# Croatian Agency for Medicinal Products and Medical Devices

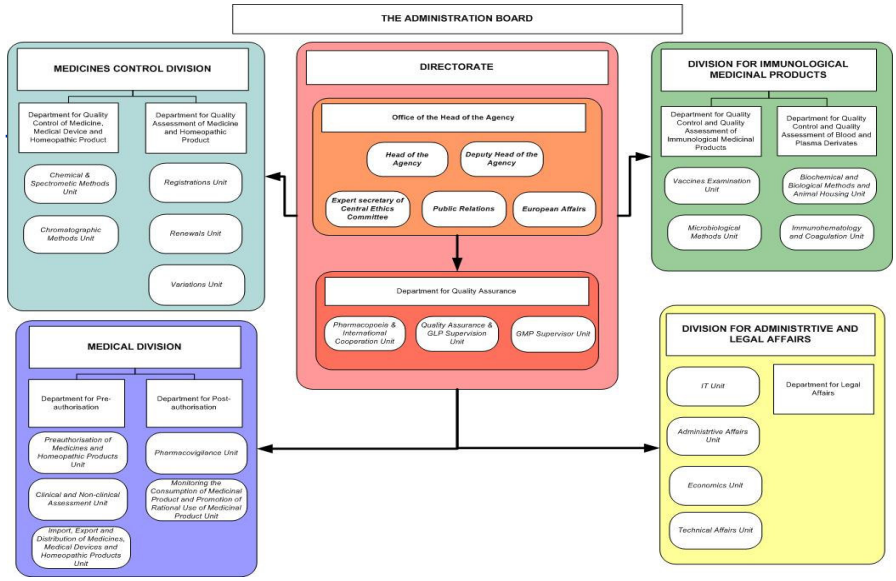
**Presented by: Siniša Tomić, Ph. D.**
**Position: Head of the Agency**

REPUBLIKA HRVATSKA
REPUBLIC OF CROATIA
Agencija za lijekove i medicinske proizvode
Agency for Medicinal Products and Medical Devices

## Organisation

The Agency was established on 1st October 2003 by the Government of the Republic of Croatia

- Legal compliance of the Agency is supervised by the Ministry of Health and Social Welfare
- Pharmacovigilance, authorisation of the medicines and their quality control under the competence of the Agency
- Pharmaceutical inspection under the competence of the Ministry of Health and Social Welfare



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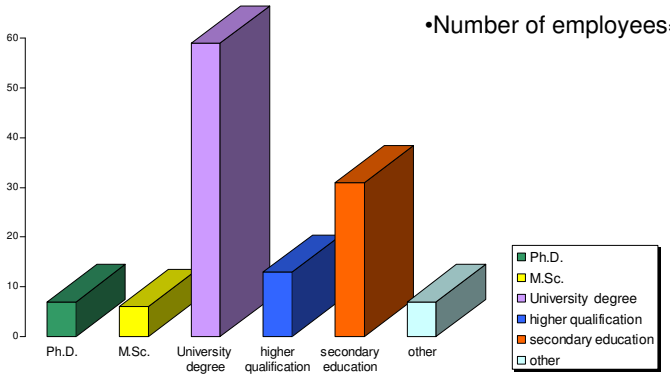
# Agency's staff members profile

•Number of employees=123



## Pharmaceuticals Industry

- Several generic manufacturers, one vaccine manufacturer and few manufacturers in the process of staring operations

- In total over 3 000 authorised medicinal products in the database available on the Agency website



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## Level of implementation of the acquis communautaire

THE ACT ON MEDICINAL PRODUCTS (MP)

- published on June 21, 2007
- came into effect on October 1, 2007
- amended in 2009
- harmonized with:
- 2001/83/EC on Medicinal Products for Human Use

  amended by:

  2001/20/EC, 2002/98/EC, 2003/63/EC, 2004/24/EC, 2004/27/EC

## Level of implementation of the acquis communautaire (cont'd)

**NEW ORDINANCES**

MARKETING AUTHORISATIONS (MA)

-Ordinance on Granting the MA (2008)

-Amendments to the Ordinance on Granting MA (2009)

-Ordinance on Special Conditions for EU Authorised Products(2008) - **nCADREAC** procedures for CP, MRP and DP

PHARMACOVIGILANCE

-Ordinance on Pharmacovigilance (2009)

ADVERTISING

-Ordinance on Advertising MP and Homeopathic products (2009)



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## Level of implementation of the acquis communautaire (cont'd)

**OTHER**

1. NEW ACT ON MEDICAL DEVICES (2008)

2. SPECIAL ORDINANCES REGULATING LICENSING OF RETAIL STORES, GMP REQUIREMENTS, VIGILANCE OF MEDICAL DEVICES (2008-2009)

# Programme with EMA

**CO-OPERATION WITH EMA**

- Participation of ALMP representatives in EMA`s working groups/parties and Committees
- Participation of ALMP representatives in focused trainings on specific technical topics
- Eudravigilance
- Jointly organised conferences



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# Programme with EMA (cont'd)

**JOINTLY ORGANISED CONFERENCES**

1. Conference on "Pharmaceuticals' Regulation – Croatia's Road to EU Membership", 2-3 April 2007, Split
2. "Séminaire sur les développements récents en Pharmacovigilance européenne et la gestion du risque", 9-10 June 2008, Vukovar
3. Conference on "'EU Regulatory Network - Challenges and Opportunities for Croatia", 13-14 November 2008, Rijeka



## Programme with EMA
## Challenges, Solutions, Outcomes

**CHALLENGES**

-dossier upgrading, transition period ?

-maintaining one operational regulatory framework in the pre-accession period

- having ready to implement another one fully transposed for the day 1 of the accession

- How to implement topics covered by EC regulations (variations, ANTP, orphans...)

- How to address global public health issues

## Programme with EMA
## Challenges, Solutions, Outcomes

**SOLUTIONS AND OUTCOMES**

-promoting dialogue with stakeholders and exchanging experiences with international partners in the field of pharmaceutical legislation

-fostering the international and regional network (expanding the nCADREAC agreement)

-Sthrenghtening the capacity building (Twinning light project)

-Promoting work and resource sharing

-Closer co-operation with internat'l network (observership in PhWP, CHMP, CMD(h), HMA ?)



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## International conference announcement

1. OMCL Annual Meeting, 17-21 May 2010, Split
2. WHO National Centres Meeting, 2011, Dubrovnik
3. AFSSAPS-ALMP Conference, 2011, Dubrovnik
4. EMA-ALMP Conference, 2011, Zagreb