



Opportunities for Change

Vakhtang Megrelishvili
2009

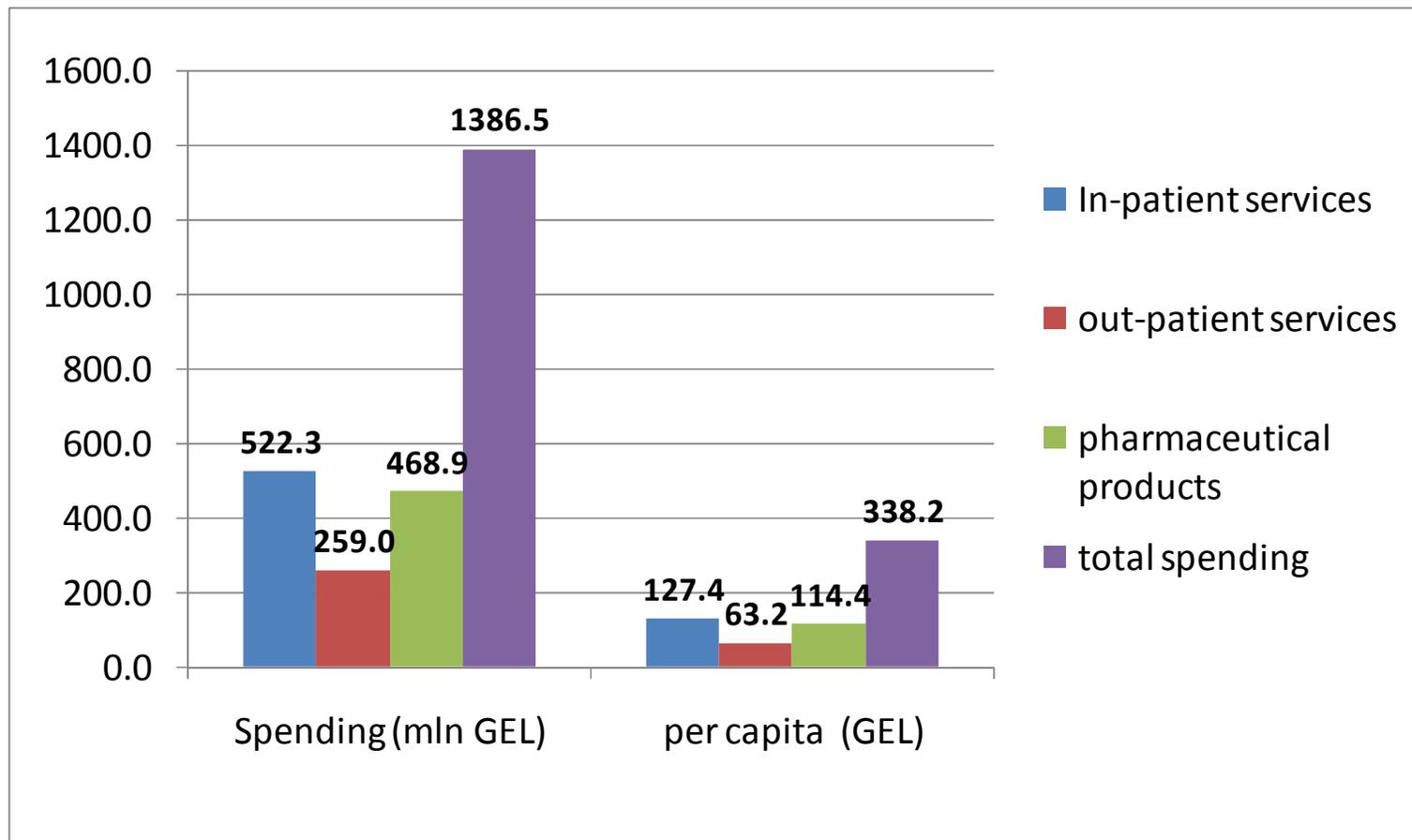
The Presentation Topic

- The importance of the pharmaceutical sector;
- Recommendations rendered to the Ministry of Labor, Health and Social Affairs in 2007;
- Accepted and ignored recommendations;
- Further improvement of legislation.

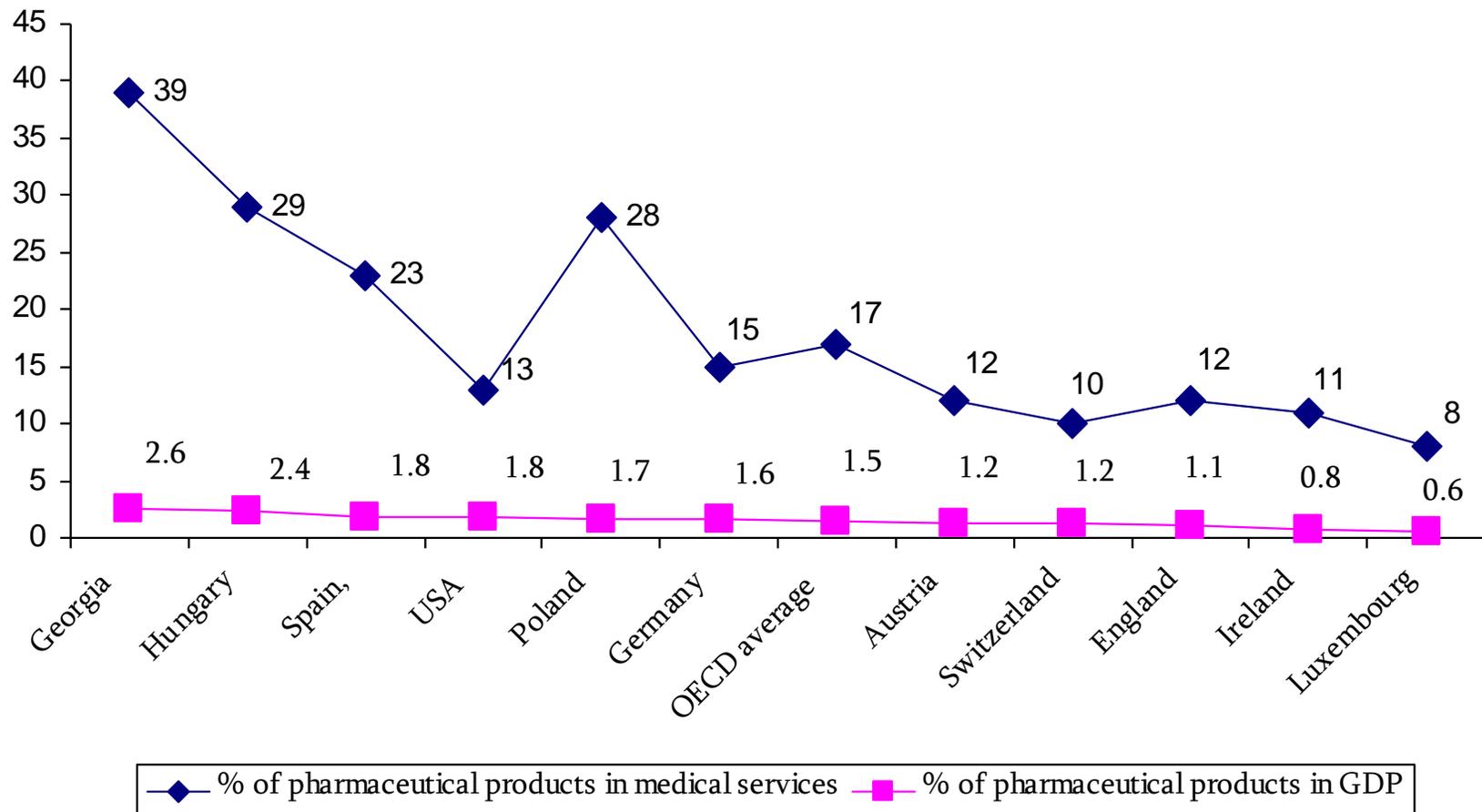
The Importance of the Pharmaceutical Sector

- The share of pharmaceutical products in total spending on medical services;
- Pharmaceutical products:
 - Security;
 - Quality;
 - Efficacy.

Health Care Spending Structure



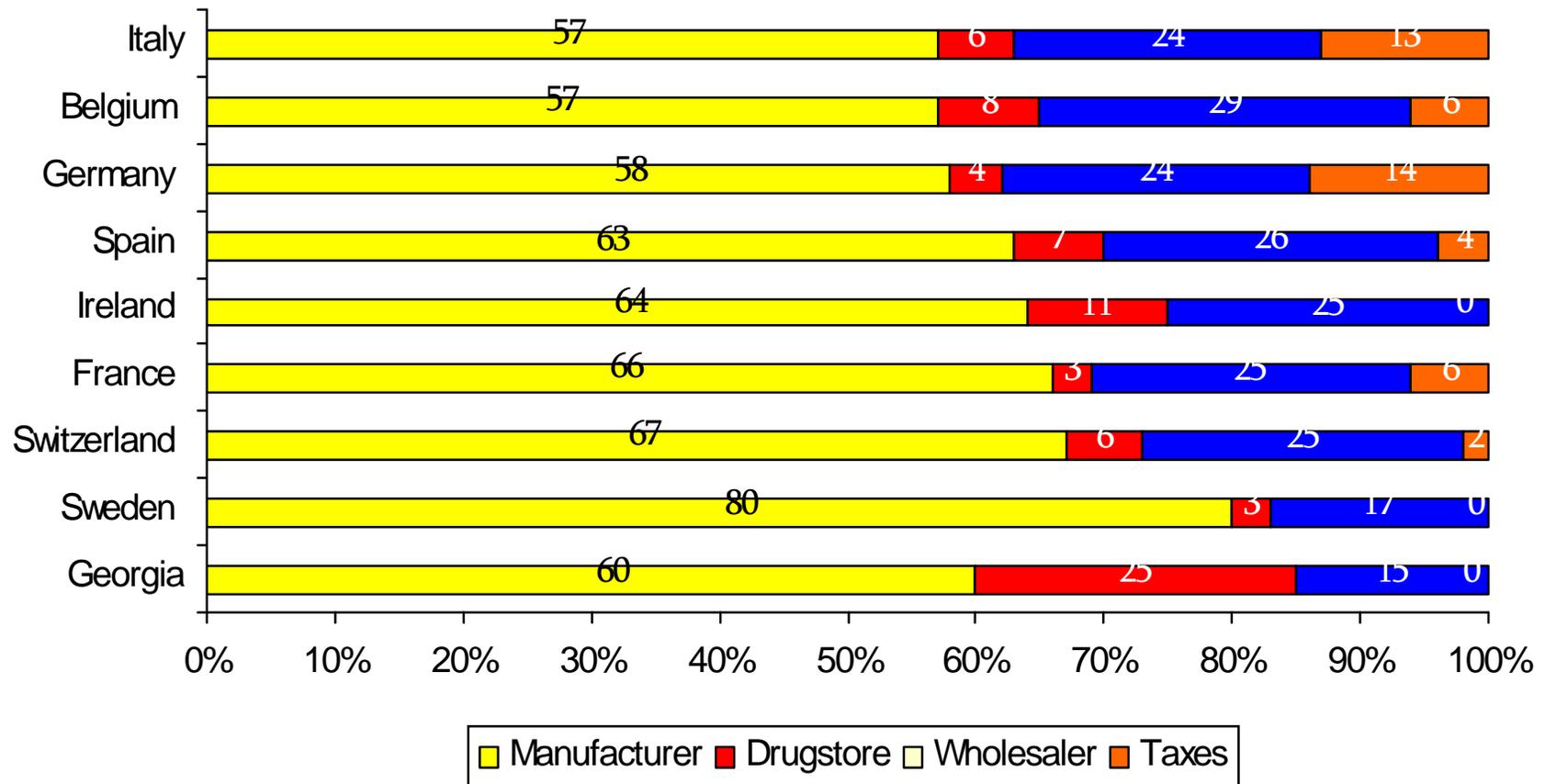
The Share of Pharmaceutical Products in the Consumption of Medical Services



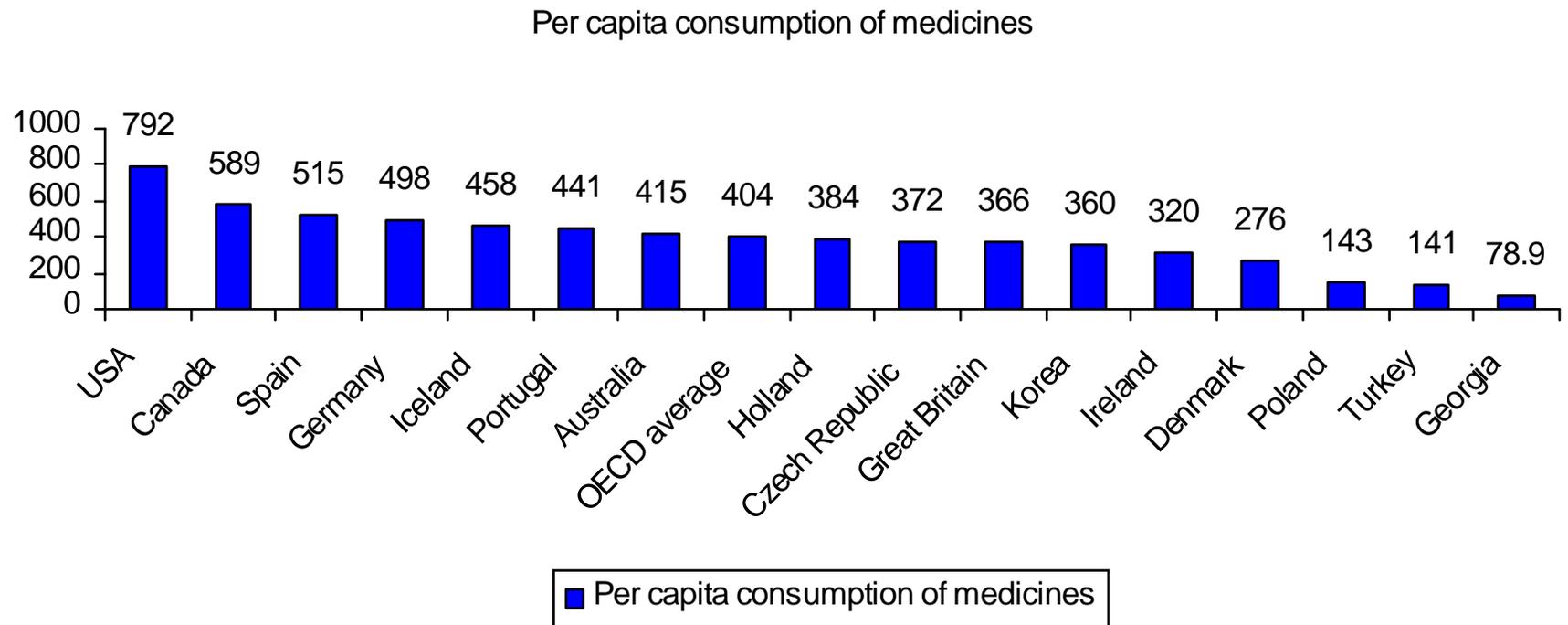
Reasons for Retail Price Differences across Countries

- **Manufacturer's price;**
 - **Is related to market specifics :**
 - **The number of consumers;**
 - **The income of consumers.**
- **The amount added at the wholesale distribution stage;**
- **The amount added in the retail network;**
- **Tax burden.**

Product Price Components in the Retail Network



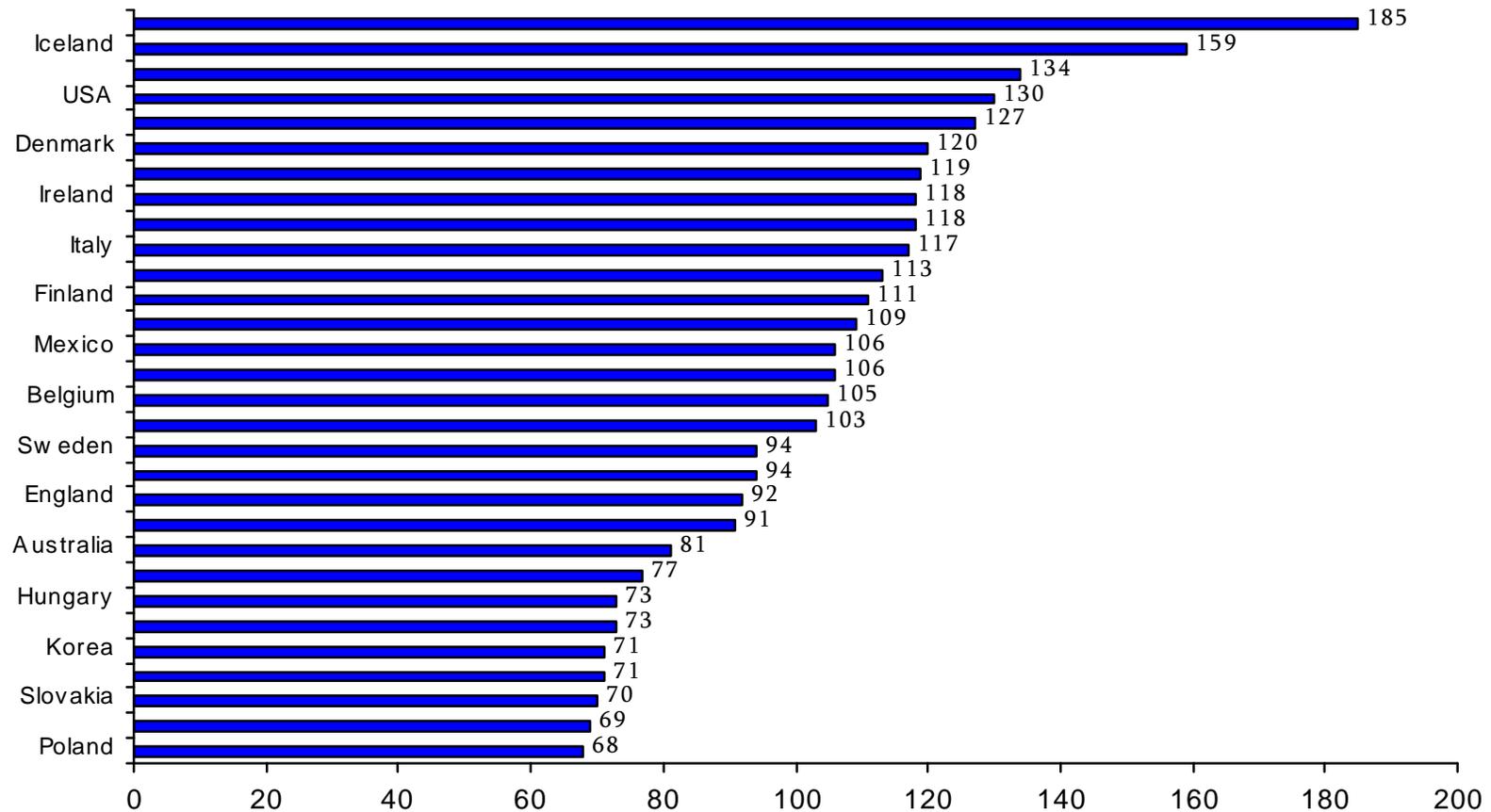
Per Capita Consumption of Pharmaceutical Products in OECD Member States



Source: OECD Health Data 2007 and authors' estimates.

Example # Retail Price Differences across OECD States

OECD=100



Series 1

Recommendations rendered to the Ministry of Labor, Health and Social Affairs in 2007

Policy Goals and Tasks

- Goal:
 - Increase access to products through supporting the creation of a competitive environment on the pharmaceutical market.

Policy Goals and Tasks

- **Tasks:**
 - **Lifting administrative barriers to entry of products to the pharmaceutical market – Differentiating the registration procedure;**
 - **Supporting the imports of pharmaceutical products that are adequately investigated and accepted to the market by developed countries;**
 - **Introducing effective tool for the identification of a person responsible for product adulteration and heightening administrative and criminal responsibility in order to prevent product falsification.**

Pharmaceutical Sector Regulation Concept

- The key issue in the regulation of the pharmaceutical sector is the identification of a person that bears responsibility for the safety, quality and efficacy of the product;
 - Either a product manufacturer or trade license holder is responsible;
 - The state shares that responsibility by allowing the product to enter the market.

Pharmaceutical Sector Regulation Concept

- The essence of changing the policy in terms of responsibility is adding the person that bears responsibility;
- In a number of cases the manufacturer's responsibility transfers to the importer;
- The state remains responsible.

Regulation

1. One procedure for each product (Equivalent to market authorization);
 2. Control over the distribution and sale of pharmaceutical products through licensing entities (permit control);
 3. Control over advertising;
 4. Control over the import and export of products (permits);
 5. Control over professional activities.
1. Differentiated registration;
 2. The expansion of the network of distribution and realization of pharmaceutical products through decreasing barriers to entry to the market;
 3. Banning mass media advertisement of pharmaceutical products or vice versa; removing administrative supervision;
 4. Wide use of a serial control tool (traceability);
 5. Freedom of professional activities.

Registration

- Registration - A procedure of state investigation of a pharmaceutical product, on the basis of which the permit for the circulation of the product on the market is issued;
- Goal - Prove the safety, quality and efficacy of the product and secure traceability.
 - Safety, quality and efficacy
 - Good Manufacturing Practice (GMP);
 - Pre-clinical and clinical investigation.
 - Traceability:
 - Product labeling;
 - Product analysis - methods and parameters.

Registration Procedures - Term and Price

- Same registration regime for all pharmaceutical products:
 - Registration term – 3 months;
 - Time given to remedy shortcomings - 2 months.
 - Registration procedure - 5 months.
- Registration fee (for most of the products) - 2500 GEL.

Recommendation – The Year 2007

Automatic Registration

A List - EU member states, Switzerland, the USA, Canada, Australia, Japan.

If this is technically possible, the inspection obtains the information necessary for identification;

If the importer presents the information that is essential for product identification

Registration takes 24 hours without fees

Simple Registration

B List drawn up by the government – May include Ukraine and others

If the entity seeking registration presents full information essential for the identification of pharmaceutical products

Registration takes 14 days without fees

Full Registration

Products registered by agencies of the countries not included in the A and B lists or the products that are presented for the first time for registration in Georgia

If the entity seeking registration presents full information essential for the identification of pharmaceutical products

The administrative body conducts full administrative and scientific investigation

Registration takes 60 days. The applicant is given 60 days to remedy shortcomings; a fee for a generic drugs is minimal; A fee for an innovative product is very high (for instance. 10 0000 GEL).

Production

- Gradual introduction of so-called Good Manufacturing Practice (GMP) guidelines over the period of 10 years;
- GMP guidelines will be introduced through gradual tightening of terms of issuing permits;
- The circulation of complementary (homeopathic, anthroposophical, homotoxicological etc.) remedies will not be regulated.

Distribution

- The key requirement for the distribution chain set by the state:
 - Secure traceability of a product;
 - Follow the terms of storage of medicines;
- An administrative tool of traceability:
 - Serial control
- Use:
 - The serial control would make it possible to detect and recall from the retail network the product announced defective for some reason;
 - In case of adulteration, detecting a person responsible for the adulteration in the distribution chain.

Retail Sales

Before Adopting the Law

- only I and II group drugstores maybe pharmaceutical product retail sellers

After adopting the law

- Drugstore – a pharmaceutical entity that provides a full package of services, including selling prescription medicines and preparing medicines following the prescription;
- Retail trade units (for example, supermarkets) – selling non-prescription medicines;
- Considering geographical conditions doctors will be authorized to sell pharmaceutical products (in villages).

Desirable Results of Pharmaceutical Policy

1. The prices correlated with the lower limit of international prices;
2. Fast entry of innovative products into the Georgian market;
3. An increased product range;
4. A decrease in the share of a pharmaceutical product price in the total price of medical services;
5. A big share of safe and quality products in the pharmaceutical market;
6. Improved availability of medicines (mostly in the regions).

Accepted and Ignored Recommendations

Recommendations	Accepted	Improving/Worsening
Differentiation of states in terms of their credibility - three regimes	Two regimes	Neutral change
Banning advertisement	Regulation of advertisement	Neutral change
Parallel Imports	Notification procedure	Technical replacement
Canceling regulation of homeopathic, herbal, anthroposophical and other remedies	Voluntary regulation	Neutral change
Banning registration	Permitted	Worsening
Canceling fees with some exceptions	Reduced volume	Worsening
A registration fee of an innovative product registered in Georgia for the first time – 100 000 GEL	Will not be shared	Important

Further Improvement of Legislation

- Integration into the information system of the regulating bodies of recognized states;
- Improvement of normative acts as needed;
- Changes required for the introduction of technologies against adulteration;
- Abolishing the law.

Other Issues

- Question -- Why does not the law require moving to the system of selling prescription drugs?
- Two answers:
 - World outlook:
 - The person has the right to decide himself/herself how to treat himself/herself;
 - Technical:
 - Resources needed for control, which is not limited to just checking whether a patient has a doctor's prescription or not; checking of the adequacy of treatment is also needed;
 - Medical services become more expansive.

Other questions

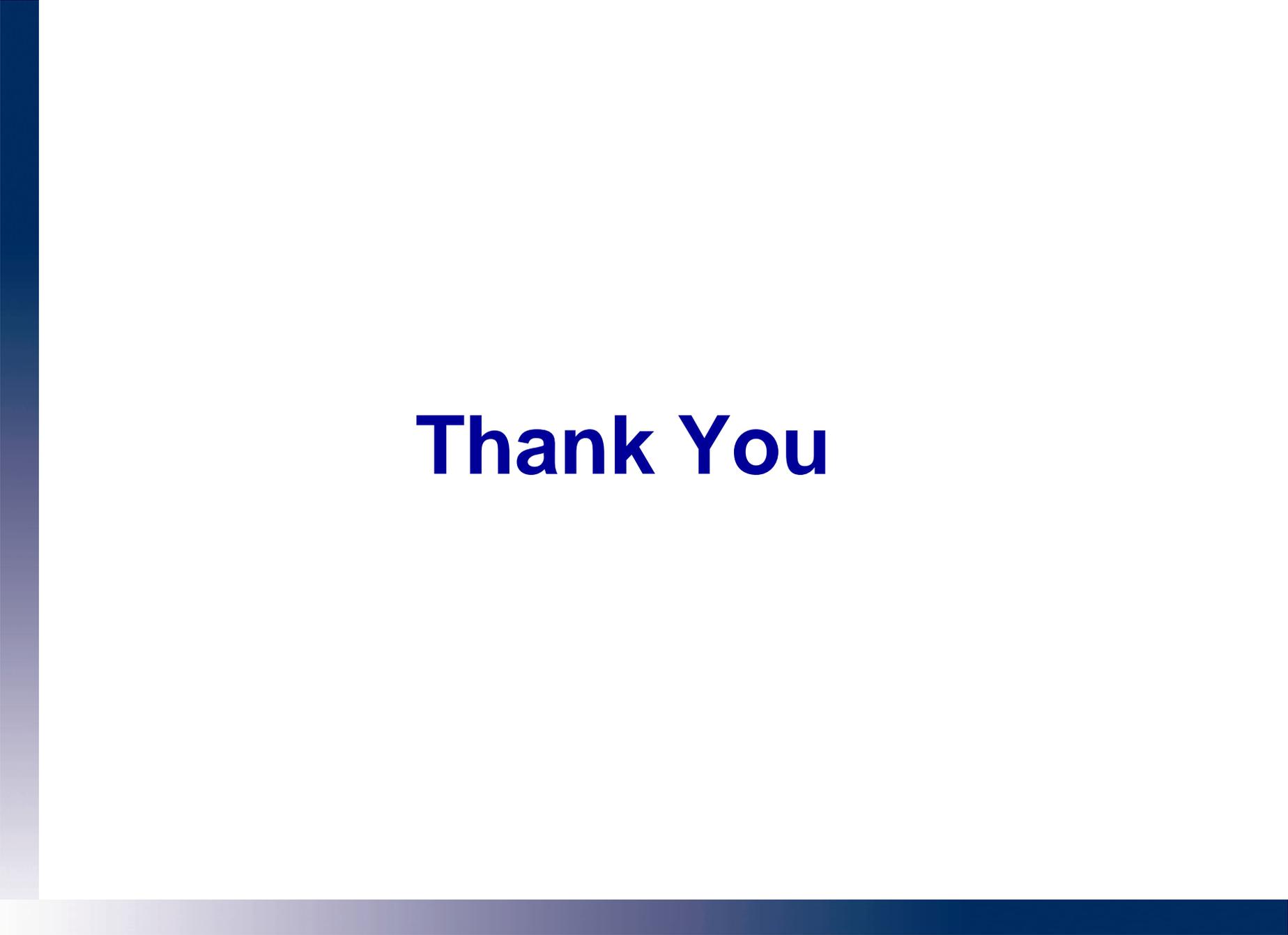
- Question – One month has passed since the law became effective. Is the impact of a new law already felt on the pharmaceutical market? We understand, however, it is too early to discuss the issue.
- Answer – It is good that we understand. There were some delays in issuing part of normative acts. Which means that by the time the law became effective, on October 15, amendments to the #282/n Order of the Minister on approving rules of furnishing drugstores and sanitary norms of exploitation issued on November 12, 2003 had not been, and are not still introduced to the electronic program of the Code. It has been prepared, though.

Other Questions

- Question – How can the non-governmental sector help?
- Answer:
 - Register medicines itself through the recognition regime;
 - Check the conditions in which medicines are stored and sold;
 - If violations are found demand responsive measures from regulators.

Other questions

- Question: Which are those recommendations that have not been taken into account, which poses a problem to the pharmaceutical market?
- Answer: The registration of innovative (non-generic) products in the Georgian market using the national regime is associated with high risk;
- We thought such products should not have been permitted into the Georgian market using the national registration regime, or a specifically high financial barrier should have been set, which would also make it possible to carry out a high quality scientific investigation.

A decorative L-shaped bar in the bottom-left corner, composed of a vertical bar on the left and a horizontal bar extending to the right, both with a blue-to-white gradient.

Thank You