

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

**World Health Organization
Pharmaceutical Policies**

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WHO, HSS/EMP/QSM



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WHO activities with global impact

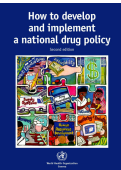
- Standard setting (guidelines, GxPs)
- International Pharmacopoeia and reference standards (ICRS)
- INNs, ACTs
- Monitoring of Adverse Drug Reactions
- Listing of Essential Medicines
- Therapeutic guidelines and rational pharmacotherapy
- Procurement of medicines and quality control (counterfeiting, APIs)
- Drug Policies
- Support to regulatory authorities and ICDRAS
- Prequalification of priority medicines and vaccines



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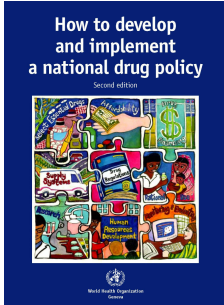
History of guidance for Drug Policies

- 1985 Nairobi Conference of Experts on rational Use of Drugs
- 1987 Working group of Experts to draft guidelines for NDP's
- 1988 Guidelines for NDP's released
- 1995 Expert Committee on NDPs met report issued
- 2002 New Guidelines published




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How to develop and implement a national drug policy




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Objective of National Drug Policies

- Assure access, quality and rational use of medicines
- Government medium- to long-term goals (5 years) for the pharmaceutical sector, including main strategies.
- Primarily serves health-related objectives, but may include other goals, e.g. economical.
- Serves to co-ordination of activities of involved parties and actors.
- Should be broadly discussed with stakeholders and publicly available as government plan and commitment.



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Components of NDPs

- Selection of essential drugs (for supply and reimbursement)
- Affordability
- Drug financing
- Supply systems
- Regulation and quality assurance
- Rational use
- Research
- Human resources
- Monitoring and evaluation

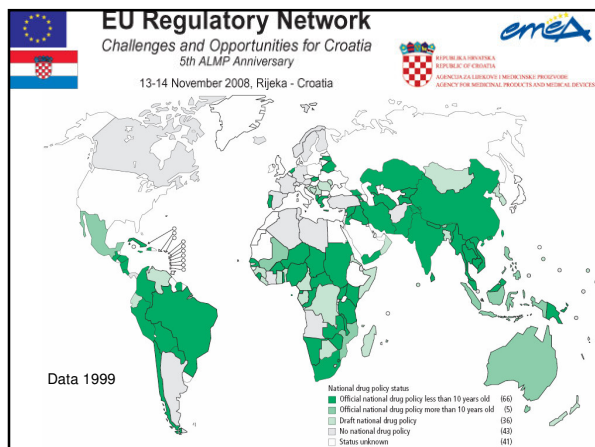
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WHO guidance

- Drug policy is broader than regulation of quality, safety and efficacy
- Access/availability issues are treated in several components
- Does not specifically include industrial policy
- Does not discuss regional/economic bloc drug policies

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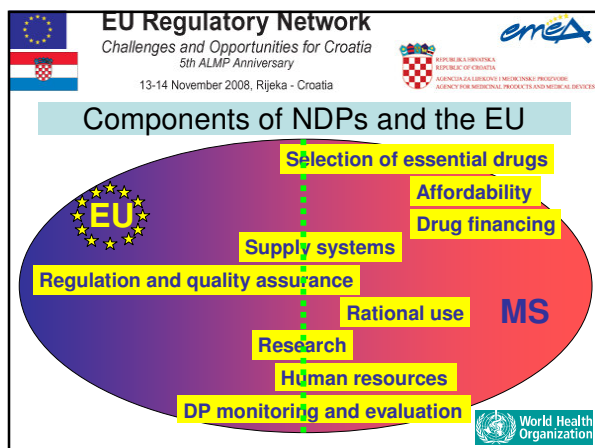


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EU Pharmaceutical policies

- EU - Enterprise & Industry
 - Regulatory policy
 - Industrial policy
 - International cooperation
- "Key (EU) objectives are to guarantee access to medicines at an affordable cost, ensure that medicines are safe and effective, and improve the quality and dissemination of information to citizens to enable them to make informed choices about their own treatment."
- National policies (Portugal, Netherlands, Hungary, Greece)

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National and EU drug policies complementary

- Acquis communautaire as the basis
- Balance between objectives and resources
- Work-sharing and specialization across the EU
- EU and national industrial policies
- EU and national research policies
- EU and national support to developing countries

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Issues relevant for national policies

- Compliance with EU Acquis
- Investment into common EU system
- Organization of national regulatory system
- Access to medicines / affordability / pricing
- Rational use of medicines
- Industrial policy and wholesale/retail system
- Relations to national stakeholders
- Other issues of national interest

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EU contribution to developing countries

- Various EU capacity building projects appreciated
- European & Developing countries Clinical Trials Partnership
- European Centre for Disease Prevention and Control
- Article 58 of Regulation 726/2004 – no major effect yet
- EU serves as a model of regulatory network
- EMEA (EC) respected, but available regulatory argumentation/assessment rarely utilized
- Information outputs viewed insufficient (CT database, EudraGMP, product quality data, etc.)
- EU MS not viewed as equivalent yet

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Countries of PQ products manufacture (August 2008)

Country	Count
India	145
France	16
South Africa	11
UK	10
Canada	9
Germany	9
Spain	9
Switzerland	8
Netherlands	8
USA	6
China	3
Australia	1
Pakistan	1

EU - 52 manufacturing sites out of 244

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Thank you for attention

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