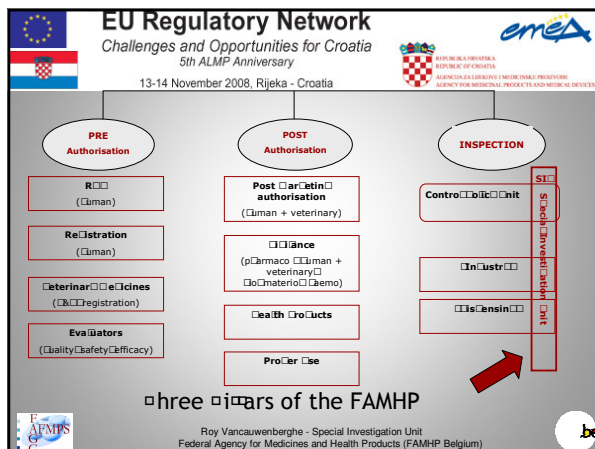
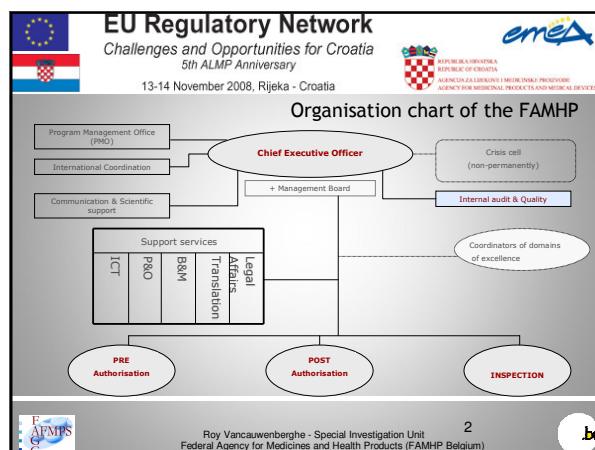


EU Regulatory Network
Challenges and Opportunities for Croatia
5th ALMP Anniversary
13-14 November 2008, Rijeka - Croatia

Fighting Pharmaceutical Crime and Counterfeit Medicines

Roy Vancauwenberghe
Federal Agency for Medicines and Health Products
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Regulation Medicinal Products

- Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the community code relating to Medicinal Products for Human Use
- Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products
- Medicines Act 25 march 1964 (Belgium)

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Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the community code relating to Medicinal Products for Human Use

Legal obstacles to Pharmaceutical Crime and Counterfeit medicines

Art.1.2 : Definition Medicinal Product
Art.1, 17: Definition Wholesale distribution (procure, hold, supply, export)
Art.2: Directive applies to the MS market
Art.6: Mandatory MA for placing on the market
Art.40: Authorization for manufacturing / imports from third countries
Art.51 : MP coming from third countries — qualitative / quantitative analysis
Art.77: Wholesale distribution: mandatory authorization
Art.80: From authorized to authorized distributors / recalls / records / GDP

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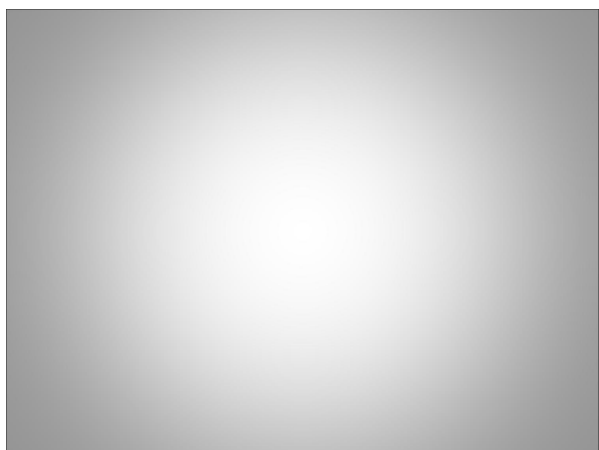
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Regulation

Guidelines on Good Distribution Practise of Medicinal Products for Human Use (94/C 63/03)

Art.31. Counterfeit medicinal products found in the distribution network should be kept apart from other medicinal products to avoid any confusion. They should be clearly labelled as not for sale and competent authorities and the holder of marketing authorisation of the original product should be informed immediately.

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