

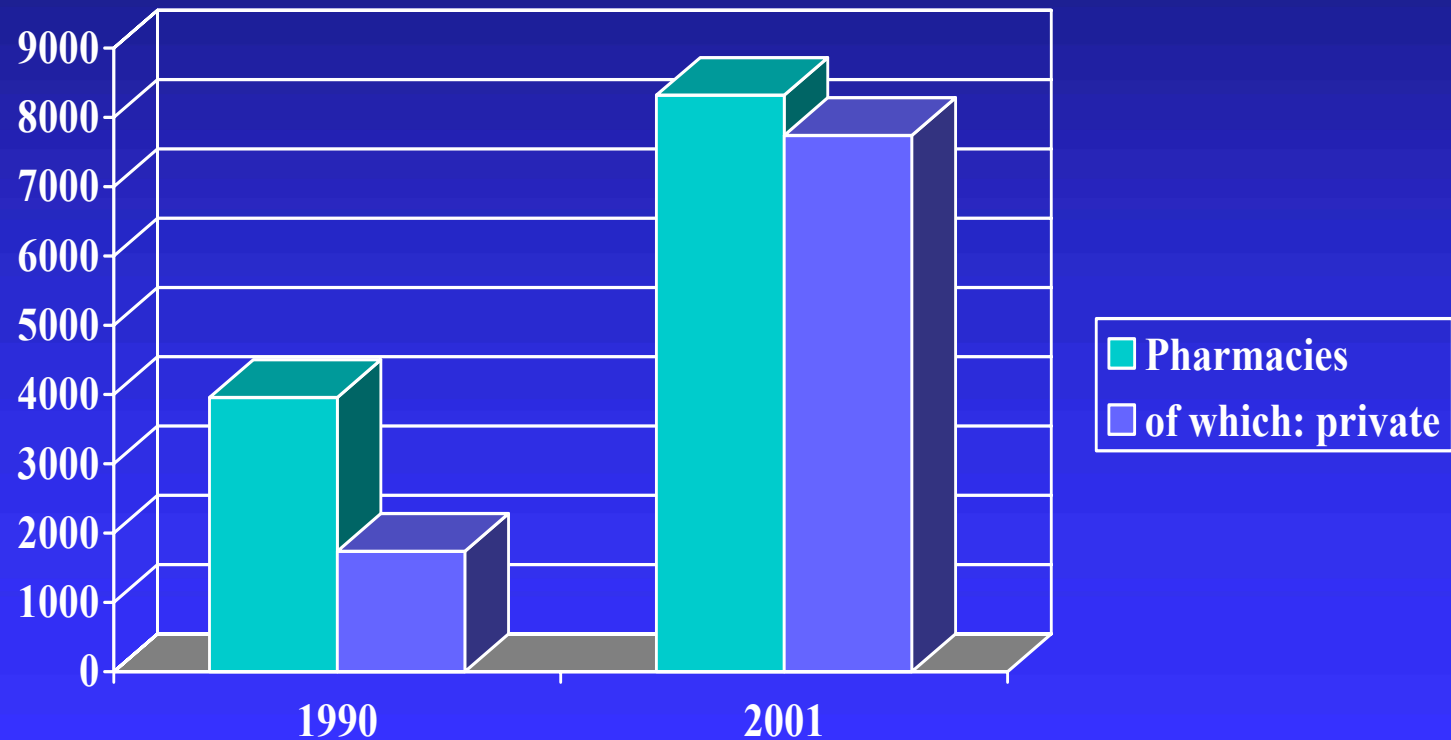
Public Policy Issues in Privatization: Licensing and Regulation of the Pharmaceutical Industry

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History

- 1988 beginning of pharmacies' privatization



Histor

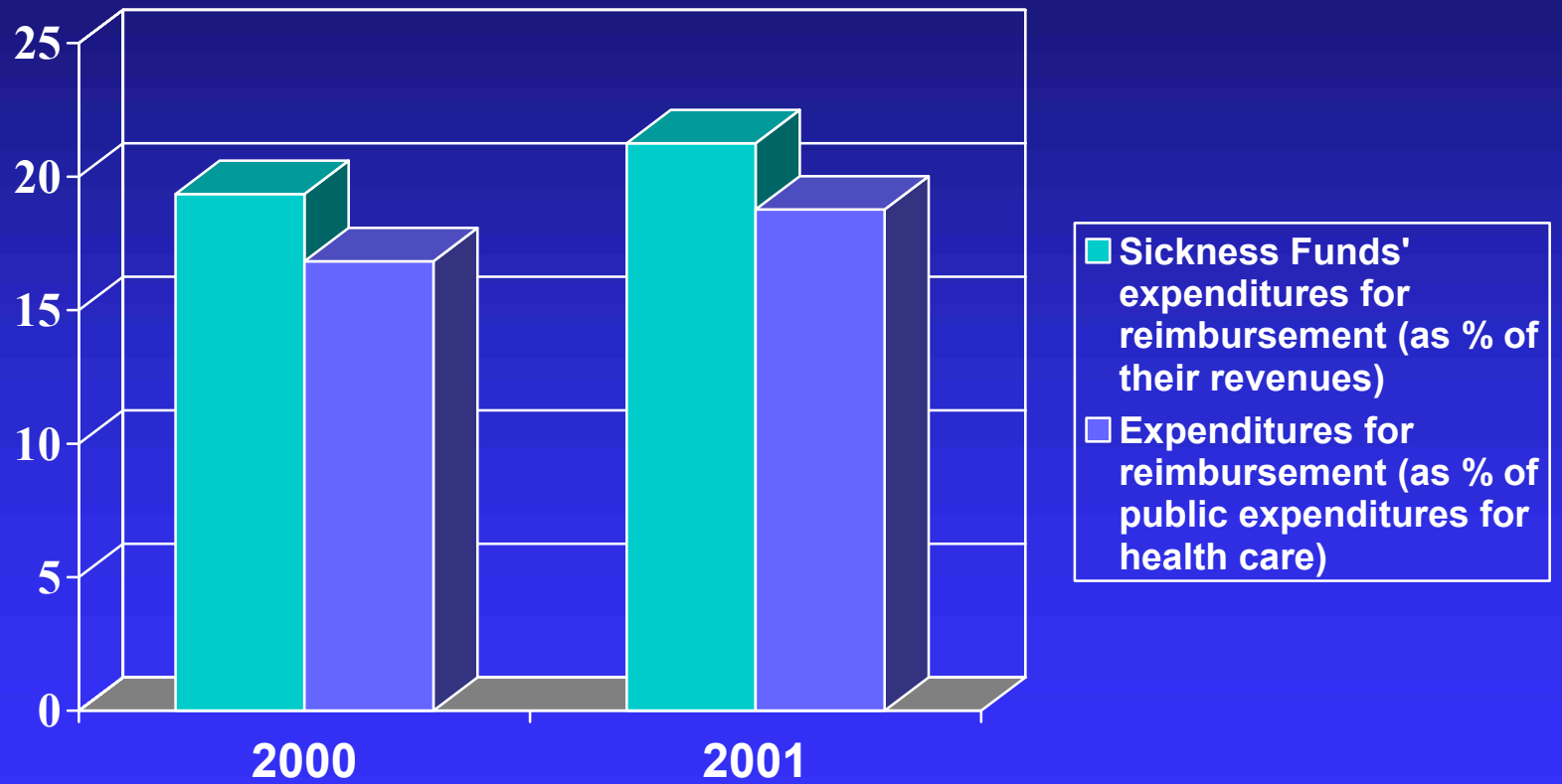
- Privatization of pharmaceutical companies began in 1994/95 (Jelfa, Polfa Kutno – public offerings)
- 1997 – foreign investors bought: Polfa Kraków, Polfa Rzeszów, Polfa Poznań

History

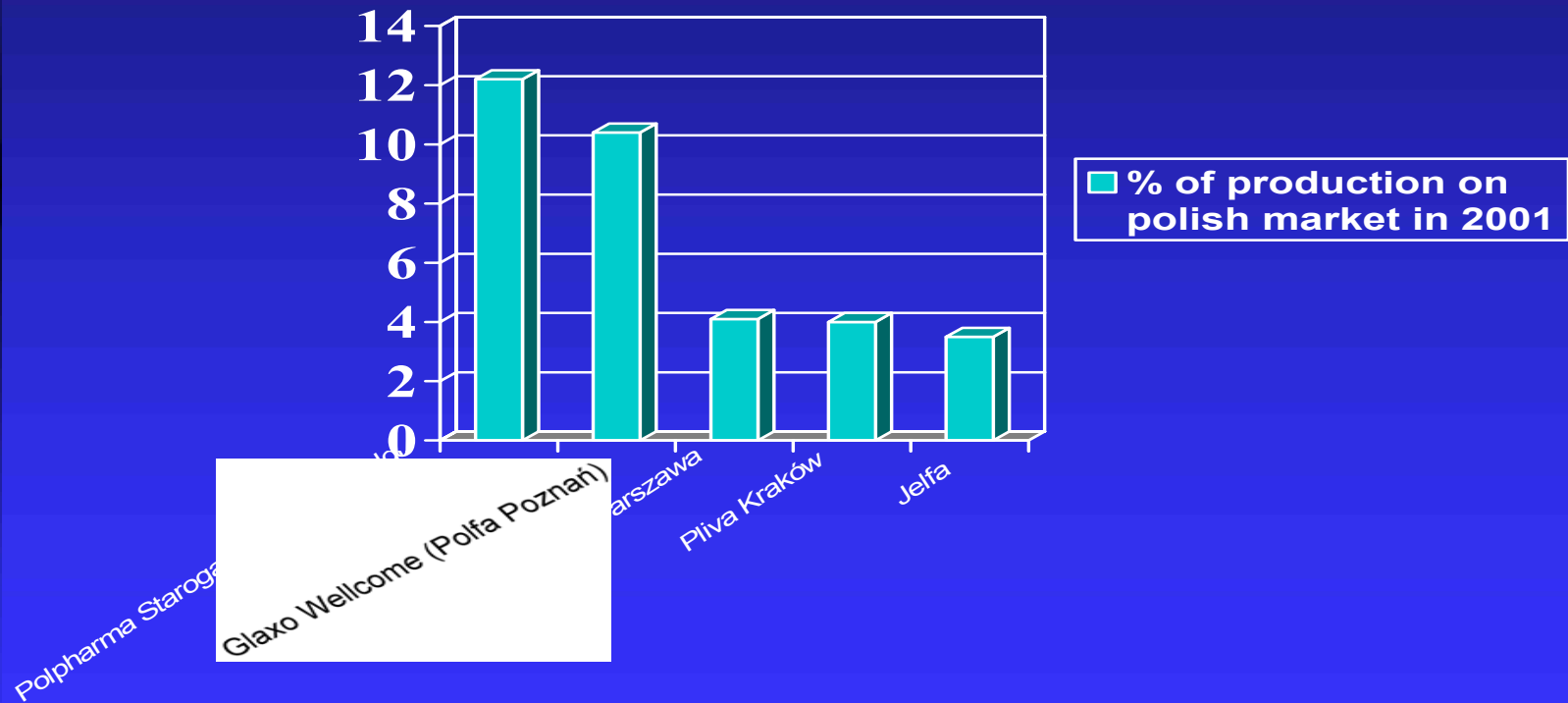
Value of drugs' sale in Poland from 1996 to 2001



Reimbursement



■ Strong concentration of production:



Issues

- Registration
- Reimbursement
- Price setting
- Prescription
- Monitoring and control

Drug Registration

■ PROBLEMS:

- ◆ **Before:** lack of clear registration procedures (delays in sending the information about registration, varied pace of registration), unclear procedure for evaluating applications
- ◆ **Today:** there are no significant delays in informing about rejection or acceptance of a given drug; producer receive information about the reasons for rejecting a given drug;

Drug Registration

■ RECOMMENDATION

- ◆ Introduce European Union directives which precisely define the process of drug registration: (i) what the registration application has to contain; (ii) what the description of the product reported for registration is to be like; (iii) the period of registration; (iv) the conditions of rejecting an application – **all of these are in the new Pharmaceutical Law which will be introduced on 1st October 2002**

Reimbursement

■ PROBLEMS:

- ◆ Lack of clear rules and procedures of creating the reimbursement lists - establishment of lists of refunded drugs took place in the form of negotiations with the pharmaceutical companies, some of the Sickness Funds created their own reimbursement lists that was banned by the Supervisory Office, however today these lists of Sickness Funds are not obligatory - can be treated as an informative tool

Reimbursement

■ RECOMMENDATIONS:

- ◆ implementation of clear, legal procedures of creating the reimbursement list (it can not be done behind the curtains)
- ◆ Sickness Funds should take part in creation of reimbursement lists (at present the Minister of Health creates the lists after only obtaining the opinion of Sickness Funds)

Prices

■ PROBLEMS

Before

The pricing setting process in Poland differed depending on drug's origin.

Prices of all Polish drugs were established by the Ministry of Finance while prices of reimbursable foreign drugs were established through negotiations with the pharmaceutical companies at the Ministry of Health (behind the closed doors)

Prices

Today - according to new Act on Prices of July 2001:

There is special Board for Drug Administration by Ministry of Health (there are three representatives from each ministry: Ministry of Health, Ministry of Finance and Ministry of Economy) which presents its opinion on drugs' prices.

Representatives of Sickness Funds can take part in the works of the Board for Drug Administration but they have small influence.

Prices

■ RECOMMENDATION

Representatives of Sickness Funds must be involved in price setting process

Prescribing and Purchasing of Drugs

■ PROBLEMS

- ◆ Pharmaceutical companies use various methods to convince physicians that their product should be prescribed (trips, gifts, „sharing profits”)

Prescribing and Purchasing of Drugs

■ RECOMMENDATIONS

- ◆ forbid access of pharmaceutical companies to health care institutions
- ◆ restrict acceptance of gifts for physicians and institutions
- ◆ education of physicians' environment

Control

■ PROBLEMS

Sickness Funds do not have legislative tools for regular monitoring of expenditures

- every 15 days Sickness Funds reimburse pharmacies' expenditures for drugs against collection of prescription reimbursement
- Sickness Funds are allowed to control pharmacies ad hoc but it is not pattern (pharmacies are obliged to present whole documentation)
- lack of pattern tools for complete monitoring of drug expenditures of Sickness Funds (exception: Silesian Sickness Fund)

Control

■ PROBLEMS (Silesian Sickness Fund case)

START system – electronic system of settling accounts of medical services

- Hospitals and clinics send information about their services every day
- System enables constant services' monitoring and controls correctness of settling the accounts of the contracts
- It is the basis of monthly accounts' settings with services' suppliers

Control

■ RECOMMENDATIONS

- ◆ a decree of the Minister of Health obliging pharmacies to send to Sickness Funds information on prescription reimbursement was issued finally
 - ◆ Now pharmacies are obliged to send the information to Sickness Funds on floppy disks once a month (not later than 14 days since the end of the month)
- ◆ Sickness Funds should create tools for regular monitoring of expenditures (example: Silesian Sickness Fund)