

Why should be member of EDMA on Local Level?



SIEDMA - Slovenian National Association (NA) of EDMA

SIEDMA is NA member of EDMA



- | | |
|--------------------------|----------------------------|
| 1. AFPM Romania | 13. IPDDL Poland |
| 2. APIFARMA Portugal | 14. ODGH Austria |
| 3. Arted Turkey | 15. SAI-LAB Finland |
| 4. Assobiomedica Italy | 16. SEDMA Slovakia |
| 5. BIVDA UK | 17. SEIV Greece |
| 6. CZEDMA Czech Republic | 18. SIDIV France |
| 7. DADIF Denmark | 19. SVDI Switzerland |
| 8. DIAGNED Netherlands | 20. Swedish Labtech Sweden |
| 9. FENIN Spain | 21. UNAMEC Belgium |
| 10. HIVDA Hungary | 22. VDPGH Germany |
| 11. IMDA Ireland | 23. SIEDMA Slovenia |
| 12. LabNorge Norway | |

SIEDMA members (2016)



Representing:

Representing:

Representing:



Ortho Clinical Diagnostics



Why should be member of SIEDMA

Main Objective:

- Evaluate, pursue and represent common IVD industry interests on a local level.

SIEDMA objectives

- ▶ **IVD promotion**
 - ▶ creating added value to different stakeholders, g from legislators to Pharma, patients
- ▶ **Common voice**
 - ▶ enable respectful partnership with authorities and professional organizations
 - ▶ speak as one voice to different stakeholders
 - ▶ support implementation of EU regulations (also reducing local specifics)/anomalies

Why should be member of SIEDMA

SIEDMA objectives

- ▶ **Foster and maintain professional ethics and fair competition principles**
 - ▶ increase ethical attitude in business at all levels and stakeholders
 - ▶ promote MedTech Code of ethics
 - ▶ promote vigilance in Labs and Pharmacies, to Diabetologists
 - ▶ lead as example
- ▶ **Other common interests**
 - ▶ MIS EDMA – market intelligence
 - ▶ co-operation with local EUCOMED NA (SLO-MED)

Important projects

IVD promotion

- ▶ www.siedma.si
- ▶ „The future of Laboratory medicine“ in cooperation with „Medicina danes“ medical newspaper, we prepared special edition on IVD in 2014. The edition was distributed to regular subscribers (DRs, HCs), all labs, diabetologists, pharmacies.
- ▶ Participating in „MedTech Week“ (2015)
- ▶ Kick off meeting with Clin. Chemistry Ass. on **Lab Test Online** for Slovenia (2015).



Important projects

IVD promotion

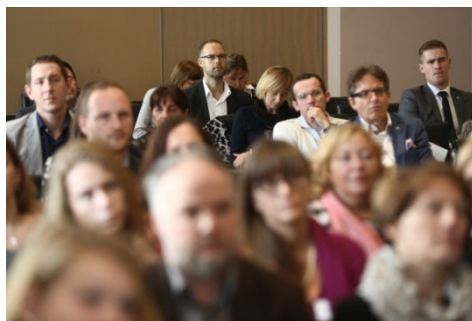
- ▶ Round table on „Central Public tenders“ (2015)

INTERVJU: VODJA RAZISKOVALNE GRUPE ZA RAZISKAVE TRGA IN EKONOMSKIH POLITIK PRI ZDROŽENJU EDMA IN SVETU MEDICINE YVES VERBOVEN

»Ste sredi zdravstvene reforme in imate veliko priložnost za spremembe pri javnih razpisih«



Javnih razpisov se držijo obtožbe o neučinkovitosti, saj se o njih poroča predvsem v primeru revizij in ugotovljenih nepravilnosti. Veliko je nezadovoljstva, ker je glavno merilo izbora (prej pogosto) najnižja cena. Ta mora biti le eno izmed meril, pravi strokovnjak za ocenjevanje medicinskih tehnologij Yves Verboven.



CENTRALNI JAVNI RAZPISI
Kako do boljše kakovosti in
transparentnosti v zdravstvu?

Spoštovani,

vljudno vas vabimo, da se nam pridružite
12. novembra v hotelu Slon v Ljubljani,
med 10.00 in 12.30, na problemski konferenci,
kjer bomo razpravljali o stanju, spremembah
in izboljšavah trga medicinske laboratorijske
diagnostike v Sloveniji.

Udeležba je brezplačna,
prijava pa zaradi zagotovitve prostih mest obvezna.

Oddate jo lahko na: www.medicina-razpisi.si

Veselimo se srečanja z vami!

Important projects

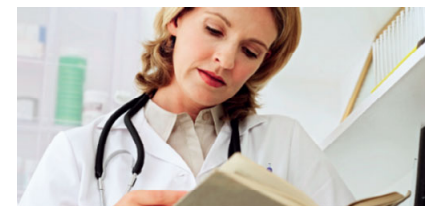
Common voice to authorities and professional organizations

- ▶ Regular communication with Agency of drugs and Med. devices in Slovenia (**JAZMP**) in the areas of vigilance and new EU IVD regulation.
- ▶ SIEDMA represents industry in **The Commission for the preparation of technical standards for Medical devices in Diabetes**.
- ▶ Participating in discussion with Ministry of Finance and Ministry of Health on the **VAT issue of controls and calibrators** (2012, 2015)

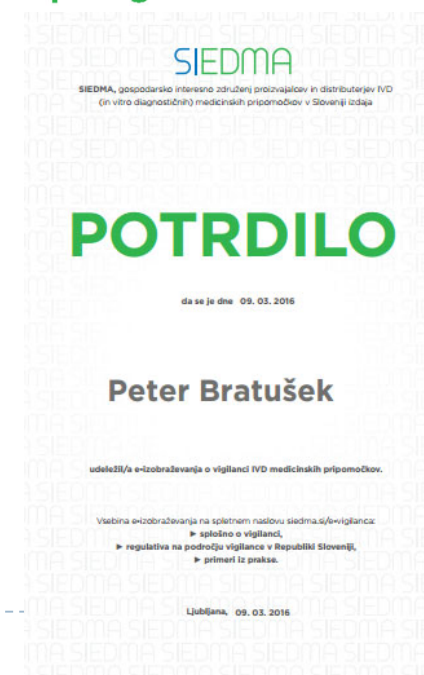
Important projects

Foster and maintain professional ethics and fair competition principles

- ▶ Update of local **Code of Ethics** and **Comission for Ethics** established in 2014 .
- ▶ **MedTech Code** presentation and promotion on the market (the 2016 goal!)
- ▶ **e-vigilance** – e-learning (www.siedma.si/e-vigilanca) tool was developed to promote vigilance and appropriate handling of incidents in the labs.
- ▶ SIEDMA supports education **on vigilance to students at Faculty of Pharmacy, Ljubljana.**



Tudi vi imate
**pomembno vlogo
pri vigilanci.**

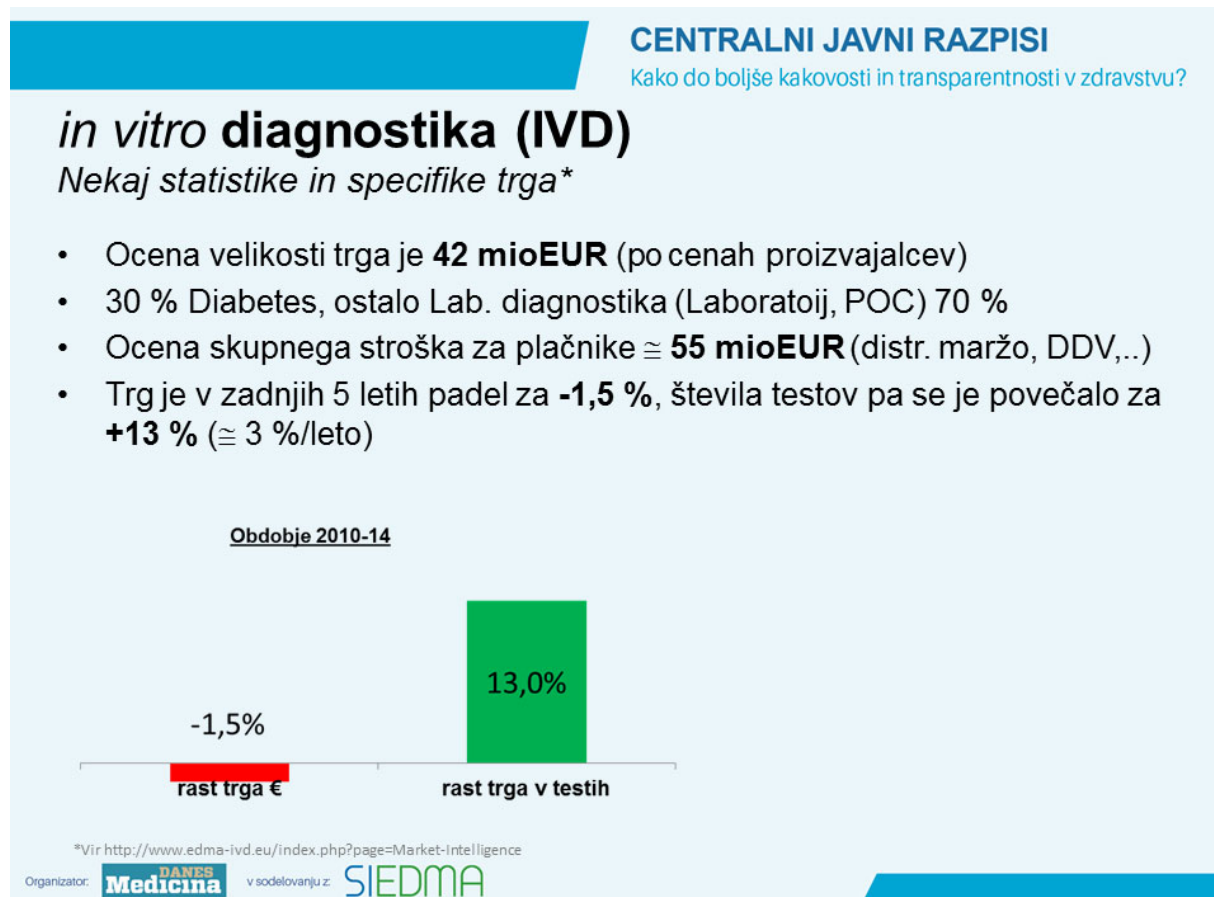


Vigilance – a system of reporting incidents in medical devices area

Important projects

Other common ineterests

- ▶ MIS EDMA represents the refference data of Slovenian IVD market
- ▶ Slovenian Statistics report available also in „European IVD Market Statistics Report “



Data presented by SIEDMA at the Round table on „Central Public tenders“ (2015)