



SCREENING CHAPTER 20 ENTERPRISE AND INDUSTRIAL POLICY

AGENDA ITEM IX: PHARMACEUTICALS

**Country Session: The Republic of TURKEY
4-5 May 2006**



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Overview

- The industry is supplying about 85% of the pharmaceuticals need of the population with local production.
- Pharmaceuticals industry is able to produce all, except a few products requiring highly specialised technology or having unfeasible high production costs.



Overview (CONT'D)

Number Of Pharmaceutical Enterprises

There are approximately 300 entities operating in Turkey.

Among 52 multinational firms, 11 of them have manufacturing facilities in Turkey. The others import and/or make contract manufacturing.

Domestic manufacturing facilities concentrate on generic products.

From these entities, Pharmaceutical Manufacturing Plant of the Social Security Institution (production is stopped) and Army Pharmaceutical Manufacturing Plant of the Ministry of Defense are publicly owned.



Overview (CONT'D)

Human Resources Profile

Pharmaceuticals industry personnel with university education is 51.3%.

Source: Pharmaceutical Manufacturers Association, 2005



Overview (CONT'D)

Employment (only in manufacturing)

2001	10,826
2002	11,554
2003	12,734
2004	14,707
2005 (app.)	18,466

Source: Ad-Hoc Committee Report on Pharmaceuticals, 2005



Overview (CONT'D)

Production

Year	Box	Value (mio euro)
2001	693	2,260
2002	698	2,677
2003	769	3,085
2004	855	3,448
2005	1,212	5,348

Source: Intercontinental Marketing Service, 2006



Overview (CONT'D)

Consumption

Per capita pharmaceuticals consumption is € 115 in 2005 (€ 98 in 2004).

Source: Pharmaceutical Manufacturers Association, 2005



Overview (CONT'D)

Export

(Mio Euro)

Year	Raw Material	Finished Products	Total
2001	73	43	116
2002	88	81	169
2003	24	74	98
2004	180	229	409
2005	25	246	271

Source: Ministry of Health- DG of Pharmaceuticals and Pharmacy, 2006

(The industry exports to more than 70 countries.)



Overview (CONT'D)

Import

(Mio Euro)

Year	Raw Material	Finished Products	Total
2001	692	575	1,267
2002	985	813	1,798
2003	2,184	1,636	3,820
2004	1,708	2,283	3,991
2005	1,946	1,911	3,857

Source: Ministry of Health- DG of Pharmaceuticals and Pharmacy, 2006



Overview (CONT'D)

Import

The pharmaceuticals industry is importing some products in finished forms;

- Pharmaceuticals needing brand new and high technologies,
- Biotechnological preparations,
- Implanted pharmaceuticals,
- New pharmaceuticals transport systems (e.g. TTS),
- Vaccines,
- Blood factors,
- Pharmaceuticals with controlled secretion system,
- Insulin,
- Cancer drugs,
- Several hormones,
- Radionuclides,
- Some ophtalmic preparations,
- Antidotes.



Overview (CONT'D)

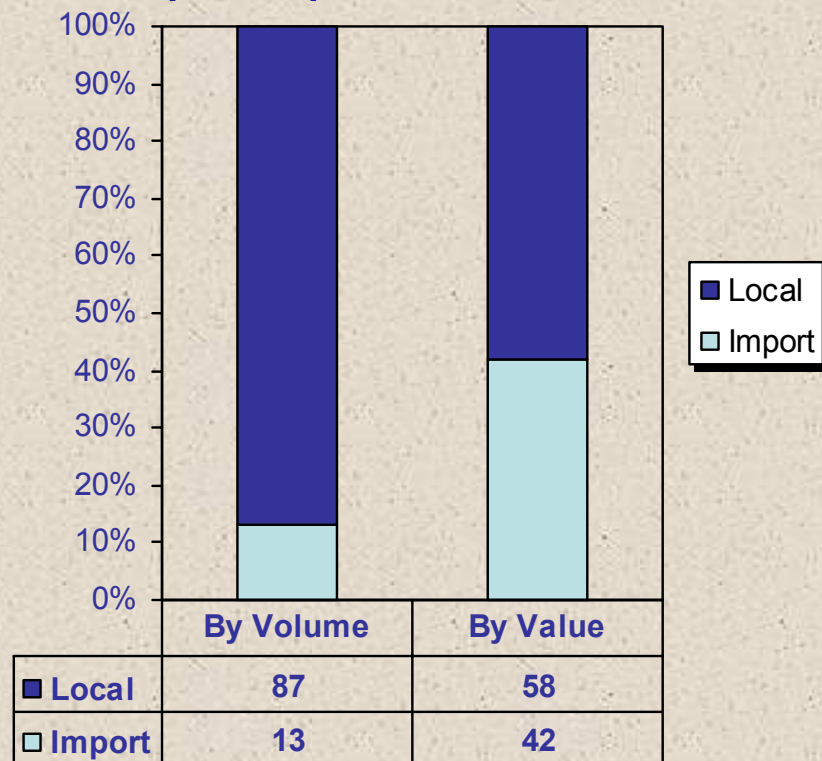
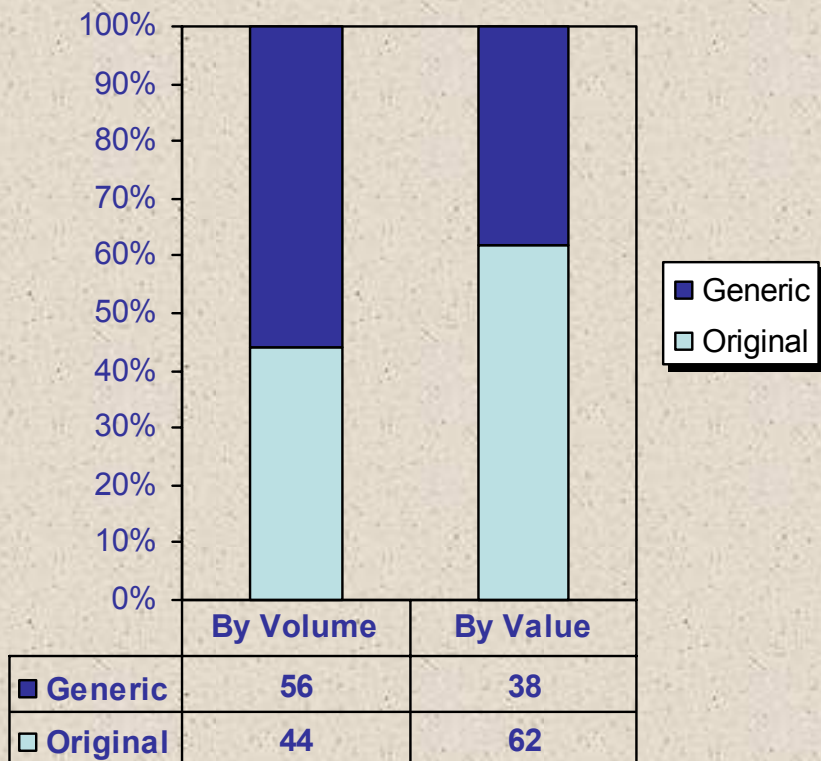
Pharmaceutical Market

Reimbursement Institutions are the largest buyers (around 80% of pharmaceutical purchases).



Overview (CONT'D)

Distribution of Pharmaceutical Market (2005)

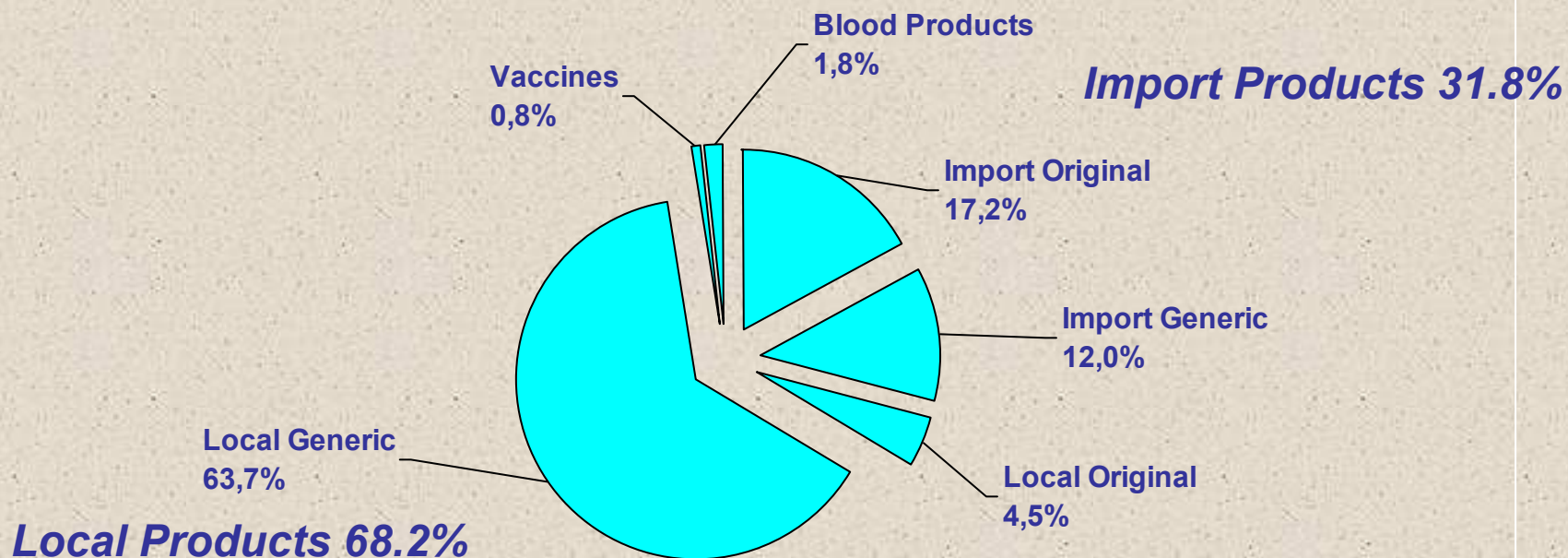


Source: Pharmaceutical Manufacturers Association, 2005



Overview (CONT'D)

Distribution of 5,338 pharmaceutical forms (2005)



Source: Ministry of Health- DG of Pharmaceuticals and Pharmacy, 2006



Overview (CONT'D)

Investments

(Mio Euro)

2001	47.72
2002	77.60
2003	121.19
2004	57.60
2005 (approx.)	61.18

Source: Ad-Hoc Committee Report on Pharmaceuticals, 2005



Policy Documents

8th Five Year Development Plan (2001-2005)

- Strengthening of infrastructure in the Ministry of Health,
- Applying patent protection to pharmaceuticals and their manufacturing processes.



Legal Framework

- Law No 1262, on Pharmacy Related and Medicinal Preparations
(26 May 1928)
- By-law on the Human and Pharmacy Related and Medicinal Preparations
(Official Gazette, 12 August 2005, 25904)
- By-law on the Licensing of Human Medicinal Products
(Official Gazette, 19 January 2005, 25705)
- By-law on the Manufacturing Practices for Human Medicinal Products
(Official Gazette, 23 October 2003, 25268)



Legal Framework (CONT'D)

- By-law on the Monitoring and Evaluation of the Safety of Human Medicinal Products
(Official Gazette, 22 March 2005, 25763)
- By-law on the Classification of Human Medicinal Products
(Official Gazette, 17 February 2005, 25730)
- By-law on Packaging and Labeling for Human Medicinal Products
(Official Gazette, 12 August 2005, 25904)
- By-law on the Promotion of Human Medicinal Products
(Official Gazette, 25268, 23 October 2003)



Legal Framework (CONT'D)

- By-law on the Variation of Human Medicinal Products
(Official Gazette, 23 May 2005, 25823)
- Communiqué concerning the colouring substances for human medicinal products
(Official Gazette, 18 January 2005, 25704)
- By-law on the Establishment of Scientific Advisory Commissions for Human Medicinal Products.
(Official Gazette, 09 October 2003, 25254)



Legal Framework (CONT'D)

- Decree on the Pricing of Human Medicinal Products
(Official Gazette, 14 February 2004, 25373)
- The Decrees Amending the Decree on the Pricing of Human Medicinal Products
(Official Gazette, 14 April 2004, 25433, and Official Gazette, 25 November 2004 25651)
- Communiqué on the Pricing of Human Medicinal Products
(Official Gazette, 03 March 2004, 25391)



Institutions Involved

Institution	Relevant Body	Roles and Responsibilities
Ministry of Health	<i>GD of Pharmaceuticals and Pharmacy</i>	Designates rules and standards relevant with pharmaceuticals, pharmacy and licensing. Approves prices of pharmaceuticals.
Ministry of Finance	<i>Retirement Fund</i>	Reimburses.
Ministry of Labour and Social Security	<i>Social Insurance Institution for Tradesmen and Craftsmen and Other Self Employed (Bag-Kur)</i>	Reimburses.
Ministry of Labour and Social Security	<i>Social Insurance Institution (SSK)</i>	Reimburses.
Social Security Institution		Will take over responsibilities of three reimbursement institutions mentioned above.



Institutions Involved (CONT'D)

Ministry of Industry and Trade	Arranges pharmaceutical sector at industrial area.
Ministry of Internal Affairs	Cooperates on precursors.
Ministry of Agriculture and Rural Affairs	Has common communiques with Ministry of Health. (e.g. The Comminique concerning the colouring substances for human medicinal products).
Ministry of Environment and Forestry	Cooperates on chemicals and waste matters.
Undersecretariat for Foreign Trade	Informs MoH about foreign pharmaceuticals sector's structure and prices.
State Planning Organisation	Prepares development plan and annual programmes.



Consultation Mechanism

Ad-Hoc Committee Report on Pharmaceuticals (2005)

- Current status
- Expecting developments
- Priorities and provisions
- Institutional infrastructure requirements



Instruments- Tools and Finance Public Support Programmes

Institution	Basic Programmes
Undersecretariat of Treasury	Support for investments, regional development
Undersecretariat for Foreign Trade	Support for training and R&D
TURK EXIMBANK	Export credits and insurance
Ministry of Finance, Turkish Revenue Administration	Tax exemption and exceptions, public land sales, regional aid
Ministry of Industry and Trade	Regional aid, R&D support (Organised Industrial Zones, Technology Development Zones)
TUBITAK	Support for R&D



COMPETITIVENESS

- The new reference-pricing system having objective criteria has positive effect on competitiveness,
- Generic licensing after the data exclusivity period of original products also contributes to competitiveness.



Thank you for your attention.