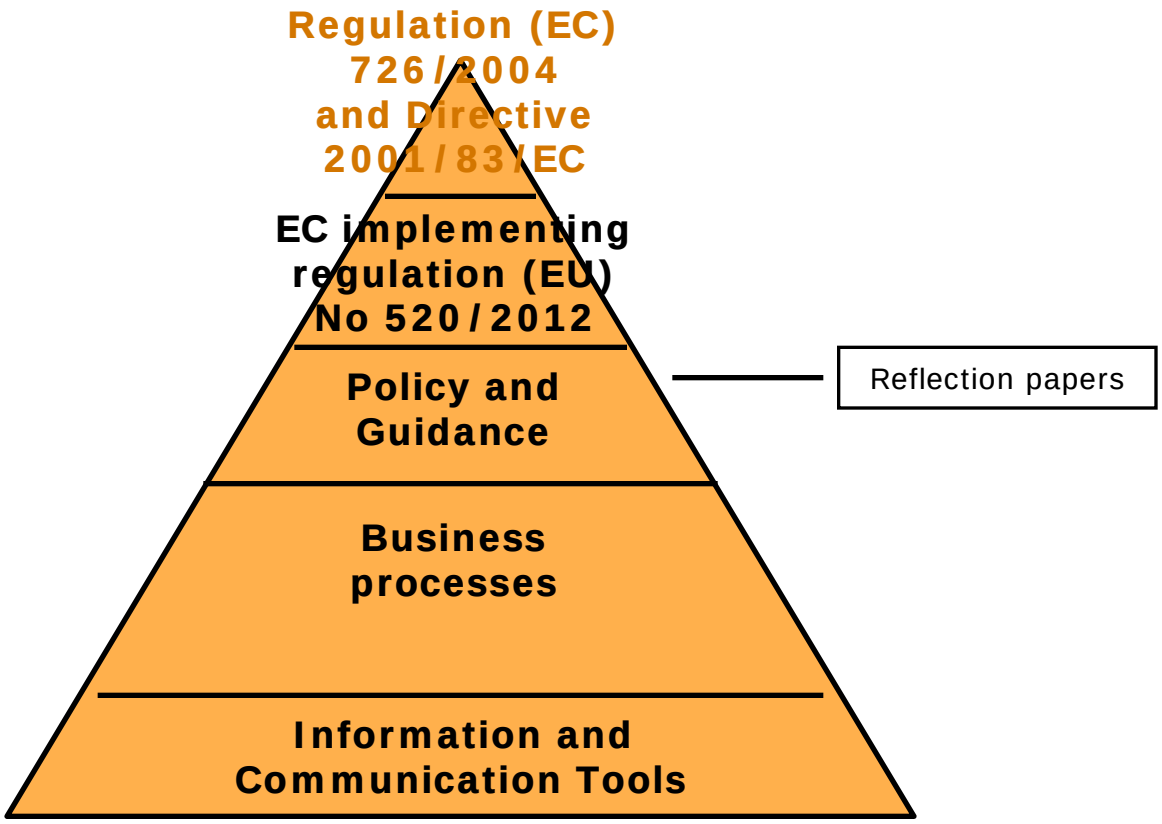

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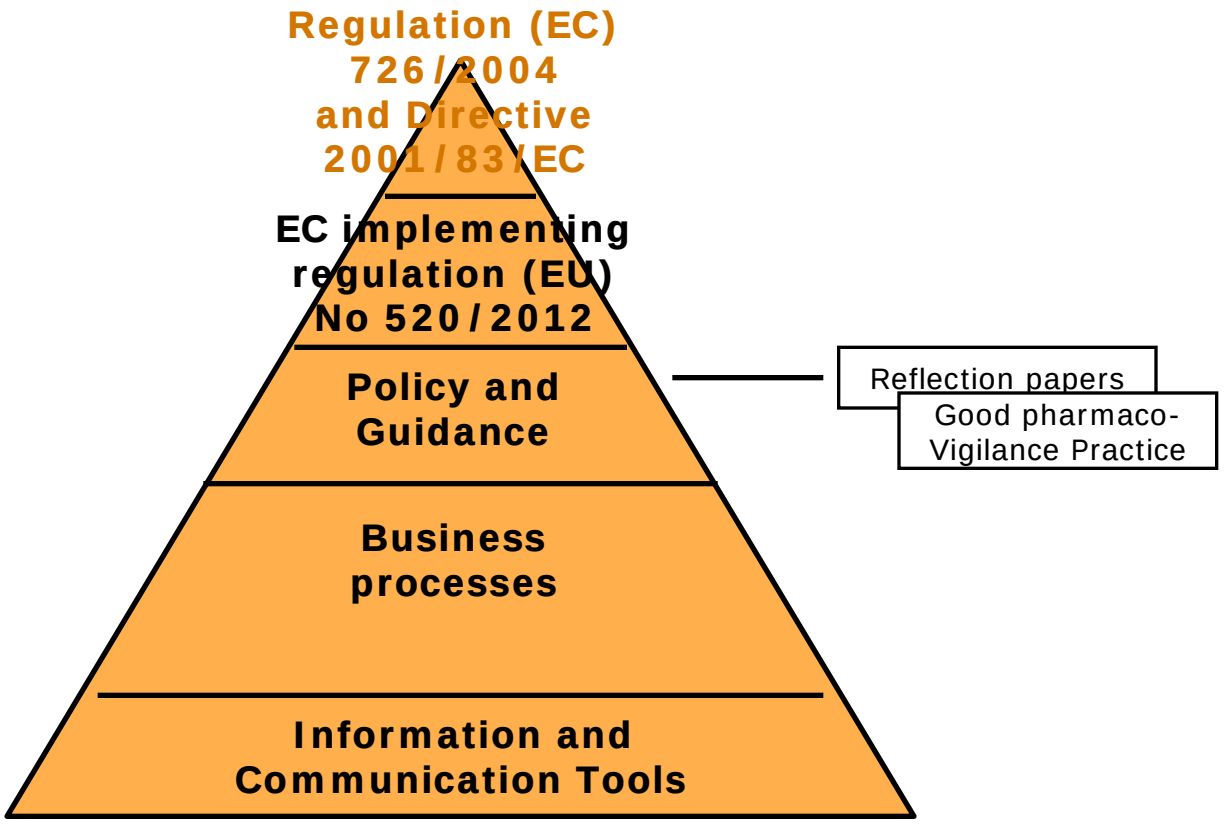

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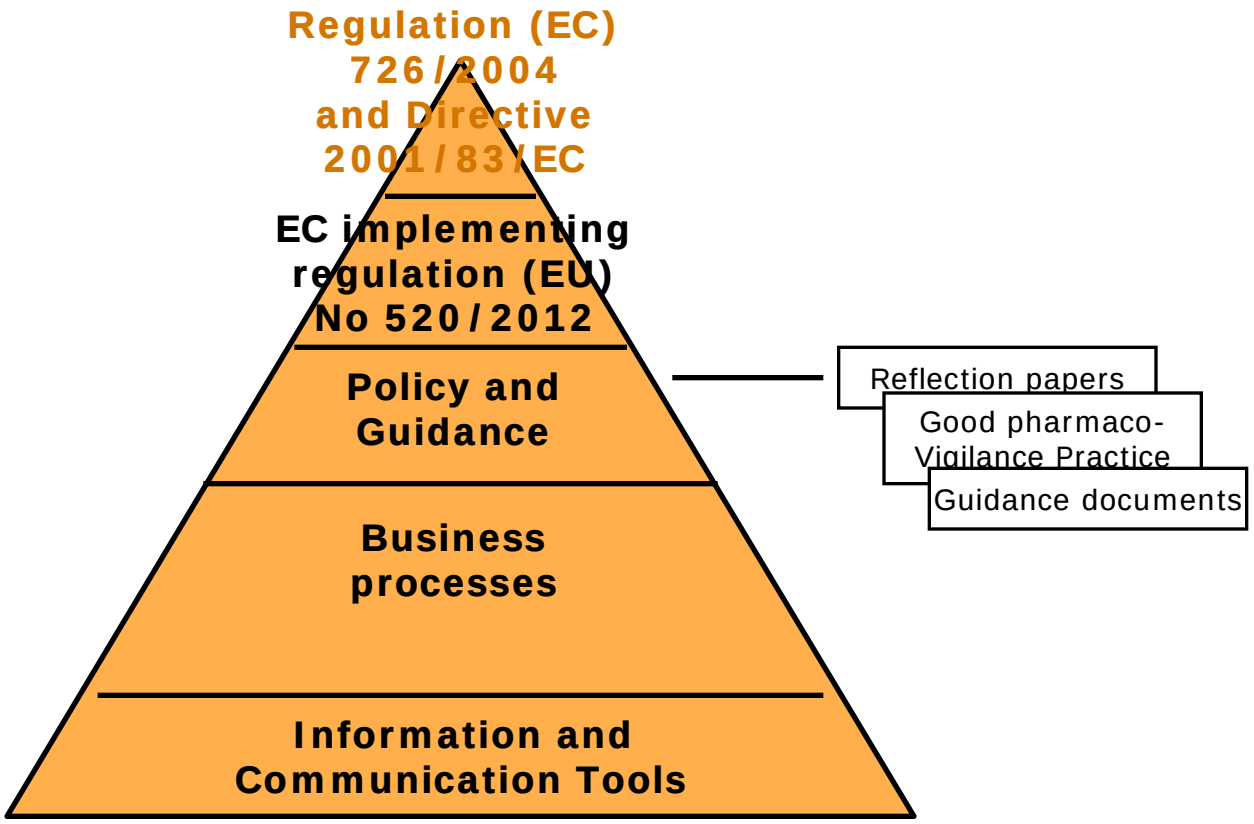

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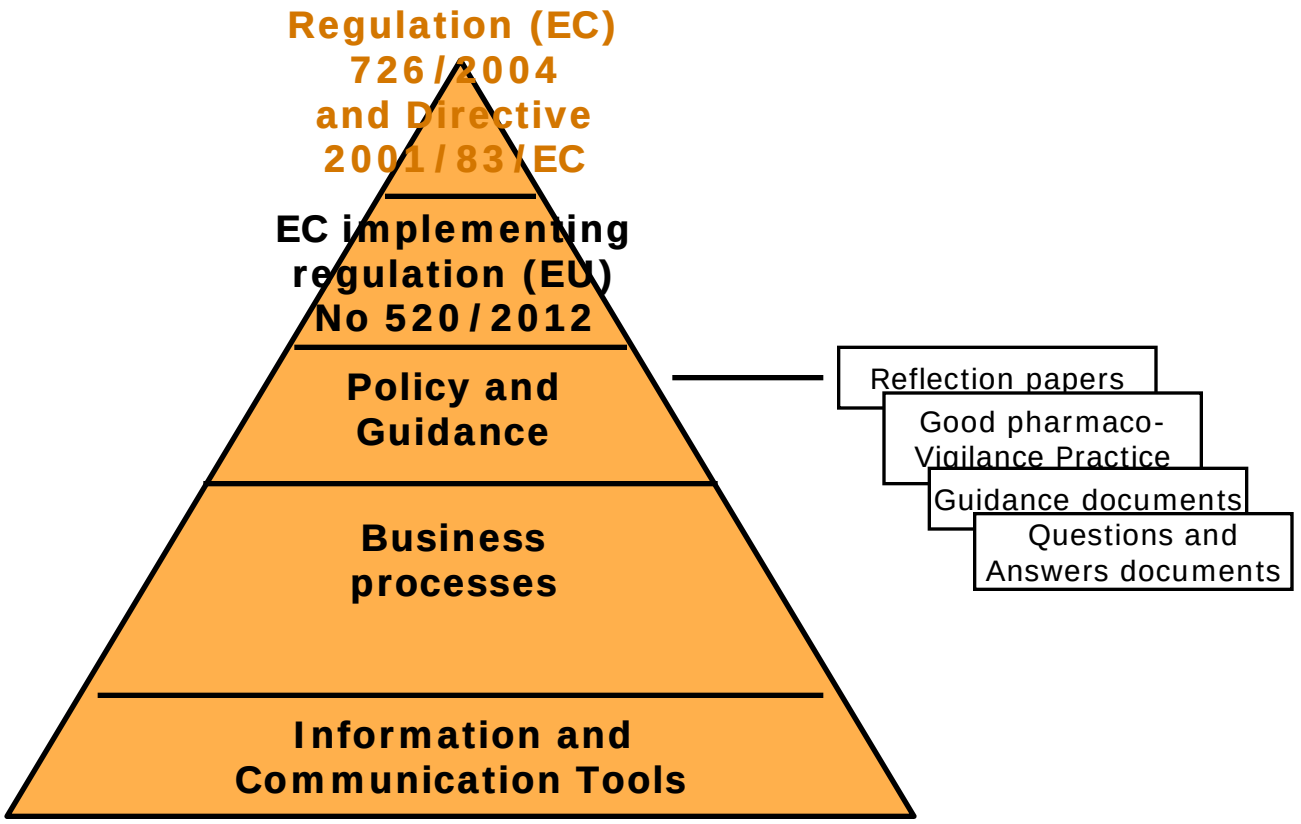

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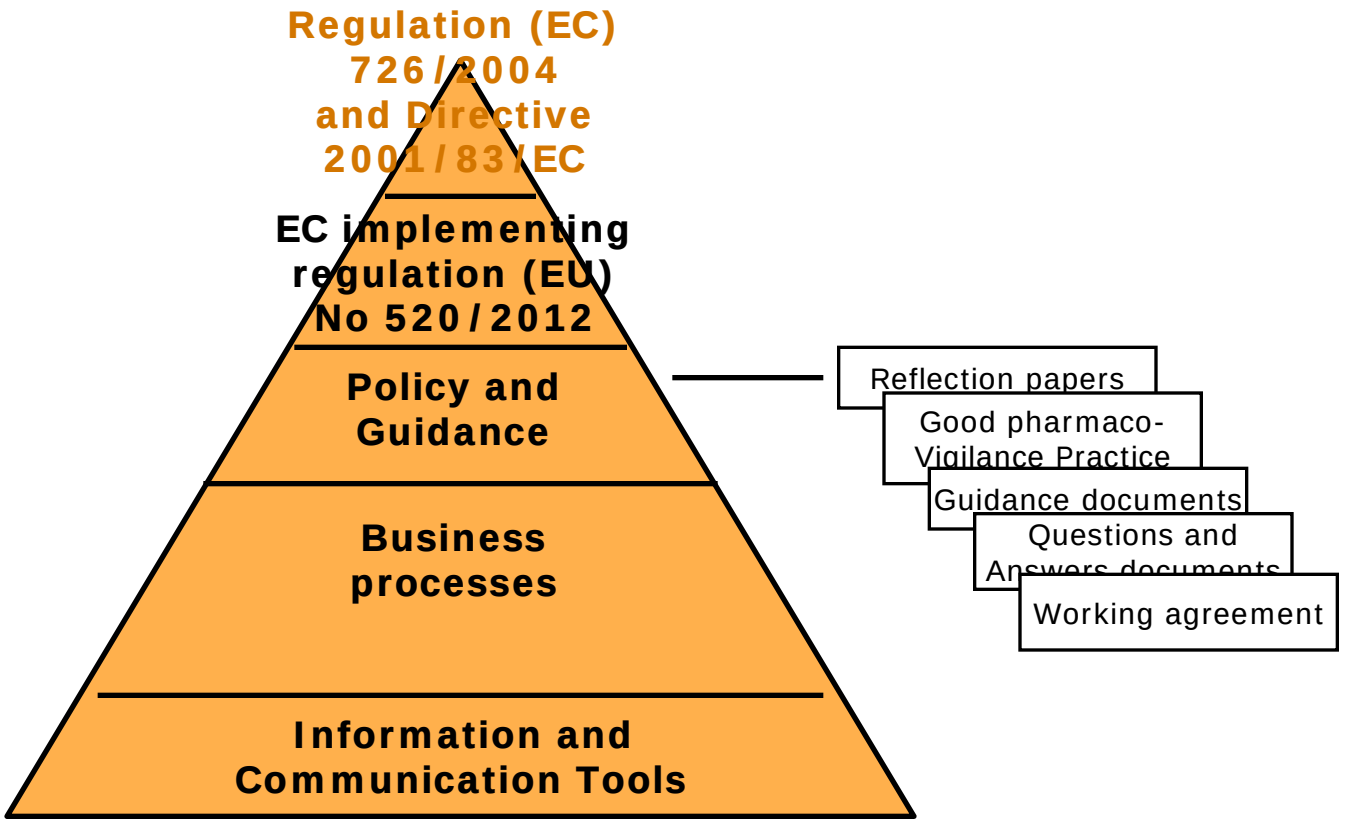
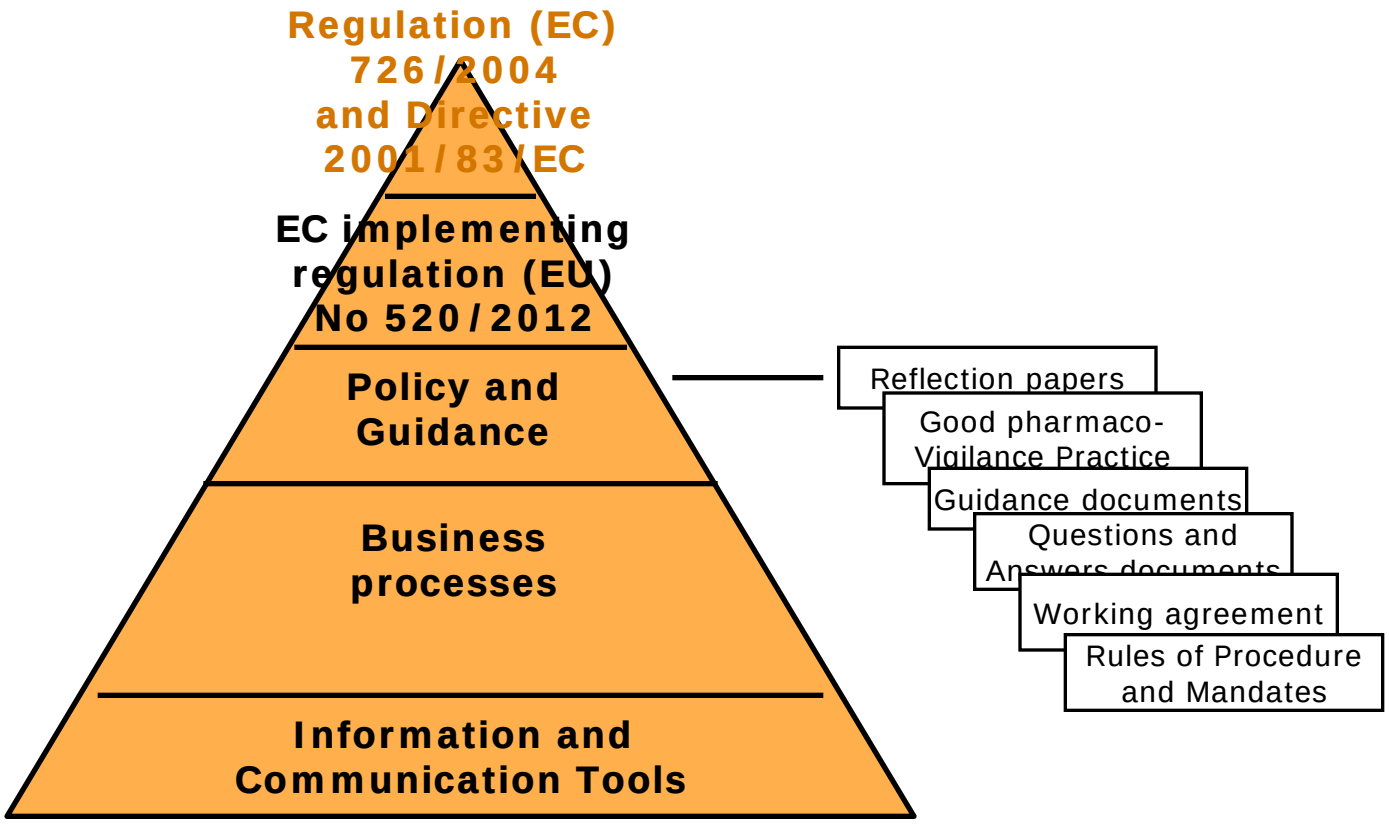


Working agreement to enhance cooperation with EMCDDA*

- 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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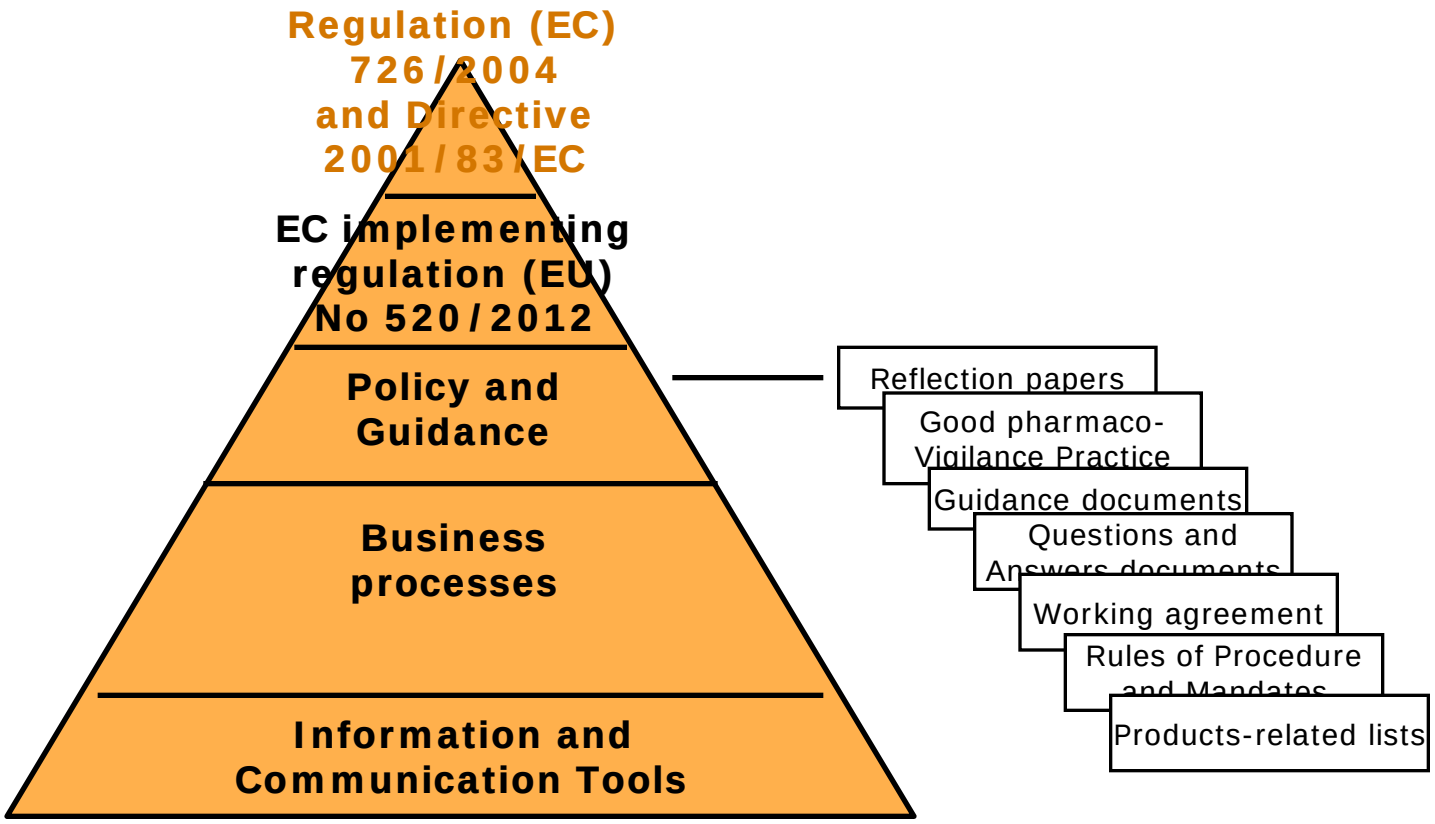

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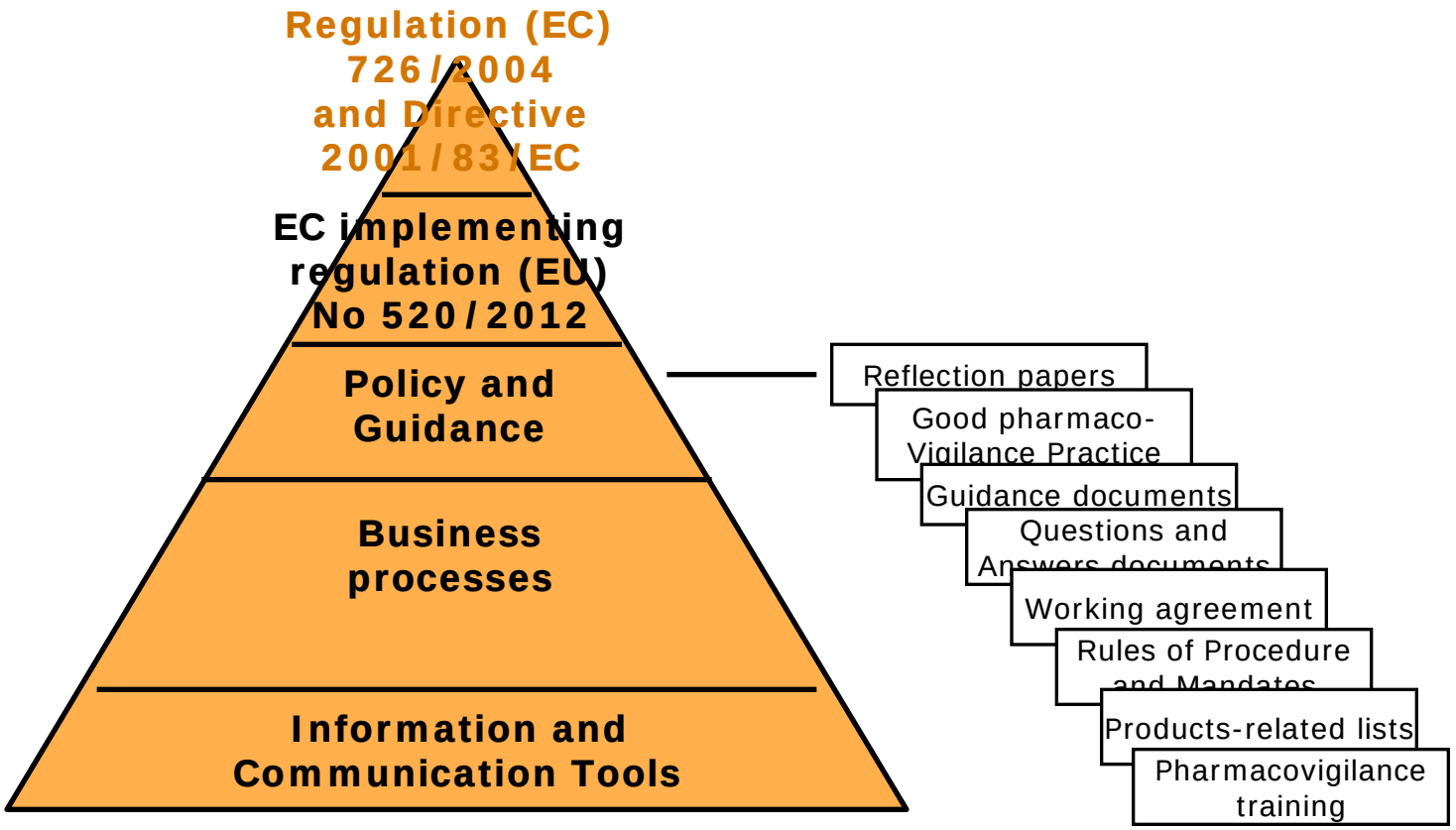

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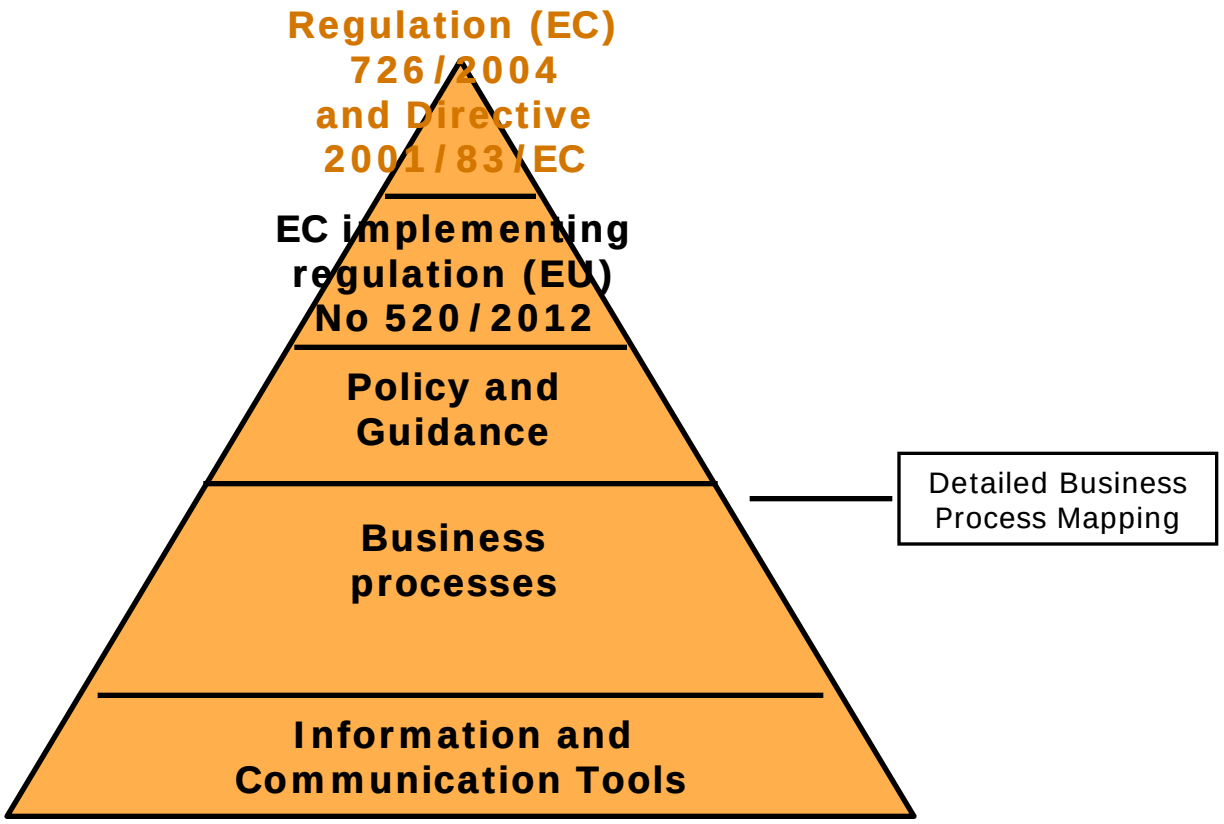

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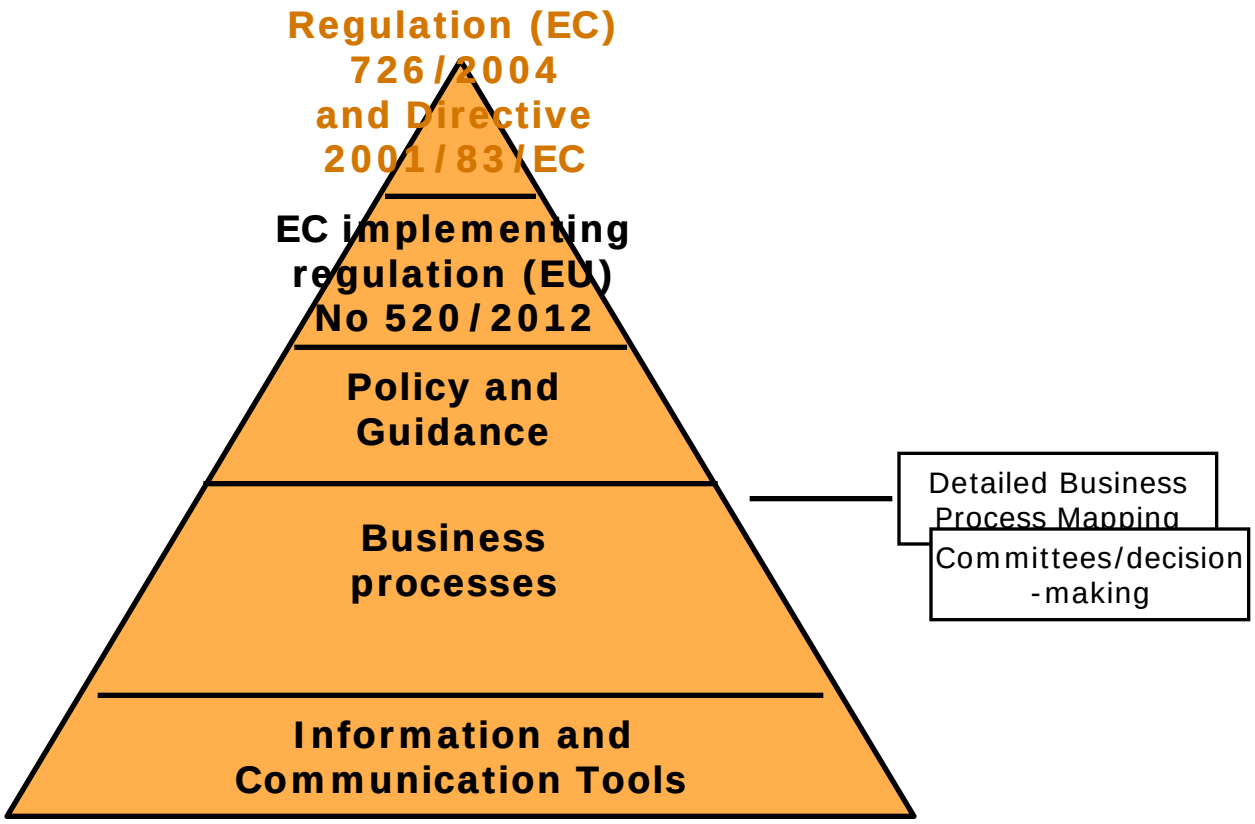

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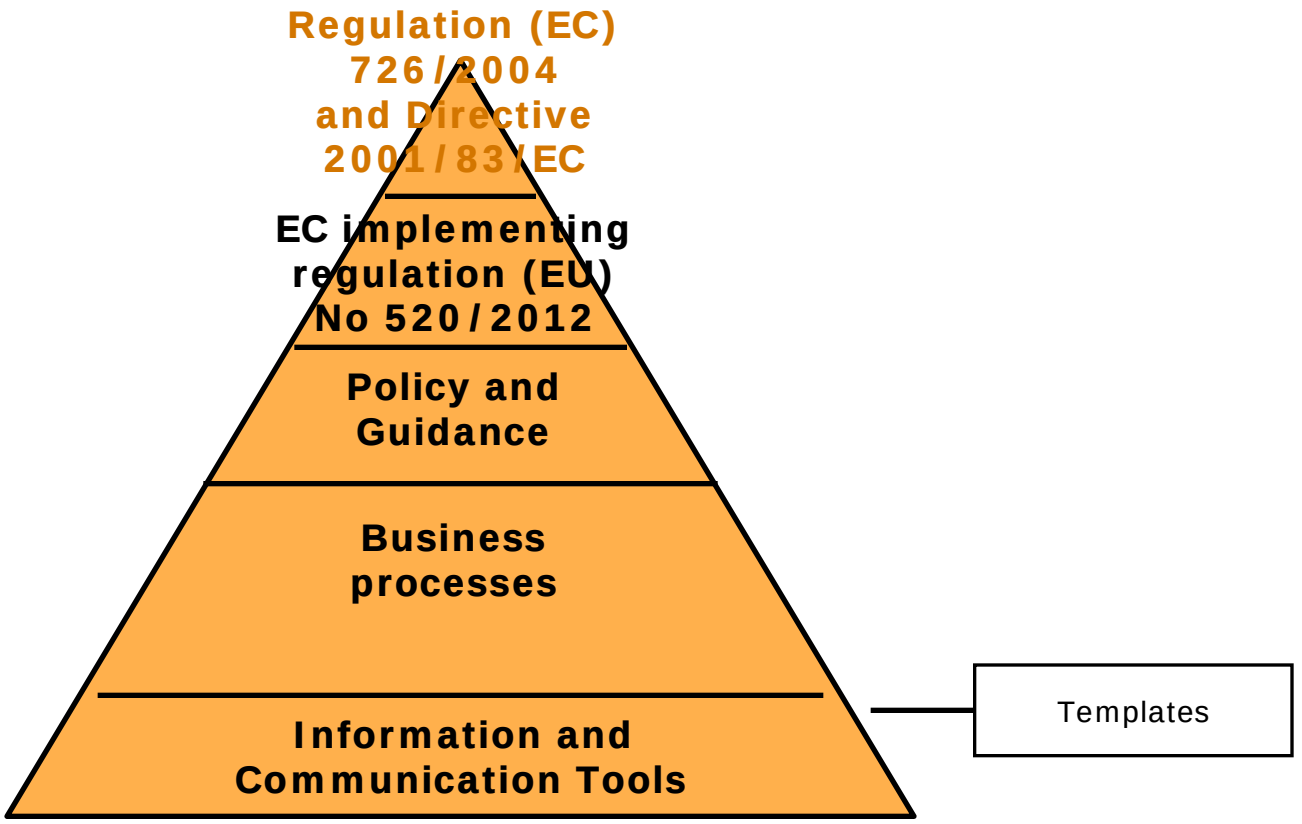

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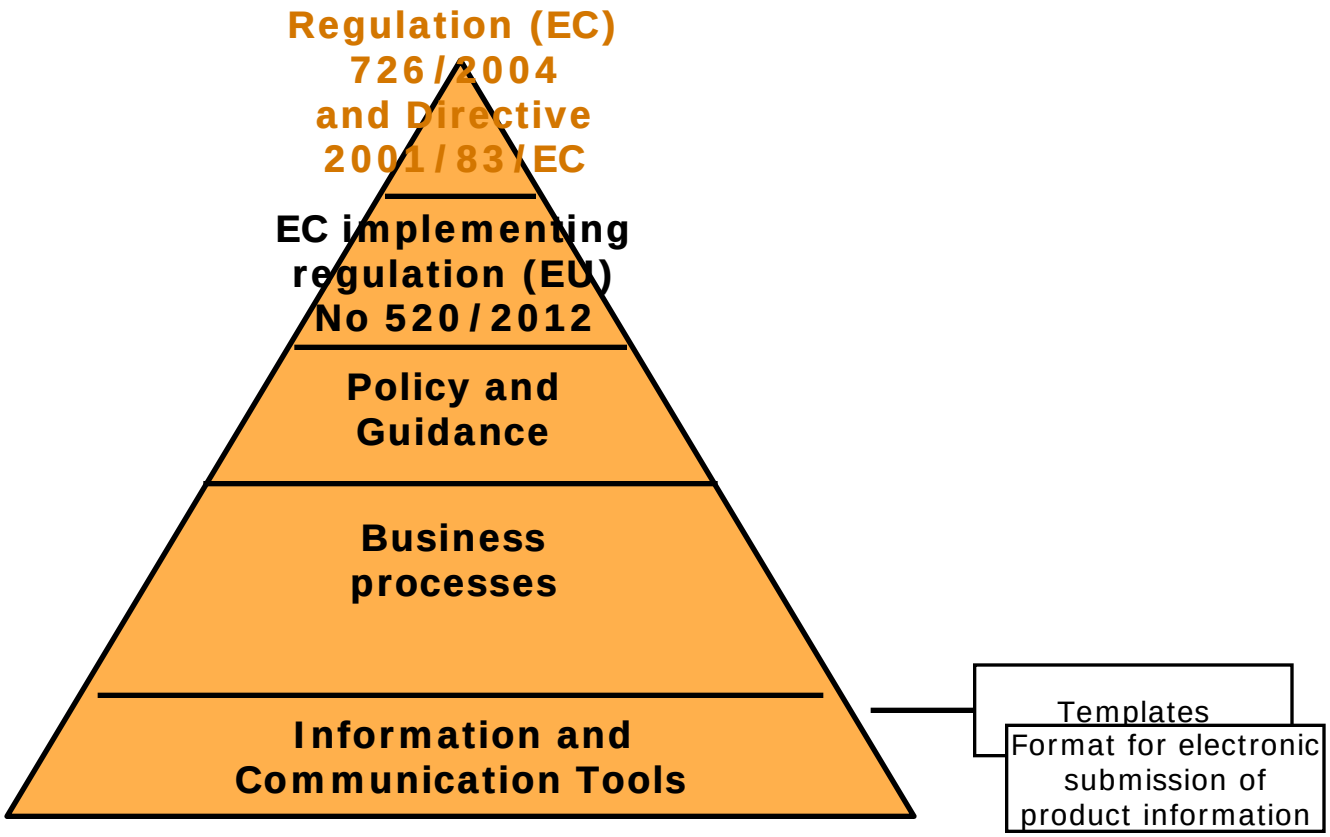

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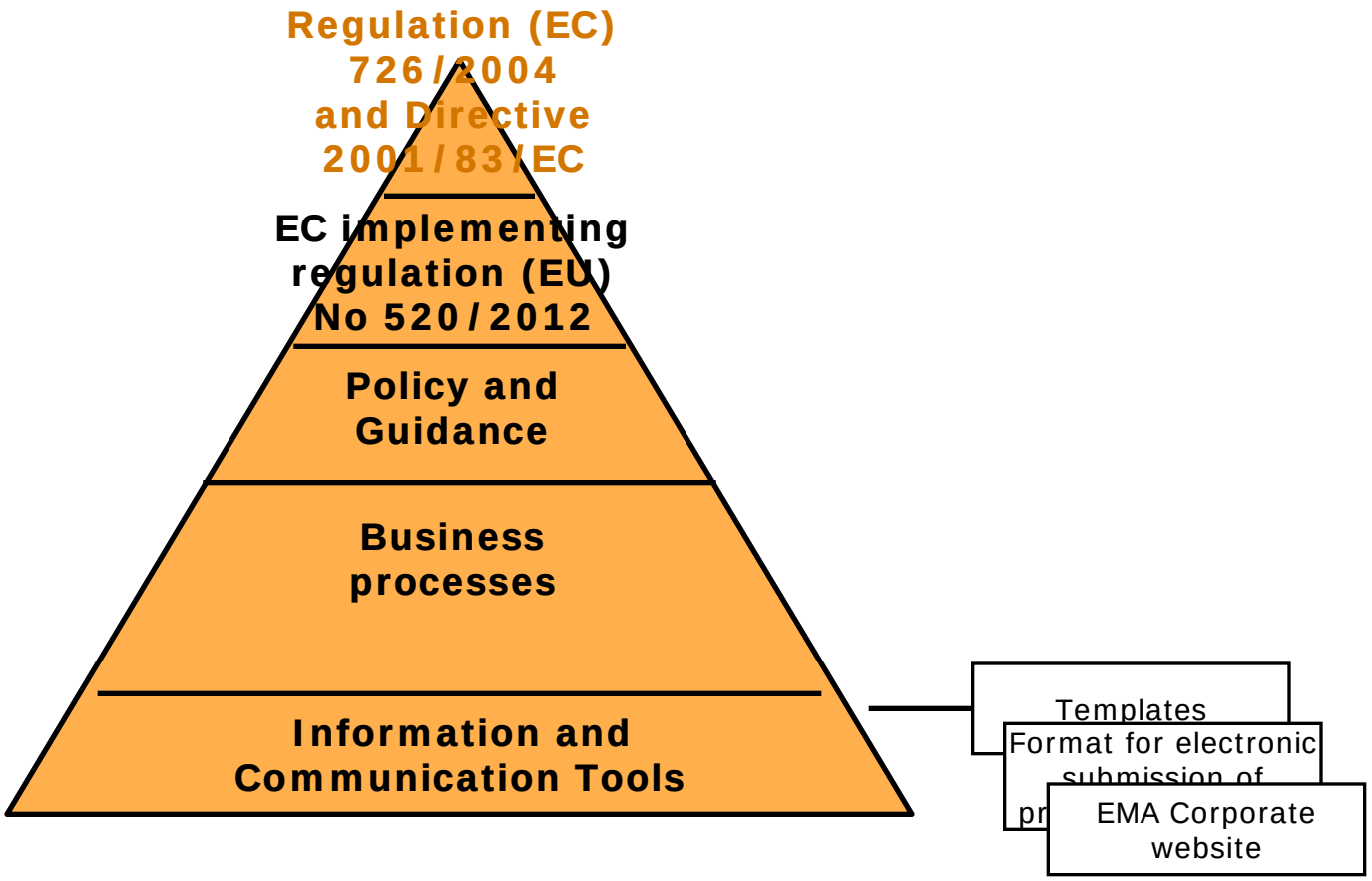


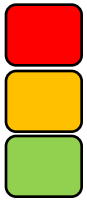
EMA Corporate website

- 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:**



Not started

On-going implementation

Implemented

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

What will continue in 2013?

- 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

What is likely to be new in 2013*?

**Subject to agreement by EMA Management Board/HMA:*

- Legal proposal from the European Commission on fees for pharmacovigilance
- Several key scientific workshops to be held at the EMA (e.g. Medication error, Efficacy studies)
- Maintenance, core validation and publication of structured product information
- Establishment of procedure for collaboration joint industry safety studies
- Publication of list of products under additional monitoring and introduction of new 'black symbol' and specific statement in product information
- Public Hearings for Urgent Union Procedure
- Publication of CHMP and CMDh agendas and minutes for Pharmacovigilance (further increase in transparency)
- Revised process for Pharmacovigilance inspections
- First EMA and National Competent Authority system audits

Beyond 2013…?

- 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

Strengthen 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 (provisional booking for 2 Stakeholders fora in 2013 (June and September))
- Expectation management
- Focus on the key objective: promotion and protection of public health

Conclusions

- Prioritised implementation 2012 – on target
- Work on-going taking into new amendment to the 2010 legislation and remaining deliverables
- Funding (and staffing) remains the key risk to system sustainability
- Journey is not over yet but we have a direction of travel: focus on promotion and protection of public health!

Thank you!