



Human and veterinary pharmaceuticals regulation

Towards EU accession: Serbia's regulatory challenges, expectations and opportunities

29-30 November 2010

Hotel Holiday Inn, Belexpo Convention Centre, Belgrade, Serbia



Republika Srbija
Ministarstvo zdravlja
Ministarstvo poljoprivrede,
šumarstva i vodoprivrede,
Uprava za veterinu

Republic of Serbia
Ministry of Health,
Ministry of Agriculture, Forestry
and Water Management,
Veterinary Directorate



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

“Phasing-in” issues in Marketing authorizations – Lithuanian perspectives

Romaldas **Maciulaitis** and Gintautas **Barcys**
State Medicines Control Agency



VALSTYBINĖ VAISTŲ KONTROLĖS TARNYBA
PRIE LIETUVOS RESPUBLIKOS SVEIKATOS APSAUGOS MINISTERIJOS



Topics

- Introduction of Lithuanian national competent authority SMCA
- Challenges in implementation of ACQUIS
- Lessons learned

Lithuanian NCA: Small Agency in a Small Country

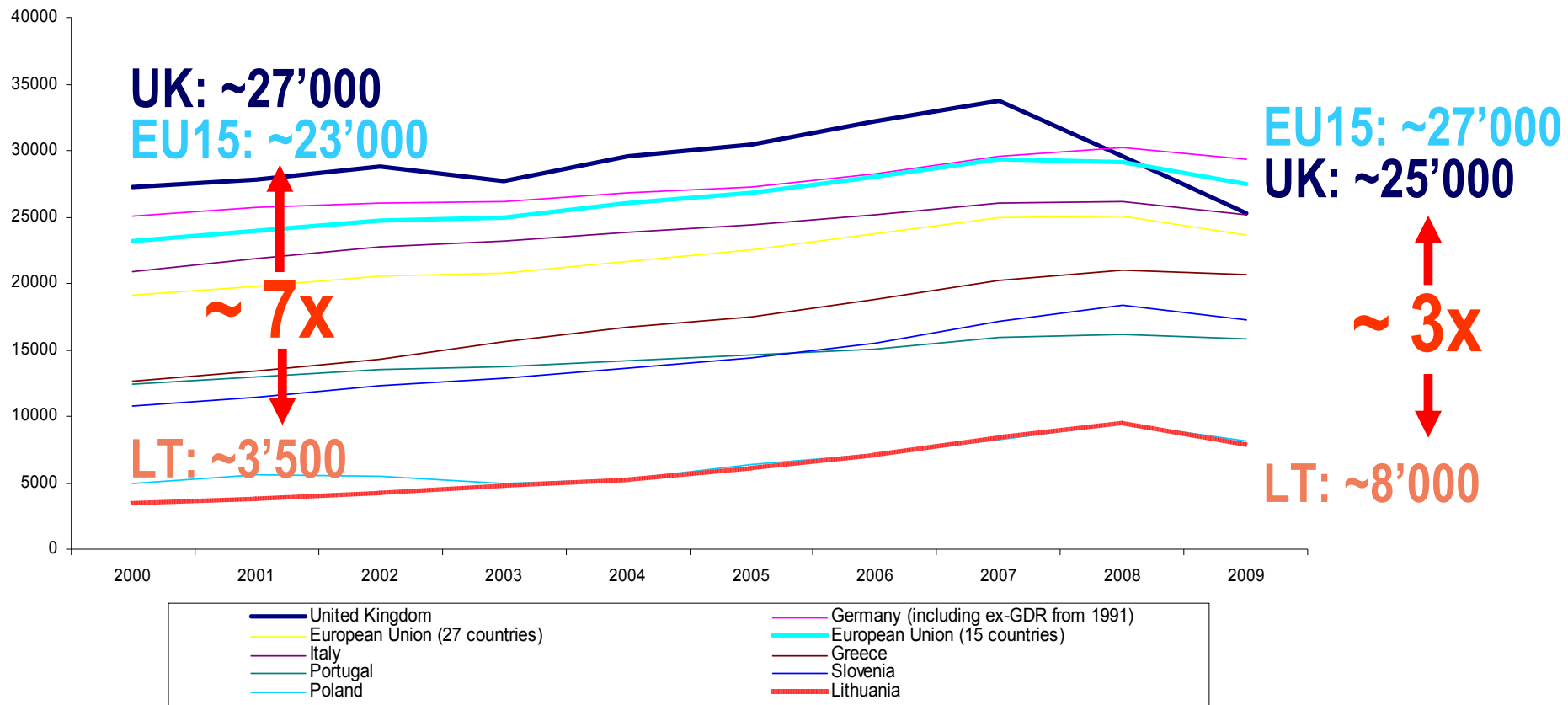


Population (in millions):
from 3.7 (in 1990)
to ~3.3 (in 2010)

Monthly salaries (netto):
from ~ \$100 (in 1995)
to ~ \$1000 (in 2010)



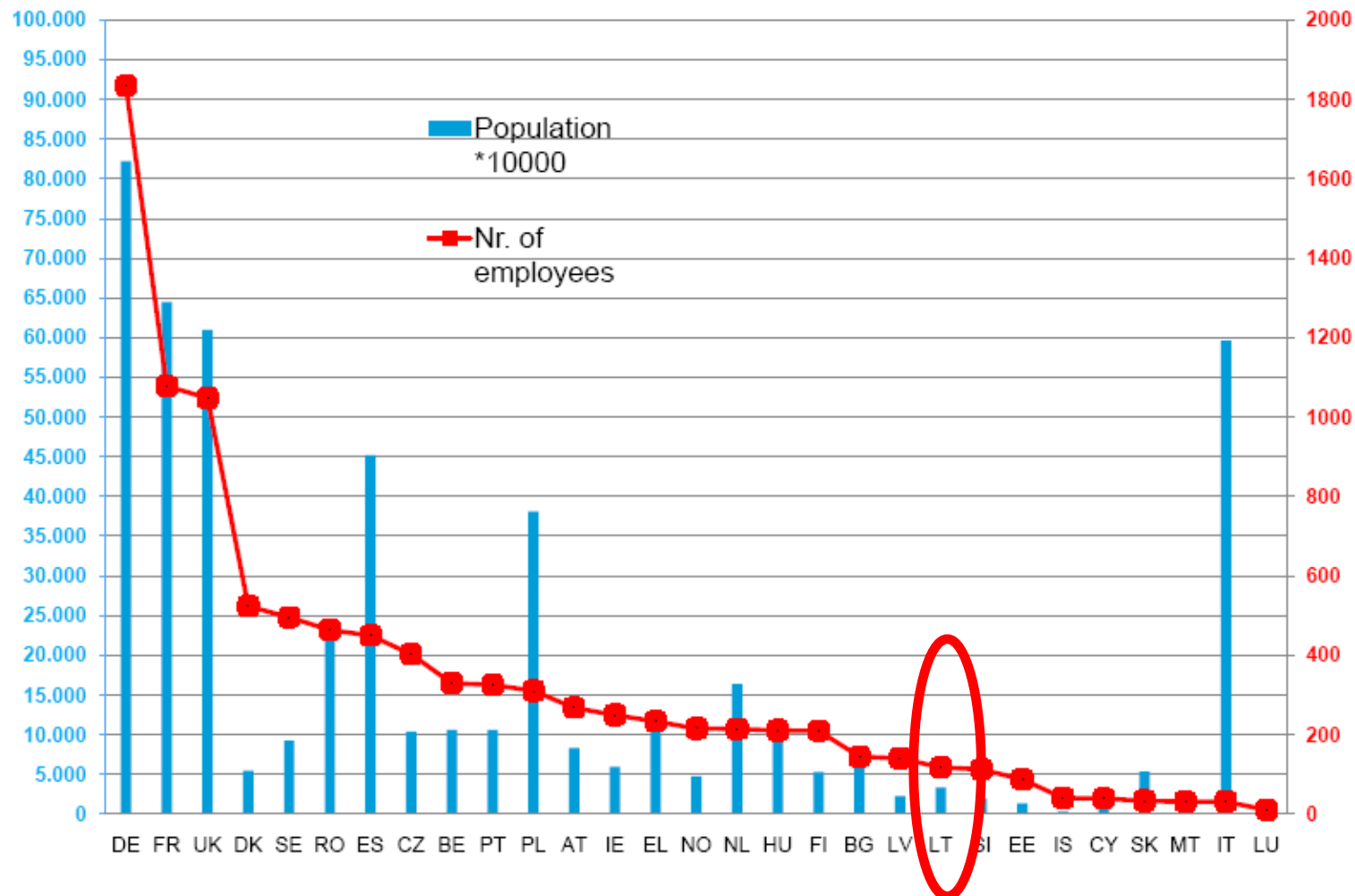
GDP per capita evolution in LT and EU (€)



Populations and employees per Agencies

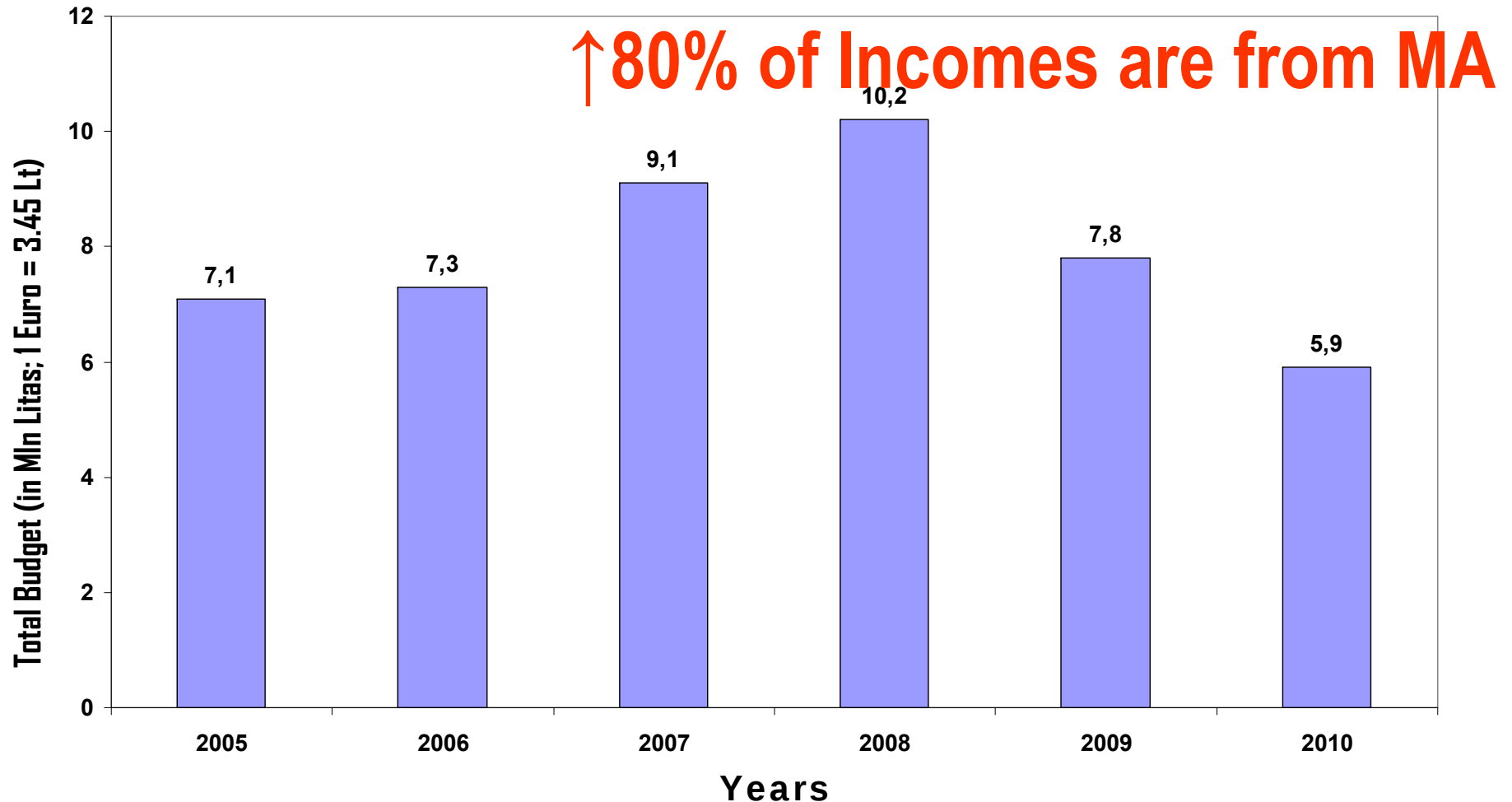
Population x 1.000

Employees /NCA





Budgetary Conditions of the Agency





Challenges during “Phasing-in” and implementing ACQUIS (1 / 2)

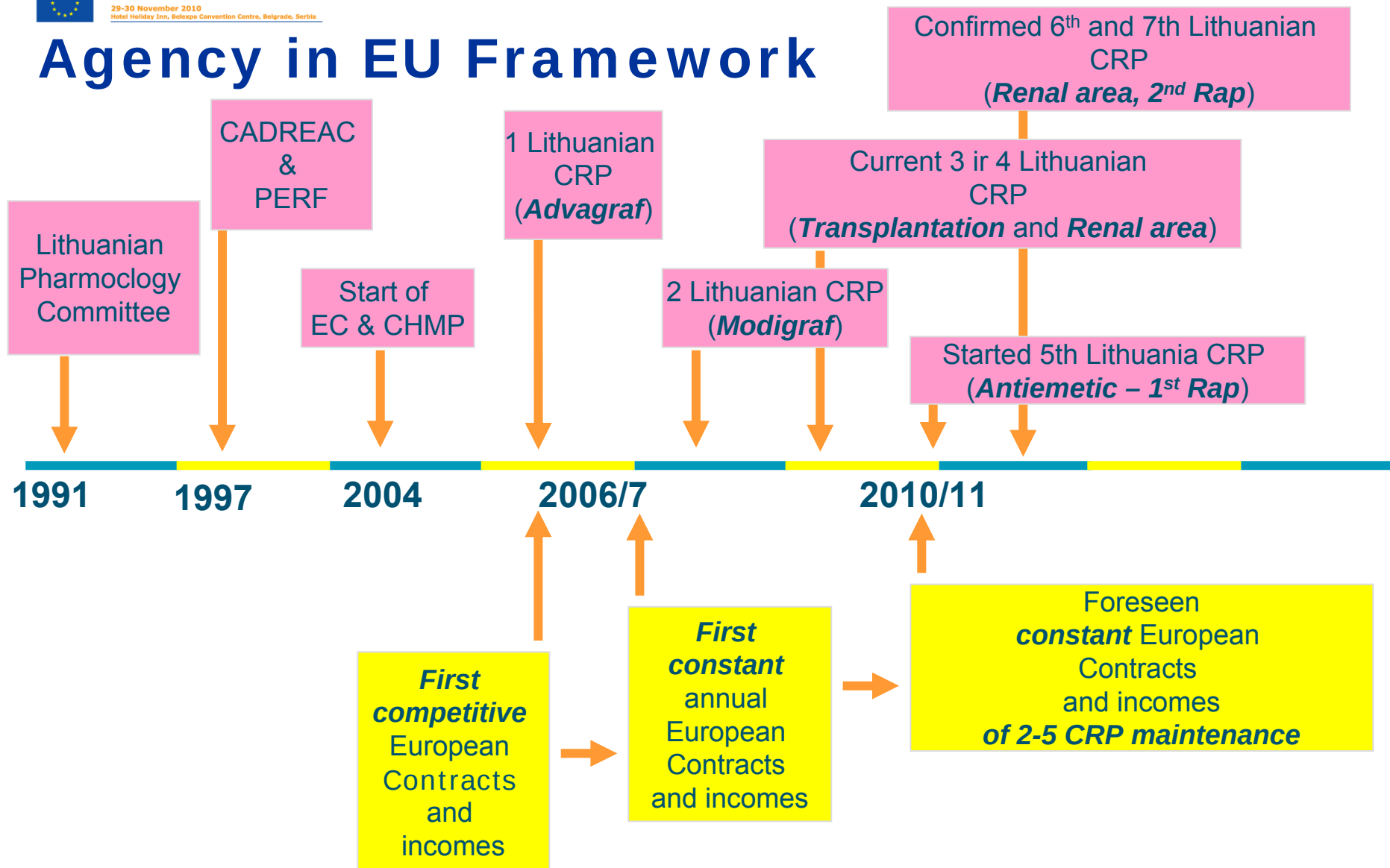
- Continuously changing ACQUIS
 - (2 Pharma laws → 1 Consolidated law + Orders)
- Challenges with SOPs, deadlines, communication with applicants
- Too limited number of priorities from the activities expected by upper government bodies



Challenges during “Phasing-in” and implementing ACQUIS (2 / 2)

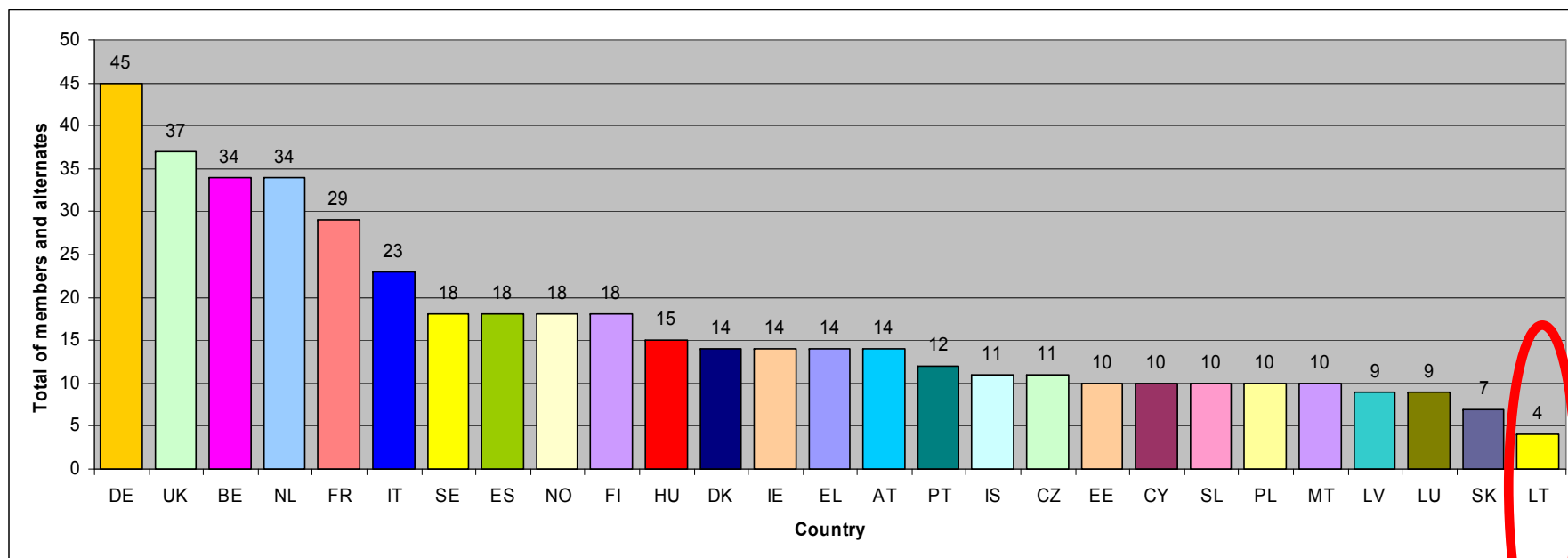
- Too long time for MA procedures and sometimes just minimal quality in performances
- Too big turnover of experts makes additional burdens to keep constant national competence
- Need for competence development for active participation in EU regulatory framework

Agency in EU Framework



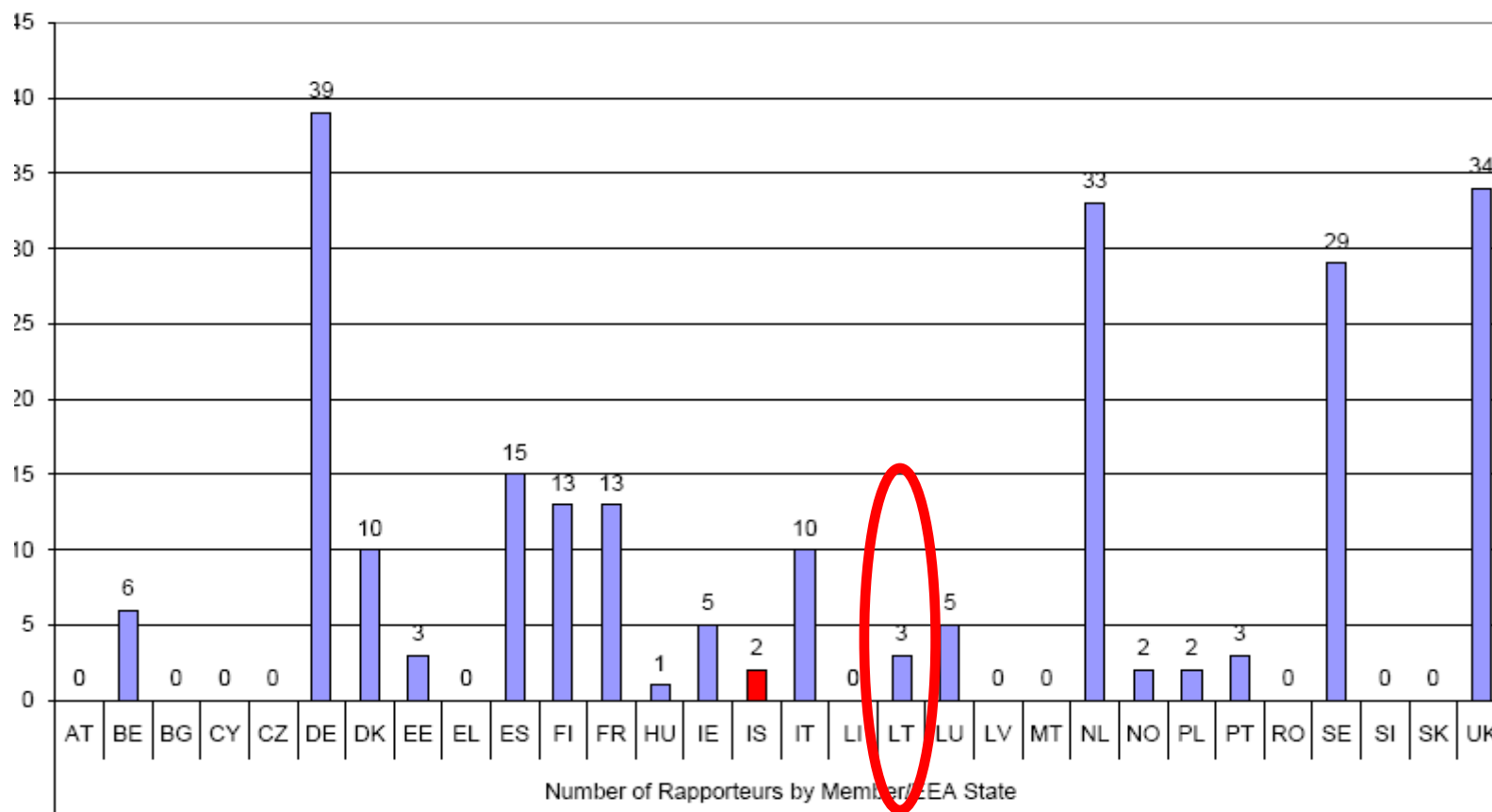


Count of members and alternates in the CHMP and WPs





Concept papers / Guidelines developed by the CHMP in 2007





Impact on national authorizations

- Conversion of numbers of herbal and “medical purpose” products based on revised benefit/risk assessments
- Not-upgraded dossiers
- Authorization of ex-concertation type of products
- Availability problems, including limited consistency in supplies to pharmacies



After 5 years we finally confirmed a status of food supplement for popular MP

Validolis – ne vaistas, o maisto papildas

2009-07-21

Valstybinė visuomenės sveikatos priežiūros tarnyba prie Sveikatos apsaugos ministerijos (VVSPT) informuoja, kad nuo š. m. liepos 1 dienos validoliu prekiaujama kaip maisto papildu. VVSPT atkreipia dėmesį į tai, kad maisto papildas yra ne vaistas, o maisto produktas, neturintis gydomojo poveikio ir nevartotinas jokioms ligoms gydyti.

Lietuvoje validolis nebepriskiriamas vaistams nuo 2003 m. Valstybinė vaistų kontrolės tarnyba atsisakė jį registruoti kaip vaistą, nes nėra įrodyta, kad jis padėtų sergant kokia nors liga. 2004-aisiais validolis buvo įtrauktas į medicininės paskirties produktų sąrašą, kuris š. m. liepos 1 dieną panaikintas.

Ilgą laiką validolis vartotas esant širdies veiklos sutrikimams.



Food supplement



Iron products



Medicinal product



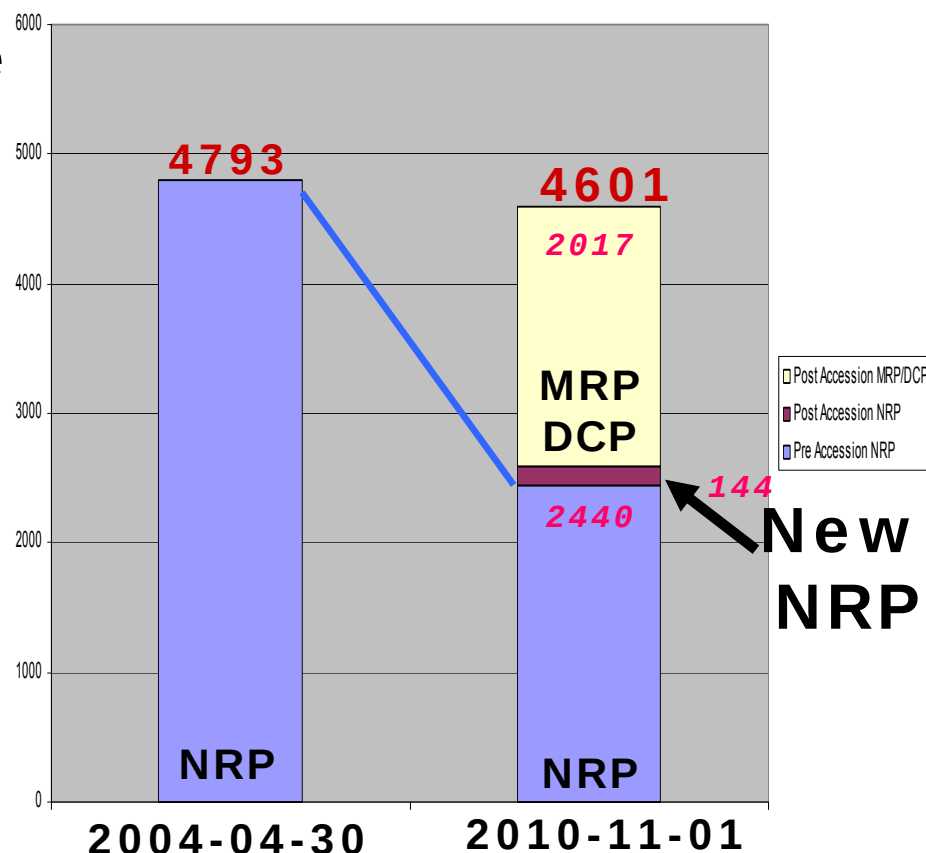


Impact on National MA procedures

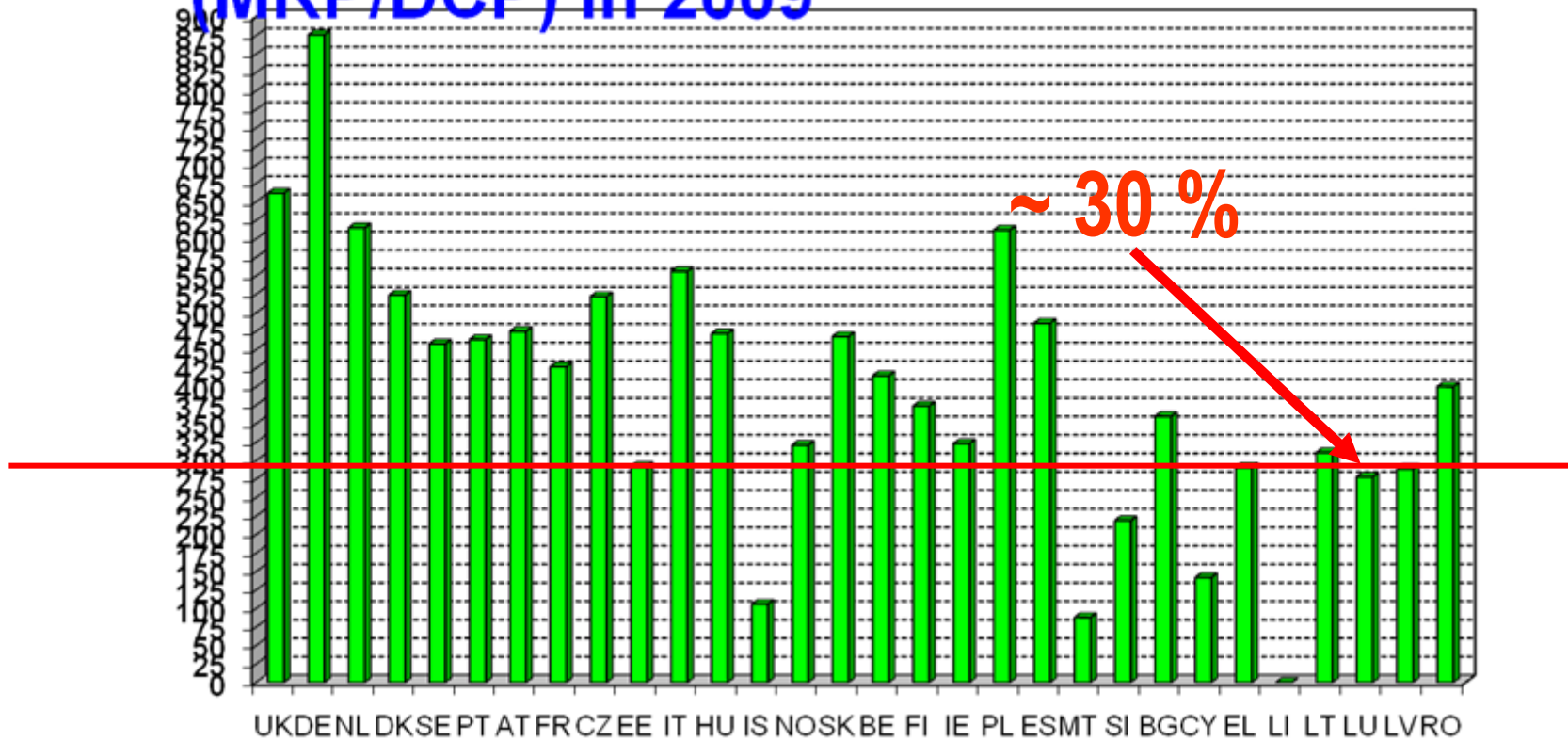
Evolution of MA in Lithuania (including all strengths and forms)

Dramatically changed profile
of procedures:

- decrease in NRPs
- constant increase in MRP/DCP
- introduction of CRPs



CMS for MA-Applications (MRP/DCP) in 2009



Availability problems used to be observed once upon a time....

As a consequence, medicines availability is not always sufficient with the **absence** of **essential** ones, such as:

- Anticoagulants – **heparinum**
- Hormones – **hydrocortisonum**
- Antibiotics – **izoniazidum**, **amphotericinum**, **tazocinum**
- Cardiovasculars – **nitroglycerinum**, **clonidinum**, **labetololum**, **prazosinum**, **norepinephrinum**, **digoxinum inj.**, **verapamilum inj.**
- Immunosuppressants: **tacrolimus (all formulations)**, **MMF i/v**, **ciclosporinum i/v**
- Other – **40% glucosum**, **calcium i/v**, and various **antidotes**

Employed solutions to availability problems in Lithuania

Different **additional measures** have to be introduced to overcome the shortages putting with an additional burden to all stakeholders:

- **Patient named** supply chains
- Special **hospital supply** arrangements
- **Prioritizations** in MA procedures, including the for variations

Lessons learned: 10 “DON'Ts”

- (1) Do not mix regulatory pharma science with economic politics
- (2) Do not limit NCA to national competences only
- (3) Do not spend too much on not essential activities
- (4) Do not just simply copy CRP practices for NRP purposes
- (5) Do not delegate national expert(s) to EMA without clear objectives



Lessons learned: 10 “DON'Ts”

- (6) Do not experiment in key areas
- (7) Do not assume that applicants know always what they are doing
- (8) Do not intent to be ideal everywhere from the very beginning
- (9) Learn how to translate scientific judgment into legal language
- (10) and...

10. Do not miss opportunity to build / negotiate the Strategy on NCA Evolution

PENKIOLIKA LIETUVOS RESPUBLIKOS VYRIAUSYBIŲ, 1990-2010 M.

Vyriausybė, ministras pirmininkas	Laikotarpis
Pirmoji Vyriausybė atkūrus Lietuvos nepriklausomybę, ministrė pirmininkė Kazimira Danutė Prunskienė	1990 03 17 – 1991 01 10
Antroji Vyriausybė, ministras pirmininkas Albertas Šimėnas	1991 01 10 – 1991 01 13
Trečioji Vyriausybė, ministras pirmininkas Gediminas Vagnorius	1991 01 13 – 1992 07 21
Ketvirtoji Vyriausybė, ministras pirmininkas Aleksandras Algirdas Abišala	1992 07 21 – 1992 12 12
Penktoji Vyriausybė, ministras pirmininkas Bronislovas Lubys	1992 12 12 – 1993 03 10
Šeštoji Vyriausybė, ministras pirmininkas Adolfas Šleževičius	1993 03 10 – 1996 02 23
Septintoji Vyriausybė, ministras pirmininkas Laurynas Mindaugas Stankevičius	1996 02 23 – 1996 12 04
Aštuntoji Vyriausybė, ministras pirmininkas Gediminas Vagnorius	1996 12 04 – 1999 06 01
Devintoji Vyriausybė, ministras pirmininkas Rolandas Paksas	1999 06 01 – 1999 11 03
Dešimtoji Vyriausybė, ministras pirmininkas Andrius Kubilius	1999 11 03 – 2000 11 09
Vienuoliktoji Vyriausybė, ministras pirmininkas Rolandas Paksas	2000 11 09 – 2001 07 04
Dvyliktoji Vyriausybė, ministras pirmininkas Algirdas Mykolas Brazauskas	2001 07 04 – 2004 11 29
Tryliktoji Vyriausybė, ministras pirmininkas Algirdas Mykolas Brazauskas	2004 11 29 – 2006 07 06
Keturioliktoji Vyriausybė, ministras pirmininkas Gediminas Kirkilas	2006 07 06 – 2008 11 17
Penkioliktoji Vyriausybė, ministras pirmininkas Andrius Kubilius	2008 11 17 – ?

* Pastaba: įskaitant pratęstus vyriausybių įgaliojimus

Stabilization
In EU

Lessons learned: 10 “DOs”

- (1) Strategic positioning of NCA in Big EU
- (2) Follow examples of those NCAs that do control flow of their budgets
- (3) Invest into key national scientific competences
- (4) Make use of administrative support available from EU, including IT developments
- (5) Utilize worksharing opportunities of EU regulatory framework



Lessons learned: 10 “DOs”

- (6) Start contributing to EU network asap
- (7) Employ regional initiatives (multilingual packages)
- (8) Initiate pro-active agreements with other stakeholders, including the applicants
- (9) Select 4 – 5 persons for key areas and motivate them to do long-term commitments
- (10) and...



10. Arrange consultations within a EU regulatory framework

Thus, You are welcome to meet
the experts of
The State Medicines Control Agency



GintautasBarcys@vvkt.lt
RomaldasMaciulaitis@vvkt.lt



Conclusions

- Small NCA will not necessary get smaller
- Learn from mistakes of others
- Invest into local competences and explore EU opportunities



Special thanks to:

- Dr **Sif Ormarsdóttir**, Islandic MCA, CHMP London
- Dr **Truus (G.M.) Janse-de Hoog**, Chair CMD (h), London
- Dr **Daniel Brasseur**, Former Chair of CHMP, London



VALSTYBINĖ VAISTŲ KONTROLĖS TARNYBA
PRIE LIETUVOS RESPUBLIKOS SVEIKATOS APSAUGOS MINISTERIJOS

Let's do all to meet in EU

Thank you

ian Challenges during Phasing-In