

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

Advances to the Croatia's
rapprochement to the EU

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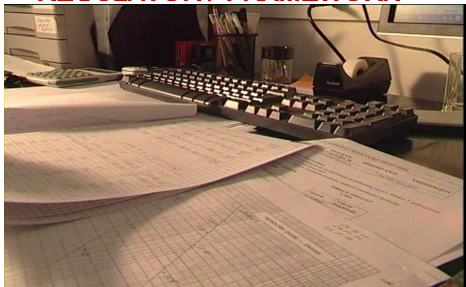
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DEVELOPMENTS IN CROATIAN
REGULATORY FRAMEWORK



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Developments in Croatian regulatory
framework

- harmonisation with the *acquis communautaire*
- New Act on Medicinal Products (2007)
- New Ordinances
 - Ordinance on Granting the MA (2008)
 - Ordinance on Special Conditions for EU Authorized Products (2008)
- New Act on Medical Devices (2008)



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The Act on Medicinal Products (MP)

- published on June 21, 2007
- came into effect on October 1, 2007
- harmonized with:
 - 2001/83/EC on Medicinal Products for Human Use
 - amended by: 2001/20/EC, 2002/98/EC, 2003/63/EC, 2004/24/EC, 2004/27/EC

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New aspects of the Act on MP

- MP not on the market for 3 years = authorisation cease to valid
- well-established use
- generic MP
- orphan MP
- traditional herbal MP
- biosimilars



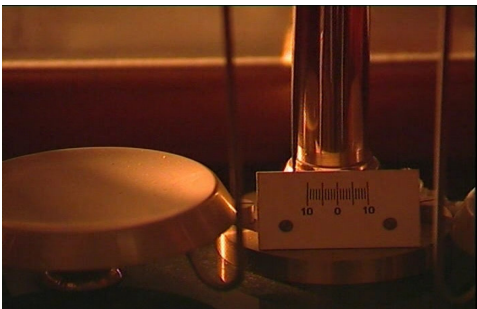
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Deadlines

MA	210 days 150/180 days (EU products)
Renewal	180 days
Variation	90 days

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MARKET SURVEILLANCE IN CROATIA



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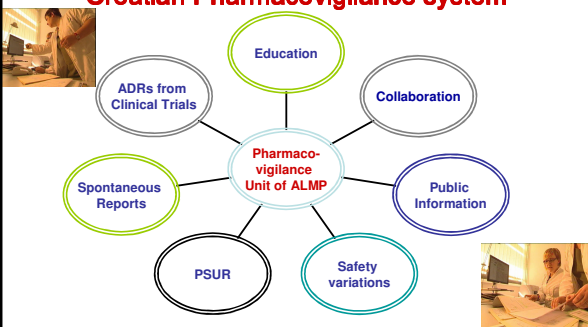
Market surveillance in Croatia

- **Pharmacovigilance system in Croatia**
 - adverse reactions
 - safety issues
- **Off-shelf control of quality defects**
- **Counterfeit medicines**
 - not found in an official supply chain
 - cooperation with police



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Croatian Pharmacovigilance system



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Pharmacovigilance unit activities

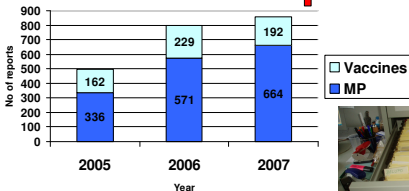
- **more than 60 workshops for physicians and pharmacists about the pharmacovigilance system in Croatia**



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Number of Spontaneous Adverse Reactions Reported in Croatia

↑ + 71%



Year	Vaccines	MP
2005	162	336
2006	229	571
2007	192	664



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Achievements and plans of Croatian pharmacovigilance

NEW

- EudraVigilance MemberState Edition installation (September/October 2008)
- Electronic submission of ADRs (Pilot phase – will start in November 2008) – cases from EU and third countries
- Risk management plan
- Pharmacovigilance plan
- WHO National Centres Meeting, Dubrovnik, 2011

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COMMUNICATION STRATEGY OF ALMP



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Communication strategy of ALMP

- provision of relevant information to patients, healthcare professionals and the media

- newspapers, radio, TV
- articles in medical papers
- brochures
- informational material
- on-line enquiries



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Communication strategy of ALMP

- update of medicinal products base and medical devices base (with PIL and SPC)
- organization of international conferences and workshops



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