

HALMED achievements during IPA project period

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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



- Croatia applies
for EU
membership

21.02.2003.

01.04.2004.

- Commission
approves
Croatia's
application for EU
membership

- 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

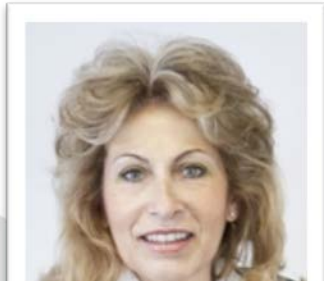
Started July 2006



European Medicines Agency
Communications and Networking

**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.”

**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.

**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!





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	(<i>Hans-Georg Wagner</i>)
9.15 - 9.45	Project description, administrative information	(<i>Sylvie Bénéfice</i>)
9.45 - 10.15	EMEA activities	(<i>Martin Harvey-Allchurch</i>)
10.15-10.45	The Centralised Procedure	(<i>Patrick Le Courtois/David MacKay</i>)
10.45-11.05	Ensuring consumer safety during authorisation of veterinary medicines	(<i>Isaura Duarte</i>)

11.05-11.30 Coffee break

11.30-11.50	Croatian Agency for Medicinal Products and Medical Devices activities	(<i>Sinisa Tomic</i>)
11.50-12.10	Croatian Ministry of Agriculture, Forestry and Water Veterinary Institute activities	(<i>Mate Brstilo</i>)
12.10-12.30	Turkish General Directorate of Pharmaceuticals and Pharmacy activities	(<i>Mahmut Tokac/ Eda Cindoglu</i>)
12.30-12.50	Turkish Ministry of Agriculture and Rural Affairs/General Directorate of Protection and Control activities	(<i>Olcay Ture Gosku</i>)

13.15-14.30 Lunch in room 3B

14.30-15.00	Acquis Communautaire	(<i>Sandra Vanlievendael</i>)
15.00-15.30	Pharmacovigilance including Eudravigilance	(<i>Panos Tsintis</i>)
15.30-16.00	GxP Inspections and Associated Groups	(<i>David Cockburn</i>)
16.00-16.30	EU Telematics Implementation Plan	(<i>Hans-Georg Wagner</i>)
16.30-17.00	Benchmarking European Medicines Agencies	(<i>Marijke Korteweg</i>)
17.00-17.15	Closing remarks End of the meeting	(<i>Hans-Georg Wagner</i>)

Multi-beneficiary programme Participation of Croatia and Turkey in Competent Authority Agencies in 2006 and 2007

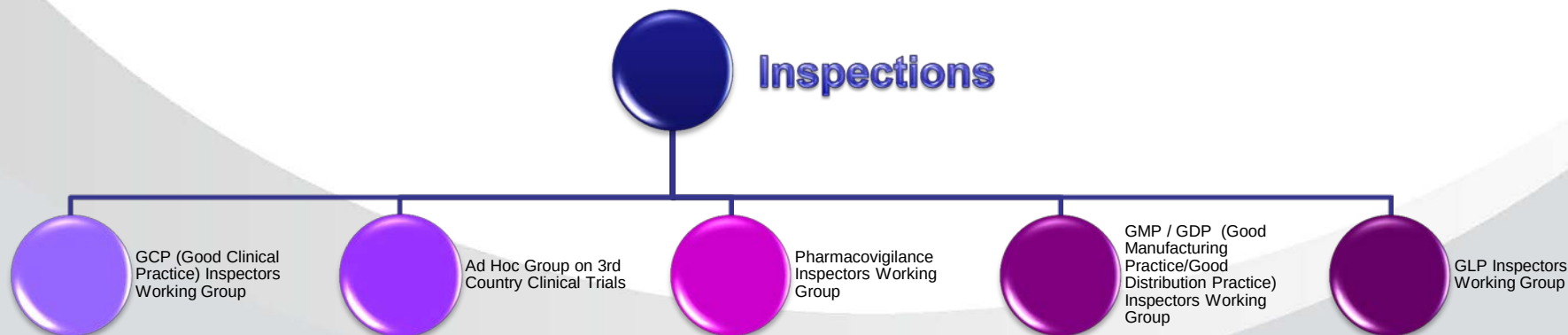
Participants at this meeting included:

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

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

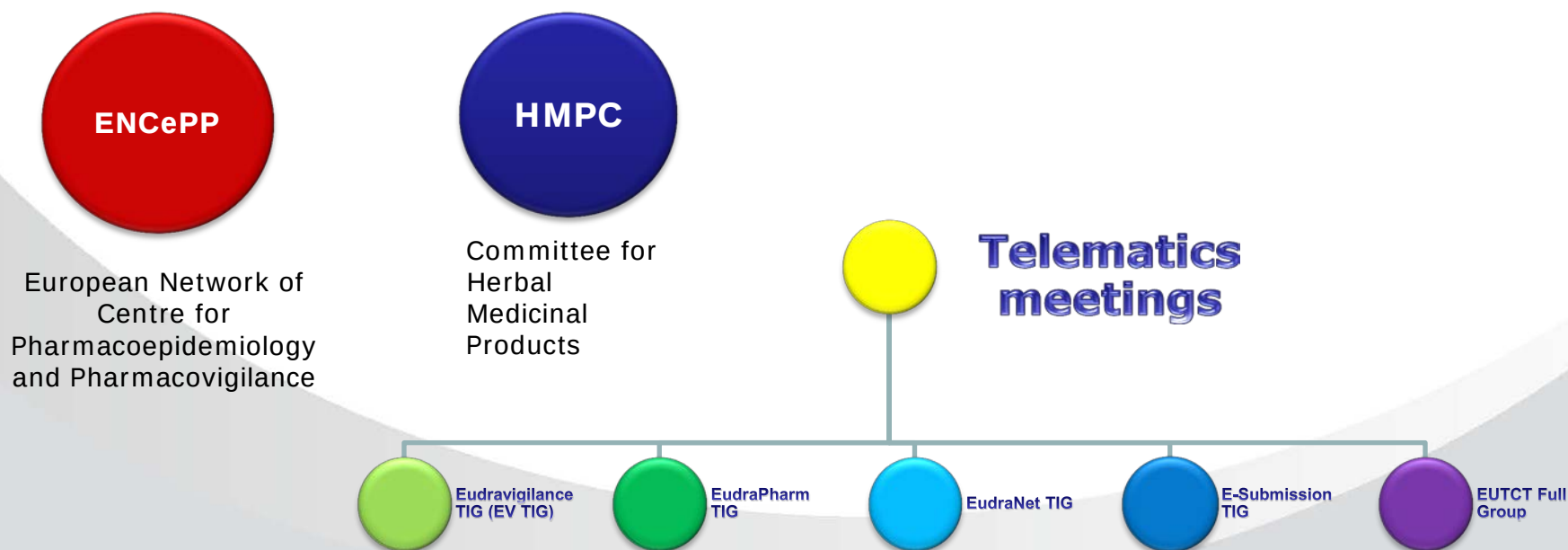
Participation in meetings as observers

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.



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

Participation in meetings as observers



**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.

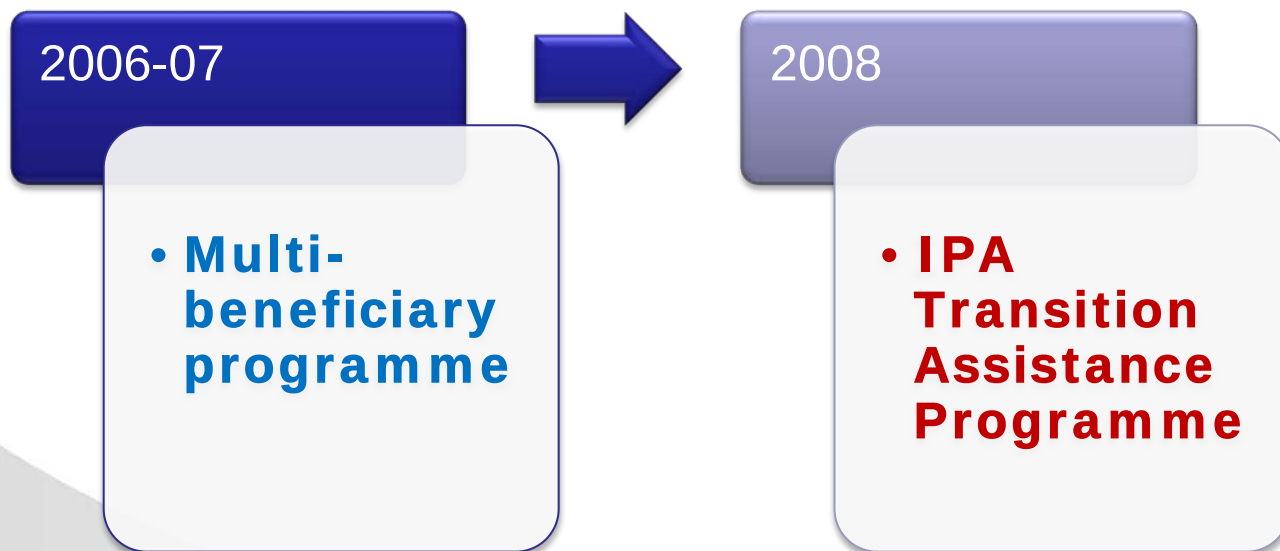














Successful Rijeka conference strengthens EU-Croatian cooperation on medicines regulation

PRESS RELEASE
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 (EMA).

Organised as part of the fifth anniversary celebrations of the European Union (EU) 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 EMA, 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 EMA 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 --

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

Conference Secretariat
European Medicines Agency
15, Avenue de la Libération
E14 4HB, UK
+44 20 75 23 74 15
+44 20 74 18 85 01
enquiries@ema.europa.eu
ema.europa.eu

Conference Venue
Croatian Cultural Centre at
Ušak Rijeka
Brodsmayerova 1
51000 Rijeka -Croatia

IPA Transition Assistance Programme 2008



SEMINAR
NOVOSTI U EUROPSKOJ
FARMAKOVIGILANCIJI
I UPRAVLJANJU RIZIKOM

9. – 10. lipnja 2008., Hotel Lav, Vukovar

SÉMINAIRE
SUR LES DÉVELOPPEMENTS
RÉCENTS EN PHARMACOVIGILANCE
EUROPÉENNE ET LA GESTION
DU RISQUE

Vukovar, Hôtel Lav, du 9-10 juin 2008

Pod pokroviteljstvom / sous l'égide du:
Ministarstvo zdravstva i socijalne skrbi Republike Hrvatske

Suorganizatori / coorganisateurs:

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



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 Bénédicte.

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 Bénédicte
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 Altor, 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	

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 Llinars 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 Bénédicte
11.45 – 12.15	Closing remarks	Andreas Pott + Sylvie Bénédicte





Reinforcing patient
safety in Europe

14-15 June 2011
Zagreb, Croatia



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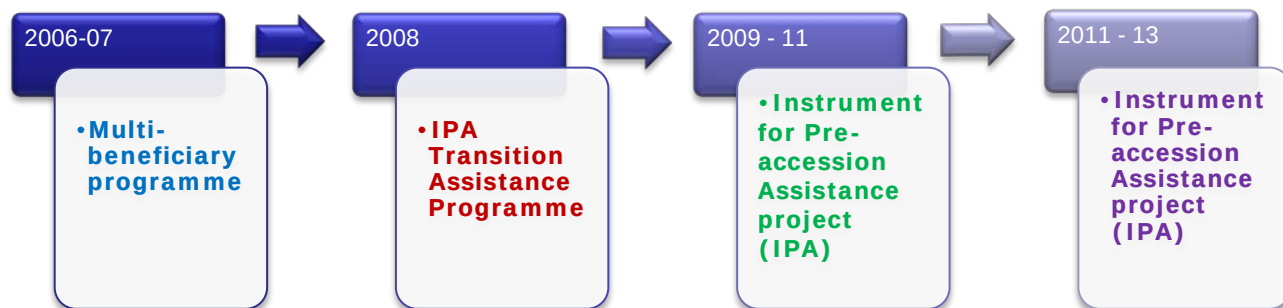
E-mail info@ema.europa.eu Website www.ema.europa.eu

An agency of the European Union



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Assistance
Project 2009-2011



- 1st chapter of accession negotiations opens

12.06.2006.

30.06.2011.

- Last of the 35 negotiating chapters is closed

- EU and Croatia sign accession treaty

09.12.2011.

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

Started July 2006

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



European Medicines Agency
Communications and Networking



EUROPEAN MEDICINES AGENCY
SCIENCE · MEDICINES · HEALTH

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.

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.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Further information

European Medicines Agency
IPA Conferences Secretariat

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London E14 4HB
United Kingdom

IPA conferences queries
E-mail ipa.conferences@ema.europa.eu

External participant queries
E-mail extpax@ema.europa.eu

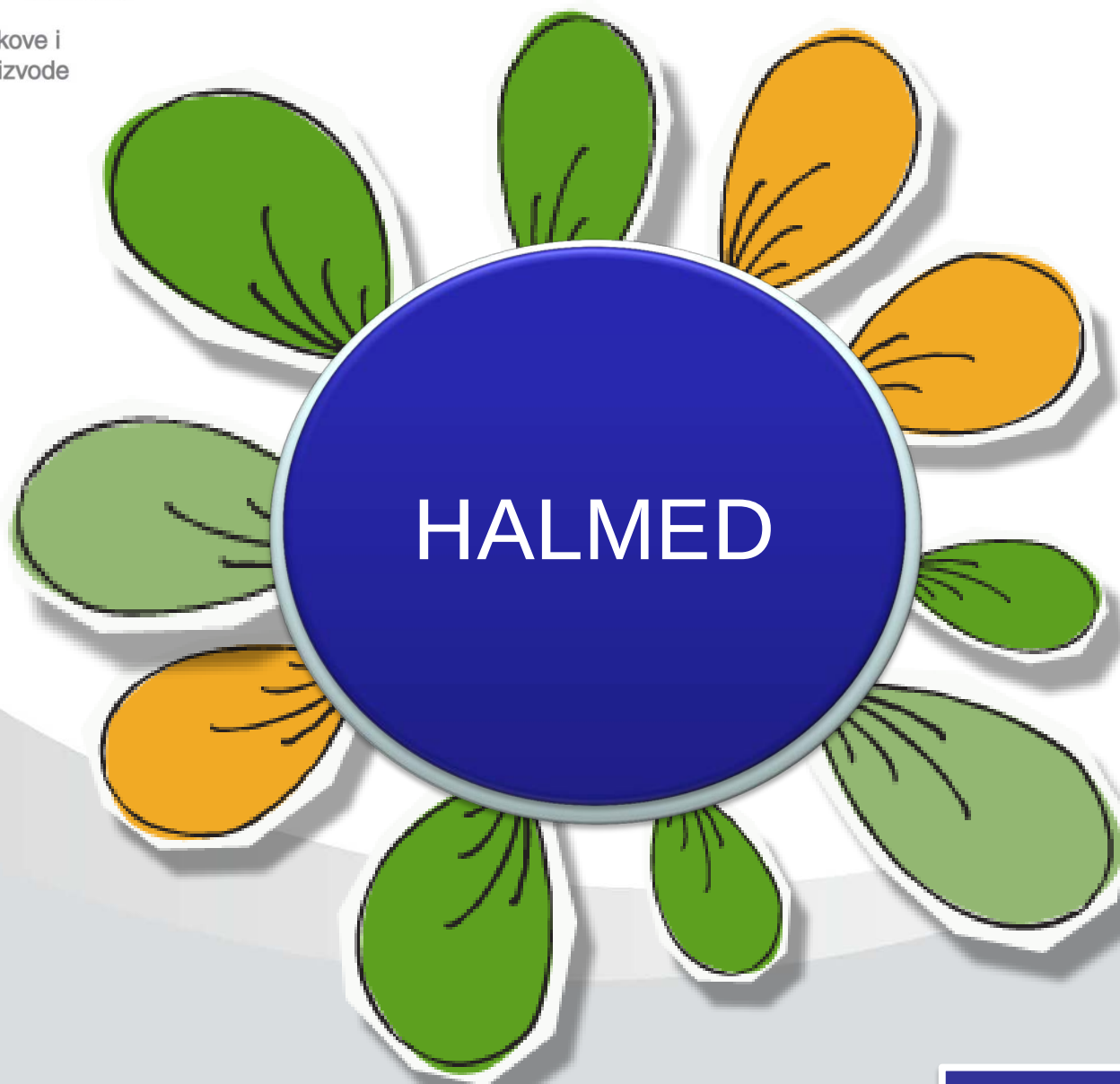
Telephone +44 (0)20 7523 7546
Facsimile +44 (0)20 7418 8501
Website www.ema.europa.eu

Partners & networks > Europe & the Agency > EU enlargement

EU enlargement
programme









2013

The Administration Board

Directorate

Central Ethics Committee
Secretary's Office

Head of Agency's
Office

Office for Quality
Management

Public Relations
Office

Office for
International
Cooperation

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

Regulatory Affairs
Department

Department for
Distribution of
Medicines and
Medical Devices

Dept for Cooperation
with Inspectorate
and Manufacturing
Licenses

Department for
Financial, Legal and
General Affairs

Physico-Chemical
Laboratory
Department

Department for
Quality, Safety and
Efficacy Assessment

Department for
Pharmacovigilance
and Rational
Pharmacotherapy

Department for
Pharmacoeconomics
and Drug Utilisation

IT Department

Office for
Pharmacopeia

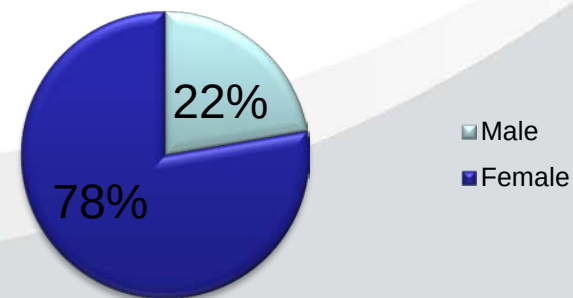
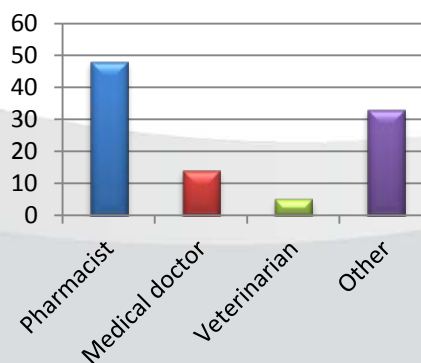
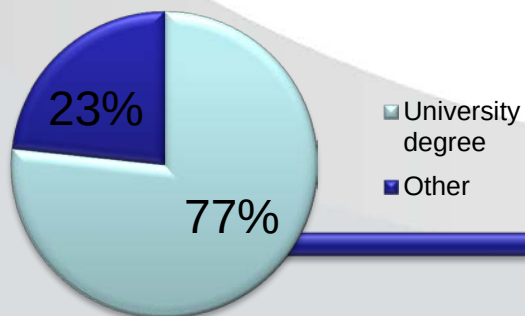
Department for
Medical Devices

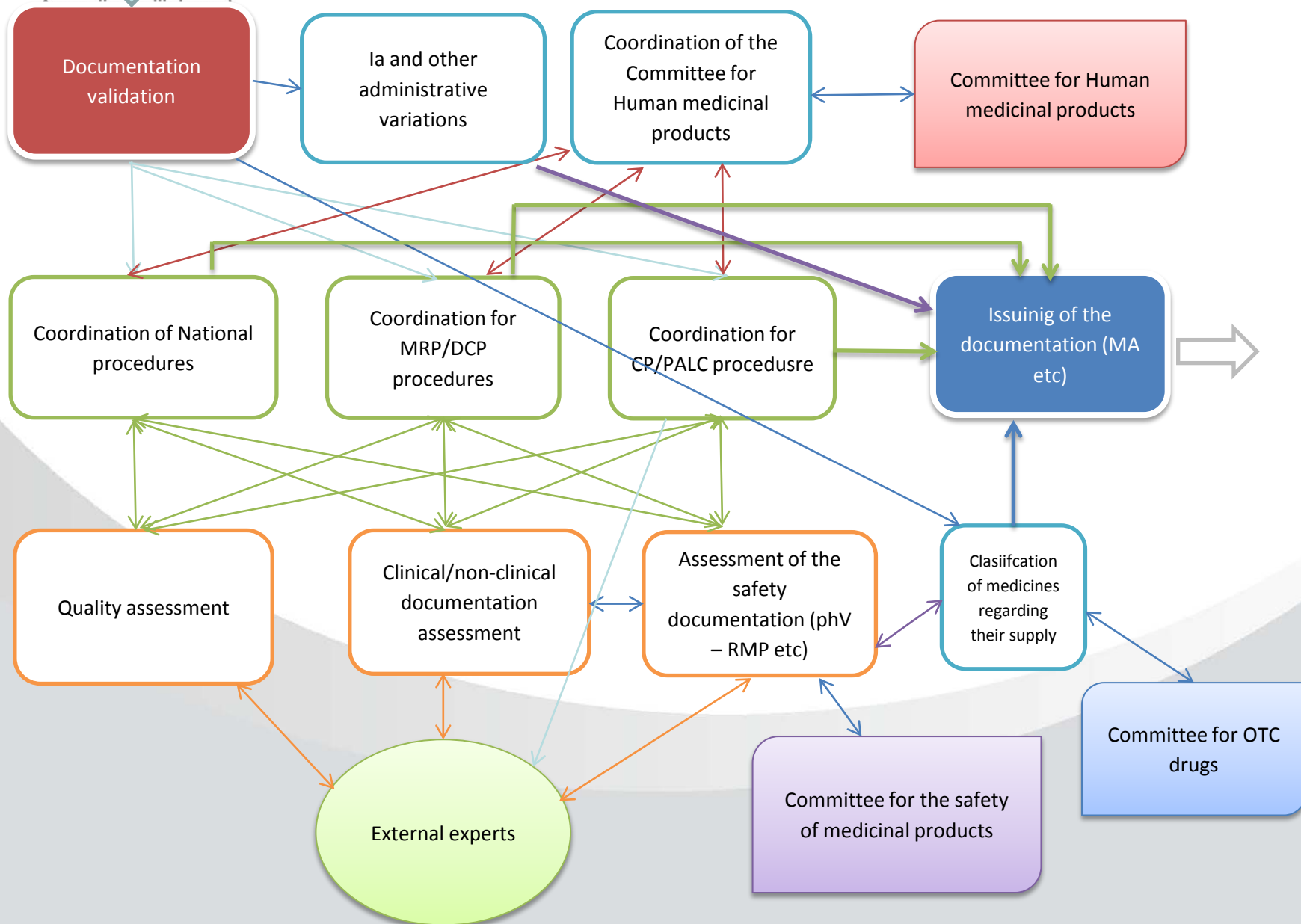
Document Records
and Project
Management
Department



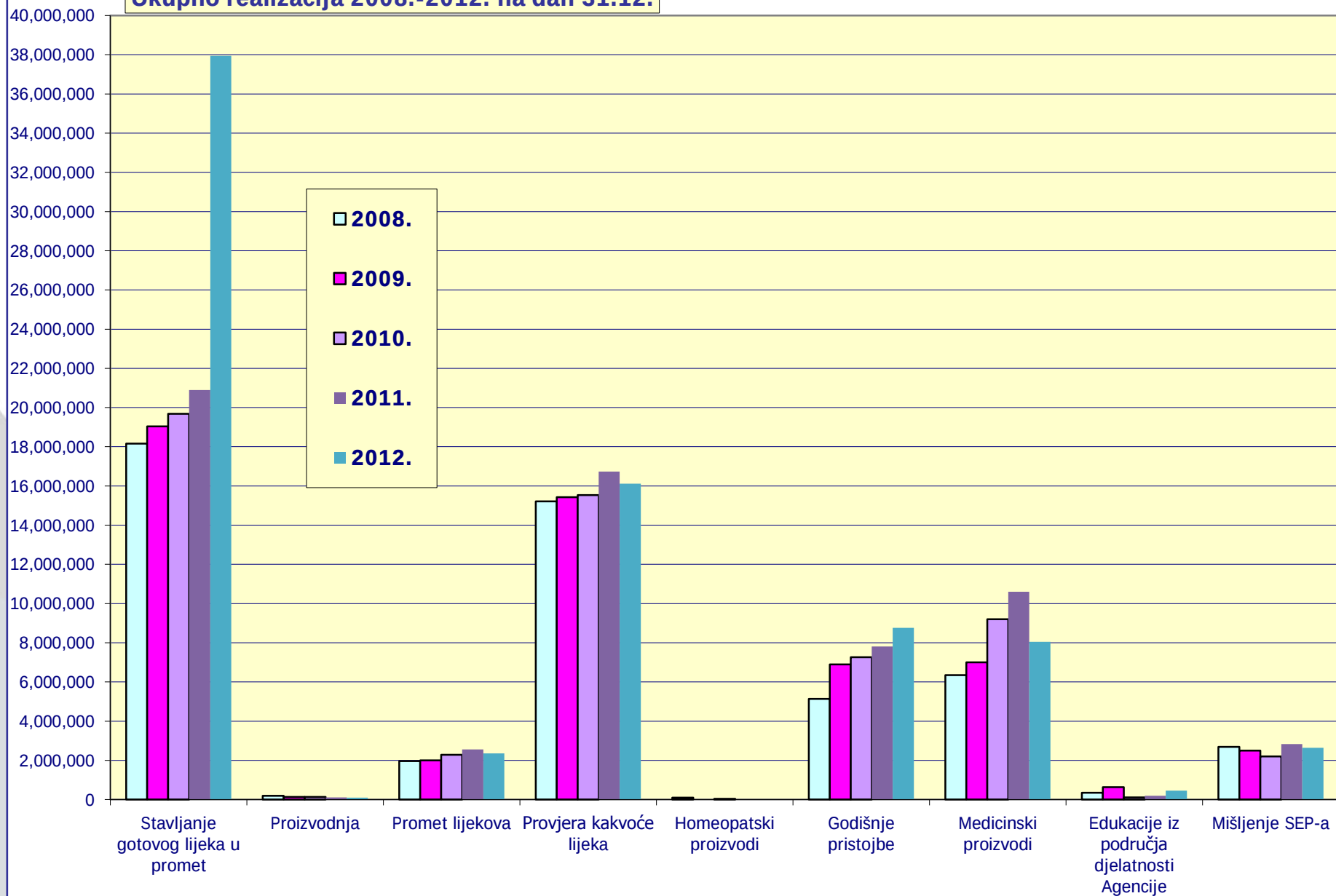


194 EMPLOYEES IN 2013

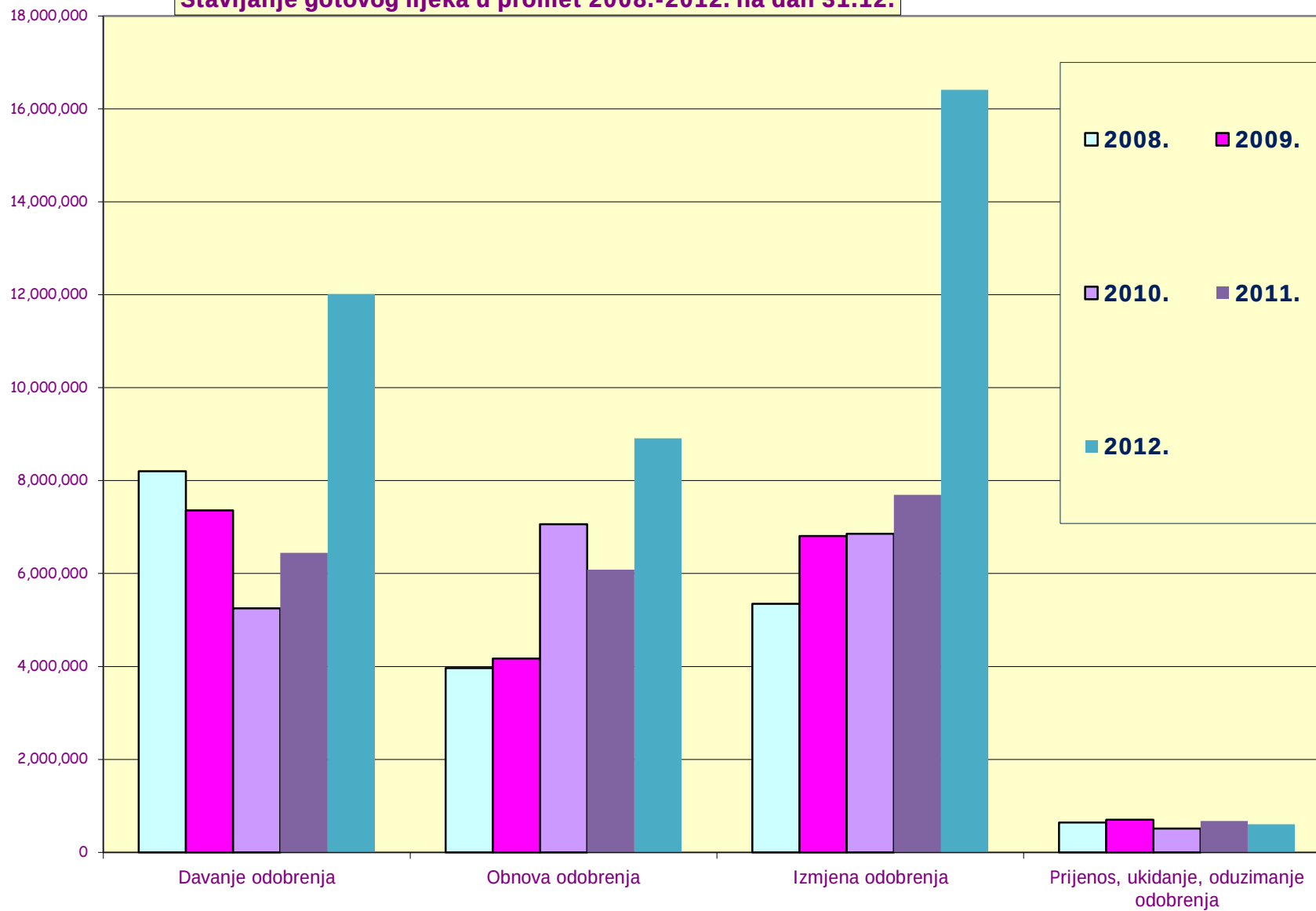




Ukupno realizacija 2008.-2012. na dan 31.12.



Stavljanje gotovog lijeka u promet 2008.-2012. na dan 31.12.



HALMED's IT system

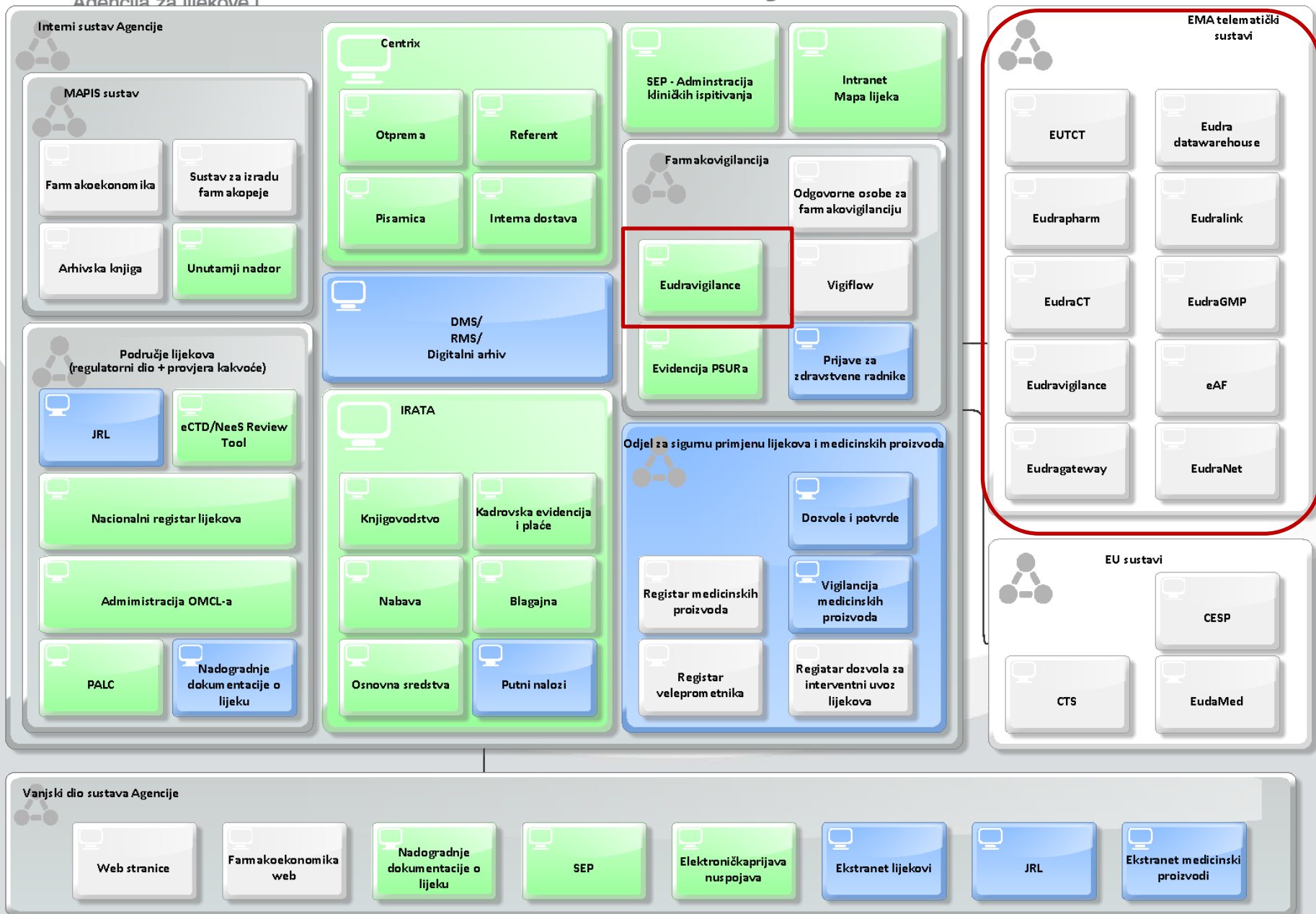


Centralni registar lijekova

2004 - 2006

HALMED's IT system

Agencija za lijekove i



EudraVigilance MSe User Group in 2006



vmacolic (ALMP) @ Production - Windows Internet Explorer

http://srv-ev.halmed.local/x/76

Display Settings

Create and Send ICSRs ICSRs Medicinal Products MedDRA

Reset Application Reset Section Clear ReRun Modify Delete Excel Export Follow Up Forward Load

Safety Reports (-)

ICHCSR Messages (-)

Queries

Case Tracking List

All Reports

Fields

Conditions (AND)

Results

Result 19, trajni

Reports with Warnings

Reports with Errors

ICHCSR Messages

Tracking

Num	Local Report Number	Transmission date	Primary Source Coun...	Safety Report ID	Report Type	Case type	Case number	Report Classification	Report Correctness
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0002	1119412	02/04/2013	United States	US-ROCHE-784607	Spontaneous	Marketing Authorisati...	US-ROCHE-784607	Case Report	Report with Warnings
0003	1119423	02/04/2013	France	FR-ROCHE-1203053	Report from studies	Marketing Authorisati...	FR-ROCHE-1203053	Case Report	Report with Warnings
0004	1119560	29/03/2013	United States	US-GlaxoSmithKline...	Spontaneous	Marketing Authorisati...	US-GlaxoSmithKline...	Case Report	Report with Warnings
0005	1119568	01/04/2013	France	FR-PFIZER INC-2013...	Report from studies	Marketing Authorisati...	FR-PFIZER INC-2013...	Case Report	Report with Warnings
0006	1119570	01/04/2013	Japan	JP-PFIZER INC-2013...	Spontaneous	Marketing Authorisati...	JP-PFIZER INC-2013...	Case Report	Report with Warnings
0007	1119659	02/04/2013	Japan	JP-AstraZeneca-2012...	Spontaneous	Marketing Authorisati...	JP-ASTRAZENECA-2...	Case Report	Report with Warnings
0008	1119737	29/03/2013	Italy	IT-SZ09-PHY2013IT...	Spontaneous	Marketing Authorisati...	IT-002147023-PHY2...	Case Report	Report with Warnings
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0035	1119551	29/03/2013	Bolivia	BO-GlaxoSmithKline...	Spontaneous	Marketing Authorisati...	BO-GlaxoSmithKline...	Case Report	Report with Warnings
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0042	1119038	01/04/2013	United States	US-ROCHE-722538	Spontaneous	Marketing Authorisati...	US-ROCHE-722538	Case Report	Report with Warnings
0043	1119173	01/04/2013	New Zealand	NZ-ROCHE-1190588	Spontaneous	Marketing Authorisati...	NZ-ROCHE-1190588	Case Report	Correct Report
0044	1119374	01/04/2013	United States	US-GlaxoSmithKline...	Spontaneous	Marketing Authorisati...	US-GlaxoSmithKline...	Case Report	Report with Warnings
0045	1119495	29/03/2013	United States	US-GlaxoSmithKline...	Spontaneous	Marketing Authorisati...	US-GILEAD-2013-007...	Replaced Report	Report with Warnings
0046	1119541	29/03/2013	Italy	IT-GlaxoSmithKline-B...	Spontaneous	Marketing Authorisati...	IT-GlaxoSmithKline-B...	Case Report	Report with Warnings
0047	1119609	01/04/2013	France	FR-PFIZER INC-2013...	Spontaneous	Marketing Authorisati...	FR-PFIZER INC-2013...	Case Report	Report with Warnings

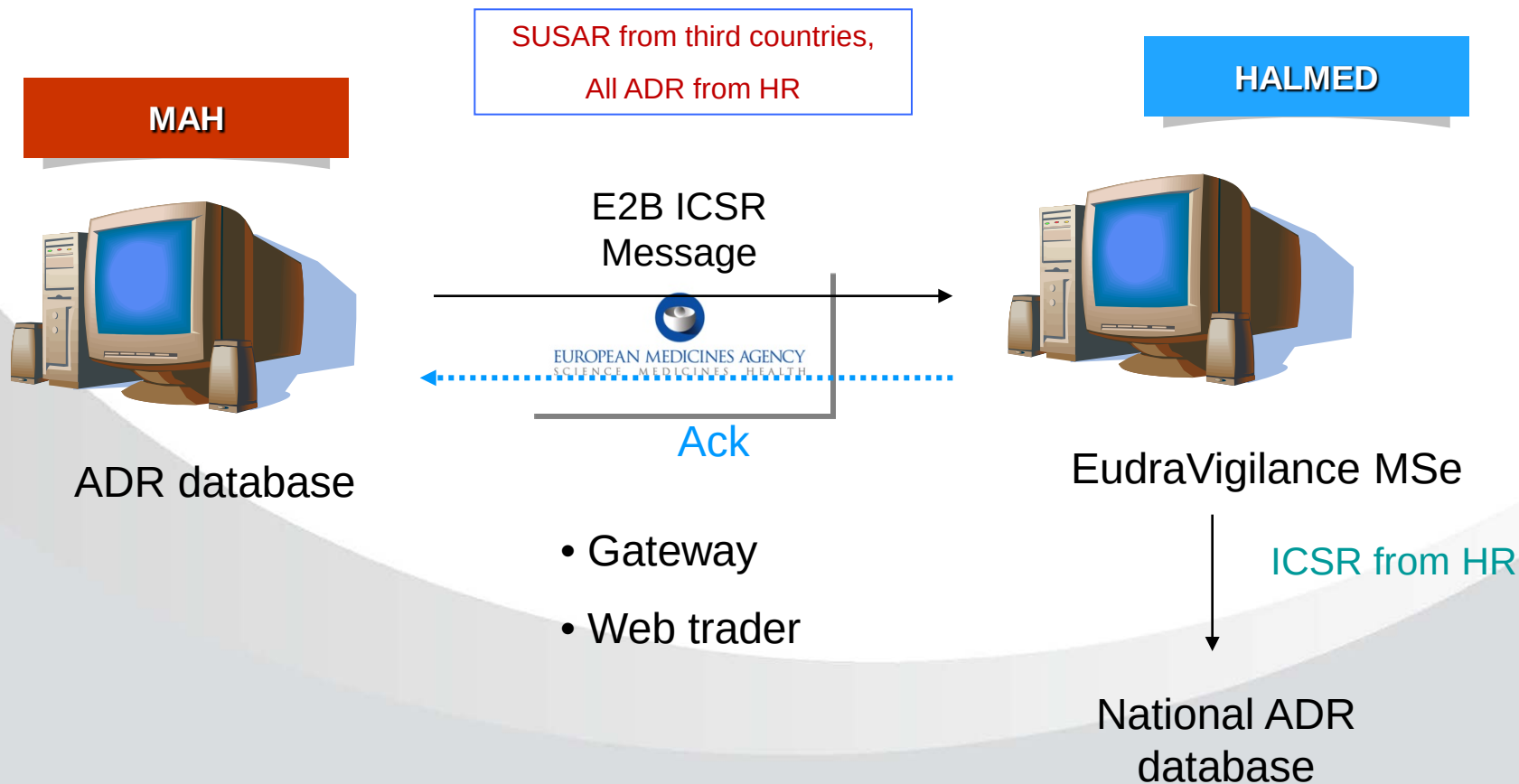
Message Receive date (From) = 01/04/2013

Local intranet | Protected Mode: Off

9:15 19.4.2013.

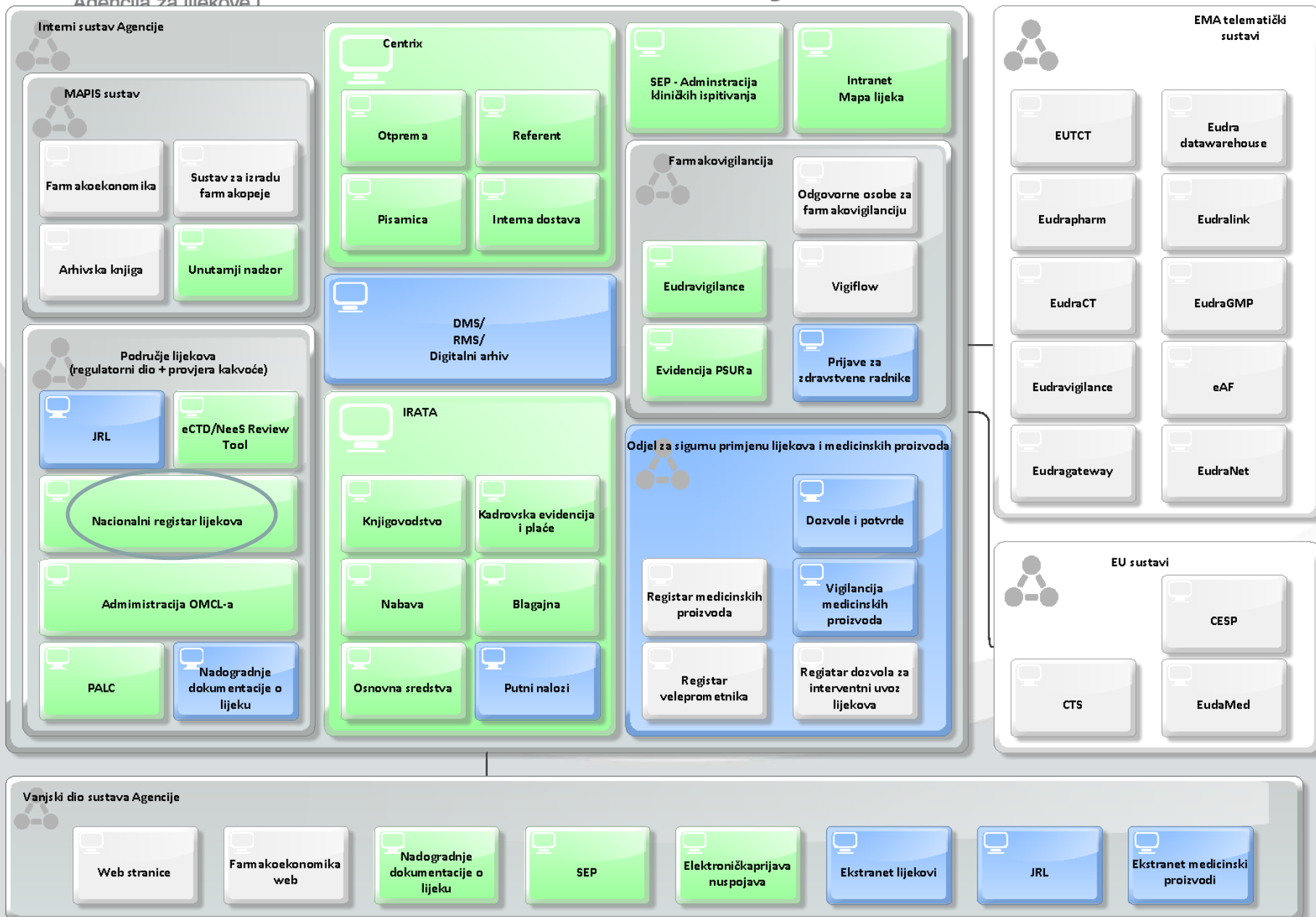
EudraVigilance Member State Edition – e- ICSR reports from April 2010

ICSR from MAH



HALMED's IT system

Agencija za lijekove i



eRegistri - Windows Internet Explorer

http://nrl.halmed.local:8090/NRL_Reg/Registers/NacionalniRegistarLijekova/ObradaPredmeta/MainSearcher/Searcher.aspx

Agencija za lijekove i medicinske proizvode
Nacionalni registar lijekova

HALMED \vmacolic

POČETNA STRANICA IZVJEŠTAJI KOORDINACIJA

Nacionalni registar lijekova

Središnji podaci o lijekovima

Obrada predmeta

Tražilica

Radna lista

Centrix - Novi predmeti

Lista naloga za fakture

Lista za Narodne novine

Case

Novi zapis

Tražilica obrada predmeta

Vrsta zahtjeva - Odaberite -

Klasa

Datum zaprimanja

Od Do

Naziv lijeka

Datum rješavanja

Od Do

Predmeti po rješenosti

Svi Riješeni Neriješeni

Način rješavanja predmeta

Svi Pozitivno Drugo

Status predmeta

Zahtjev zaprimljen u NRL

Zahtjev zaprimljen u pisarnicu

Ocjena - Valjanost zahtjeva

Ocjena - Dokumentacija o kakvoći

Ocjena - Klinička/neklinička dokumentacija

Ocjena - Dokumentacija o sigurnosti primjene

Donošenje odluke (RGIIO)

Status faze predmeta

Čeka

U radu

Završeno

Grupa lijeka

biljni

derivat krvi i krvne plazme

homeopatski

imunološki

lijek

lijek za naprednu terapiju

lijek za rijetke i teške bolesti ("orphan")

Šifra postupka

EU šifra izmjene

Podaci o lijeku

Nositelj odobrenja

Proizvođač

Djelatna tvar

ATK Klasifikacija

Vrsta postupka

Nacionalni

EU

-

Podvrsta postupka

RH

EU

Drugi nacionalni postupak

CP

DCP

MRP

-

Zakonska osnova

Dodatni zahtjev za isti lijek pod drugim nazivom

Svi Da Ne

Veća izmjena / davanje odobrenja čl. 45. NjZ, 113/08

Svi Da Ne

Zakonska osnova

nova djelatna tvar (čl. 14. Zakona)

poznata djelatna tvar (čl. 14. Zakona)

generik (čl. 15a. Zakona)

provj. med. upotr. (čl. 15b. Zakona)

sugl. o koriš. dokum. (čl. 15c. Zakona)

hibrid (čl. 17.a Zakona)

TRAZI PONISTI UVJETE

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Done

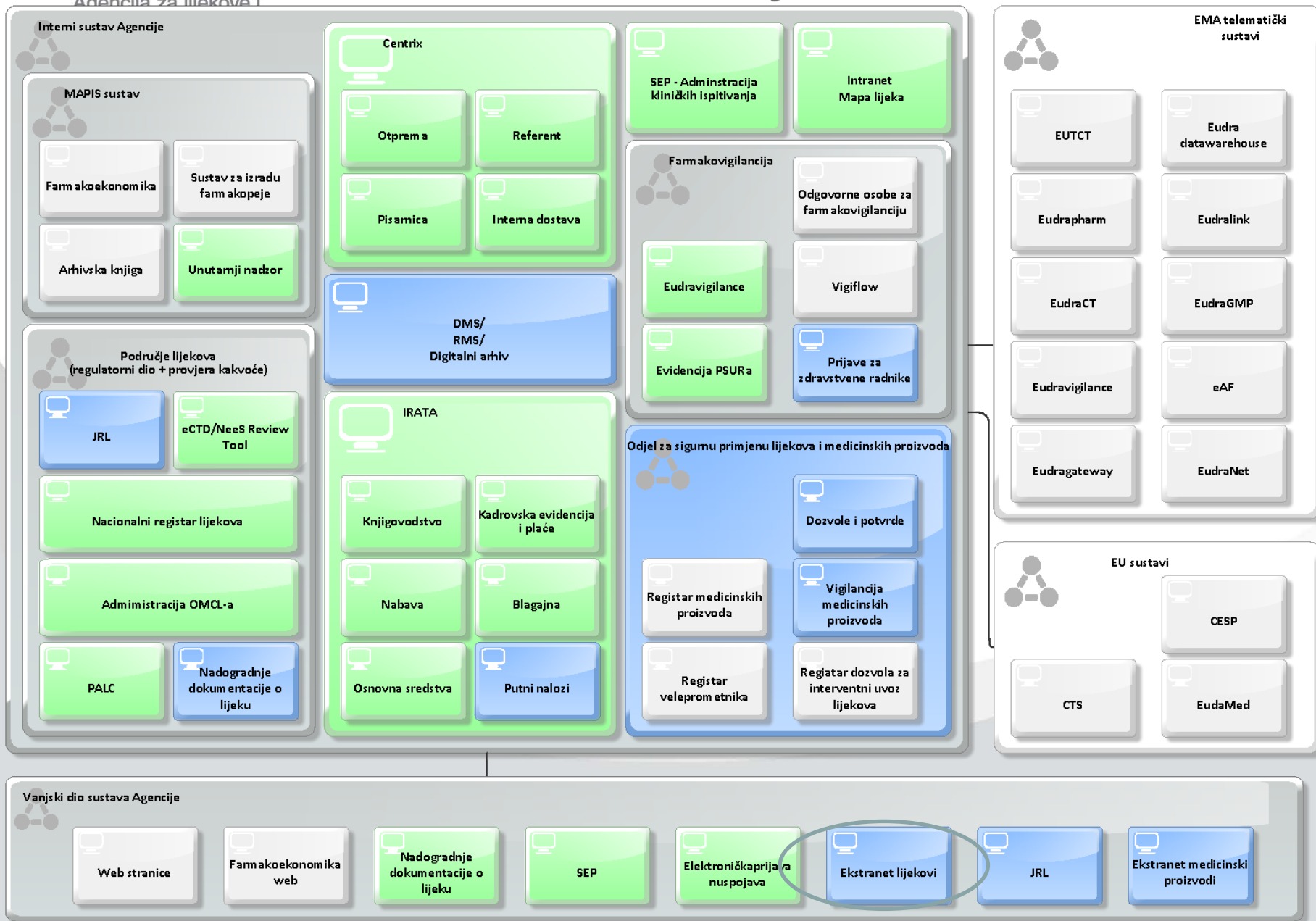
Local intranet | Protected Mode: Off

HR 7:46 19.4.2013.

NATIONAL REGISTRY OF MEDICINAL PRODUCTS

HALMED's IT system

Agencija za lijekove i



HALMED

Agencija za lijekove i medicinske proizvode

EKSTRANET PORTAL

ODJAVA / LOGOUT

KORISNIK / USER: **d.sudic/BAYER**

ODABERI ORGANIZACIJU ▼

▶ MOJA STRANICA

▶ PREDMETI U IZRADI

▶ PREDMETI U OBRADI

▶ SVI PREDMETI

▶ PORUKE

▶ IZVJEŠTAJI

▶

MOJI PREDMETI U OBRADI [21]

SVI PREDMETI U OBRADI [36]

BR. PR.	LUEK	KLASA	PREDAN	ZAHTJEV	IZMJENA	DJELATNA TVAR	FARMACEUT. OBLIK	STATUS	CLOCK STOP	AKCIJA
126787	Avelox	UP/1-530-09/08-01/308	27.07.2012.	Nacionalni. RH	Davanje odobrenja	iopromid	Filmom obložena tableta	Ocjena		
235617	Logest	UP/1-530-09/05-01/114	05.08.2012.	Nacionalni. RH	Davanje odobrenja	gestoden, etinilestradiol	Tableta	Zaprimljen		
178953	Levitra	UP/1-530-09/08-01/205	12.07.2012.	Nacionalni. RH	Davanje odobrenja	mayfloxacium	Filmom obložena tableta	Clock Stop	12/45	
155587	Yasmin	UP/1-530-09/05-01/147	10.06.2012.	Nacionalni. RH	Izmjena odobrenja	paracetamolum	Otopina za infuziju	Donošenje odluke		
119235	Ultravist 370	UP/1-530-09/08-01/348	09.08.2012.	Nacionalni. RH	Obnova odobrenja	drosiprenon, etinilestradio	Krema	Ocjena valjanosti		
178952	Avelox	UP/1-530-09/08-02/258	27.07.2012.	Nacionalni. RH	Izmjena odobrenja	clotrimazolum	Tableta	Zahtjev riješen		
146767	Logest	UP/1-530-09/08-01/369	22.12.2012.	Nacionalni. RH	Davanje odobrenja	telmisartanum	Tableta	Zaprimljen		
225178	Aspirin plus C	UP/1-530-09/05-01/528	14.07.2012.	Nacionalni. RH	Davanje odobrenja	varidenafil	Filmom obložena tableta	Clock Stop	7/50	
178971	Yasmin	UP/1-530-09/08-01/546	13.07.2012.	Nacionalni. RH	Davanje odobrenja	iopromid	Krema	Ocjena valjanosti		
119233	Ciprobav	UP/1-530-09/08-01/417	14.07.2012.	Nacionalni. RH	Davanje odobrenja	gestoden, etinilestradiol	Filmom obložena tableta	Donošenje odluke		
126787	Avelox	UP/1-530-09/05-01/471	26.07.2012.	Nacionalni. RH	Izmjena odobrenja	mayfloxacium	Filmom obložena tableta	Ocjena		
235617	Logest	UP/1-530-09/05-02/639	30.07.2012.	Nacionalni. RH	Obnova odobrenja	paracetamolum	Otopina za infuziju	Zahtjev riješen		
178953	Levitra	UP/1-530-09/08-01/693	01.08.2012.	Nacionalni. RH	Obnova odobrenja	drosiprenon, etinilestradio	Filmom obložena tableta	Zaprimljen		
155587	Yasmin	UP/1-530-09/08-02/308	04.08.2012.	Nacionalni. RH	Davanje odobrenja	varidenafil	Otopina za infuziju	Clock Stop	36/45	
119235	Canesten	UP/1-530-09/08-01/654	27.07.2012.	Nacionalni. RH	Izmjena odobrenja	iopromid	Tableta	Ocjena valjanosti		
178952	Saridon	UP/1-530-09/08-01/356	05.08.2012.	Nacionalni. RH	Izmjena odobrenja	gestoden, etinilestradiol	Otopina za infuziju	Donošenje odluke		
146767	Logest	UP/1-530-09/08-01/112	12.07.2012.	Nacionalni. RH	Izmjena odobrenja	mayfloxacium	Tableta	Ocjena		
225178	Levitra	UP/1-530-09/05-02/158	10.06.2012.	Nacionalni. RH	Obnova odobrenja	paracetamolum	Tableta	Zahtjev riješen		
178971	Yasmin	UP/1-530-09/08-02/247	27.07.2012.	Nacionalni. RH	Davanje odobrenja	drosiprenon, etinilestradio	Tableta	Clock Stop	34/60	
119233	Logest	UP/1-530-09/08-01/552	08.08.2012.	Nacionalni. RH	Obnova odobrenja	varidenafil	Tableta	Donošenje odluke		

NOVI PREDMET

PRENOS PRAVA

OBRISI OZNAČENU GRUPU PREDMETA

IZVEZI TABLICU KAO .XLS

SVI PREDMETI

17 - 36 OD 36

▶ PORUKE HALMED

PREDMET: 178952

BR. PRED.	VRIJEME	NAZIV LUEKA	VRSTA ZAHTJEVA	KLASA	POSILJATELJ	NASLOV
178952	16. 08. 2012. / 13.55	Avelox	Izmjena odobrenja	UP/1-530-09/05-		



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

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

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.

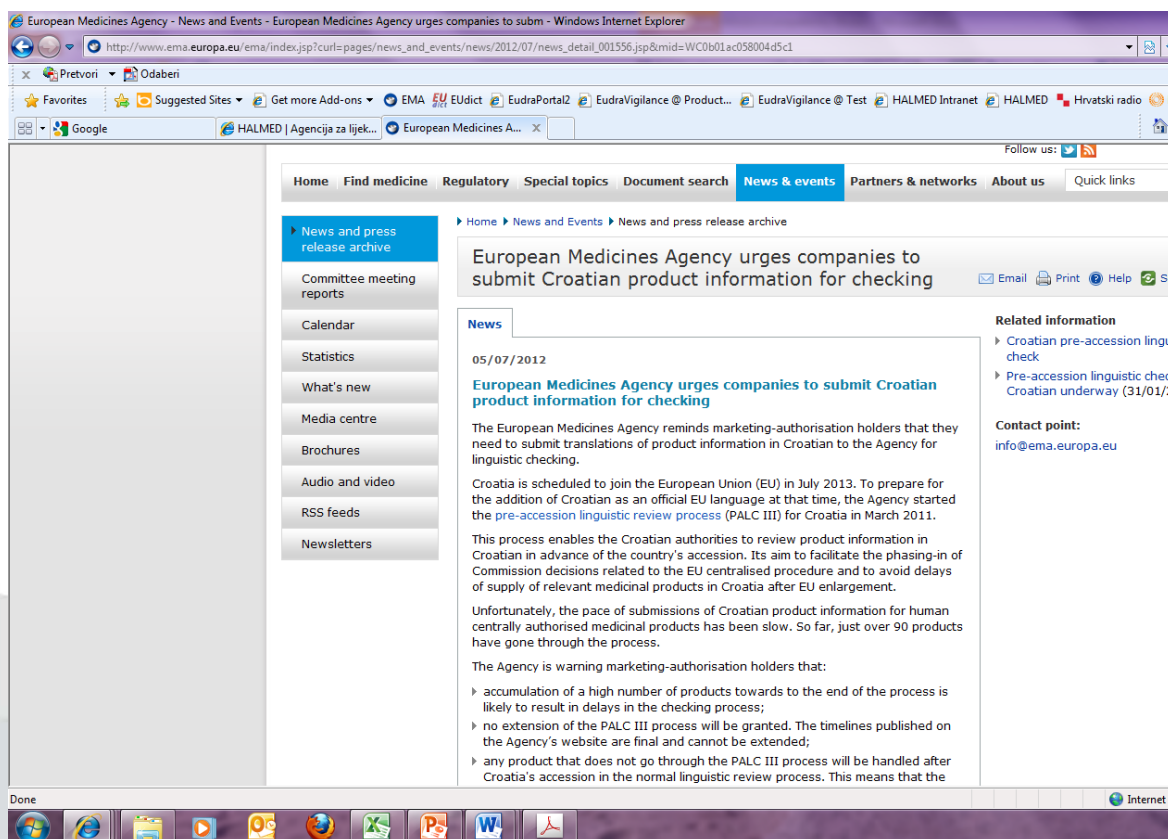
When a Croatia joins the EU, such decisions extend automatically to the territory of the new Member State.

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



• *Halmed team* for human medicines





- 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



- **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



Statens legemiddelverk
Norwegian Medicines Agency



LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY



Ravimiamet
State Agency of Medicine



 Sundhedsstyrelsen
Danish Health and Medicines Authority



Collaboration with other National Agencies

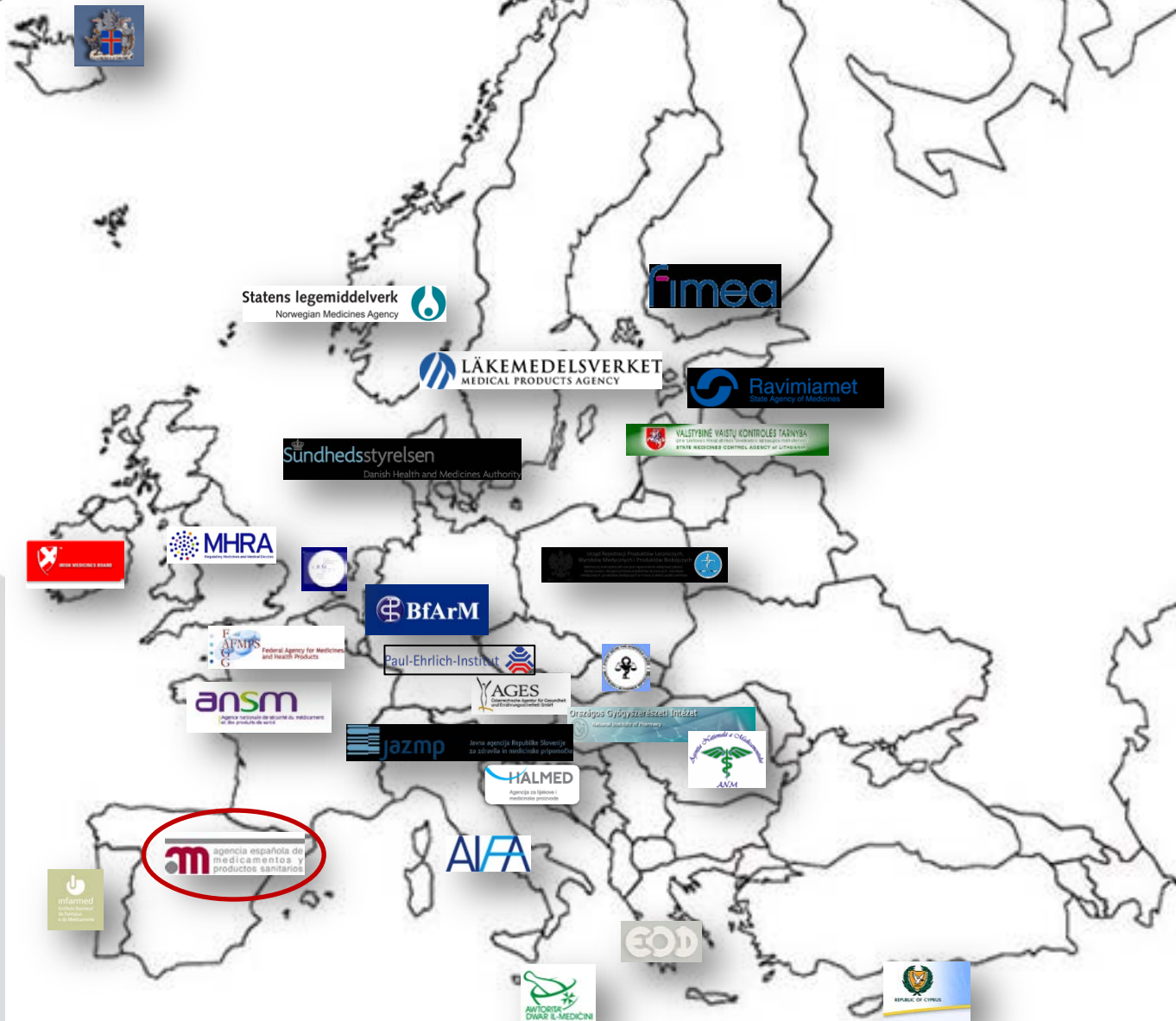


LÄKEMEDELSVERKET

MEDICAL PRODUCTS AGENCY



January 2006



Collaboration with other National Agencies



Twinning LIGHT
2010/2011
(IPA programme)

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

Collaboration with other National Agencies



Twinning LIGHT
2010/2011
(IPA programme)

- 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)

Collaboration with other National Agencies

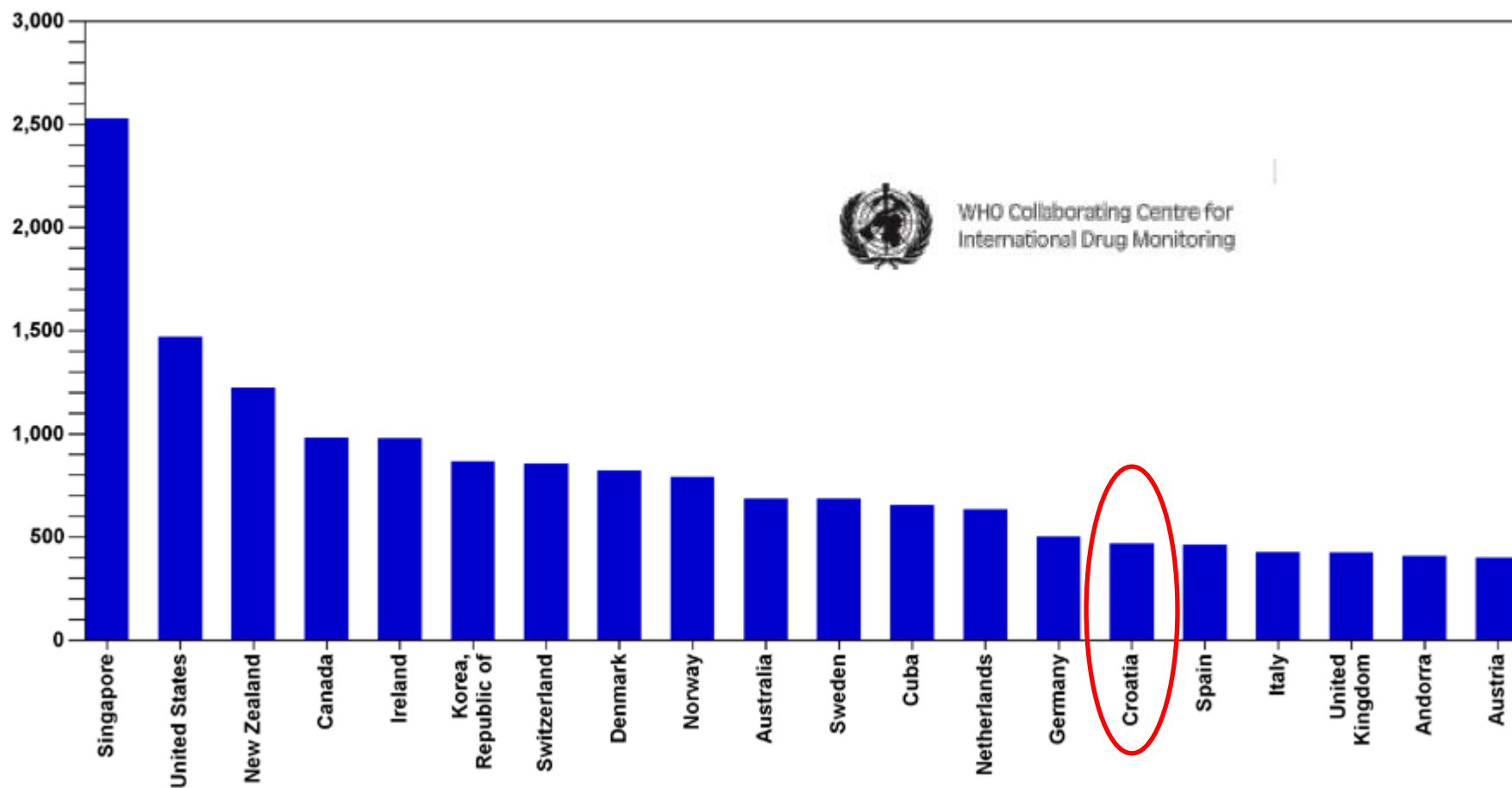




and the New

Pharmacovigilance legislation

Active ICSRs in the WHO global ICSR database per million inhabitants and year
Period covers 2008-03-22 to 2013-03-22



Patient reporting



HALMED

Agency for Medicinal Products
and Medical Devices of Croatia



WELCOME TO THE WEBSITE

OF THE AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES

SEARCH

NEWSLETTER

ENQUIRIES

RAPID ALERT SYSTEM

ANAL PRODUCTS

MEDICAL DEVICES

HOMEOPATHIC PRODUCTS

LICENCES - MANUFACTURING AND SALE

PHARMACOVIGILANCE

PHARMACOPO

OPENING HOURS OF THE
REGISTRY OFFICE

**Additional Information on
Submission of Documentation**

AVERSKA CESTA 4, ZAGREB

Customer service: 8.00 a.m. to 3.30 p.m.

Submission: 8.00 a.m. to 2.00 p.m.

Submitting more than four applications,
you are kindly asked to make a previous
arrangement at: +385 1 4884 162.

JOBERTA FRANGEŠA MIHANOVIĆA 9

For patients

INFORMATION ON MEDICINES

ON-LINE REPORTING OF ADRs



UPGRADING OF DOCUMENTATION FOR MEDICINAL PRODUCTS



MORE

NEWS

CROATIAN ACCESSION TO THE
Guidelines for Marketing

Patient reporting

Za pacijente



Primarna prijava

[Prijavitelj >](#)[Prijava >](#)[Sažetak >](#)[Završetak](#)

Dobrodošli!

* = Obavezno polje, ? = Pomoćni tekst za pojašnjenje polja

PRIJAVITELJ - CROATIA

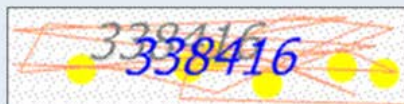
Email *

Jezik *

Hrvatski ▾

Prijavitelj ?

Korisnik lijeka ▾



August, 2012

Unesite analizu točno

ne



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 SIROČ

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 mikropetele. 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 mikropetele. 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 mikropetele. 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

available for all
registered in Croatia

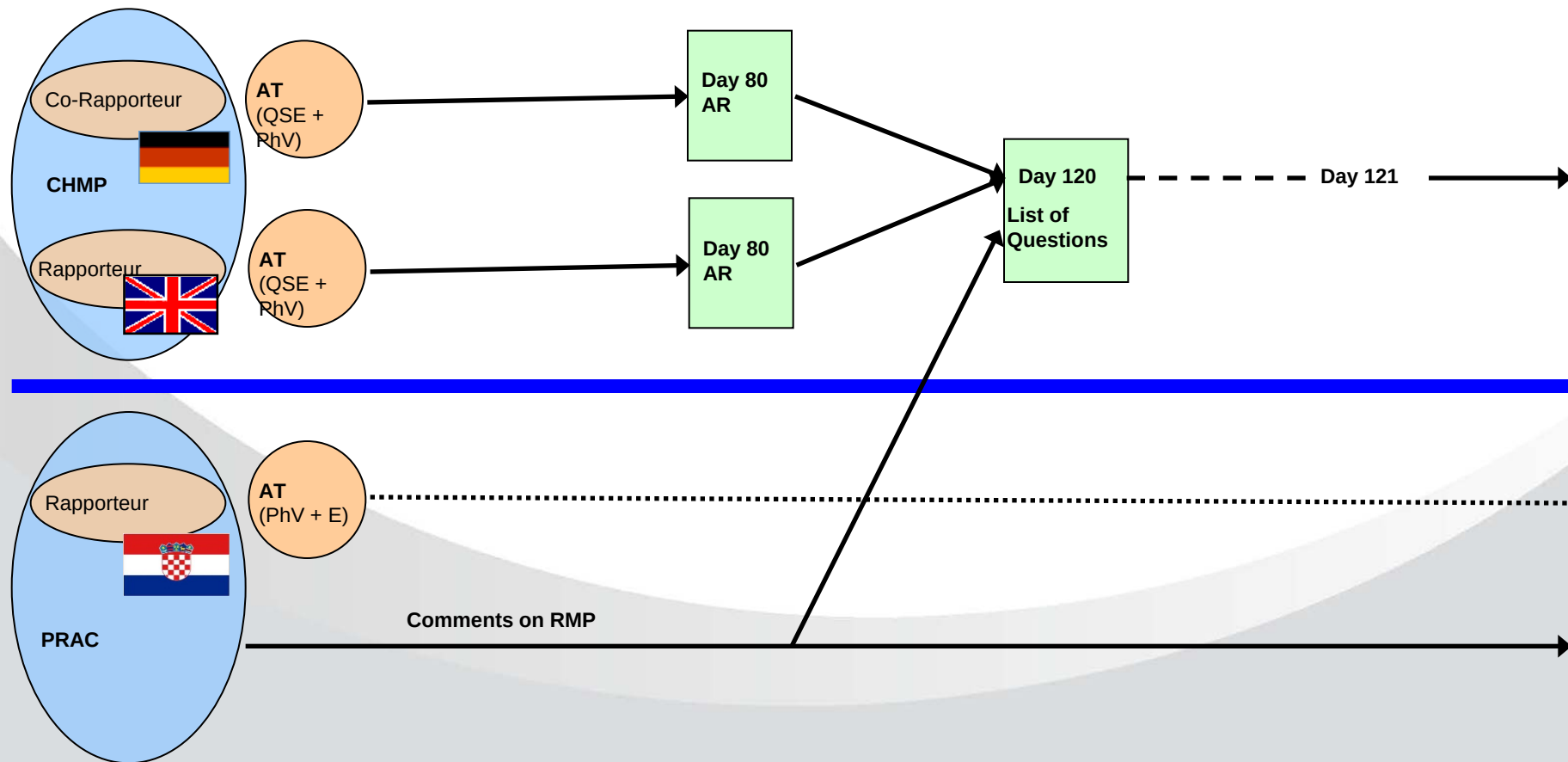
HALMED
31 - 01 - 2013
ODOBRENO



The Pharmacovigilance Risk Assessment Committee (PRAC)



PRAC rapporteurship



PRAC rapporteurship

Re: PRAC Rapporteurship - Windows Internet Explorer

https://mail.halmed.hr/owa/?ae=Item&a=Open&it=IPM.Note&iid=RgAAAAAC1rhdQkMIOSagpc2YrCVhRBwB8tSNISPeLQoGnK%2bln44onAABlqrsGAAAH3Fnp0zCTQZJNOZzGzDAAACW0u9sAAAJ&pspid=_1367694470854_285002272

Odgovori Odgovori svima Proslijedi

Re: PRAC Rapporteurship

Viola Macolić-Šarinić

Prim: 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]
Privat: (2) Pruzmi sa privitka
image001.jpg (2 KB); image002.jpg (891 B)

1. svibnja 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 4EB
United Kingdom
Tel: +44 (0)20 7418 8487
Fax: +44 (0)20 7418 8488
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 Culman; Marin Banovac; Darko Kirić
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%

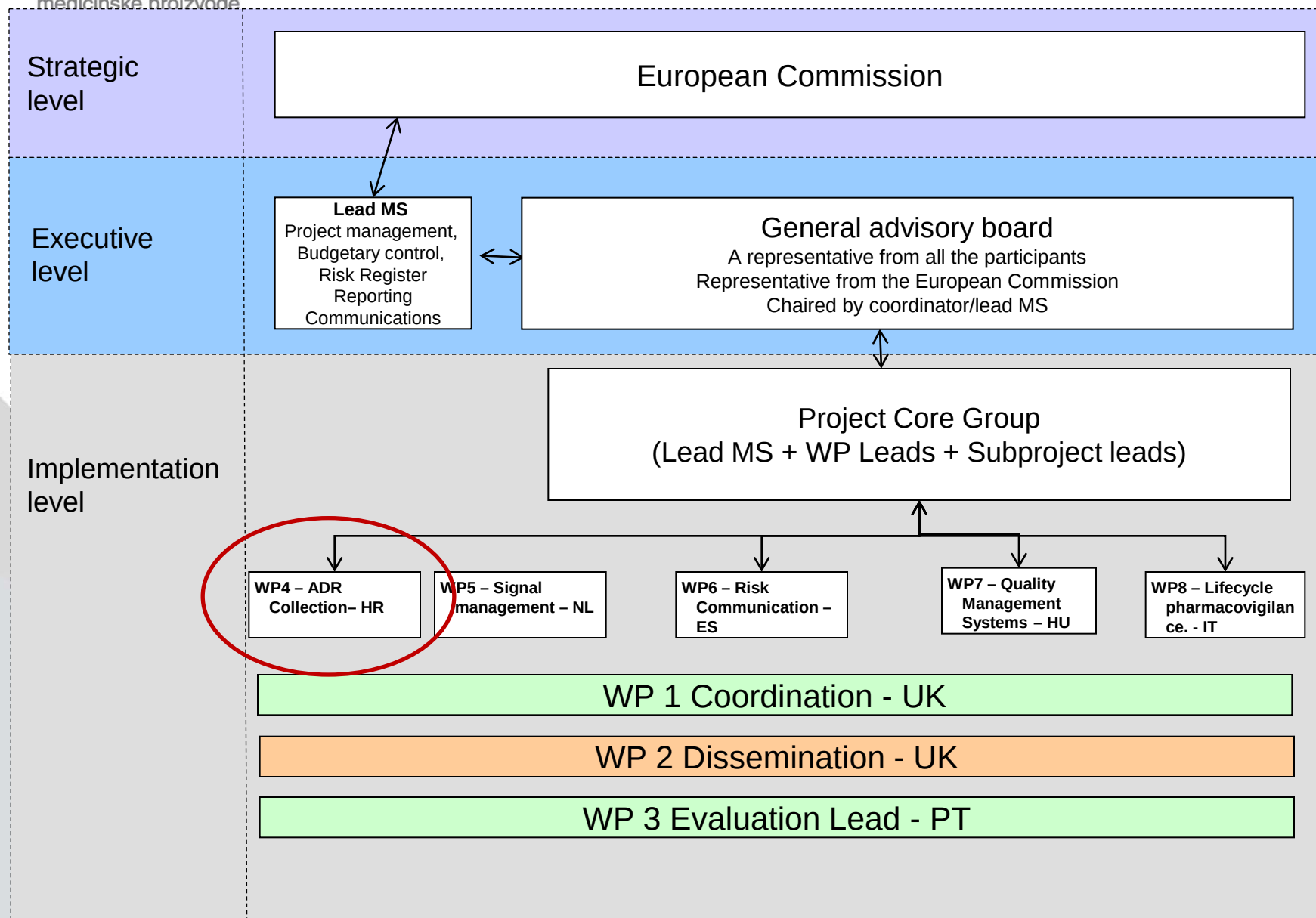
23:08
4.5.2013.

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



Governance Structure





EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Project 00305 – Implementation of pharmacovigilance legislation

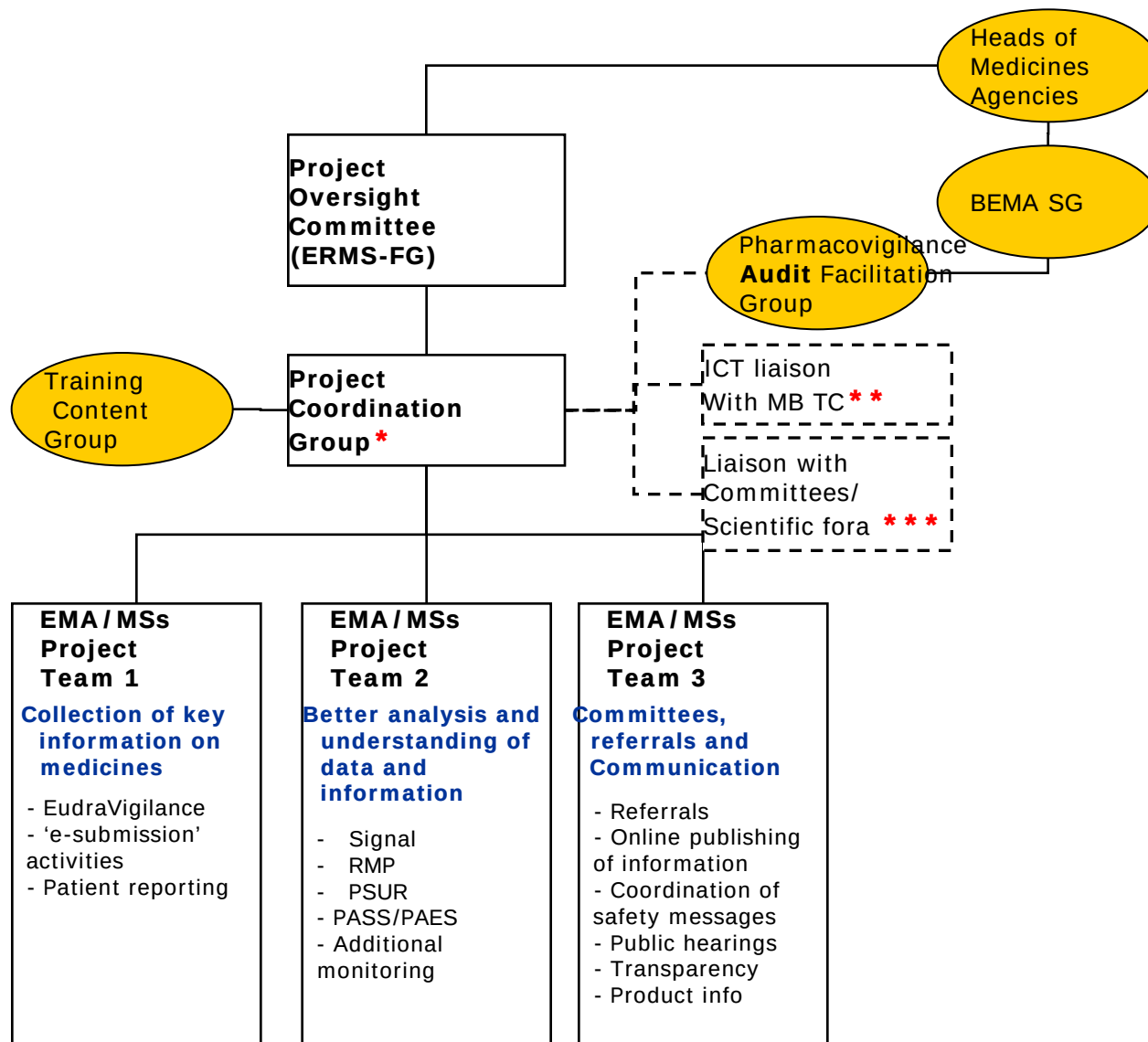
Project governance structure: slides to support the
call for Project Team nominations

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.

PRISTUPANJE HRVATSKE EU Upute za nositelje odobrenja

OPŠIRNIJE >>

Novosti

O Agenciji

Cjenik usluga

Javna nabava

SEP

Međunarodna

Predavanja i

Korisni linkovi

Zakoni i pravil

Publikacije i iz

Obrasci

Suglasnosti

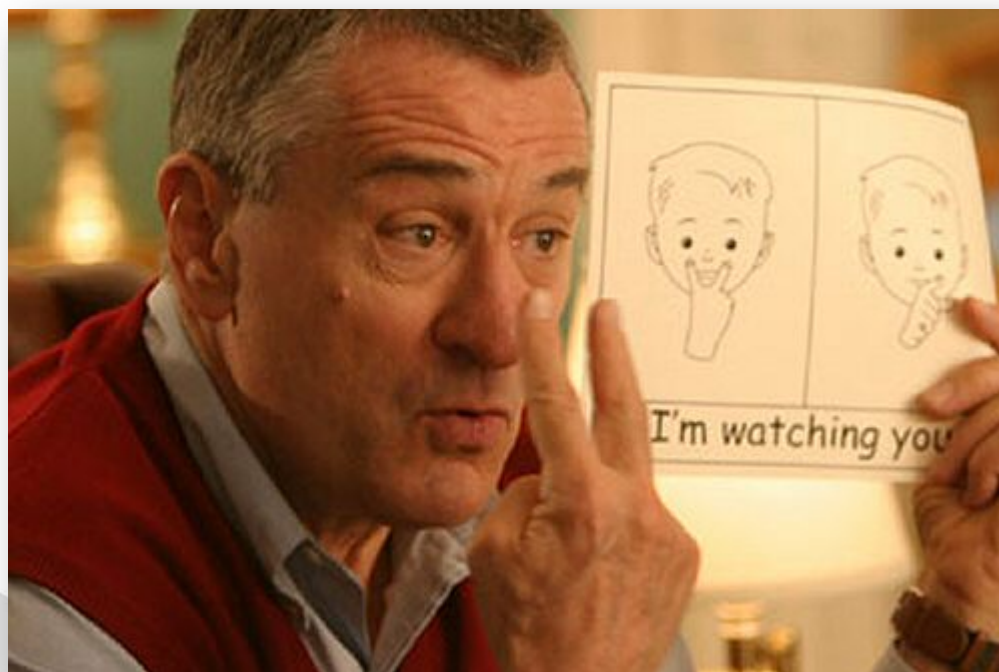
Posao i karijera

Pristupanje Hrvatske EU

QUESTIONS AND ANSWERS ON MRP & DCP AND EU ENLARGEMENT

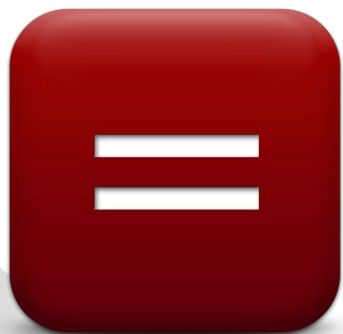
Doc. Ref.: CMDh/274/2012, Rev3
November 2012

Where can guidance and recommendations in relation to MRP and EU enlargement be found?	4
When can the new MSs be included in a MRP or DCP?	4
Do the acceding countries have the same rights as old Member States in terms of MRP and DCP?	5
What is the derogation clause contained in the Accession Treaties of some of the acceding countries and where can information about it be found?	5
Which countries have a derogation clause in their Accession Treaty?	5
Will the MA of Mutual Recognition products be recognised by the new MSs which are to join the EU?	5
Can companies based in Norway, Iceland and Lichtenstein apply for MAs in new MSs?	5
What will happen with pending national applications in the Member States for products already approved/pending in another Member State at the date of accession?	6
How should pending applications in old and new MSs be progressed where there is also an authorised product on a transitional list? The particular situation is that the authorised medicinal product is subject to a derogation clause. Can the applicant continue with the pending national applications or should they select one of the MSs with a pending application and ask them to be RMS?.....	6
Is it possible for pending applications in new MSs at the date of accession for medicinal products with a well-established use to continue national independent procedures?.....	7
Where pending applications in new MSs are rejected after the date of accession, how is it intended to regulate the financial contribution of fees paid for these applications?	7









1 July 2013

Ready to join the
European Medicines
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**Thank you
very
much!**

