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

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Agencija za lekove i medicinska sredstva Srbije
Medicines and Medical Devices Agency of Serbia

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EU/EC Acquis caummunautaire: perspectives from a member state

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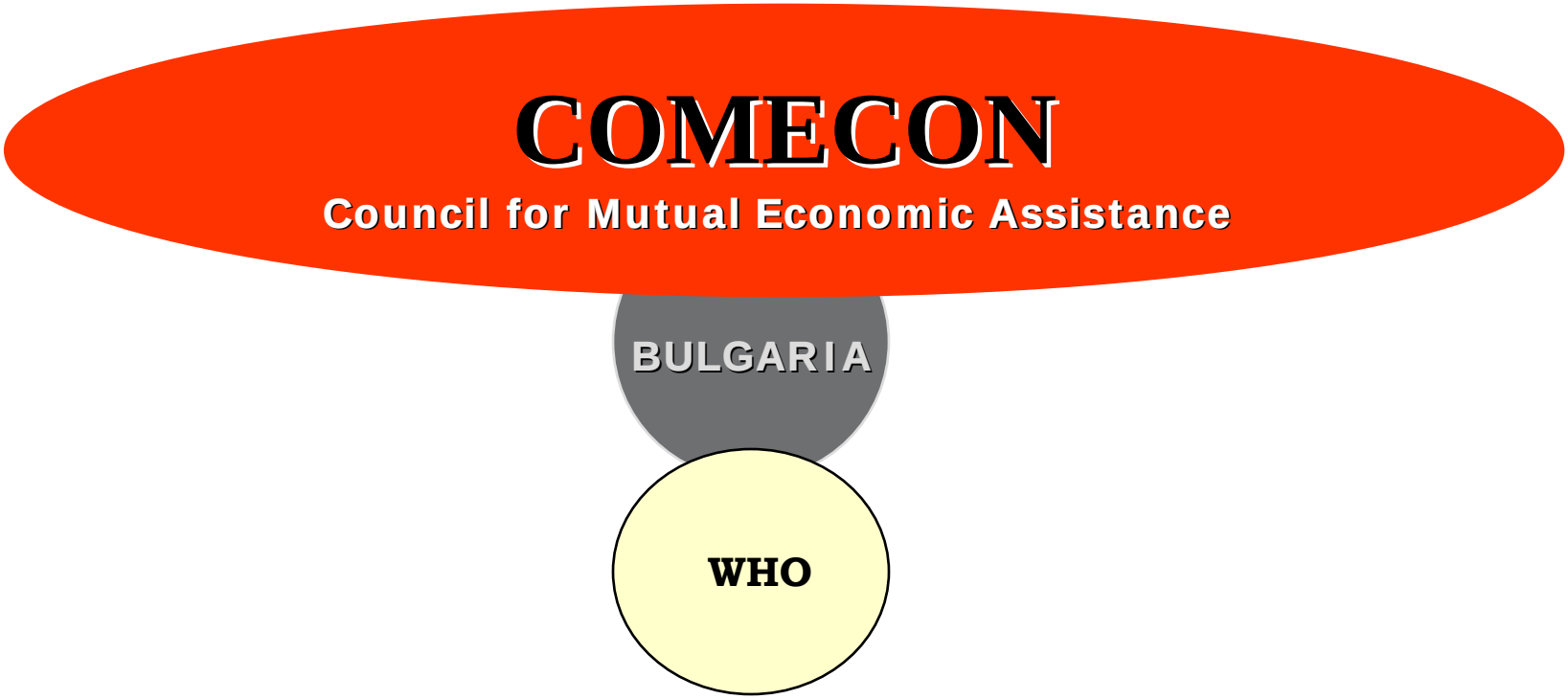
BG Pharma Sector before 1989

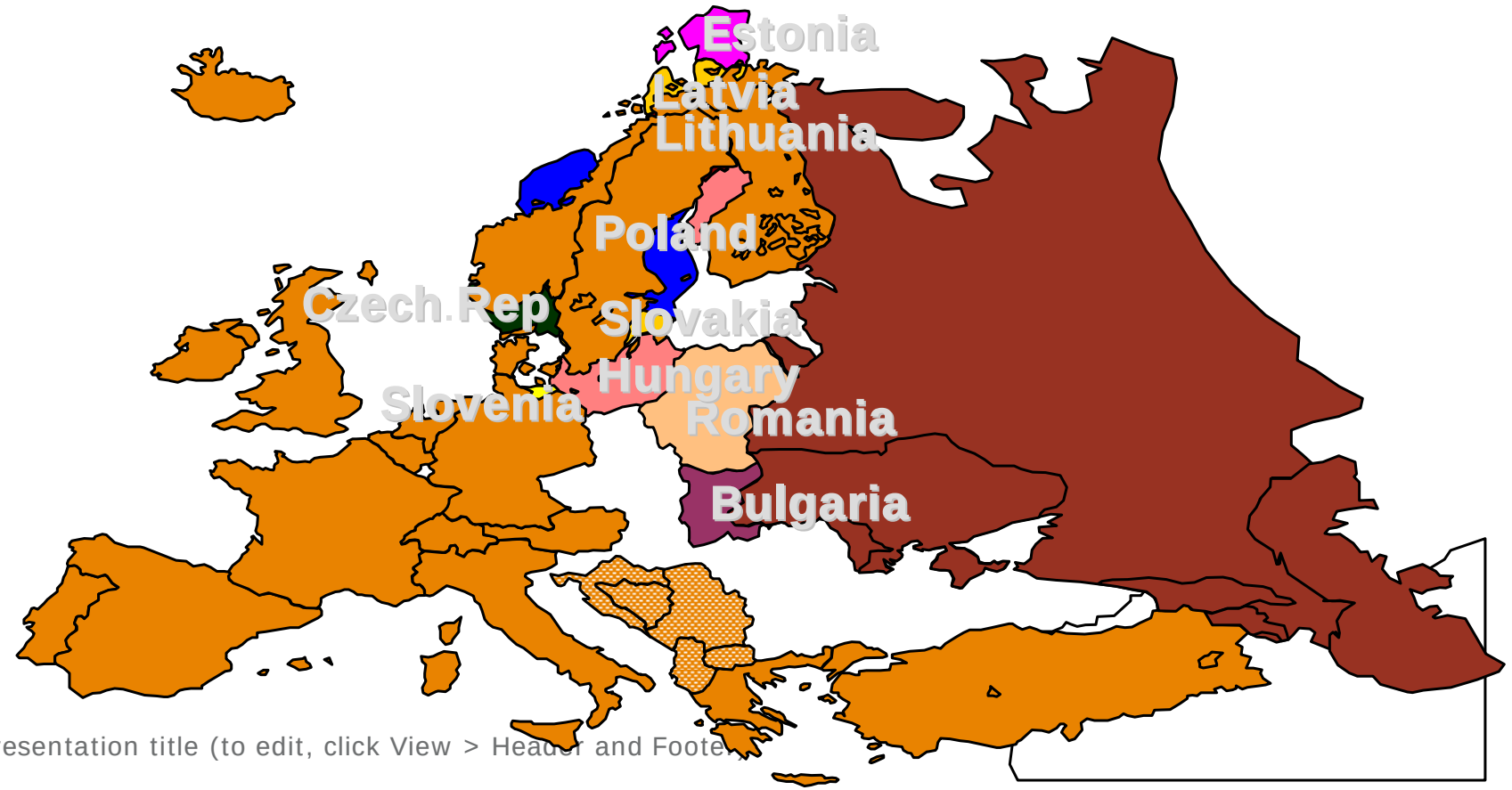
- Fully centralized
- One state owned pharmaceutical holding – ***PHARMACHIM*** (the only BG producer, wholesaler, importer, exporter, distributor of MPs and MDs)
- Institute for State Control of Drugs (laboratories for analyses + PhVG + Commission for Registration of MPs)

Harmonisation Activities before 1989



9 November 1989

European borders between CEE and EU were removed but divergences appeared



Divergences between EU and CEE

- Inadequate political instruments
- Feeble civic culture
- Different institutional and capacity development
- Week administrative capacity
- Incoherence in standards
- Disharmony in regulations and procedures

No influence on the Acquis caummunautaire according to country preferences and action capacities

PHARE BG Project 1993-1996
Targets

- Capacity building
- Institutional building
- Implementation of A.C. in national pharmaceutical law

PHARE BG Project 1993-1996
Instruments

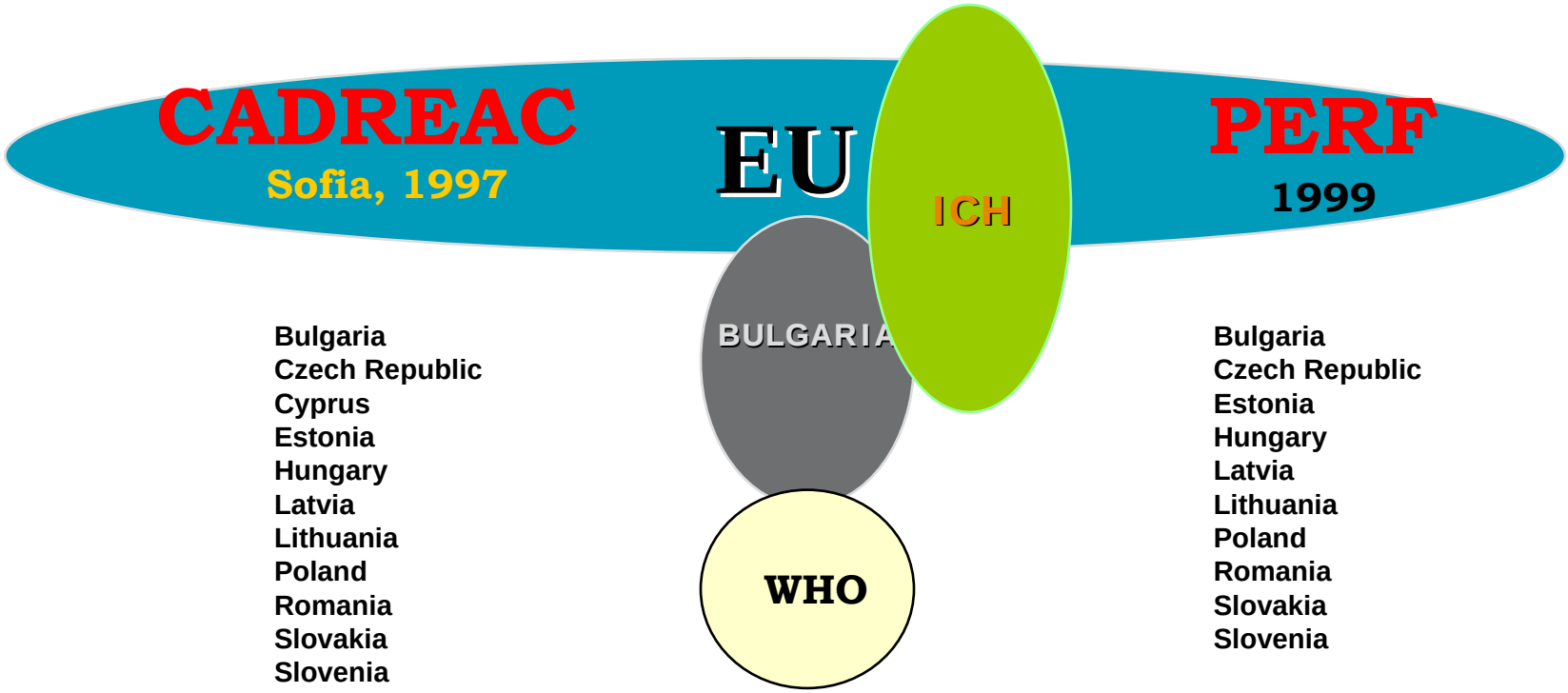
- Study tours to the EU DRAs
- Experts visits from EU DRAs
- Seminars in Bulgaria (with the industry)

***Contributing countries* – At, Be, De, Dk, Es, Fi, Fr, Nl, Pt, UK**

PHARE BG Project 1993-1996 Achievements

- New **Drug Law** (1995) + 32 bylaws based on 10 EU directives / ICH guidelines
- Transformation of ***Institute for State Control of Drugs*** into Natl. regulatory body **= Agency**
- Implementation of EU regulatory requirements in dossier assessment (Q+S+E), GMP, GCP, GLP, GDP, Pharmacovigilance, Telematics, etc.

Harmonization Activities after 1997



Bulgaria
Czech Republic
Cyprus
Estonia
Hungary
Latvia
Lithuania
Poland
Romania
Slovakia
Slovenia
Russia*
Turkey*
Ukraine*
Belarus*

Bulgaria
Czech Republic
Estonia
Hungary
Latvia
Lithuania
Poland
Romania
Slovakia
Slovenia

** - Observers*

CADREAC

Initiated in 1997 in Sofia and renewed on 1 May 2006

- Simplified EU centralized procedure introduced for the CADREAC members
- Exchange of safety and pharmacovigilance data
- Set-up of regulatory networking with MSs

PERF

Boosted mutual understanding and confidence between EU and CEE

- Inter-agency training (joint activities, exchange of scientific information and staff, attendance at EU regulatory W. Party meetings, case studies)
- Expanded networking between EU/CEE Drug Regulatory Authorities

Achievements

Regulatory environment

- Regulatory system - improved overall consistency and visibility
- Regulatory standards - open, visible, predictable and time-controlled
- Regulatory authority – transparent, efficient, flexible and independent in decision-making

Achievements

Harmonized Regulatory Practices

•Quality management systems -

- Defined performance indicators

- Transparent cost-effective procedures

•Dossier assessment - high standards + consistent in methodology and criteria

•Telematics
- secure, sound and reliable network
- usage of appropriate and compatible technology

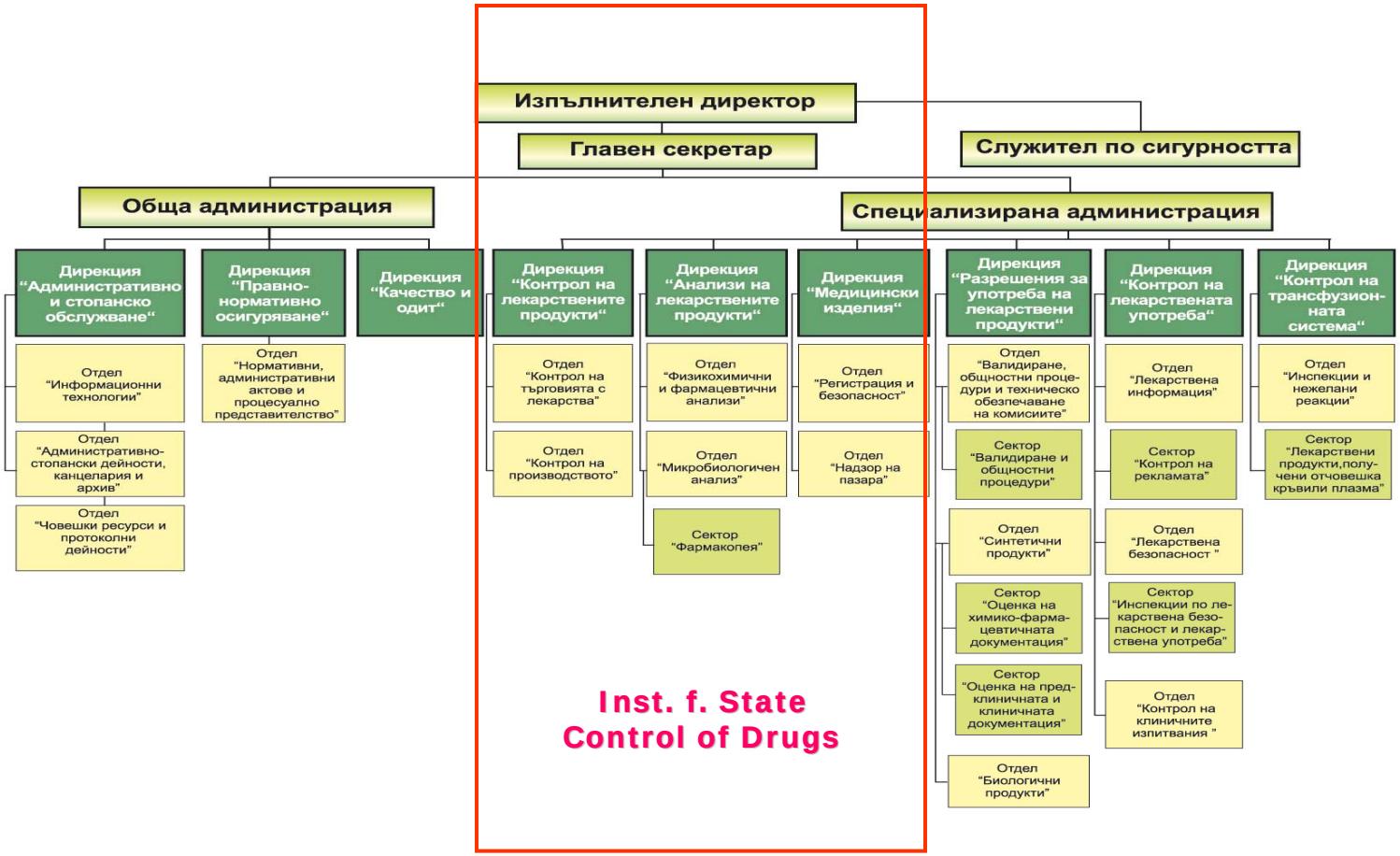
BG Drug Law in 2003

- Administrative procedure – less burden
- “Competent person”
- Data exclusivity – 10 + 1 yr for new indication
- Test and trials of generic not contrary to patent rights or to SPC – (Bolar)

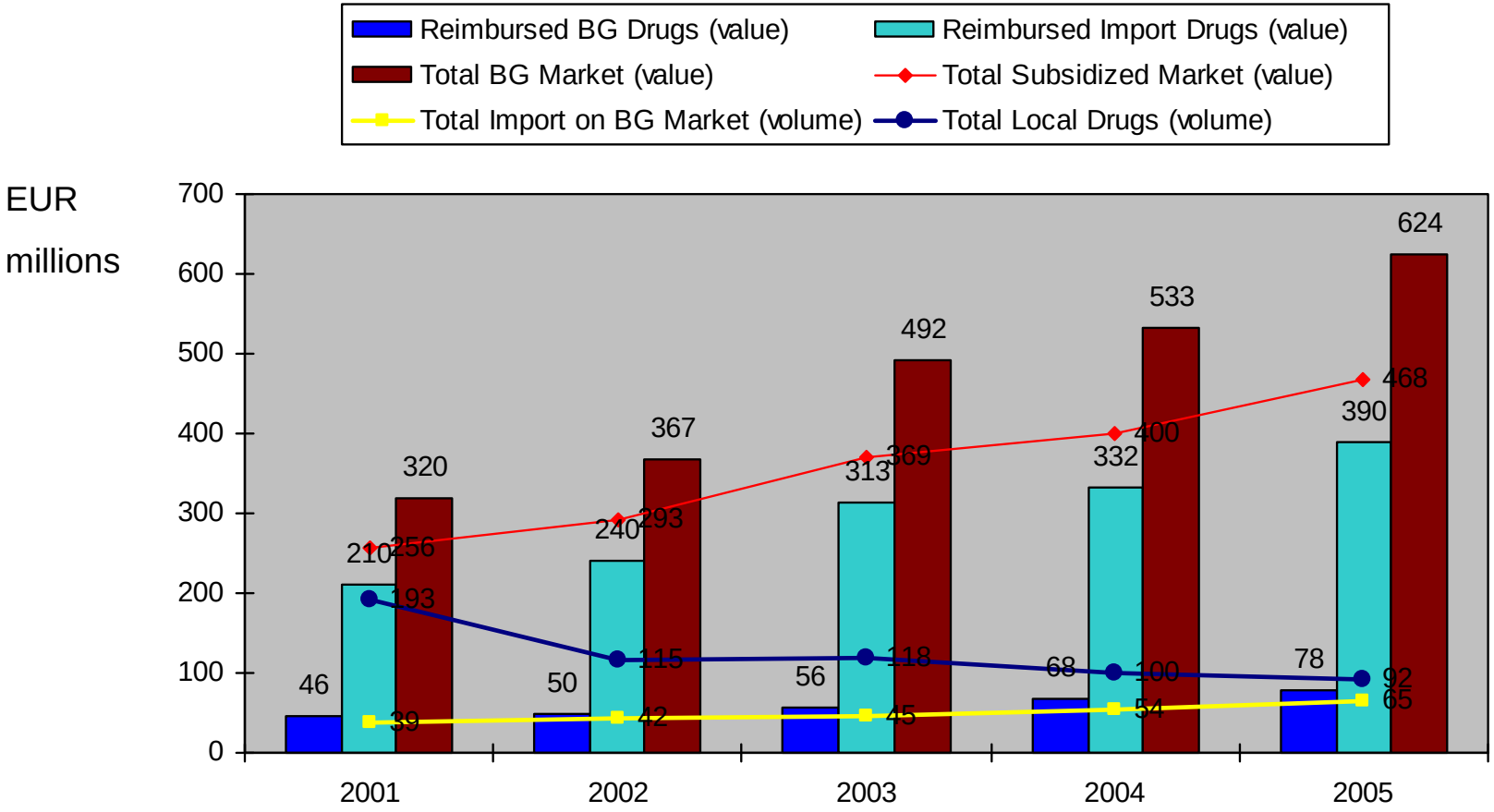
BG Drug Law in 2007

- **No transition period, no closed doors**
  - New format of applications – Feb 07
  - DMF for API introduced
  - CTD format for all new submissions and renewals
  - New registration procedure for national application
  - CP – all national registrations terminated
  - CTA format introduced for clinical trials
  - Bioequivalence – GLP requirements

Bulgarian Drug Agency



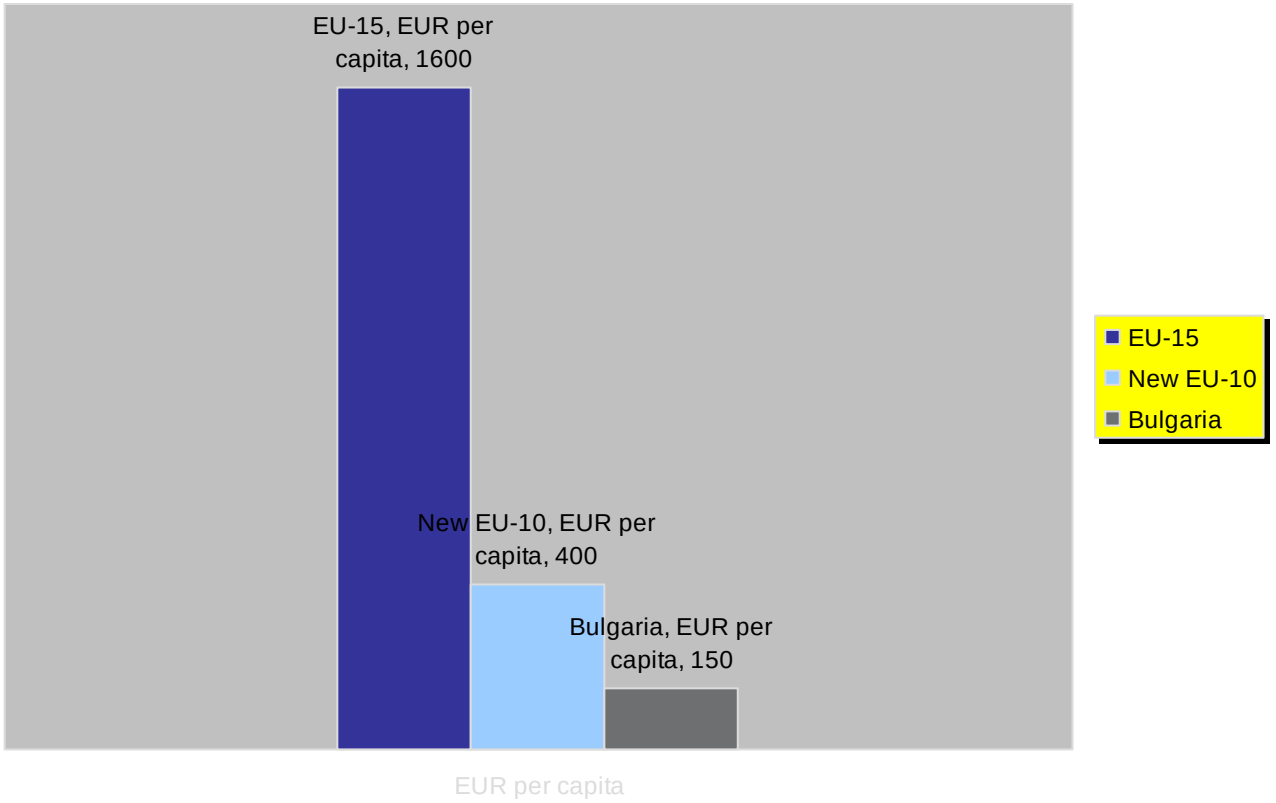
Bulgarian Drug Market



Source: BDA/ABPhM

Pressure on Health Care Budget

Gap in Health Care Budget



Outcomes for the Patients

- Quicker access to new therapeutic alternatives
- Enhance quality of life
- Better for patients information on MP

- *Regulatory information – public available*
- *Compulsory order + readability of PILs*
- *Braille*

Outcomes for the BG Pharma Business

- **Around 80 private manufacturers**
- **Over 300 private importers/distributors**
- **Over 4000 private pharmacies**

Local Manufacturers under the EU Regulatory Rules

- Consolidation of the local business - big companies have become bigger, small ones have disappeared
- Companies' portfolio have been shortened, optimized and prioritized
- New generic molecules were developed or in-sourced from attractive suppliers

Local Manufacturers Management

- Operations management – building new production facilities and maintaining GMP and other quality assurance standards
- Human resources management – cutting costs and raising the standard of professional expertise
- Financial management – raising the value for shareholders

Other Opportunities

- Geographical expansion & pipeline development and growth through penetration in new markets, acquisitions at national and above national level, Outsourcing R&D and production
- Cross-licensing and partnerships with EU based companies
- Community registration procedures

Outcomes for the Local Industry

- Technological modernization
- Increased technical expertise
- Strengthened competitiveness and research capacity
- Minimized political pressure