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Agencija za lijekove i medicinske proizvode

HALMED achievements during IPA project period

Viola Macolić Šarinić, PhD, M.D.
Agency for Medicinal Products and Medical Devices, HALMED

EU 28: science, medicines, health
A regulatory system fit for the future
6–7 May 2013, Dubrovnik, Croatia

Zagreb

4,5 mil. inhabitants

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Zagreb, Knežija

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- Croatia applies for EU membership

21.02.2003.

- Commission approves Croatia's application for EU membership

01.04.2004.

- 1st chapter of accession negotiations opens

12.06.2006.

Medicinal product and medical devices act Official gazette 121/2003 from 23 July 2003

Contract 2006/118-594
Multi-beneficiary programme
on participation of Croatia and Turkey in certain Community Agencies in 2006 and 2007

Started July 2006

emea European Medicines Agency *Communications and Networking*

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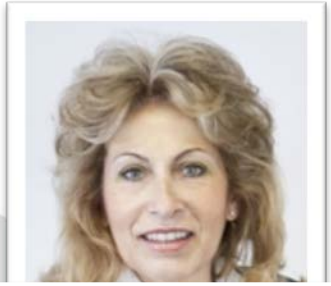
Multi-beneficiary programme on participation of Croatia and Turkey in certain Community Agencies in 2006 and 2007

- First visit in Zagreb, 11 July 2006
  - *Sylvie Bénéfice* (*Project Leader*)
  - *Hans-Georg Wagner (EU telematics)*



„...These meetings were very successful and the presentations of the Croatian representatives were very useful and informative.
The atmosphere of the meetings was encouragingly enthusiastic, and future exchanges were expected to be positive."

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Multi-beneficiary programme on participation of Croatia and Turkey in certain Community Agencies in 2006 and 2007

- The **aims** of this project were to build **contacts and relationships** with Turkey and Croatia and the EMEA **for future collaboration in the EMEA's activities:**
  - to **prepare** the NCAs, to the work carried out by the EMEA, for their future **participation** in EMEA networks
  - to contribute to the creation of **communication and information exchange systems** enabling the future participation of Croatia and Turkey in the EMEA's networks
  - to support Croatia and Turkey in their **communication activities**
  - to assist the NACs, in a practical manner, in **achieving a smooth transition to membership** of the EU.

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Multi-beneficiary programme on participation of Croatia and Turkey in certain Community Agencies in 2006 and 2007

- 15 August 2006 – Croatian participation at the **EudraVigilance Member State edition User Group** in The Netherlands (Amsterdam)
- Start of the implementation procedure in the Croatian Agency!

Multi-beneficiary programme
...pation of Croatia and Turkey in
...ity Agencies in 2006 and 2007

European Medicines Agency
Communications and Networking

Information meeting on participation of Croatia and Turkey in EMEA activities in 2006 and 2007

29 SEPTEMBER 2006
4B
Chairperson: Hans-Georg Wagner
AGENDA

Doc. Ref: EMEA/380958/2006

9.00 - 9.15	Welcome address & EMEA preparation for Enlargement	*(Hans-Georg Wagner)*
9.15 - 9.45	Project description, administrative information	*(Sylvie Bénéfice)*
9.45 -10.15	EMEA activities	*(Martin Harvey-Allchurch)*
10.15-10.45	The Centralised Procedure	*(Patrick Le Courtois/David MacKay)*
10.45-11.05	Ensuring consumer safety during authorisation of veterinary medicines	*(Isaura Duarte)*
11.05-11.30	***Coffee break***	
11.30-11.50	Croatian Agency for Medicinal Products and Medical Devices activities	*(Sinisa Tomic)*
11.50-12.10	Croatian Ministry of Agriculture, Forestry and Water Veterinary Institute activities	*(Mate Brstilo)*
12.10-12.30	Turkish General Directorate of Pharmaceuticals and Pharmacy activities	*(Mahmut Tokac/ Eda Cindoglu)*
12.30-12.50	Turkish Ministry of Agriculture and Rural Affairs/General Directorate of Protection and Control activities	*(Olcay Ture Gosku)*
13.15-14.30	***Lunch in room 3B***	
14.30-15.00	Acquis Communautaire	*(Sandra Vanlievendael)*
15.00-15.30	Pharmacovigilance including Eudravigilance	*(Panos Tsintis)*
15.30-16.00	GxP Inspections and Associated Groups	*(David Cockburn)*
16.00-16.30	EU Telematics Implementation Plan	*(Hans-Georg Wagner)*
16.30-17.00	Benchmarking European Medicines Agencies	*(Marijke Korteweg)*
17.00-17.15	Closing remarks End of the meeting	*(Hans-Georg Wagner)*

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E-mail: mail@emea.europa.eu http://www.emea.europa.eu

Participants at this meeting included:

- the Heads of National Competent Authorities,
- the Heads of Pharmacovigilance,
- Product Information, IT, Administration and the programme coordinators

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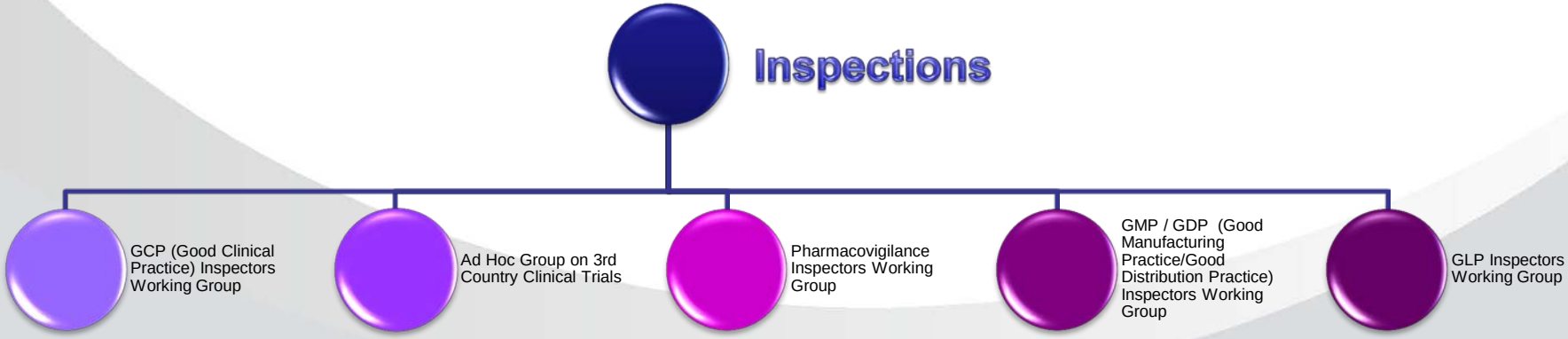
Multi-beneficiary programme on participation of Croatia and Turkey in certain Community Agencies in 2006 and 2007

Participation in meetings as observers

In line with an opinion of the legal service of the European Commission, Candidate Countries can appoint representatives as observers in non-product related meetings exclusively.



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Participation in meetings as observers

ENCePP

European Network of Centre for Pharmacoepidemiology and Pharmacovigilance

HMPC

Committee for Herbal Medicinal Products

Telematics meetings

- Eudravigilance TIG (EV TIG)
- EudraPharm TIG
- EudraNet TIG
- E-Submission TIG
- EUTCT Full Group

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Multi-beneficiary programme on participation of Croatia and Turkey in certain Community Agencies in 2006 and 2007

Pharmaceuticals' Regulation
Croatia's Road to EU Membership

2-3 April 2007

Le Méridien Hotel, Split, Croatia

Outcome of the conference

The conference was a great success in terms of participation and content relevance. The extensive overview of the EU legislation governing the regulation of medicinal products and the description of the practical application of the Acquis Communautaire and legal aspects of its implementation were welcomed by the participants.
The Participation to the conference had to be limited to 350 participants according to the conference room capacity. Therefore, the attendance from Pharmaceutical Industry was limited to 168 participants bringing the number of participants to 346.

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medicinske proizvode

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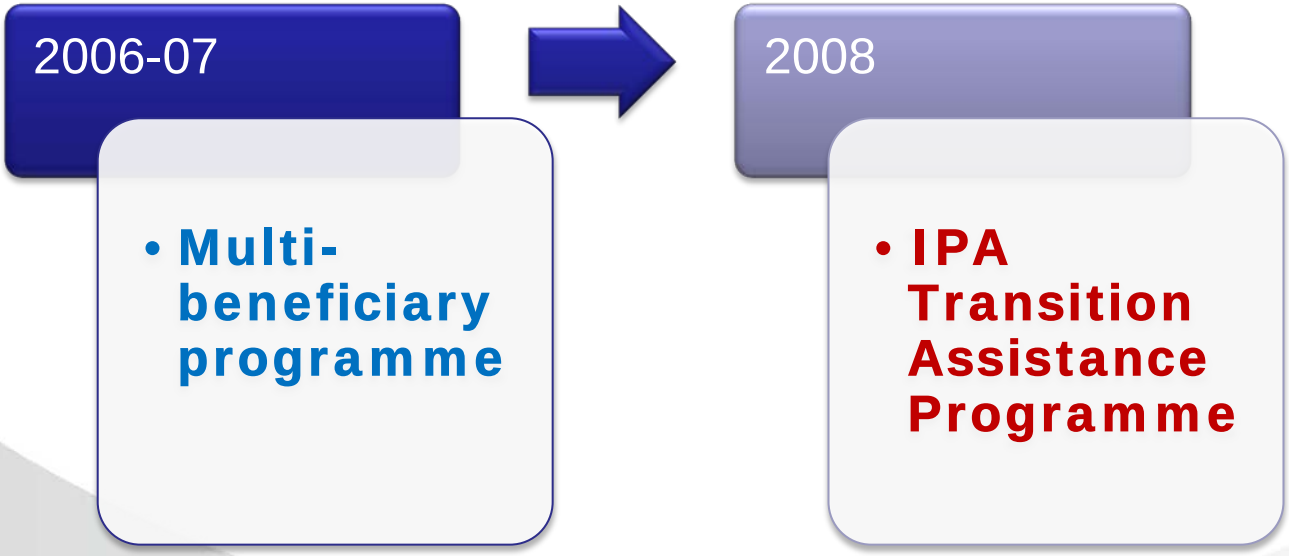

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...onference Venue
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...ušak Rijeka
...trosmayerova 1
...51000 Rijeka -Croatia

REPUBLIKA HRVATSKA
REPUBLIC OF CROATIA
AGENCIJA ZA LIJEKOVE I MEDICINSKE PROIZVODE
AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES

Further information can be found on the EMEA website at:
www.emea.europa.eu/htms/euenlargement/euenlargement.htm

Agency for Medicinal Products and Medical Devices

European Commission

European Medicines Agency

London, 18 November 2008
Doc. Ref. EMEA/605819/2008

PRESS RELEASE

Successful Rijeka conference strengthens EU-Croatian cooperation on medicines regulation

A two-day conference in Croatia has enabled regulatory authorities from the European Union (EU) and Croatia to make good progress on preparing for Croatia's integration as an equal partner in the EU regulatory network for medicines upon its eventual accession to the EU.

The conference, held in the Croatian seaport of Rijeka on 13 and 14 November 2008, was co-hosted by the Croatian Agency for Medicinal Products and Medical Devices (ALMP) and the European Medicines Agency (EMEA).

Organised as part of the fifth anniversary celebrations of the ALMP, and funded through a European Commission programme to assist pre-accession activities of the EU candidate countries, the main themes of the conference were:

- The *acquis communautaire* (the body of EU law) and its application in the regulation of medicines
- Harmonisation of existing Croatian pharmaceuticals legislation with EU legislation
- Practical measures to promote the smooth integration of Croatia into the EU medicines network upon accession

It also provided a forum for discussion and information exchanges between EU regulatory and scientific experts and their Croatian counterparts on a range of specific topics, which included advanced-therapy medicines, paediatric medicines, risk-management and safety-monitoring of medicines (pharmacovigilance), and tackling counterfeit medicines.

Presentations and panel discussions were led by experts from the European Commission, the EMEA, the ALMP and the regulatory authorities of several existing EU Member States, including the National Medicines Agency of Romania, which, as one of the most recent members of the EU medicines network, had valuable post-accession experience to offer the Croatian authorities.

The conference attracted some 320 participants, representing the whole cross-section of stakeholders in Croatia, including regulators, academics and pharmaceutical industry players.

In their closing addresses, the speakers for the European Commission, the EMEA and the ALMP all agreed that the conference had been fruitful in promoting understanding between the EU and Croatian authorities and in facilitating future cooperation.

-- ENDS --

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IPA Transition Assistance Programme 2008

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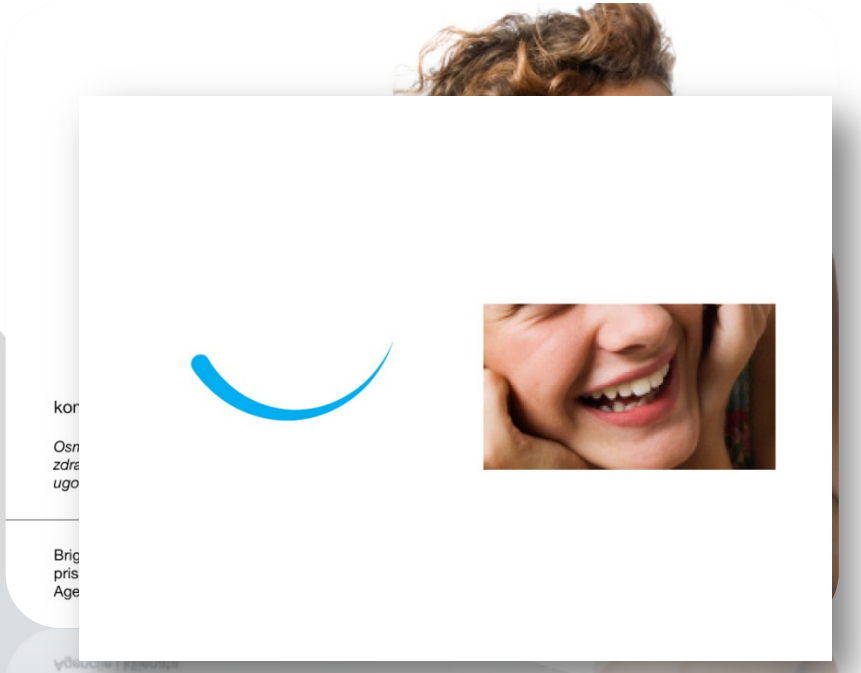
We changed from ALMP to HALMED in 2009



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Meeting agenda

Introductory meeting on the participation of candidate and potential candidate countries in activities of the European Medicines Agency (EMA)

1-2 February 2010 — EMA, London — Meeting room 4A

This meeting is being held as part of the Instrument for Pre-accession Assistance (IPA) programme.

Chairs: Andreas Pott / Sylvie Bénéfice.

Monday, 1 February 2010		
09.00 – 09.10	Opening note	*Andreas Pott*
09.10 – 09.25	Welcome address	*Thomas Lönngren*
09.25 – 09.35	Project description	*Sylvie Bénéfice*
09.35 – 09.55	The European Medicines Agency: Overview and structure	*Martin Harvey Allchurch*
09.55 – 10.35	EU authorisation procedures	*Zaide Frias + Melanie Leivers*
10.35 – 11.00	Role of the European Commission	*Sabine Atzor, EC – DG Enterprise and Industry*
11.00 – 11.30	**Coffee break**	
11.30 – 13.00	Candidate countries and potential candidate countries – presentations and discussions	*Croatia* *former Yugoslav Republic of Macedonia* *Turkey* *Albania*
13.00 – 14.30	**Lunch in room 3B (function room)**	
14.30 – 16.00	Potential candidate countries – presentations and discussions	*Bosnia & Herzegovina* *Kosovo* *Montenegro* *Serbia*
16.00 – 16.30	**Coffee break**	

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E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Monday, 1 February 2010		
16.30 – 17.10	Centralised procedure – Human/veterinary	*George Wade + Jill Kieffer*
17.10 – 17.30	Human medicines special areas: • Paediatrics • Orphan drugs • Scientific advice • SMEs	*Jordi Llinares Garcia*
17.30 – 17.50	Consumer safety and establishment of maximum residue limits (MRLs)	*Isaura Duarte*
17.50 – 18.10	GxP inspections and related Inspectors Working Groups	*Ana Rodriguez*
18.10 – 18.30	Discussions – closing remarks	
19.00 – 22.00	**Networking dinner at the Hotel Marriott (West India Quay)**	

Tuesday, 2 February 2010		
09.00 – 09.20	Biologicals/vaccines/advanced therapies/ biosimilars	*Glenda Silvester*
09.20 – 09.40	Pharmacovigilance	*Henry Fitt*
09.40 – 10.00	Authorisation of generic products in the EU	*George Wade*
10.00 – 10.20	Interactions with stakeholders – Communication at the Agency	*Juan Garcia Burgos*
10.20 – 10.40	Linguistic aspects and preparatory steps before accession to the EU	*Alexios Skarlatos*
10.40 – 11.00	**Coffee break**	
11.00 – 11.30	EU telematics implementation plan	*Hans-Georg Wagner*
11.30 – 11.45	IPA selected activities	*Sylvie Bénéfice*
11.45 – 12.15	Closing remarks	*Andreas Pott + Sylvie Bénéfice*

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ssion Assistance oject 2009-2011

Reinforcing patient safety in Europe
14-15 June 2011
Zagreb, Croatia

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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 June 2011
EMA/404541/2011 revised version2
Administration

Reinforcing patient safety in Europe

Conference programme

14-15 June 2011
Zagreb, Croatia

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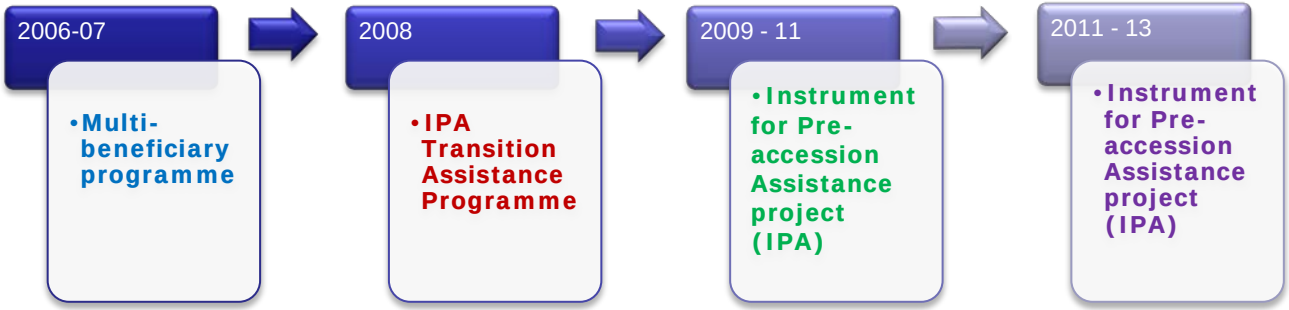

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Contract 2006/118-594
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Started July 2006

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Instrument for Pre-accession Assistance (IPA) project 2011-2013

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Instrument for Pre-accession Assistance (IPA) project 2011-2013

Extension of the IPA 2009-11 project, but now the project is focusing on **Croatia** to help foster its integration and provide further support for areas still needing development in view of its **accession to the EU on 1 July 2013.**

Pre-accession linguistic check for Croatian

In January 2011, EMA, together with the Croatian national competent authorities, started a **pre-accession linguistic checking process** for product information in the Croatian language. This procedure aims to facilitate the phasing-in of Commission Decisions on centrally authorised medicines once Croatia joins the EU.

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About the IPA programme

The Instrument for Pre-accession Assistance (IPA) programme was launched by the European Commission in 2009 to support the participation of beneficiaries in the activities of the European Medicines Agency.

Following Croatia's accession to the European Union (EU) on 1 July 2013, the programme beneficiaries are:

- Albania;
- Bosnia and Herzegovina;
- the former Yugoslav Republic of Macedonia;
- Iceland;
- Kosovo (under UNSC Resolution 1244/99);
- Montenegro;
- Serbia;
- Turkey.

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Zagreb, Knežija

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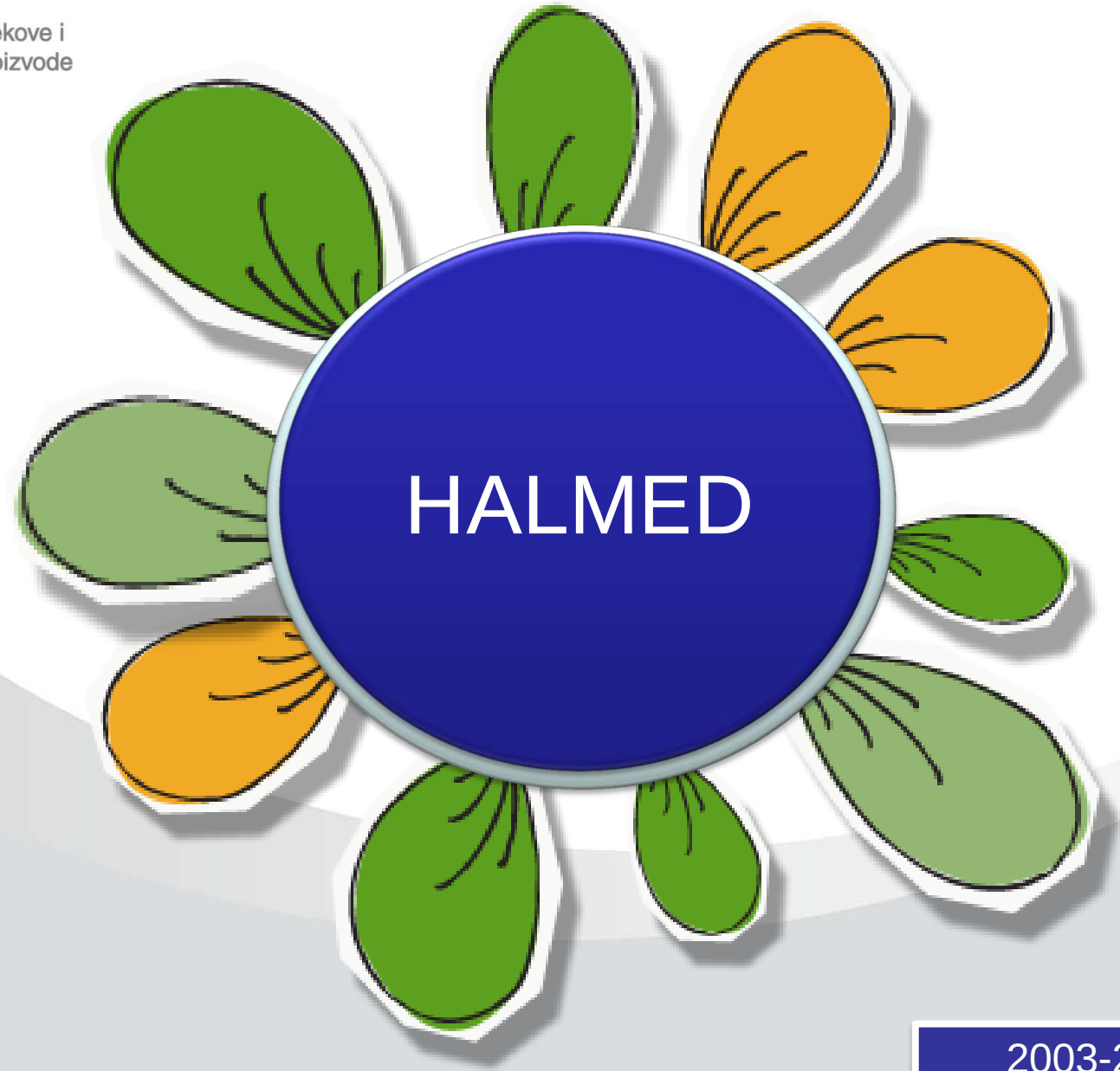

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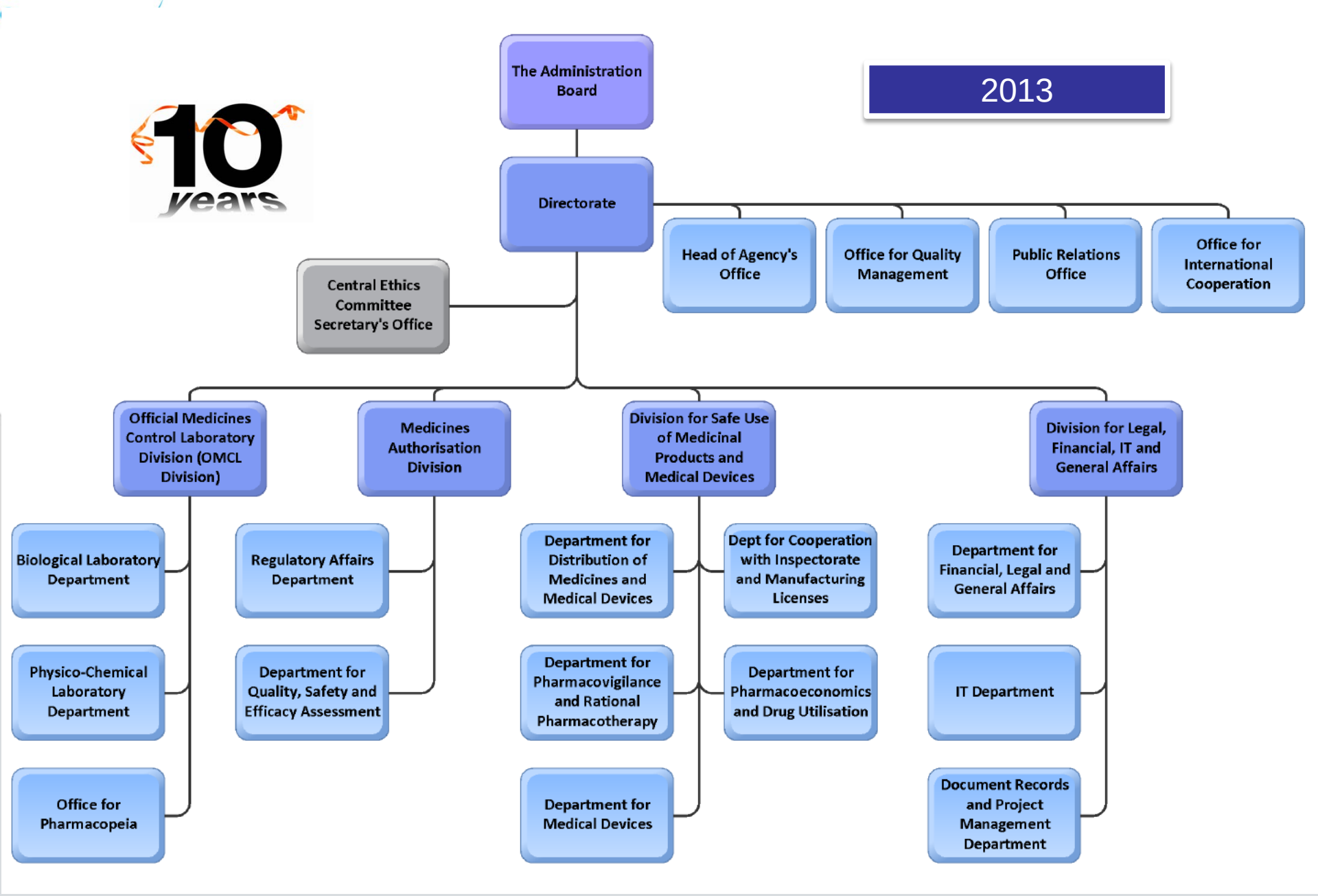
2013
The Administration Board
Directorate
Head of Agency's Office
Office for Quality Management
Public Relations Office
Office for International Cooperation
Central Ethics Committee Secretary's Office
Official Medicines Control Laboratory Division (OMCL Division)
Medicines Authorisation Division
Division for Safe Use of Medicinal Products and Medical Devices
Division for Legal, Financial, IT and General Affairs
Biological Laboratory Department
Physico-Chemical Laboratory Department
Office for Pharmacopeia
Regulatory Affairs Department
Department for Quality, Safety and Efficacy Assessment
Department for Distribution of Medicines and Medical Devices
Department for Pharmacovigilance and Rational Pharmacotherapy
Department for Medical Devices
Dept for Cooperation with Inspectorate and Manufacturing Licenses
Department for Pharmacoeconomics and Drug Utilisation
Department for Financial, Legal and General Affairs
IT Department
Document Records and Project Management Department

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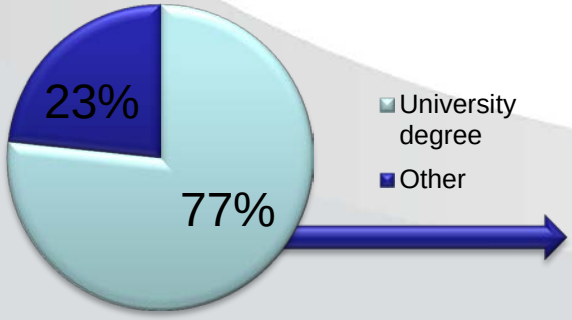
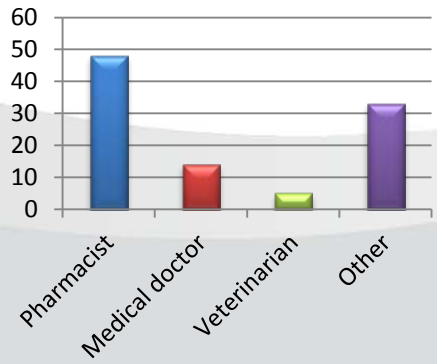
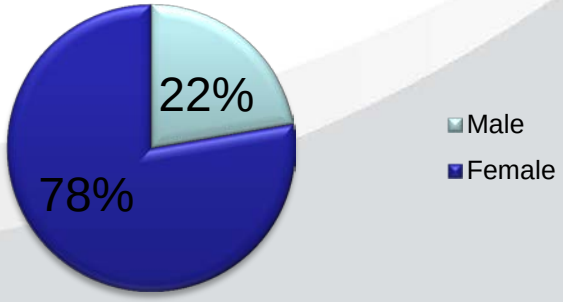
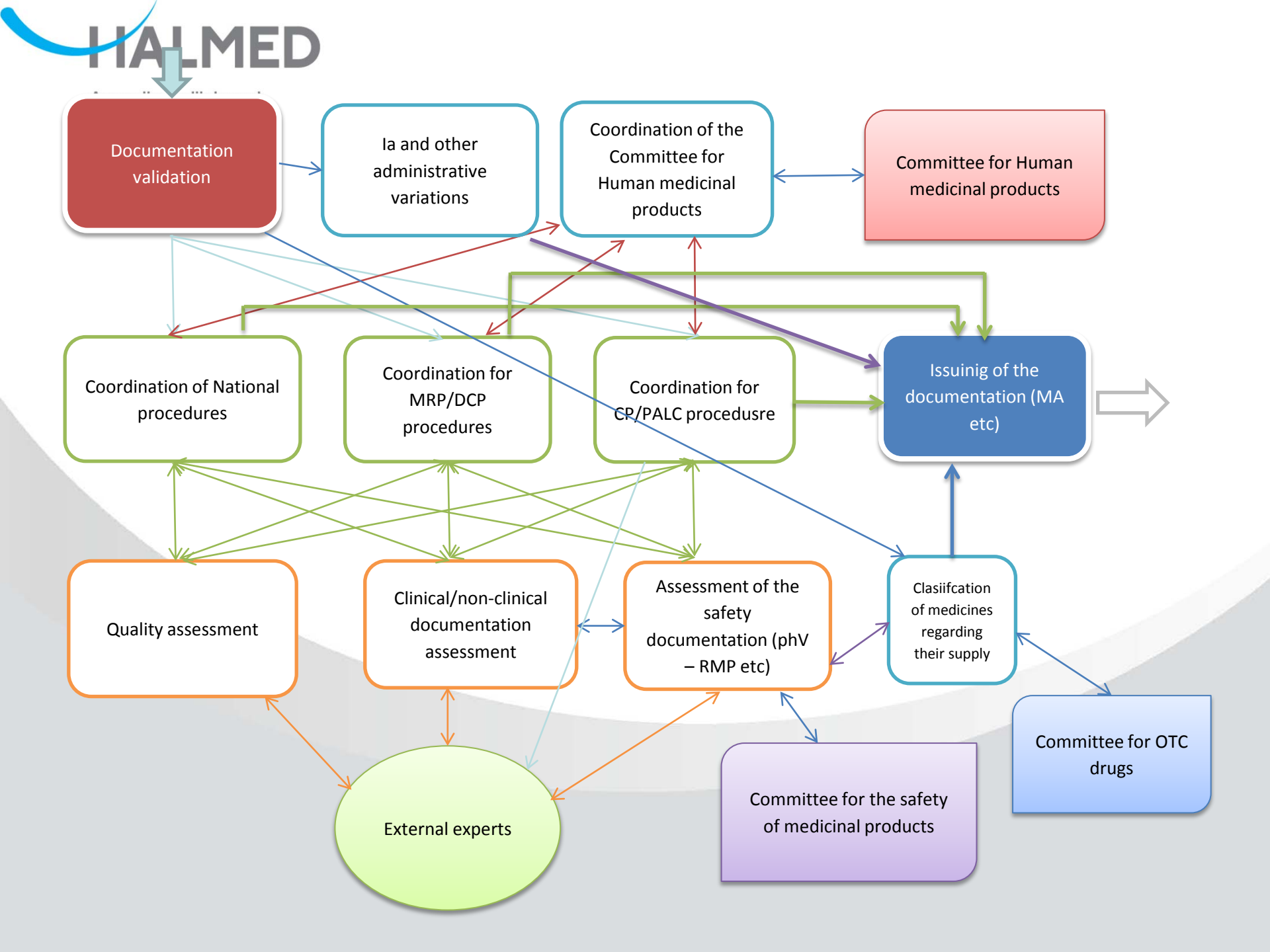
194 EMPLOYEES IN 2013





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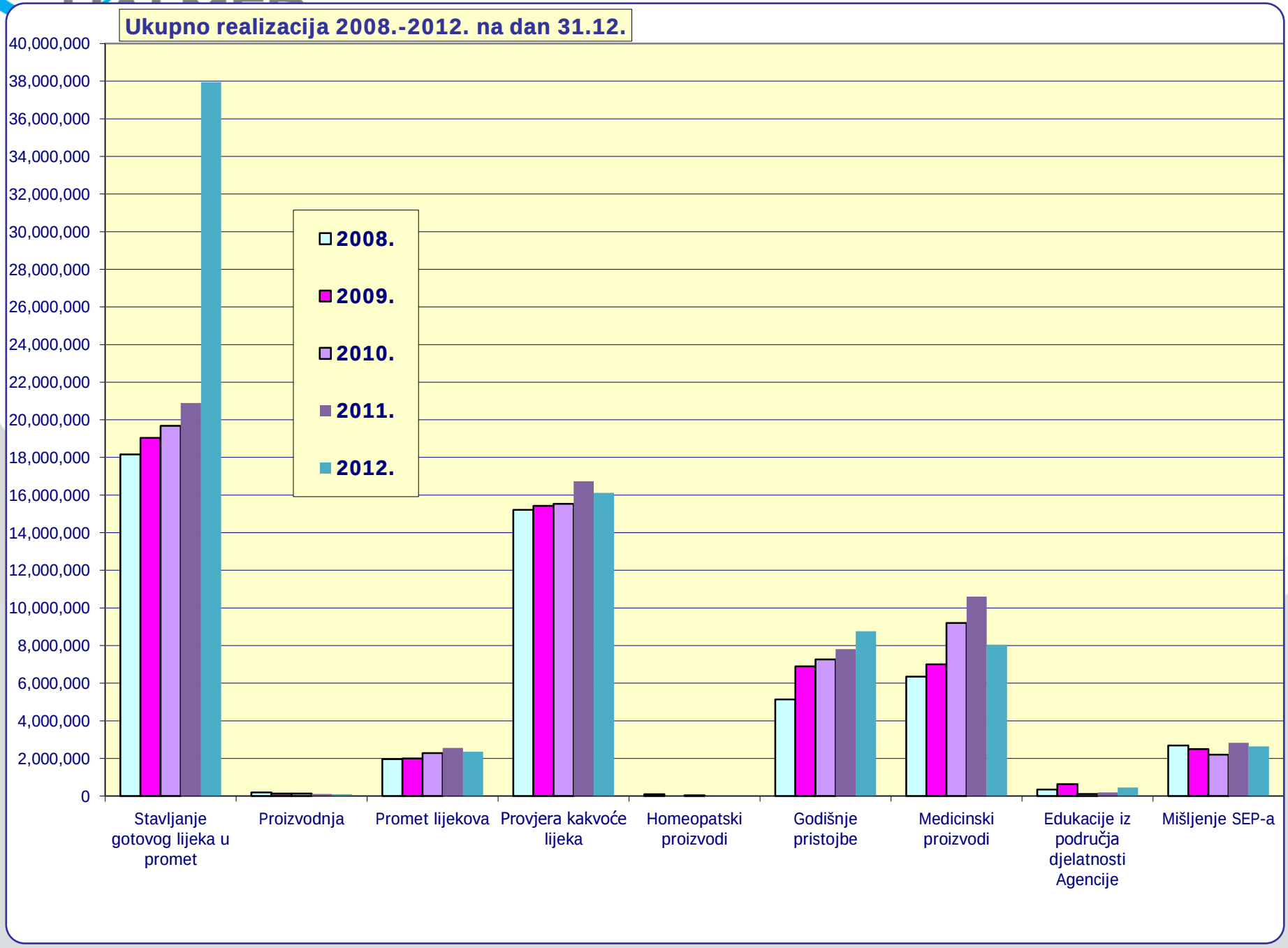
Documentation validation
Ia and other administrative variations
Coordination of the Committee for Human medicinal products
Committee for Human medicinal products
Coordination of National procedures
Coordination for MRP/DCP procedures
Coordination for CP/PALC procedusre
Issuinig of the documentation (MA etc)
Quality assessment
Clinical/non-clinical documentation assessment
Assessment of the safety documentation (phV – RMP etc)
Clasiifcation of medicines regarding their supply
Committee for OTC drugs
External experts
Committee for the safety of medicinal products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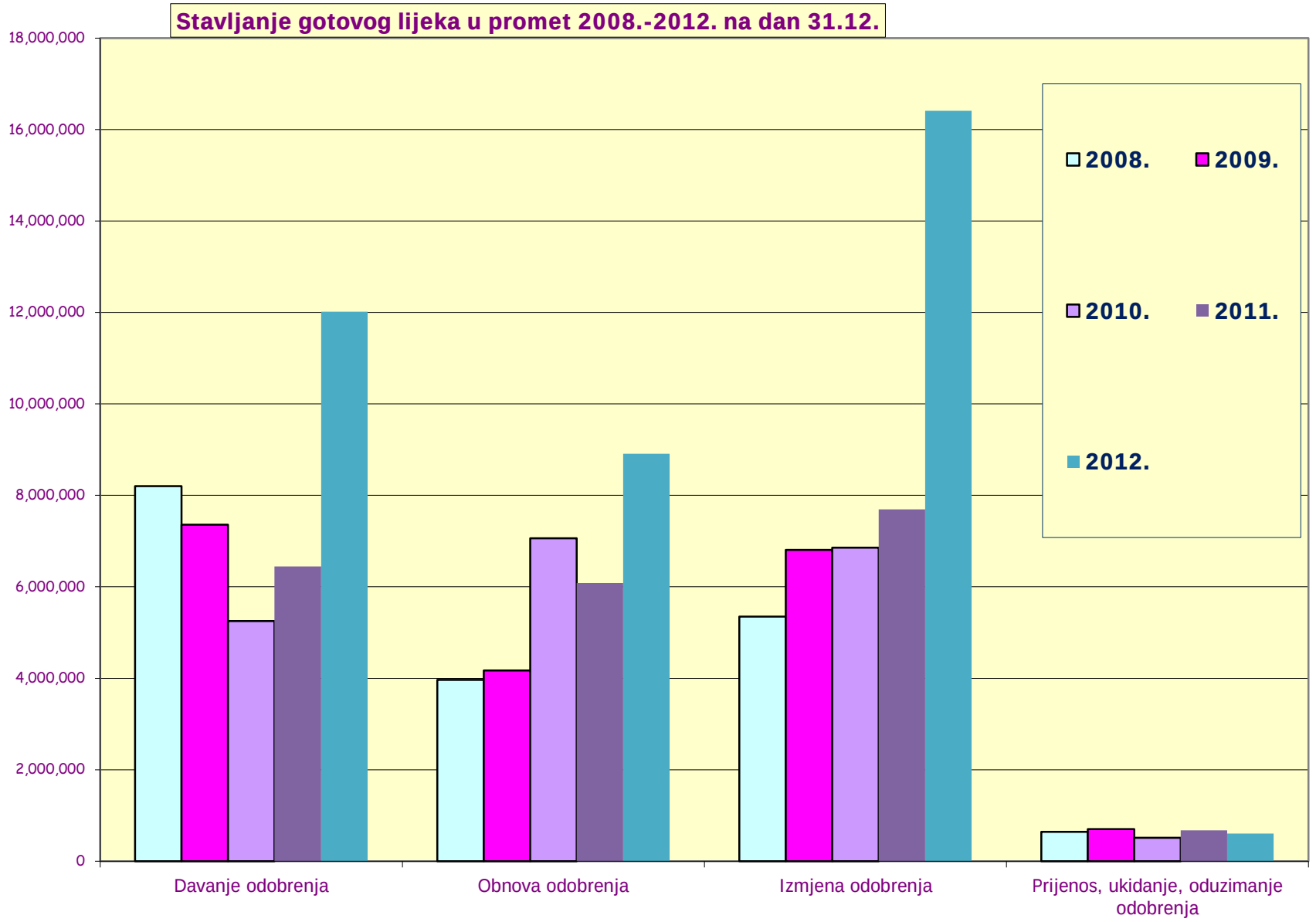
Mišljenje SEP-a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Izmjena odobrenja
Prijenos, ukidanje, oduzimanje odobrenja

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HALMED's IT system

Centralni registar lijekova

2004 - 2006

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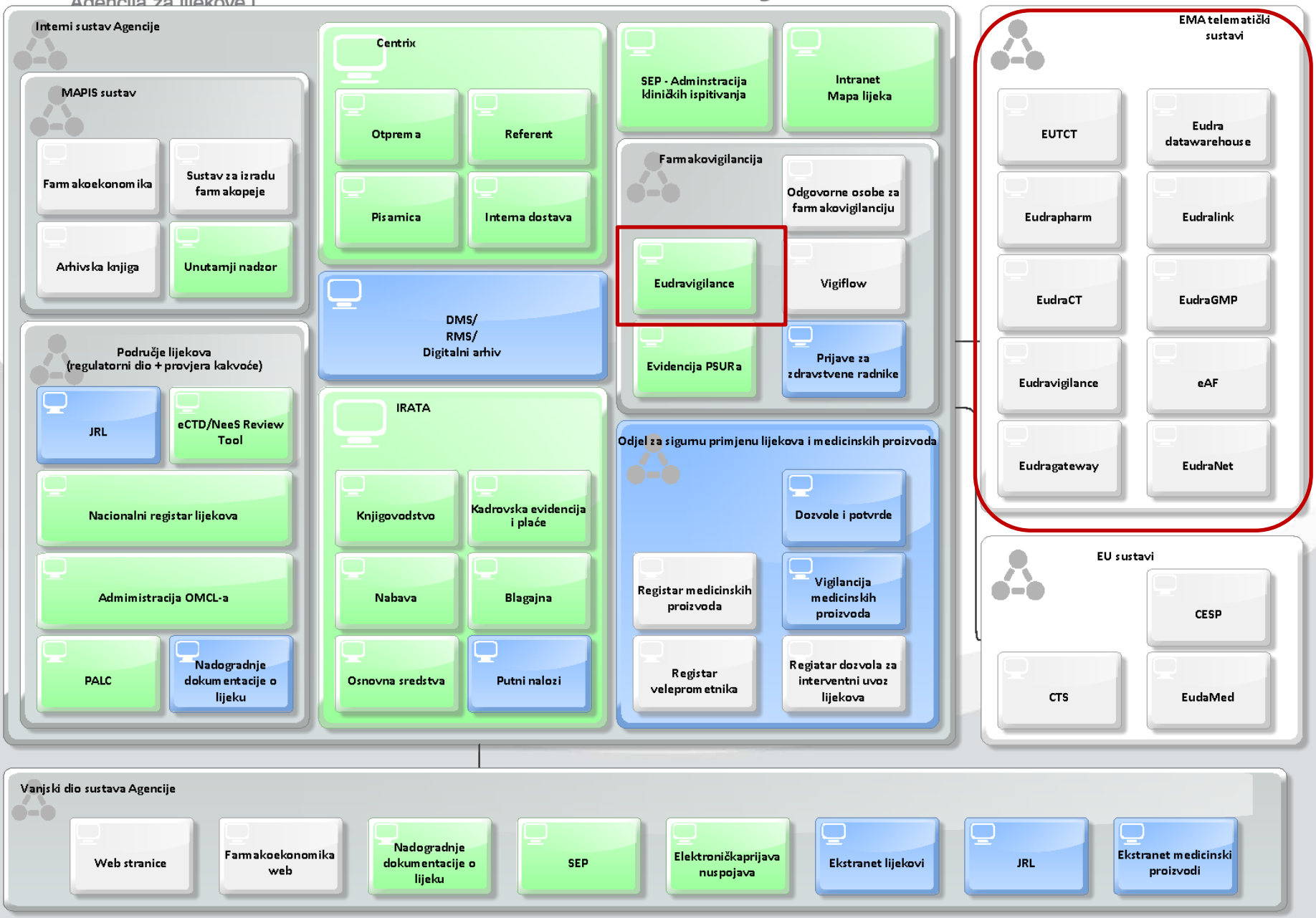
HALMED's IT system



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EudraVigilance MSe User Group in 2006

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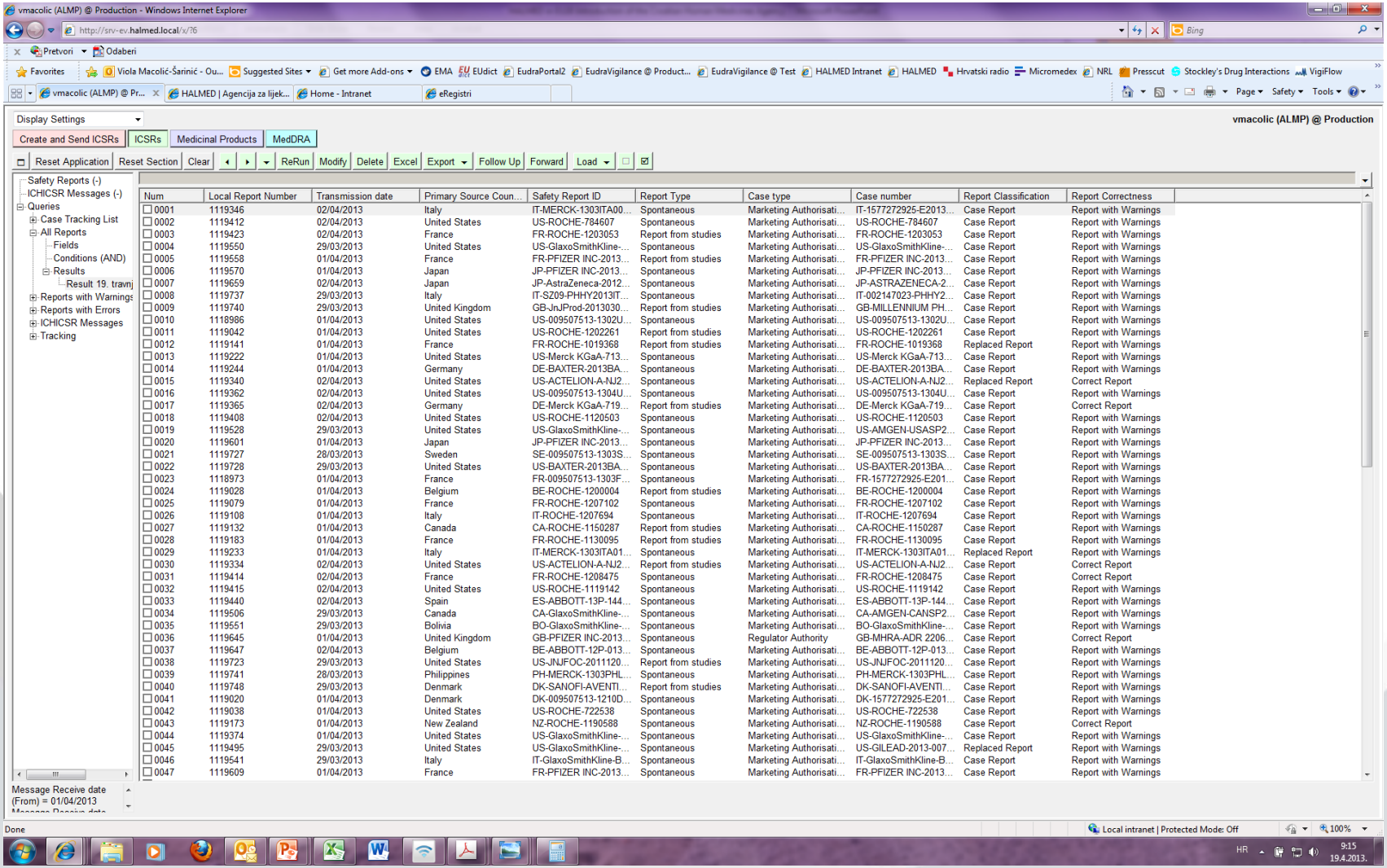

EudraVigilance Member State Edition – e- ICSR reports from April 2010

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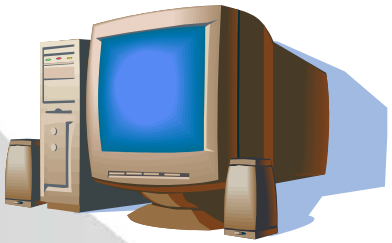
ICSR from MAH

SUSAR from third countries,

All ADR from HR

MAH

HALMED



ADR database

E2B ICSR Message

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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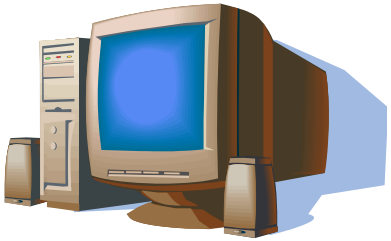

EudraVigilance MSe

- Gateway
- Web trader

ICSR from HR

National ADR database

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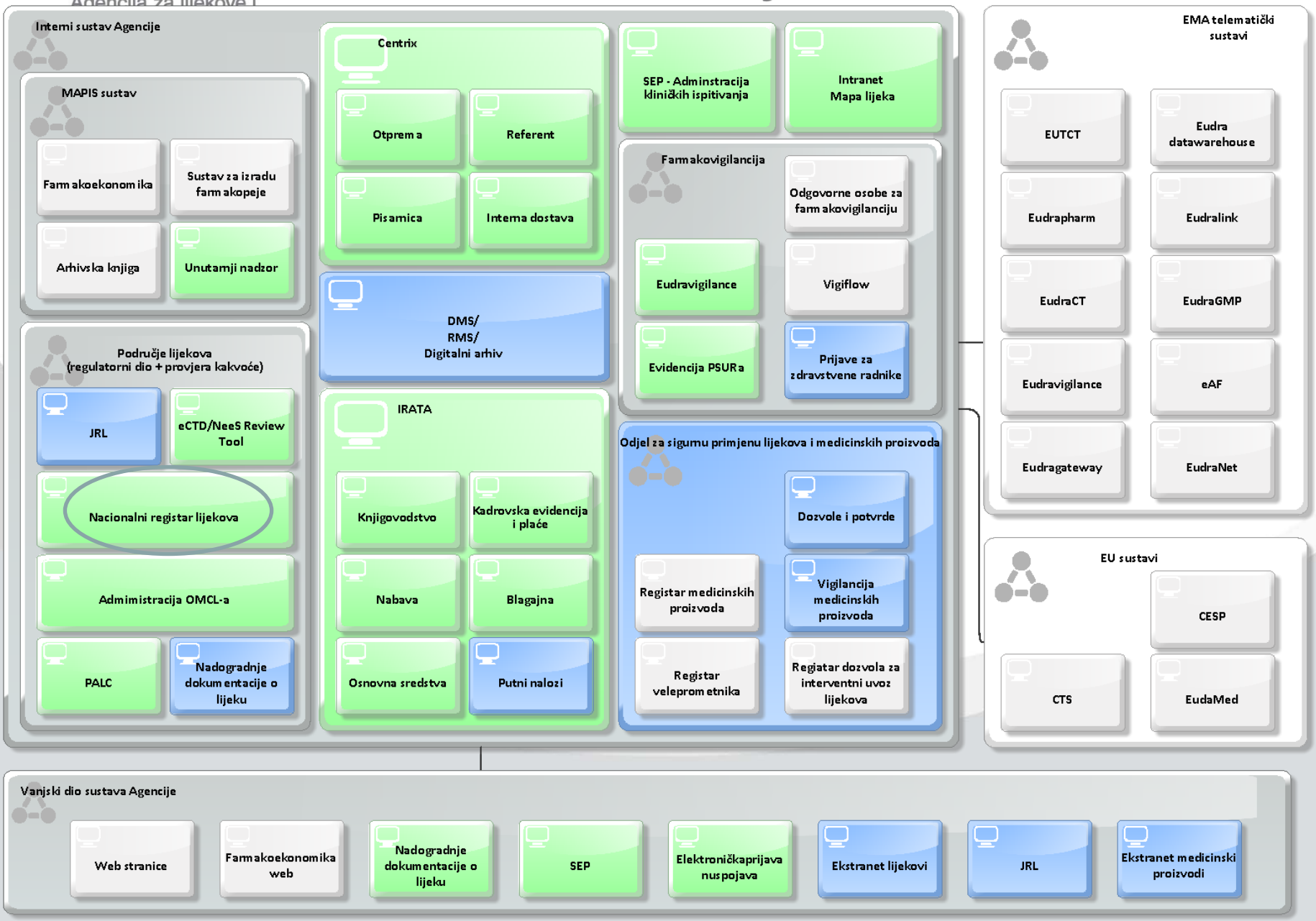
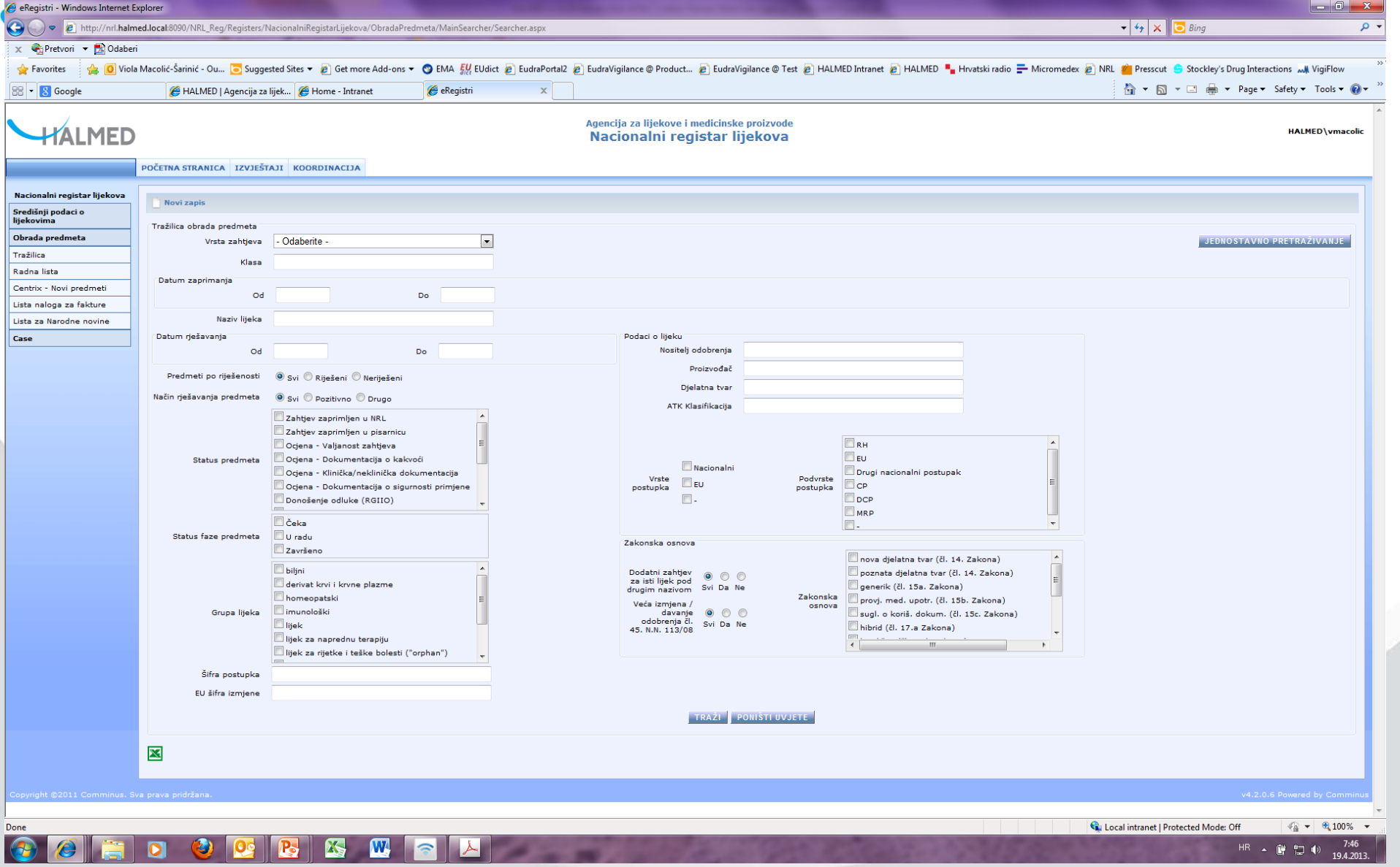
Agencija za lijekove i

HALMED's IT system





NATIONAL REGISTRY OF MEDICINAL PRODUCTS

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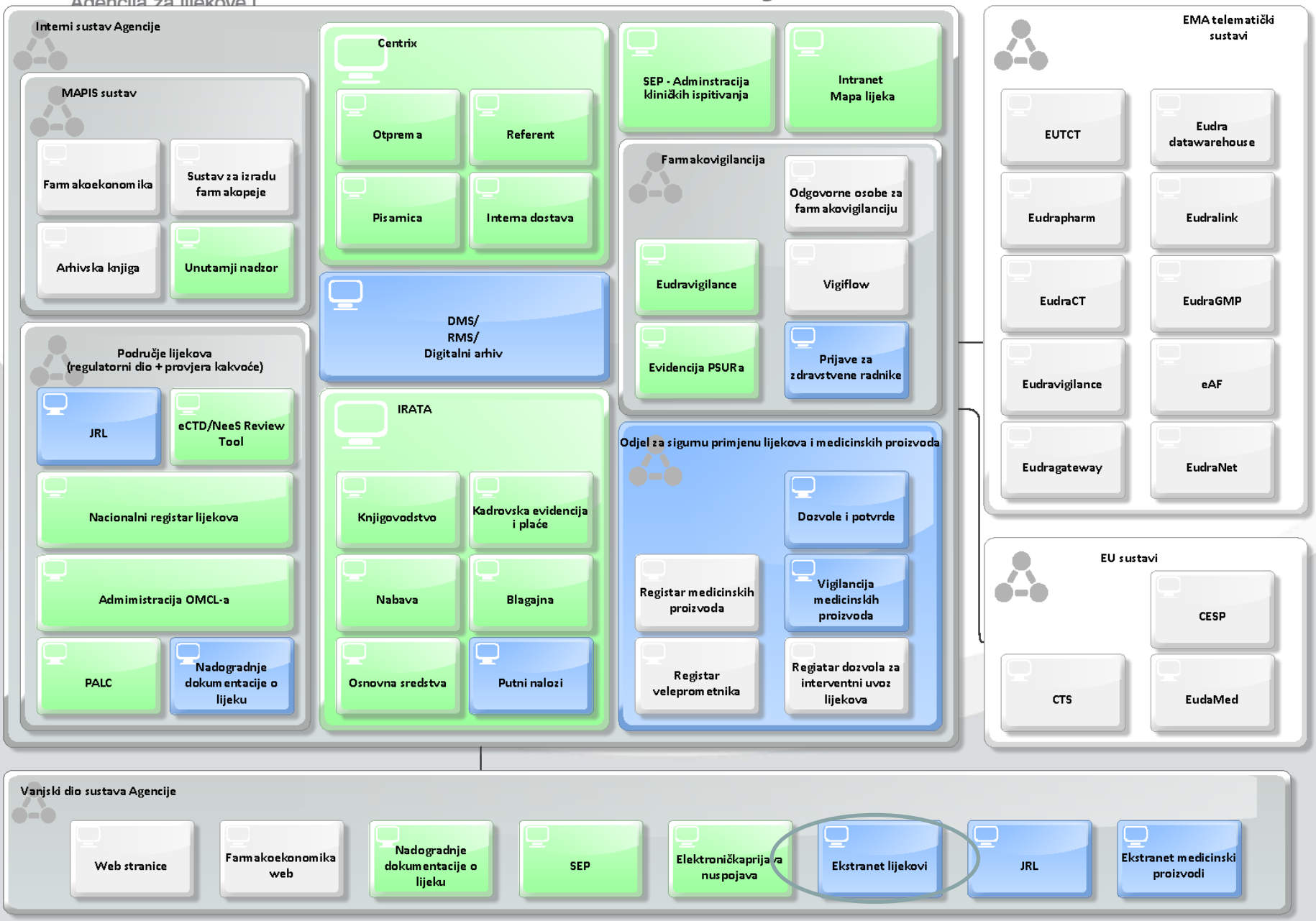
Agencija za lijekove i

HALMED's IT system

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Agencija za lijekove i medicinske proizvode
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PREDMETI U IZRADI
PREDMETI U OBRADI
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PORUKE
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SVI PREDMETI U OBRADI [36]
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HALMED • Agencija za lijekove i medicinske proizvode
UPUTE ZA KORIŠTENJA HALMED EKSTRANET PORTALA • HELP DESK • OBAVIJESTI

HALMED
Agencija za lijekove i medicinske proizvode

- Introduced in Croatia on June 30, 2010
- Welcomed to submit eCTD or NeeS format
- Not obligatory

HALMED

Agencija za lijekove i medicinske proizv

From May 2012

Medicinal Products for Human Use

Committee for Medicinal Products for Human Use (CHMP)

Meeting	Nominations
CHMP	Maja Lovrek (Member) Anita Filipović Sučić (Alternate)

CHMP Working Parties

Meetings	Nominations
Biologics Working Party (BWP)	Tamara Mandušić Nazor (Member) Dijana Lovreček (Alternate)
Blood Products Working Party (BPWP)	Marta Pipić Kosanović (Member) Vesna Osrečki (Alternate)
Joint CHMP/CVMP Quality Working Party (QWP)	Koraljka Meštrović (Member) Ksenija Sandor (Alternate)
Safety Working Party (SWP)	Blaženka Jurišić (Member) Lina Čačić (Alternate)

Pharmacovigilance and Risk Assessment Committee (PRAC)

Meetings	Nominations
PRAC	Viola Macolić Sarinić (Member) Marin Banovac (Alternate)

PALC III, (Pre-accession Linguistic Checking Procedure) 1/3/2011 – 15/4/2013

- ***Halmed team*** for human medicines

TRANSLATIONS OF AROUND 750 CENTRALLY AUTHORISED PRODUCTS

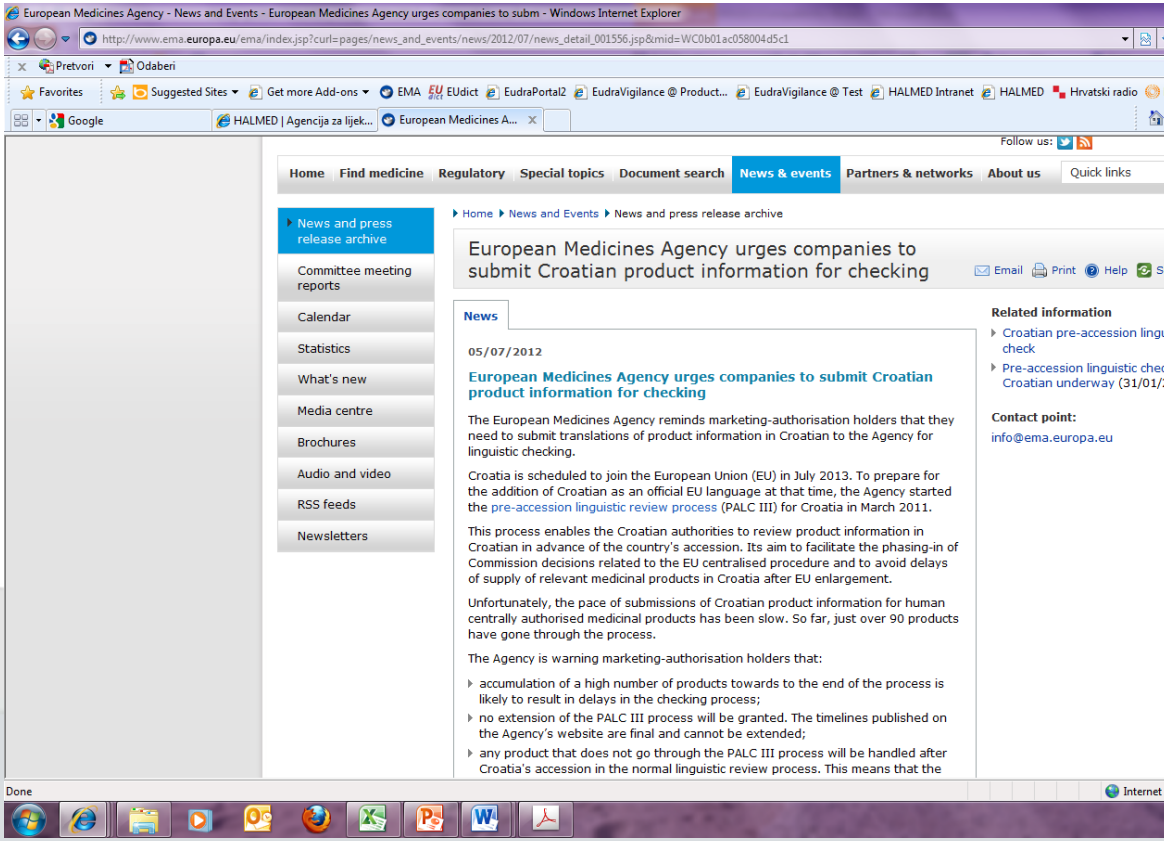
Commission Decisions concerning marketing authorisations (MAs) a MAH and are valid in the whole territory of the EU.

When a Croatia joins the EU, such decisions extend automatically to the territory of the new Member State.

However, MAHs are legally obliged to provide translations in the new official language as of the date of accession (01/07/2013).

POST-LINGUISTIC CHECKING PROCEDURE

STARTED FOR CROATIA ON THE 15TH APRIL 2013



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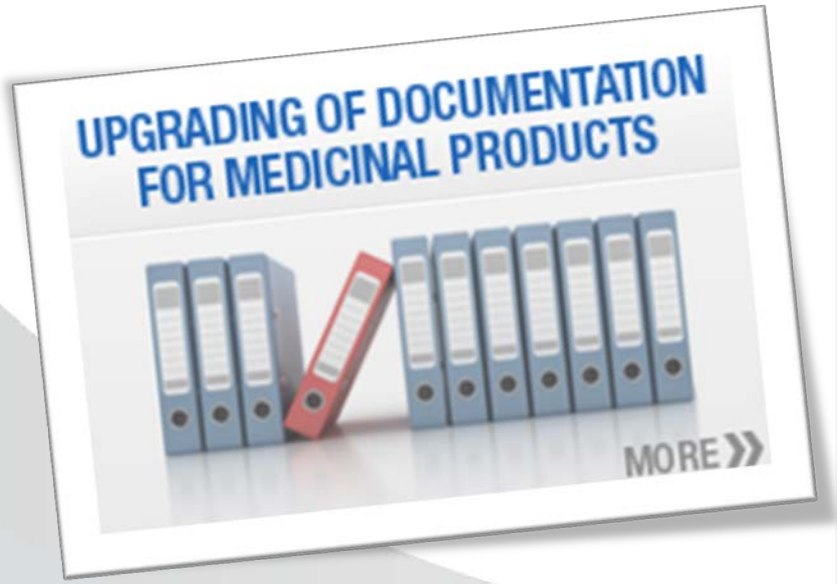
Agencija za lijekove i medicinske proizvode



- The upgrading of documentation for medicinal products is a harmonization of the documentation content with the Directive 2001/83/EC for medicinal products authorized in Croatia before the accession to the EU

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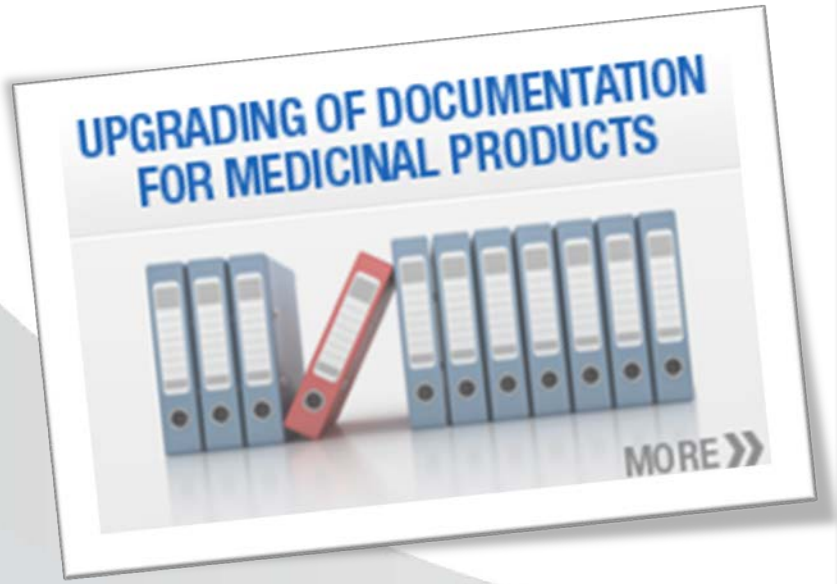


- **Deadlines for dossier upgrading:**
  - Until 30 June 2017 for medicinal products listed in the Appendix to the Annex V of the Accession Treaty.
  - Until 30 June 2013 for medicinal products that are not listed in the Appendix

Agencija za
medicinske

Collaboration with other National Agencies

HALMED

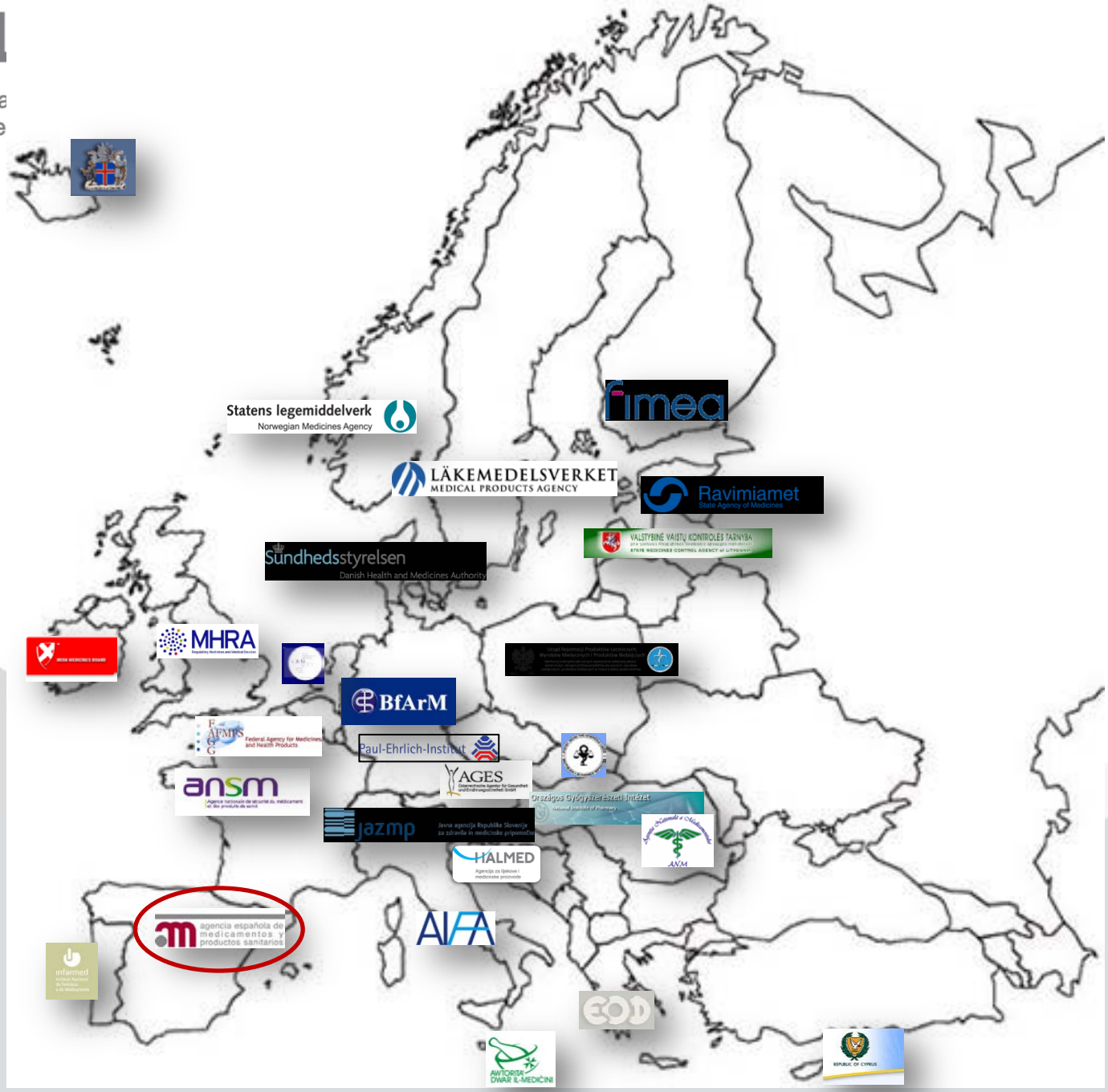
Agenci
medici

LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

January 2006

HAI

Agencija za
medicinske



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Agencija za lijekove i medicinske proizvode

Collaboration with other National Agencies

Twinning LIGHT

2010/2011

(IPA programe)

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

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Agencija za lijekove i medicinske proizvode

Collaboration with other National Agencies

Twinning LIGHT

2010/2011

(IPA programe)

- 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 visits** of HALMED's experts to Spanish OMCL (on-site experience on Quality Control of biologicals)

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Agencija za lijekove i medicinske proizvode

Collaboration with other National Agencies

HALMED

Agencija za lijekove i
medicinske proizvode

and the New

Pharmacovigilance legislation

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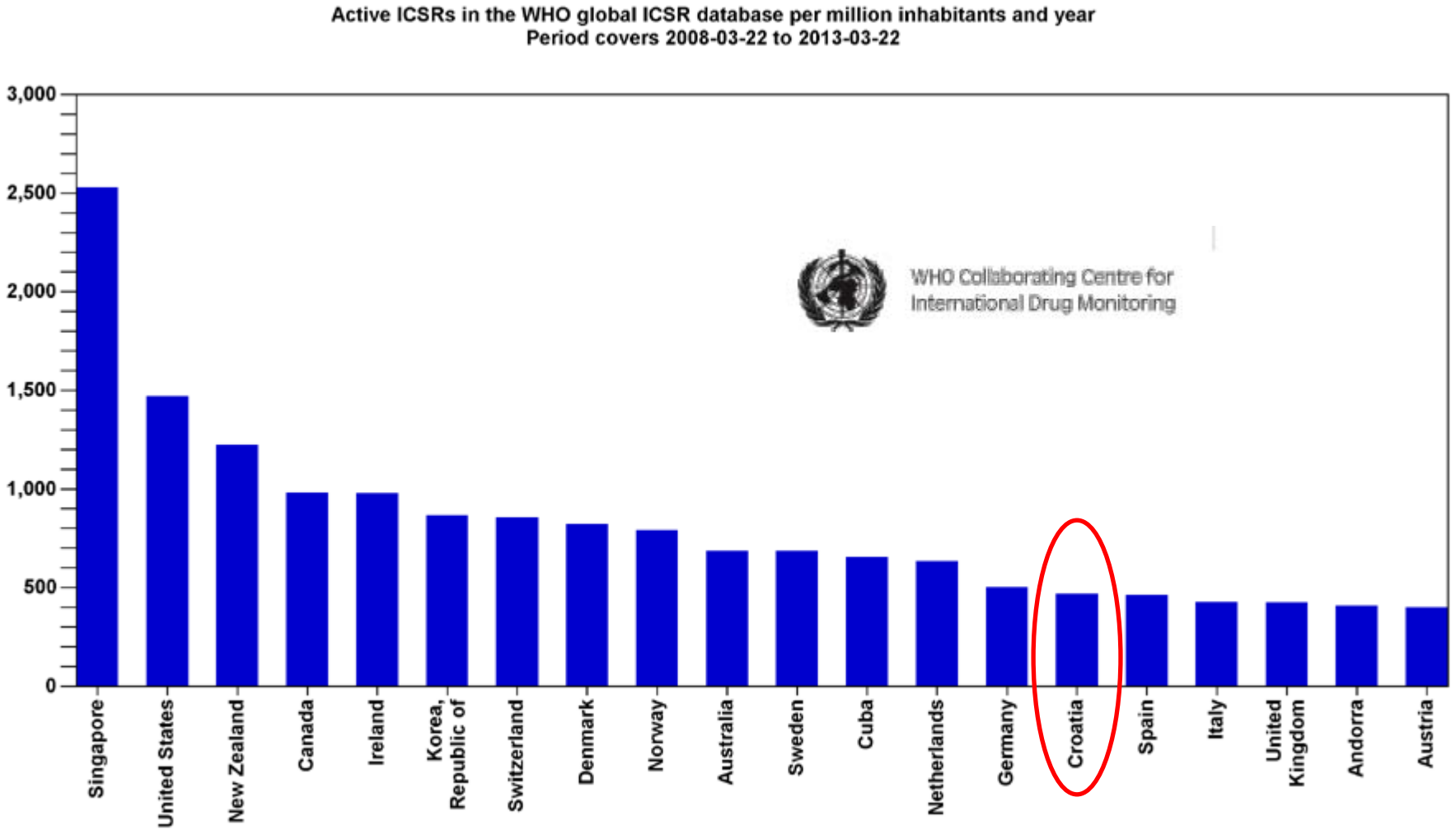
Agencija za lijekove i medicinske proizvode



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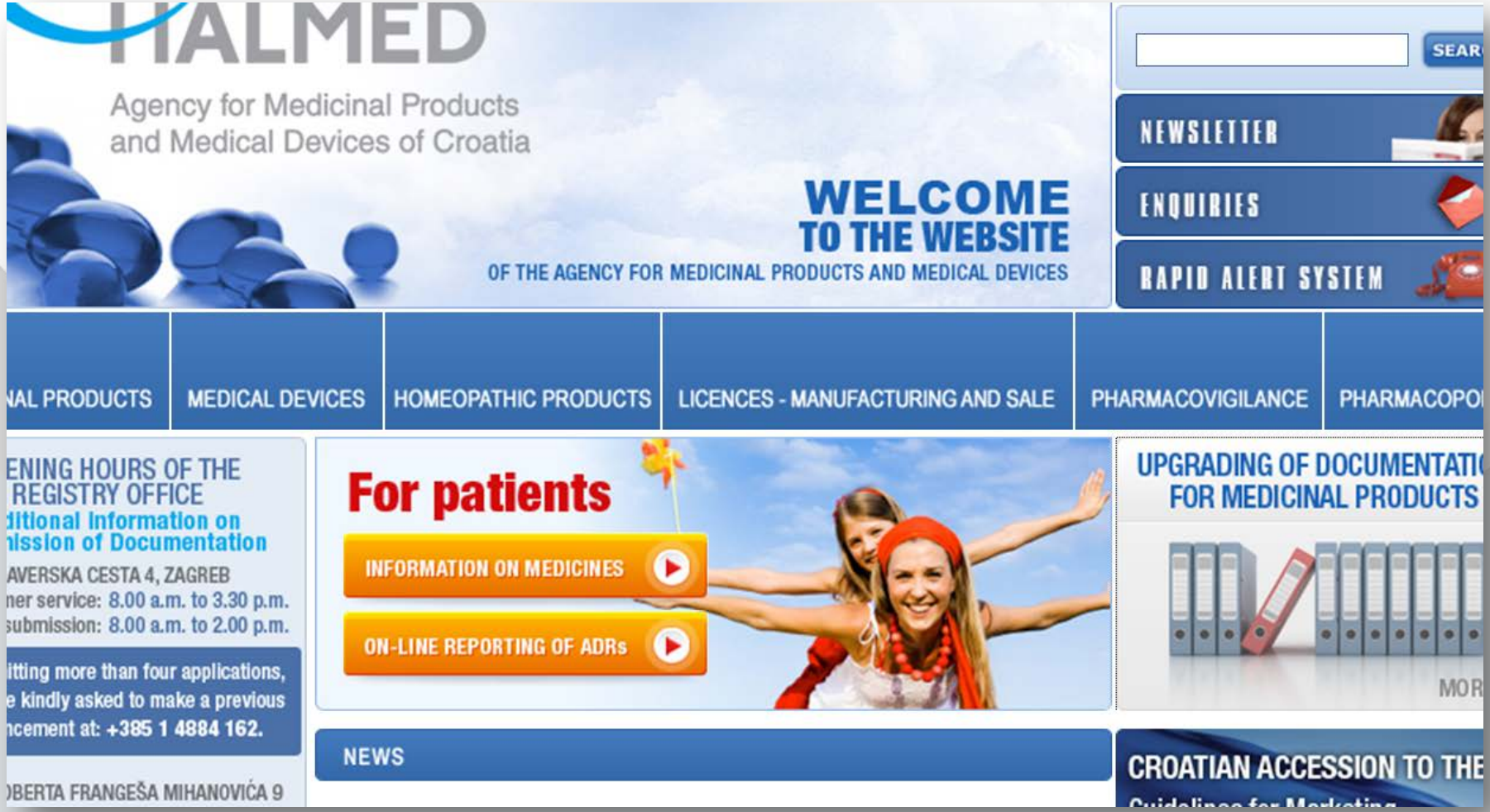
Agencija za lijekove i medicinske proizvode

Patient reporting



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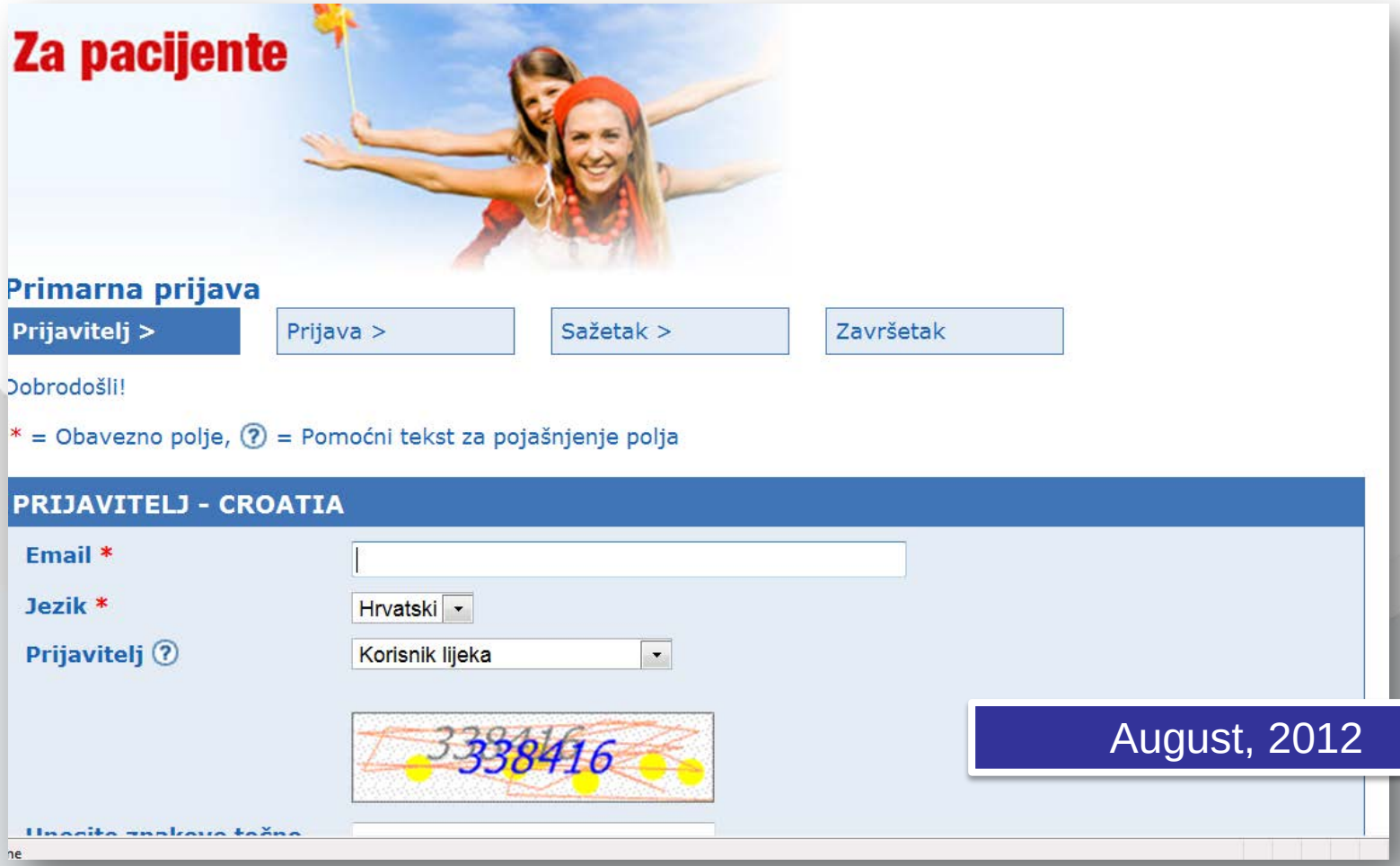
Agencija za lijekove i medicinske proizvode

Patient reporting



August, 2012

HALME

Agencija za lijekove i medicinske proizvode

LIJEKOVI ME

- Novosti
- O Agenciji
- Cjenik usluga
- Javna nabava
- SEP
- Međunarodna
- Predavanja i r
- Korisni linkovi
- Zakoni i pravil
- Publikacije i iz
- Obrasci
- Suglasnosti
- Posao i karijer
- Pristupanje Hr
- Nadogradnja d o lijeku
- Kontakti

SAŽETAK I UPUT

ZADNJE OBJAVL

LIJEKOVI SIROC

SAŽETAK OPISA SVOJSTAVA LIJEKA

1. NAZIV GOTOVOG LIJEKA

Omeprazol Pliva 10 mg želučanootporne kapsule, tvrde

Omeprazol Pliva 20 mg želučanootporne kapsule, tvrde

Omeprazol Pliva 40 mg želučanootporne kapsule, tvrde

2. KVALITATIVNI I KVANTITATIVNI SASTAV

Jedna želučanootporna kapsula sadrži 10 mg, 20 mg ili 40 mg omeprazola.

Za pomoćne tvari vidjeti dio 6.1.

3. FARMACEUTSKI OBLIK

Želučanootporna kapsula, tvrda.

Omeprazol Pliva 10 mg želučanootporne kapsule, tvrde su želučanootporne neprozirne kapsule crvene kapice i narančastog tijela, te sadrže bijele do krem mikropelete. Kapsula je označena bijelom tintom – slovo „O“ na kapici i broj „10“ na tijelu kapsule.

Omeprazol Pliva 20 mg želučanootporne kapsule, tvrde su želučanootporne neprozirne kapsule plave kapice i narančastog tijela, te sadrže bijele do krem mikropelete. Kapsula je označena bijelom tintom – slovo „O“ na kapici i broj „20“ na tijelu kapsule.

Omeprazol Pliva 40 mg želučanootporne kapsule, tvrde su želučanootporne neprozirne kapsule plave kapice i narančastog tijela, te sadrže bijele do krem mikropelete. Kapsula je označena bijelom tintom – slovo „O“ na kapici i broj„40“ na tijelu kapsule.

4. KLINIČKI PODACI

4.1. Terapijske indikacije

Omeprazol Pliva želučanootporne kapsule, tvrde indicirane su za:

Odrasli

- liječenje duodenalnog ulkusa
- prevencija relapsa duodenalnog ulkusa
- liječenje želučanog ulkusa
- prevencija relapsa želučanog ulkusa

HALMED
31 - 01 - 2013
ODOBRENO

vailable for all
zed in Croatia

HALMED

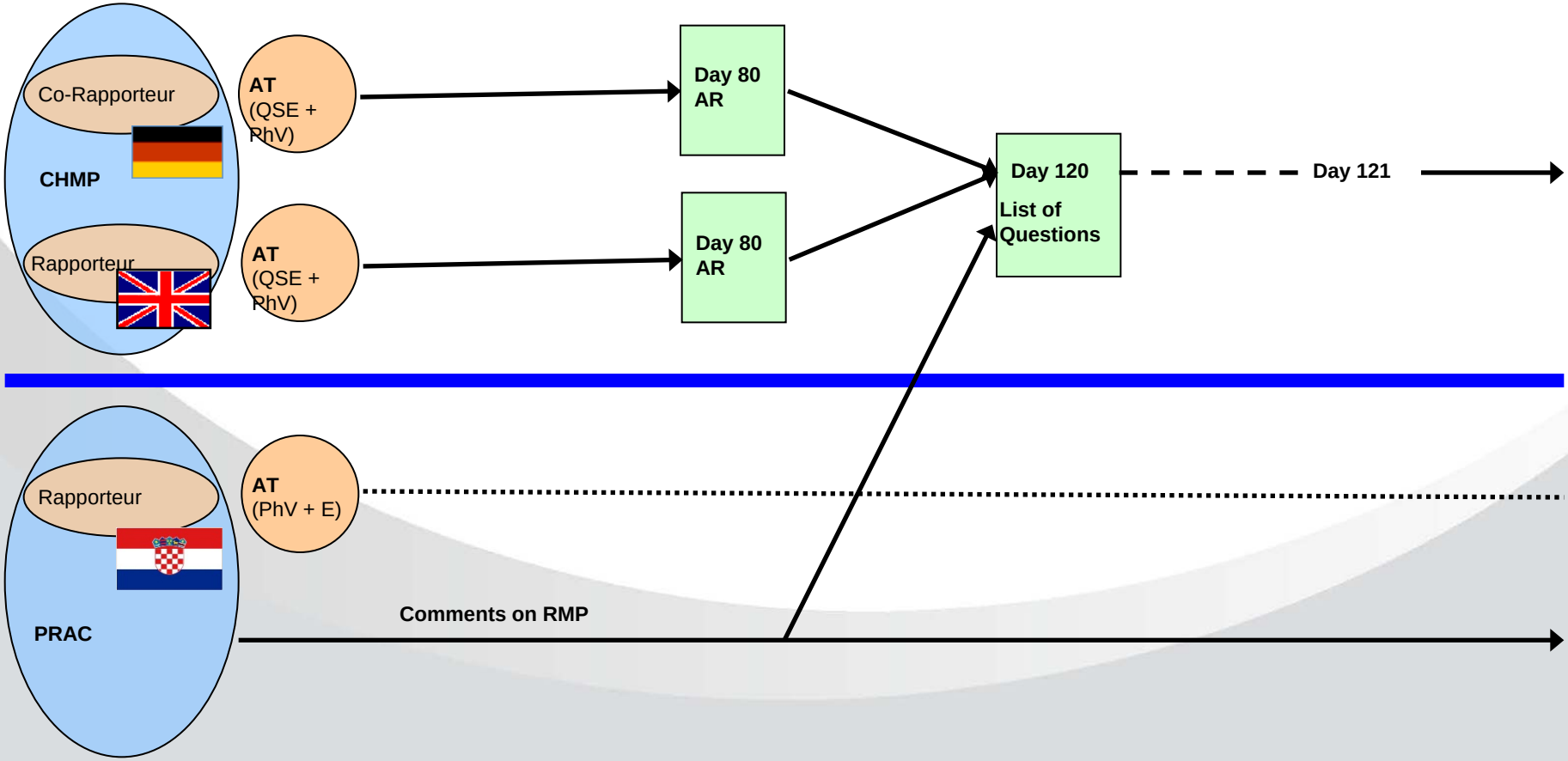
Agencija za lijekove i medicinske proizvode

The Pharmacovigilance Risk Assessment Committee (PRAC)

HALMED

Agencija za lijekove i medicinske proizvode

PRAC rapporteurship



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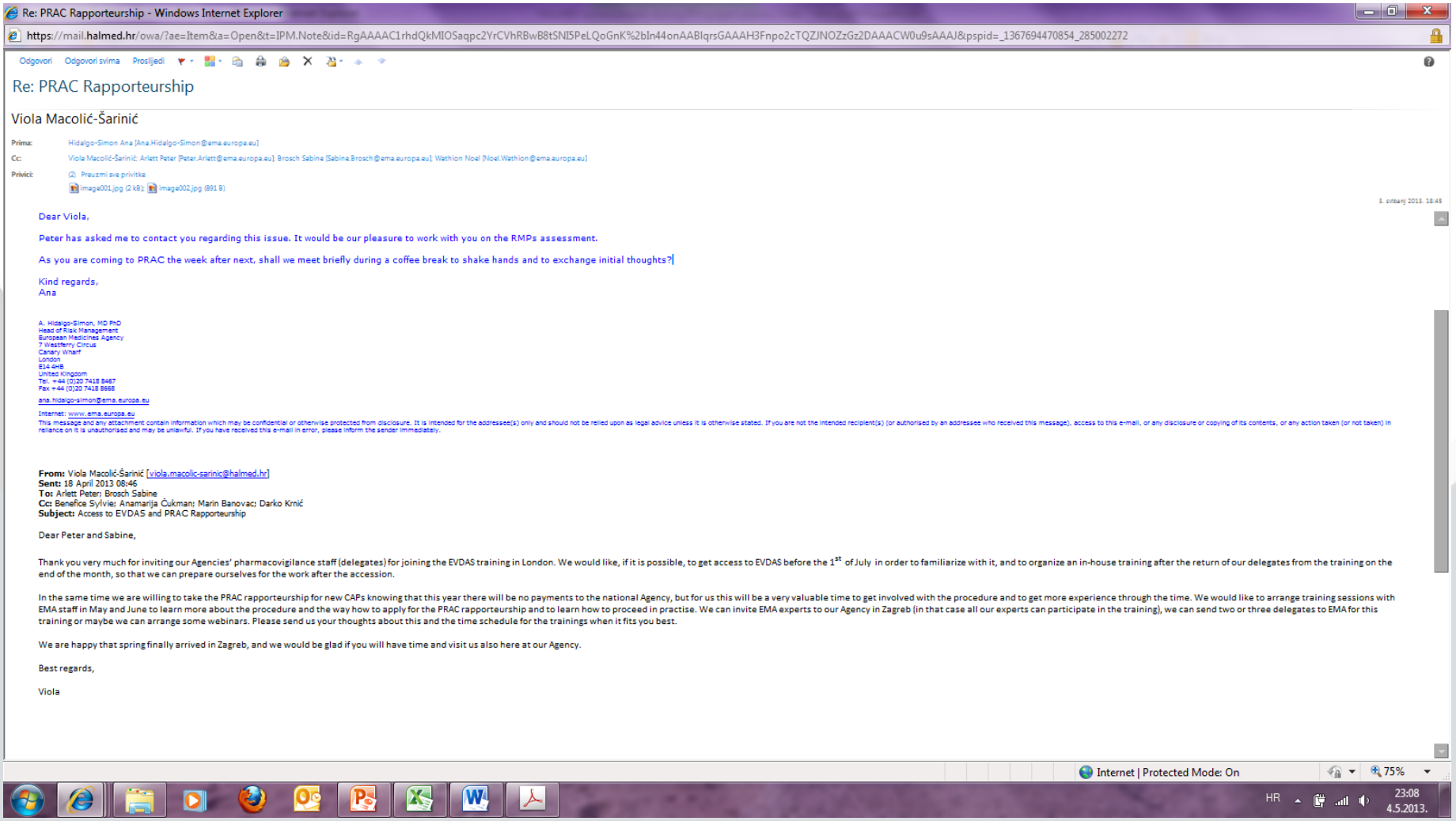
PRAC rapporteurship



Re: PRAC Rapporteurship - Windows Internet Explorer

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Odgovori Odgovori svima Proslijedi

Re: PRAC Rapporteurship

Viola Macolić-Šarinić

Prima: Hidalgo-Simon Ana [Ana.Hidalgo-Simon@ema.europa.eu]

Cc: Viola Macolić-Šarinić; Arlett Peter [Peter.Arlett@ema.europa.eu]; Brosch Sabine [Sabine.Brosch@ema.europa.eu]; Wathion Noel [Noel.Wathion@ema.europa.eu]

Privici: (2) Preuzmi sve privitke

image001.jpg (2 kB); image002.jpg (891 B)

3. svibanj 2013. 18:45

Dear Viola,

Peter has asked me to contact you regarding this issue. It would be our pleasure to work with you on the RMPs assessment.

As you are coming to PRAC the week after next, shall we meet briefly during a coffee break to shake hands and to exchange initial thoughts?

Kind regards,
Ana

A. Hidalgo-Simon, MD PhD
Head of Risk Management
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom
Tel. +44 (0)20 7418 8467
Fax +44 (0)20 7418 8668

ana.hidalgo-simon@ema.europa.eu

Internet: www.ema.europa.eu

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From: Viola Macolić-Šarinić [viola.macolic-sarinic@halmed.hr]
Sent: 18 April 2013 08:46
To: Arlett Peter; Brosch Sabine
Cc: Benefice Sylvie; Anamarija Čukman; Marin Banovac; Darko Krnić
Subject: Access to EVDAS and PRAC Rapporteurship

Dear Peter and Sabine,

Thank you very much for inviting our Agencies' pharmacovigilance staff (delegates) for joining the EVDAS training in London. We would like, if it is possible, to get access to EVDAS before the 1st of July in order to familiarize with it, and to organize an in-house training after the return of our delegates from the training on the end of the month, so that we can prepare ourselves for the work after the accession.

In the same time we are willing to take the PRAC rapporteurship for new CAPs knowing that this year there will be no payments to the national Agency, but for us this will be a very valuable time to get involved with the procedure and to get more experience through the time. We would like to arrange training sessions with EMA staff in May and June to learn more about the procedure and the way how to apply for the PRAC rapporteurship and to learn how to proceed in practise. We can invite EMA experts to our Agency in Zagreb (in that case all our experts can participate in the training), we can send two or three delegates to EMA for this training or maybe we can arrange some webinars. Please send us your thoughts about this and the time schedule for the trainings when it fits you best.

We are happy that spring finally arrived in Zagreb, and we would be glad if you will have time and visit us also here at our Agency.

Best regards,

Viola

Internet | Protected Mode: On 75%

HR 23:08 4.5.2013.

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Joint Action on pharmacovigilance

- **Objective:**
  - Facilitating collaboration among Member States for the effective operation of pharmacovigilance in the EU

- **Aim:**
  - To support Member States to find solutions for organising and running their pharmacovigilance system in the context of the new PV legislation in the EU

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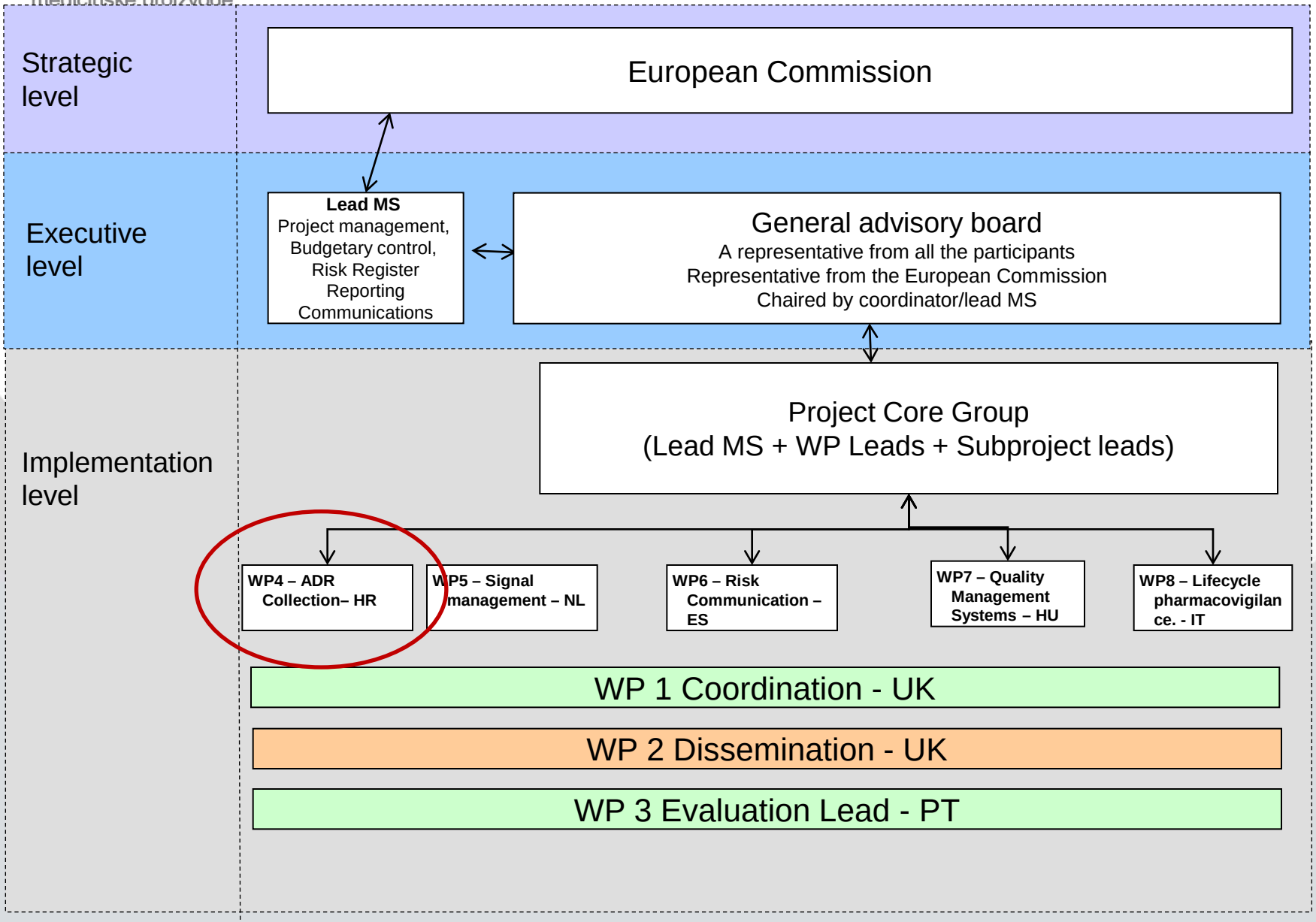
Governance Structure



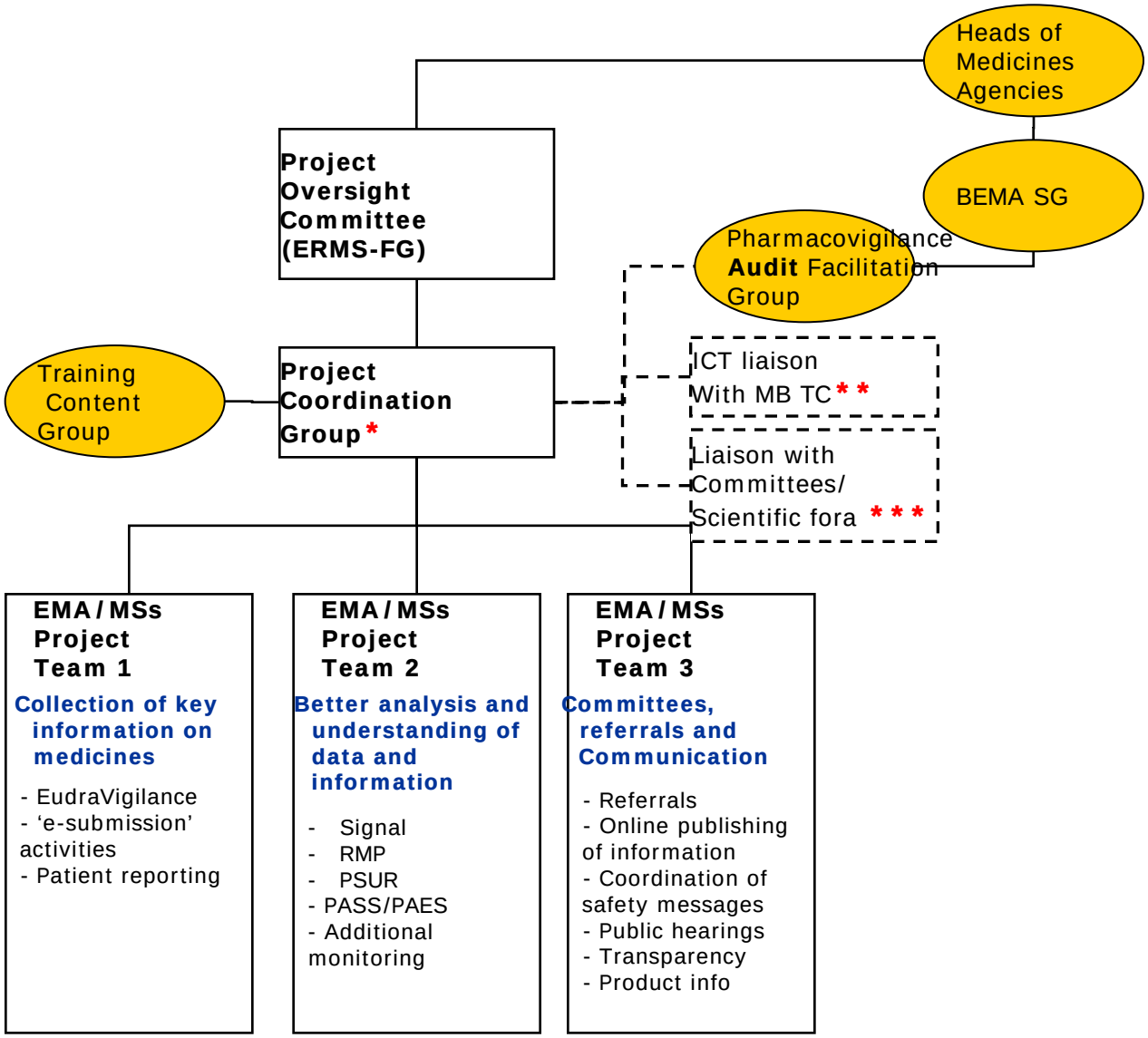
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Project 00305 – Implementation of pharmacovigilance legislation

Project governance structure: slides to support the call for Project Team nominations

20 February 2013

2013 Project governance structure – endorsed by HMA



* *including GVP coordination and maintenance.*

** *or equivalent under the new ICT governance structure.*

*** *PRAC, CHMP, CMD-h, PhVIWG.*

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medicinske proizvode

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

QUESTIONS AND ANSWERS ON MRP & DCP AND EU ENLARGEMENT

Doc. Ref.: CMDh/274/2012, Rev3
November 2012

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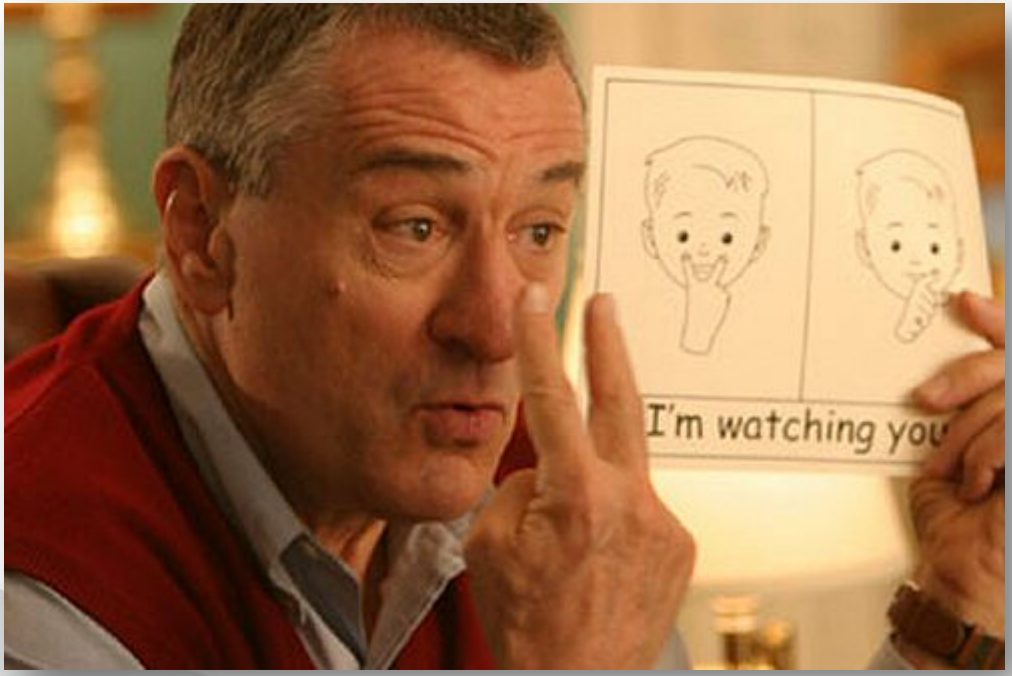
Agencija za lijekove i
medicinske proizvode



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medicinske proizvode

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Agencija za lijekove i medicinske proizvode

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Agencija za lijekove i medicinske proizvode

1 July 2013

Ready to join the European Medicines Regulatory Network

HALMED

Agencija za lijekove i medicinske proizvode

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Agencija za lijekove i medicinske proizvode

Thank you very much!