Reinforcing patient safety in Europe

14-15 June 2011
Zagreb, Croatia

HALMED
Agency for Medicinal Products and Medical Devices of Croatia

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Accession Preparation: Situation in Croatia

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Head of the Agency for Medicinal Products and Medical Devices (HALMED), Croatia

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Content:

- Croatian Agency for Medicinal Products and Medical Devices (HALMED)
- Role of HALMED
- Harmonisation of legislation with the acqui (Brief history of Croatian regulatory framework)
- Twinning Light Project
- HALMED's achievements and challenges
- Conference Announcements

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Agency for Medicinal Products and Medical Devices of Croatia

- ✓ National regulatory authority
- ✓ Provides services pertaining to human medicinal products, medical devices and homeopathic products in accordance with the Croatian legislation
- ✓ Established on October 1, 2003
- ✓ Legal compliance is supervised by the Ministry of Health and Social Welfare
- ✓ Generates its own income through service fees and annual charge

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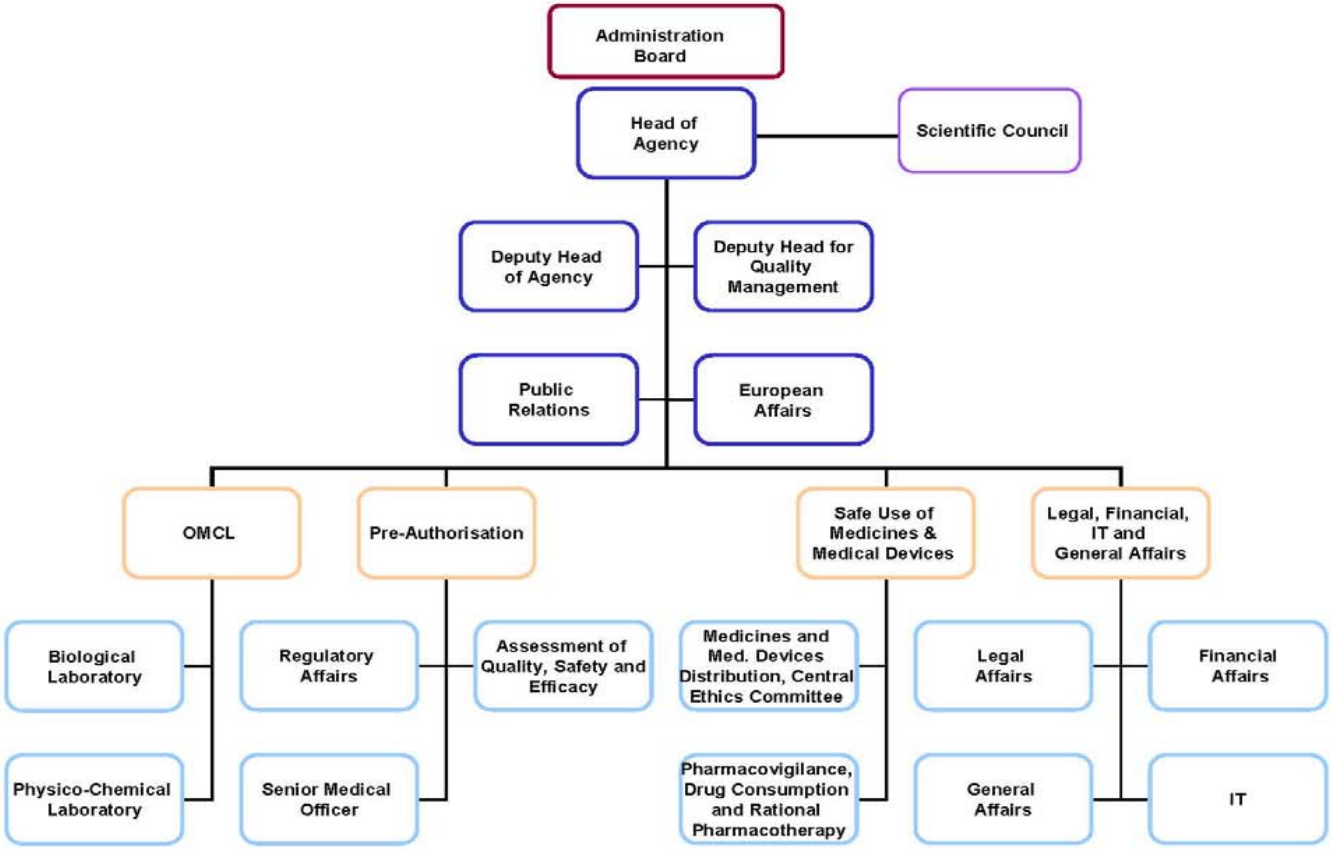

74 employees, 2003

130 employees, 2011

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Collaborates with various international institutions:

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

edqm
European Directorate for the Quality of Medicines & HealthCare

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

the UPPSALA MONITORING CENTRE

…and Medicines agencies of the EU member states:

MINISTERIO DE SANIDAD Y POLITICA SOCIAL

agencia española de medicamentos y productos sanitarios

Twinning Light Project

IRISH MEDICINES BOARD

afssaps
Agence française de sécurité sanitaire des produits de santé

…as well as Medicines agencies in the region:

AGENCIJA ZA LIJEKOVE I MEDICINSKA SREDSTVA BOSNE I HERCEGOVINE

AGENCIJA ZA LIJEKOVE I MEDICINSKA SREDSTVA

… and last, observer to :

CMDh
Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human

HMA
Heads of Medicines Agencies

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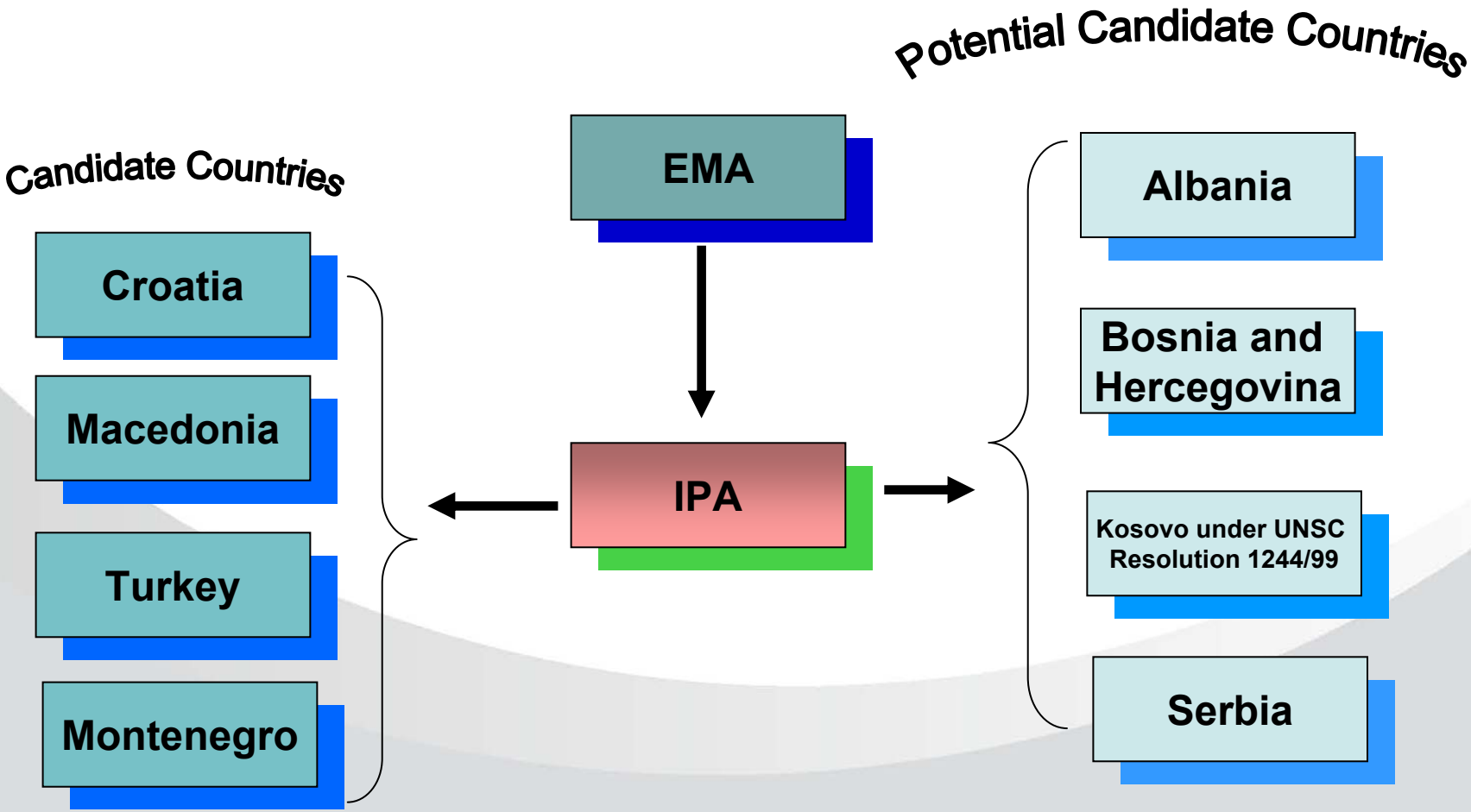
CO-OPERATION WITH EMA
IPA Programme 2009-2011



Legend:
EMA European Medicines Agency
IPA Instrument for Pre-Accession

Source: S. Tomic et al., *Regul Toxicol Pharmacol* 57 (2010) 325-332.

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HALMED'S KEY ROLE

Protecting public health by ensuring safety, quality and efficacy of medicines

Promotes public health by helping people to understand the risks and benefits of the medicines they use

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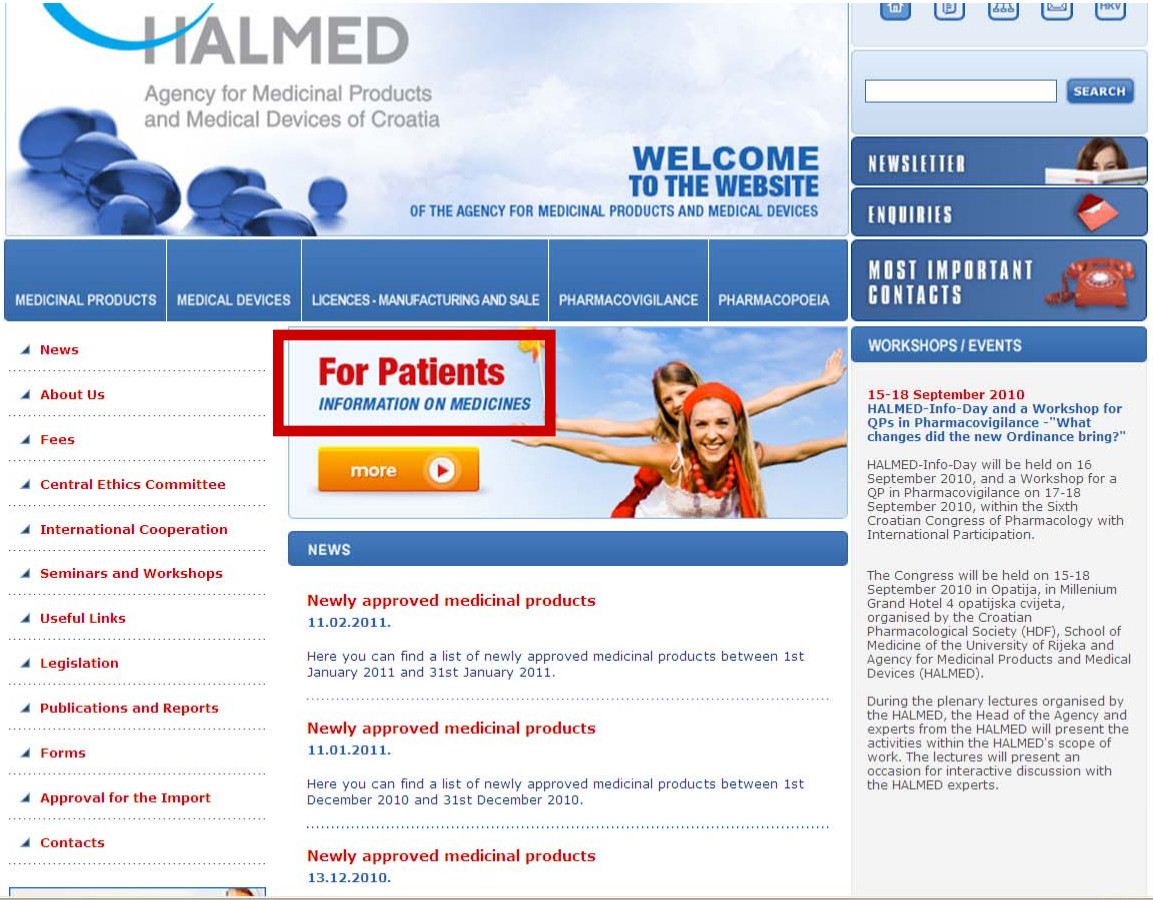
Safeguard public health by carrying out its communication role through provisions of accurate, scientifically proved and timely information on medicinal products and medical devices to healthcare professionals, patients and the general public



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New Safety Information

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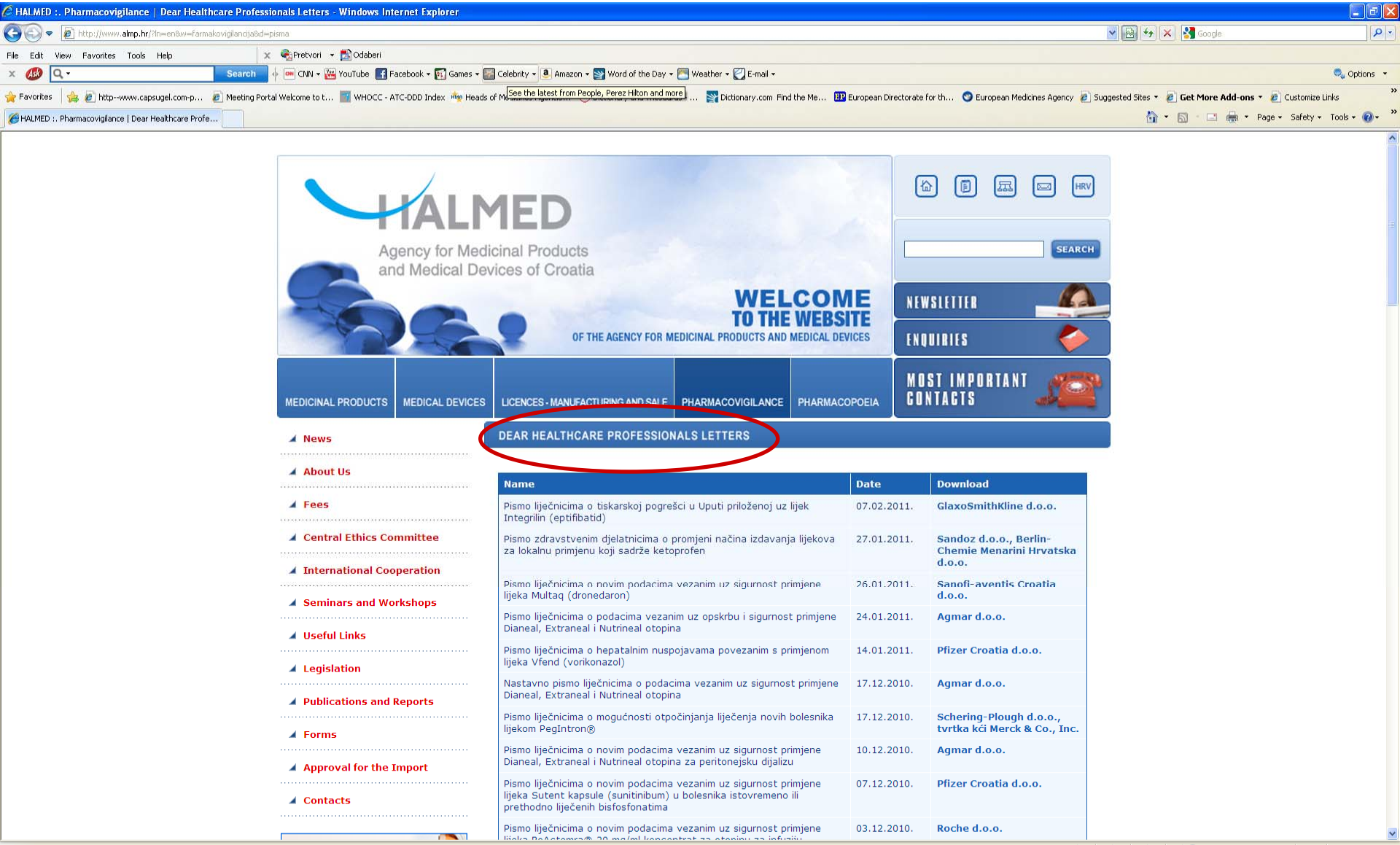
Dear Healthcare Professional Letter



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HARMONISATION

WITH THE EU LEGISLATION

- *acquis communautaire*
- negotiation procedure between Croatia and the EU: Chapter 1 “Free Movement of Goods” which defines regulation of medicines and medical devices was closed in April 2010
- continuous monitoring and harmonisation of Croatian legislation with the aquis

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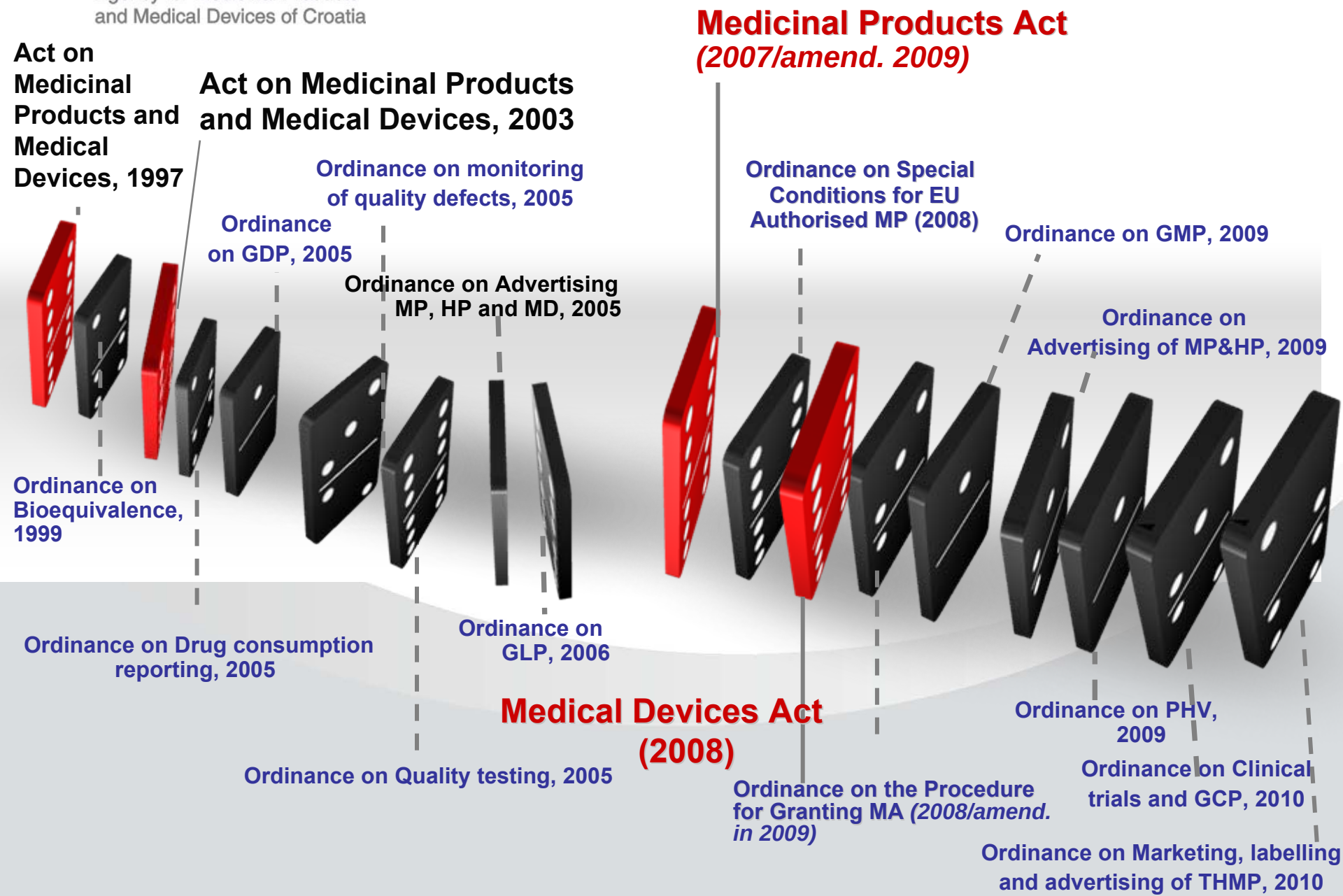
HISTORY OF REGULATORY FRAMEWORK IN CROATIA



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nCADREAC
(Authorisation of Products Previously Authorised in the EU)

- New Collaborative Agreement between Drug Regulatory Authorities in Central and Eastern European Countries (supported by EU officials and encouraged by the WHO Regional Office for Europe)
- provisions of nCADREAC- incorporated in the Croatian legislation

New Collaboration Agreement between Drug Regulatory Authorities in Central and Eastern European Countries

CADREAC 1997 (Bulgaria, Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Estonia, Poland, Romania, Slovakia, Slovenia, Turkey)

Supported also by European Union (EU) officials and encouraged by the WHO Regional Office for Europe,
We, the Heads of Drug Regulatory Authorities in Central and Eastern European Countries (further on: Signatories)
During the CADREAC Annual Assembly, March 2004 in Bucharest, followed by many discussions
Have agreed to sign the present Agreement in order to start a new informal collaboration.

Aim of the Collaboration
Article I

(1) To facilitate implementation of EU standards and professional obligations to drug regulations into practice.
(2) To create a better environment and broader possibilities for Signatories outside the EU to be involved in professional activities organised by the EU.
(3) To facilitate introduction of mutually recognisable procedures and activities relating to „Good Practices" in accordance with EU regulatory principles for the assessment and marketing authorisation of medicinal products.
(4) To establish a forum in which joint strategies concerning either approaching or later EU accession or working together with the EU are developed and particularities referring to the group as a whole are elaborated among Signatories and/or together with EU structures to avoid unnecessary duplication of work and save resources.
(5) To facilitate the preparation of future drug regulatory meetings of Central and Eastern
tates.
opean network of regulatory

nCADREAC 2006


Bulgaria


Croatia


Czech Republic


Hungary


Romania


Slovakia

orities (Participating DRAs), and
latory authority, all the latter have the
nent.
tory authorities :
r states
a signed association agreement

have valid mutual recognition
drug regulations
astern European countries.
embers of this Agreement.
field(s) in which the mutual
with the EU.
embers of this Agreement.
lementation of any of its
recommendations is voluntary for all Participating DRAs.
(4) Without prejudice to the EU internal confidentiality rules, all Participating DRAs may have access to all the information generated within the framework of the Collaboration.

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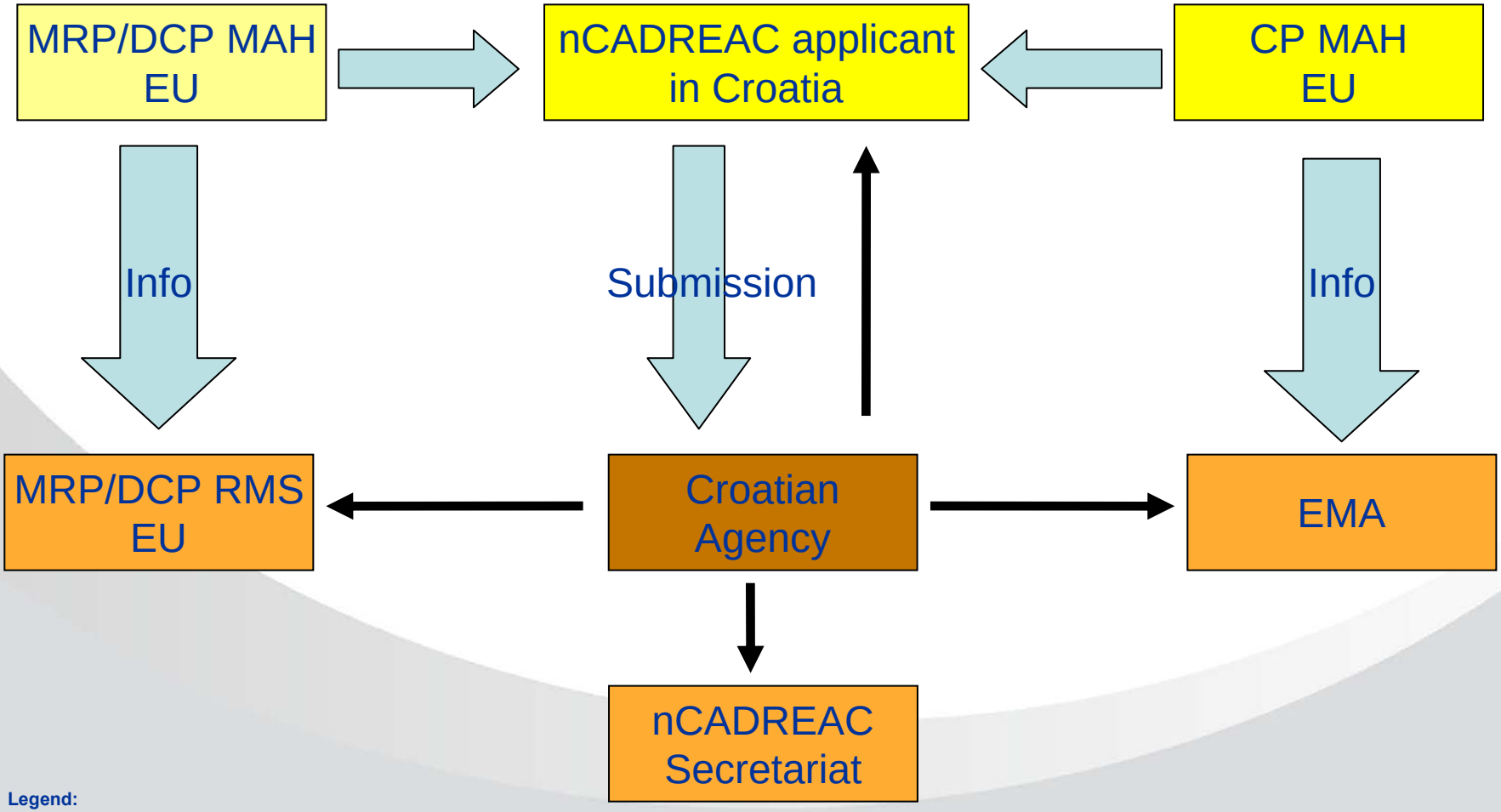
nCADREAC



Legend:

MRP/DCP MAH	**Mutual Recognition or Decentralised Procedure Marketing Authorisation Holder**
CP MAH	**Centralised Procedure Marketing Authorisation Holder**
RMS	**Reference Member State**
nCADREAC	**New Collaboration Agreement between Drug Regulatory Authorities in Central and East European Countries**

Source: S. Tomic et al., *Regul Toxicol Pharmacol* 57 (2010) 325-332.

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Current situation

▪ Fast track procedure for EU products	✓ Yes (nCADREAC)
▪ MA procedure	✓ 210 days NP; CP 150 days, MRP/DCP 180 days
▪ Data exclusivity	✓ 6 years (will be changed with the accession)
▪ Validity of MA	✓ 5 years
▪ Quality control (MA procedure)	✓ First batch required (biologicals every batch)
▪ Batch to batch control of EU products	✓ No, but CoA submitted to the Agency
▪ eCTD	✓ Yes
▪ Inspection and enforcement	✓ Ministry of Health and Social Welfare
▪ Parallel trade	✗ No
▪ New Regulation on Variations	✗ No
▪ PIP	✗ No
▪ New PhV legislation	✗ No *

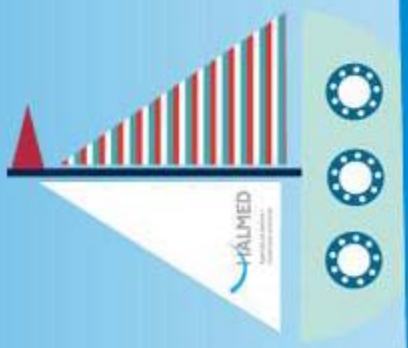
Counterfeited medicines

Safety

Adverse drug reactions

Effica

Quality defects



CROATIAN REGULATORY FRAMEWORK

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…BUT NOT OVERREGULATE

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IPA PROGRAM 2007
TWINNING LIGHT PROJECT

Strengthening of expert capacity in implementation of EU legislation on medicines in the Croatian Agency for Medicinal Products and Medical Devices"

HALMED
Agencija za lijekove i medicinske proizvode

TWINNING

MINISTERIO DE SANIDAD, POLÍTICA SOCIAL E IGUALDAD

agencia española de medicamentos y productos sanitarios

December 2010 – June 2011

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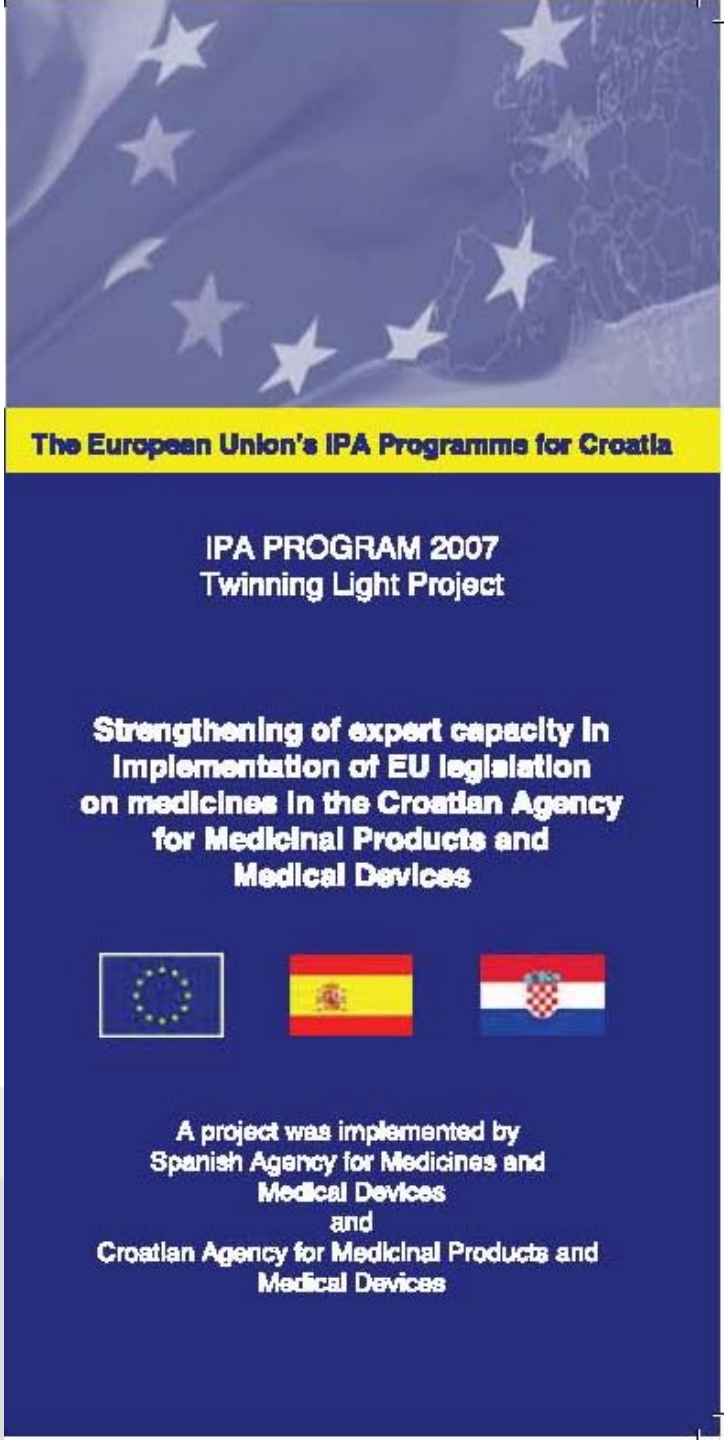
TWINNING LIGHT PROJECT

- Duration of the project: 6 months
- 30 AEMPS experts divided into 11 visits held various training seminars and workshops
- instructed and trained HALMED's experts to work in line with EU practice
- trained to implement EU directives, rules and/or procedures for specific groups of medicinal products - quality, safety and efficacy evaluation of well-established use medicines, herbal medicinal products, generics and biologicals (vaccines and sera, blood/blood products, biosimilars)
- overview of pharmaceutical inspection and enforcement
- trained to evaluate of bioequivalence data

- 2 study visit of HALMED's experts to Spanish OMCL (on-site experience on Quality Control of biologicals)



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TWINNING LIGHT PROJECT SEMINAR &WORKSHOP

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eCTD

- Introduced in Croatia on June 30, 2010
- welcomed to submit eCTD or NeeS
- national requirements – in Working documents folder
- if documentation is submitted in NeeS format, eventually it should be shifted to eCTD, not to paper; similarly if documentation is submitted in eCTD, it should not be shifted to NeeS or paper
- still mandatory to submit Module 1-3 in paper
- By June 2011, HALMED received:
  - NeeS: 4 dossiers and 32 sequences
  - eCTD: 39 dossiers and 384 sequences

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NEW PROJECTS IN HALMED

- **IPA TAIB 2009 - Project on eCTD – Preparation for eCTD and implementation of digital archival information system (worth 1 240 000 EUR)**

- **Expected start of implementation: September 2011**

IPA
INSTRUMENT FOR PRE-ACCESSION ASSISTANCE

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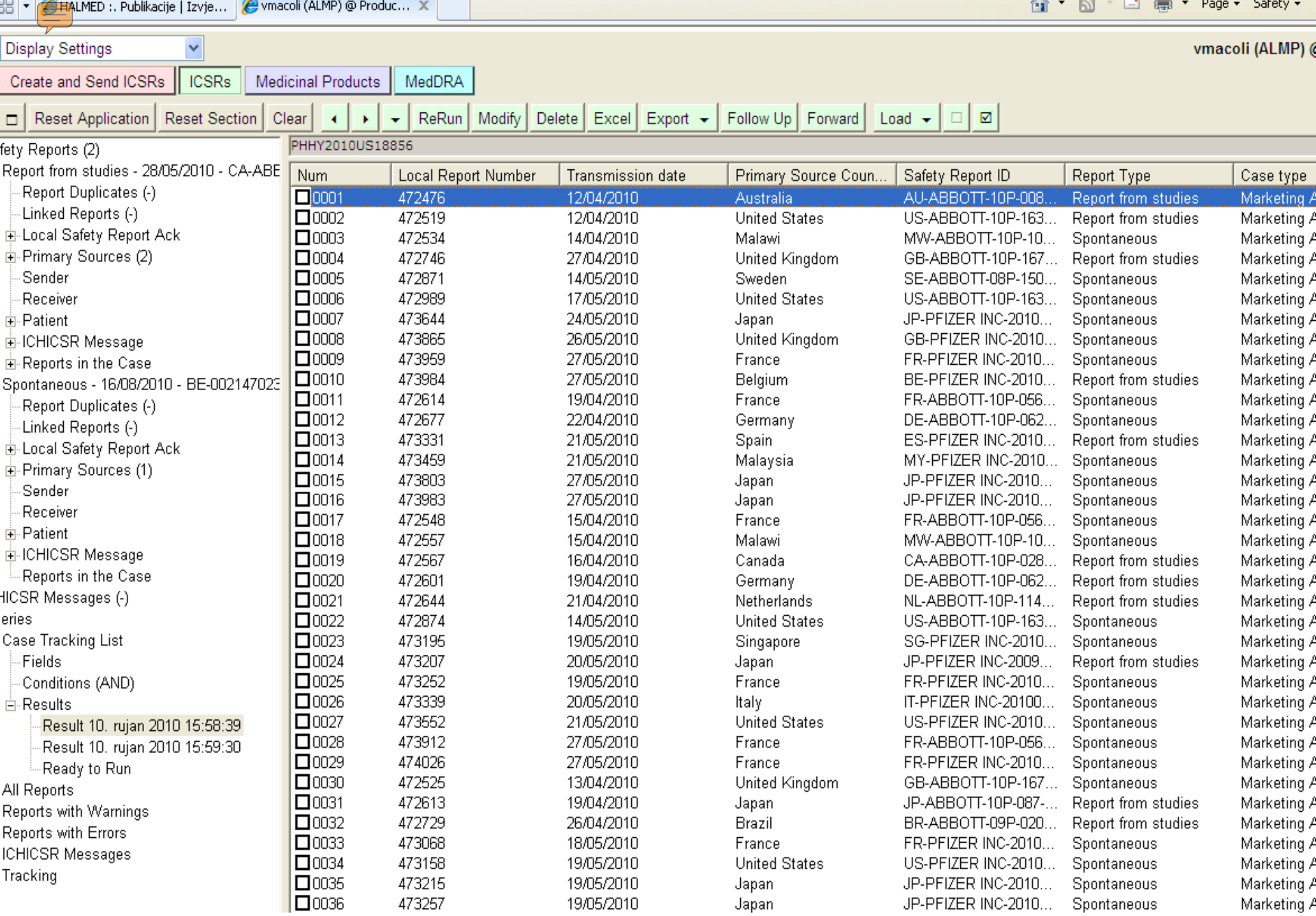
HALMED CHALLENGES ON THE ROAD TO EU ACCESSION

- Dossier upgrading
- Improving quality and consistency of the published product information
- Maintaining one operational regulatory framework in the pre–accession period …and
- …to be ready to implement another one fully transposed regulatory framework for the day 1 of the accession
- How to address global public health issues



- HALMED connected to EudraVigilance gateway since April, 2010
- e-submission of ADRs by 25 MAHs (1/4 of all MAH in Croatia)

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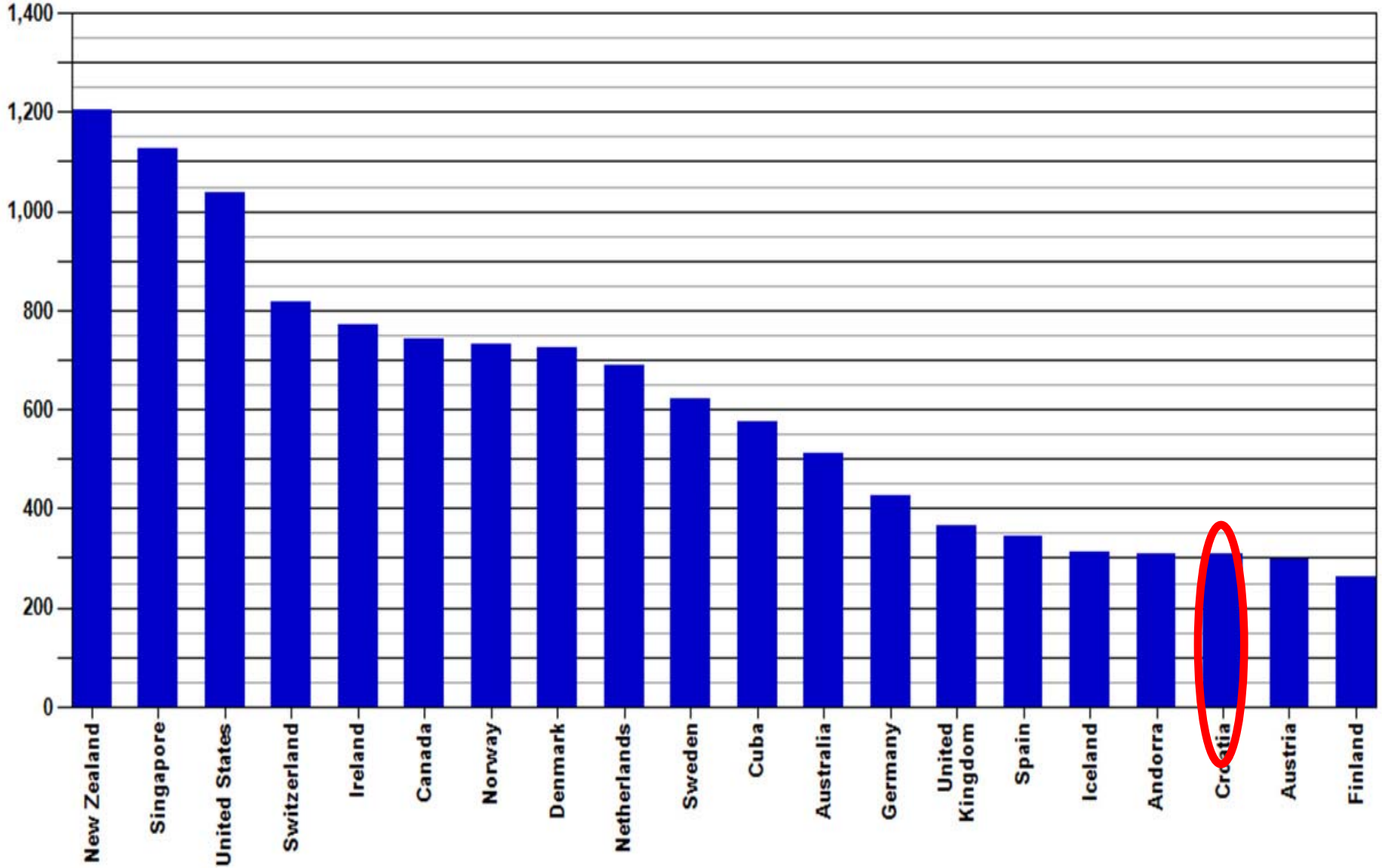
Correct and active ICSRs in the WHO global ICSR database per million inhabitants and year
Period covers: April 2006 to March 2011



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- **Afssaps and HALMED Joint Conference: Information on Medicinal Products; 29-30 September, 2011, Dubrovnik**

afssaps

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World Health Organization

•WHO National Centres Meeting, 30 October -3 November, 2011 Dubrovnik

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Thank you for your attention!