European Commission

The Pharmaceutical Package of the European Commission

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Contents:

- Communication on a vision for the pharmaceutical sector
- Pharmacovigilance (*amendment to Dir 2001/83/EC and Reg 726/2004*)
- Counterfeit (*amendment to Dir 2001/83/EC*)
- Information to Patients (*amendment to Dir 2001/83/EC and Reg 726/2004*)

Adoption by the Commission: 10/12/08

http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/pharmpack_en.htm

Commission proposals for a directive and a regulation as regards pharmacovigilance of medicinal products for human use

COM (2008) 664 final; COM (2008) 665 final

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Issue and aim

Issue:

- The current systems needs improvement

Aim:

- Clear tasks and responsibilities for all parties
- Improved decision-making procedures and efficient use of resources
- Proactive and proportionate risk management avoiding unnecessary administrative burden and providing for stronger link between safety assessements and regulatory action
- Strengthened transparency, patient involvement and oversight of non-interventional studies

Commission proposal for a directive as regards falsified medicinal products for human use

COM (2008) 668 final

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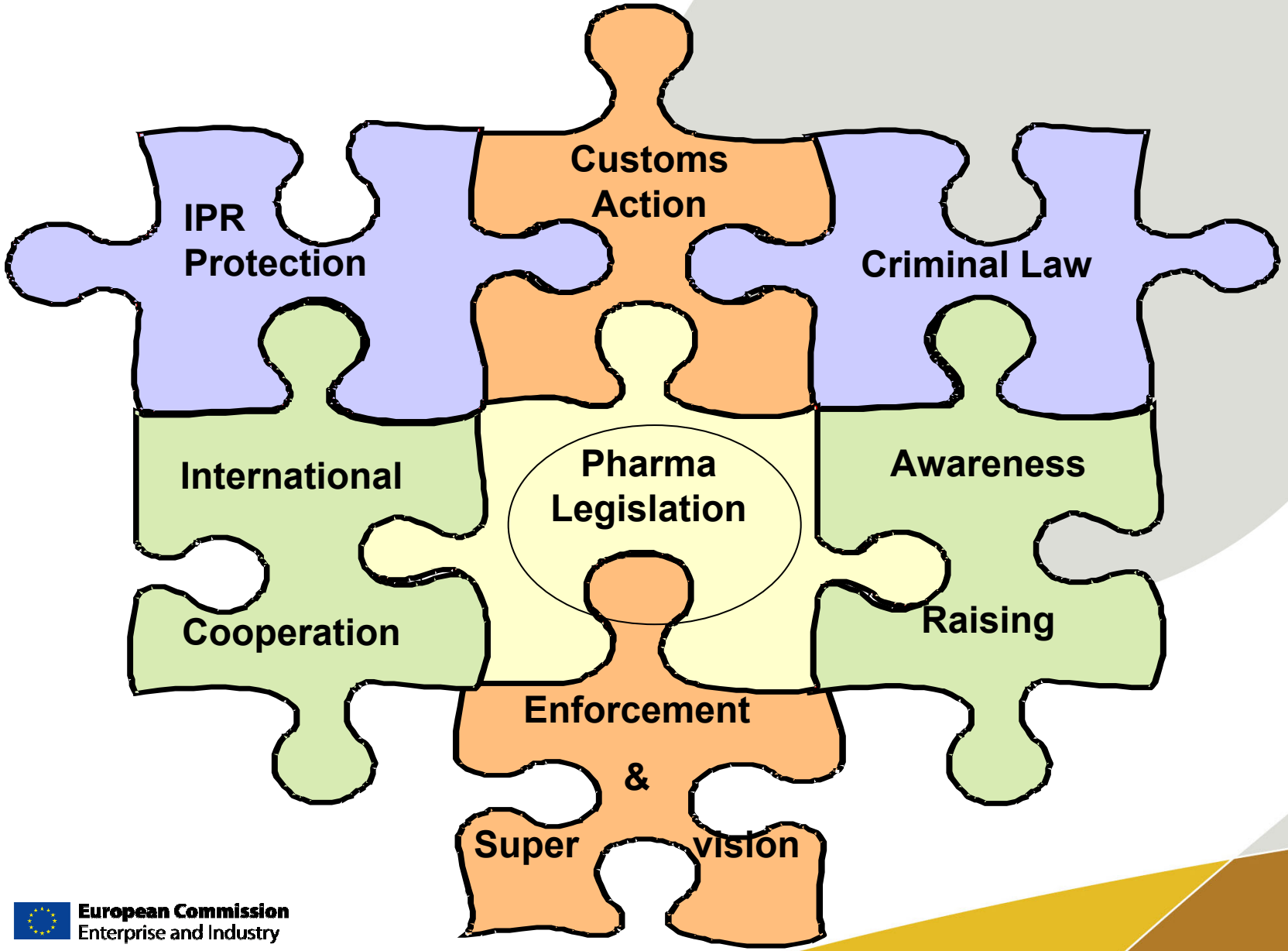
Strategies…



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3 ‚Pillars‘

1.	2.	3.
Product characteristics and **‚Good Manufacturing Practices‘ (GMP)**	**Actors in the supply chain** and **‚Good Distribution Practices‘ (GDP)**	**Active Substances** (incl. Inspections)

Commission proposals for a directive and a regulation as regards information to the general public on medicinal products for human use subject to prescription

COM (2008) 662 final; COM (2008) 663 (final)

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Issue and aim

Issue:

- Gap in current pharmaceutical legislation
- Unequal access to information on medicinal products

Aim:

- Harmonised framework for the provision by MAH of non-promotional information to the general public on prescription-only medicinal products for human use
- Maintain prohibition of advertising by MAH to the general public on prescription-only medicines

Key elements proposed relate to

- Types of information to be disseminated
- Channels for the dissemination of information
- Quality criteria and conditions to be fulfilled
- Specific rules on Internet websites
- Monitoring mechanism
- Sanctioning in case of non-compliance

THANK YOU!