The Indian Pharmaceutical Industry: Policy Developments and Growth

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ACCESS TO MEDICINES AND INNOVATION CONFERENCE

"Health in the Millennium."

5th July 2007

Regulation
1947 - 2007

- 1947 until the late 1960s
- 1970s to the early 1990s
- From mid-1990s to date

Regulation
1947 – 1960s (I)

- 1947 Independence of India
- The Indian Patent and Designs Act of 1911
- Product and process patents granted.
- Foreign firms dominate the Indian market.
- Virtual absence of a domestic pharmaceutical industry.

Regulation 1947 – 1960s (II)

- Two Patents Inquiry Committees
- The Tek Chand Committee (1948-50)
- The Ayyangar Committee (1957-59)

Regulation
1947 – 1960s (III)

Observe

- The Indian patent system had failed to "stimulate inventions among Indians ….."

Recommend

- Abolition of product patents for pharmaceuticals in order to attain self-reliance.

Regulation
1970s to the early 1990s (I)

- The 1970s: Moving to Regulation
- The Patents Act 1970
  - Product patents for pharmaceuticals abolished.
- The Drug Policy of 1978

Regulation
1970s to the early 1990s (II)

- The 1980s
- Continued growth of the domestic pharmaceutical sector.
- Foreign sales account for 12.4 % of total sales of pharmaceuticals in 1987/88. This is in contrast to 70% in 1970s.

Regulation
From mid-1990s to date

- According to WHO (2004) estimates India accounts for about 1% of the world's production by value and 8% by volume.

R&D for Drugs for Diseases Prevalent in India

- 1975: The Committee on Drugs and Pharmaceuticals identifies the need for development of anthelmintics, anti-leprotics, anti-filarials and anti-malarials.
- 2002: The Pharmaceutical Policy.
- To encourage R&D in the pharmaceutical sector in a manner compatible with the country's needs with particular focus on diseases endemic to India.

Patterns of Patenting, Market Sales Data and the Disease Incidence (I)

- India suffers from a double of burden of disease: communicable diseases such as malaria and TB co-exist with non-communicable diseases such as cardiovascular, disorders of the CNS and cancer.

Patterns of Patenting, Market Sales Data and the Disease Incidence (II)

75 % of expenses on medicines are out-of-pocket in India (WHO 2000)

Patterns of Patenting, Market Sales Data and the Disease Incidence (III)

- A sample of 4323 accepted drug patents.
- Accepted drug patents information has been divided into:
  - 1952-62: Product Patents;
  - 1963-1995: Process Patents;
  - 1996-2003: India becomes signatory to WTO.

Patterns of Patenting, Market Sales Data and the Disease Incidence (IV)

- The distribution of patents between private and public sector across different therapeutic groups reveals a correlation between private sector patenting activity and market prospects.
- The analysis of the patents mix reveals that health concerns exert greater influence on public sector patenting activity.

Patterns of Patenting, Market Sales Data and the Disease Incidence (V)

- The sales of drugs for treating non-communicable diseases have shown positive growth.
- But the sales of drugs for treating communicable diseases have largely recorded negative or declining growth rates.

Patterns of Patenting, Market Sales Data and the Disease Incidence (VI)

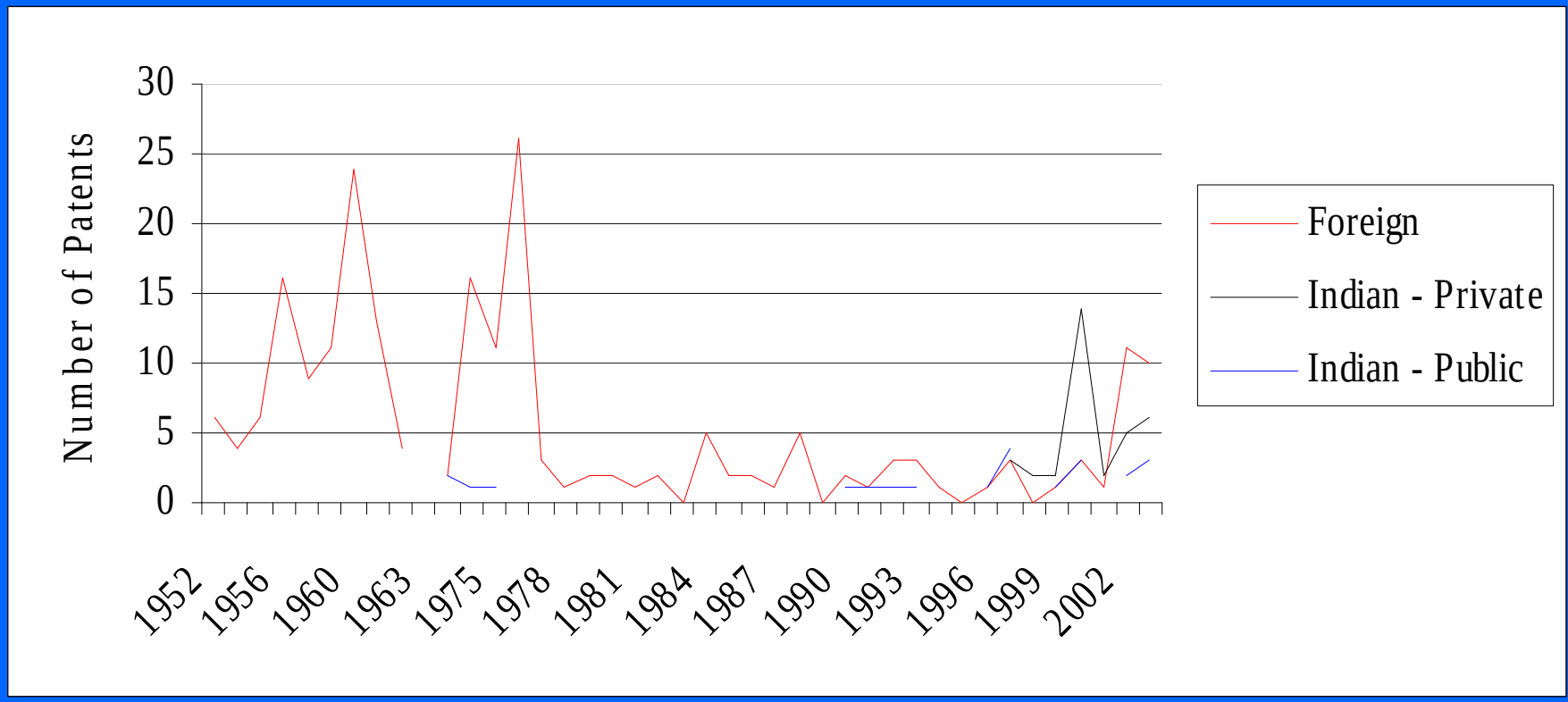
- The private sector patenting is sustained in drugs with attractive market prospects, i.e. for treating non-communicable diseases.
- However, the public sector continues to research on drugs with limited market prospects such as those to treat malaria as well as for drugs with bright market prospects such as those for cardiovascular system

Market Segments with High or Positive Growth Rates

Alimentary Tract and Metabolism:

- 1985 and 2003: 5% to 13%

Public Private Patents Mix: Drugs for Alimentary Tract and Metabolism



Market Segments with High or Positive Growth Rates

Cardiovascular System

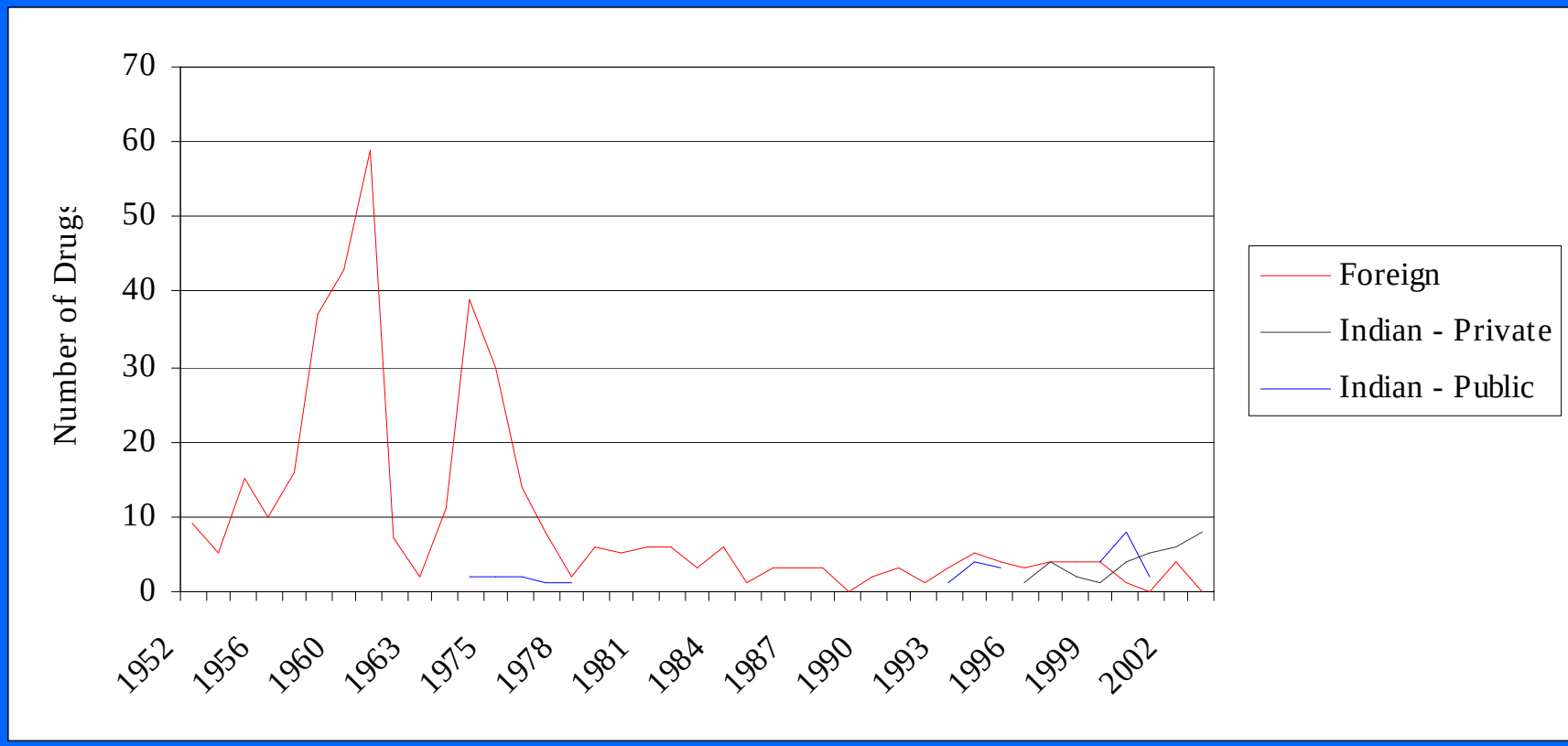
- 1985-89: 10%
- 1989-92 : 21%
- Since 1998: 15 to 17%

Market Share

Cardiovascular system

- 1969: 1.9 % to
- 2003: 9.7 %

Public Private Patents Mix: Cardiovascular Drugs



Malaria

2–3 million cases of malaria are reported each year (Government of India, 2000, WHO, 1967). According to the *World Health Report 2004*, the mortality rate due to malaria for the year 2000 was 3 per 100 000 population in India.

Market Segments with Low or Negative Growth Rates

Parasitology includes antimalarials

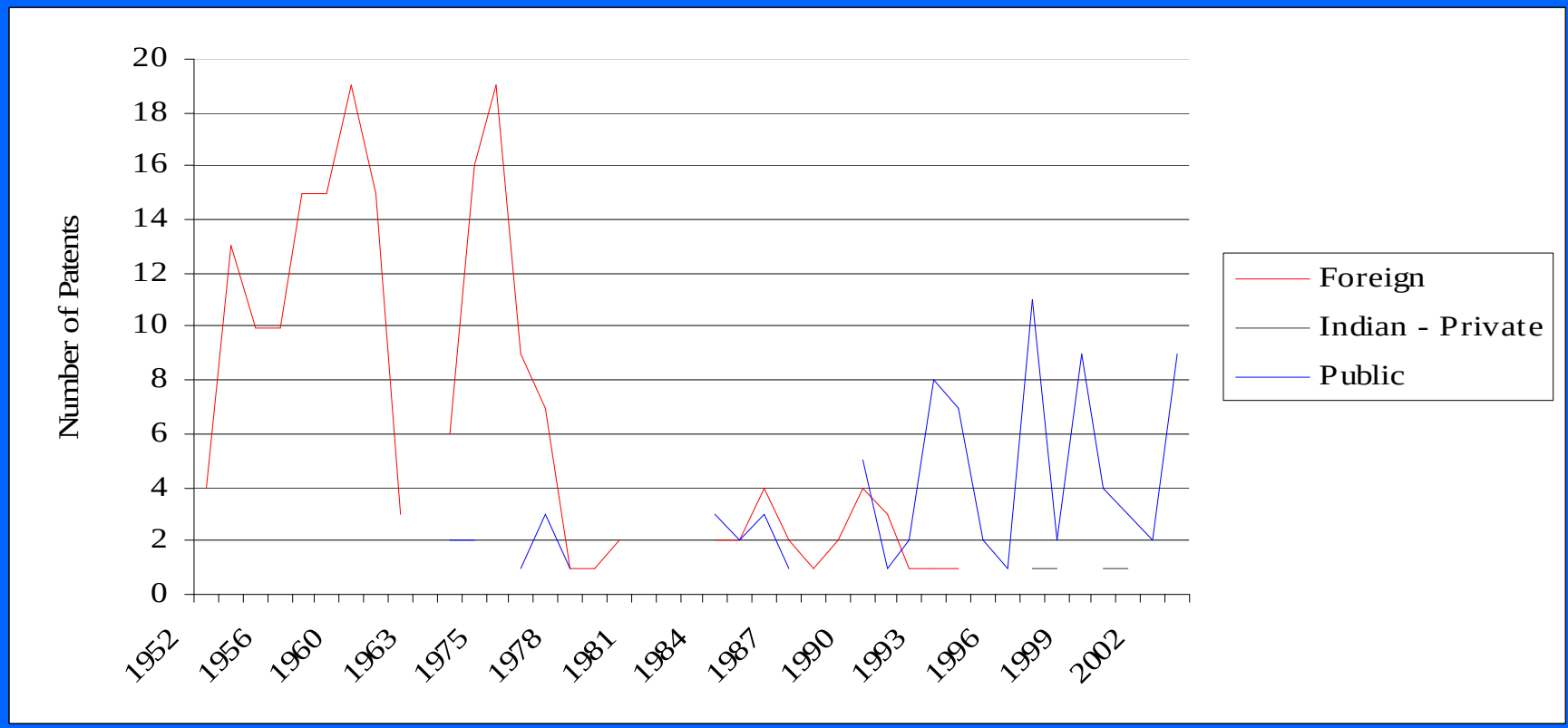
- Exhibited a negative growth between 1997-98 and 2000-01.

Market Share

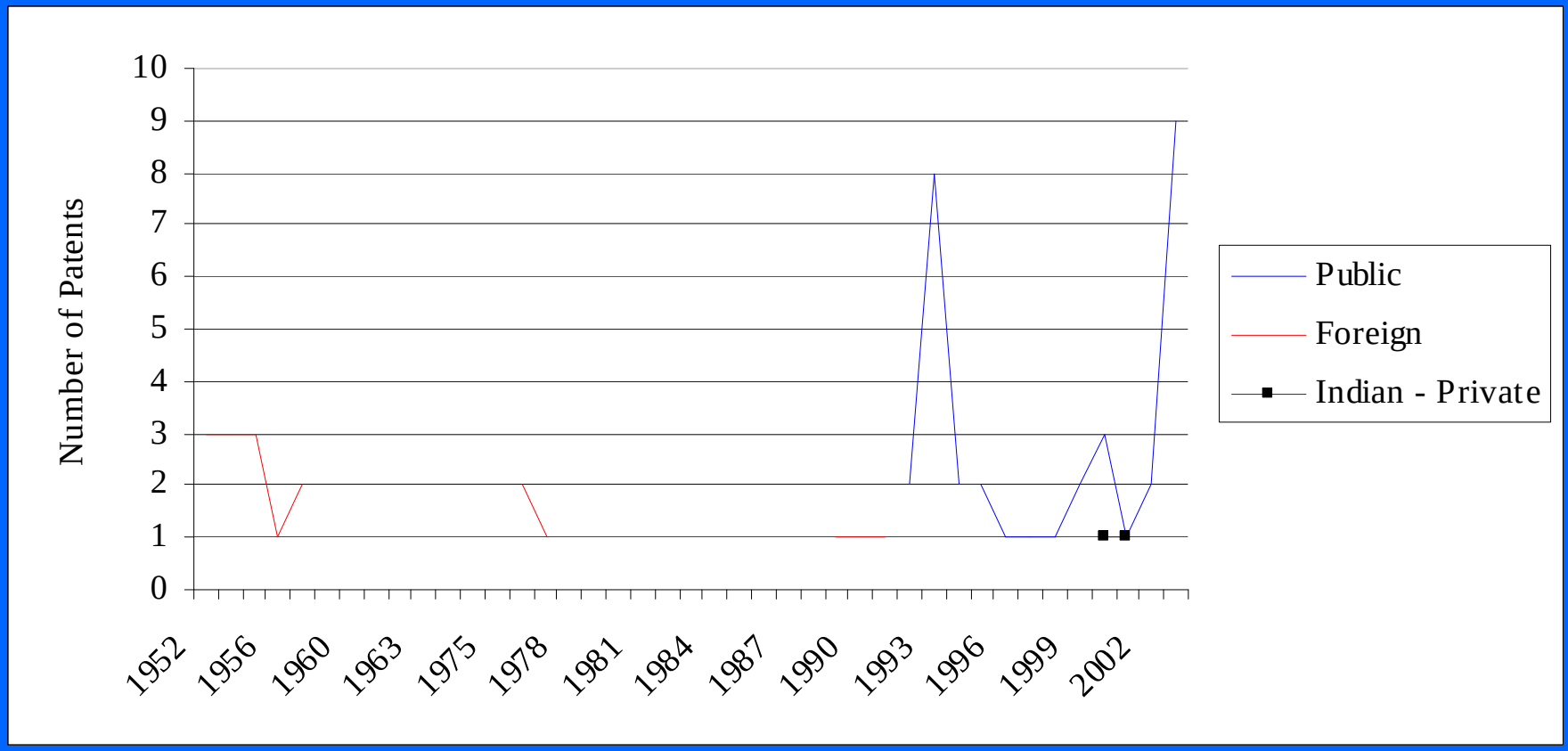
Parasitology

- 1969: 0.9%
- 1985: 5.7%
- 2003: 1.5%

Public Private Patents Mix: Parasitology



Public Private Patents Mix: Antimalarials



Parasitology

Growth Rate in Sales of Antimalarials

Years	*Annual Growth Rate*
1985-89	7.39
1989-92	10.20
1992-94	19.20
1994-97	16.59
1997-98	0.44
1998-99	0.03
1999-00	-4.40
2000-01	-13.44
2001-02	-8.75
2002-03	16.97

Tuberculosis

- 1959: A case-load of 7.5 million and over 2 million infectious patients*
- 1970s: The reported incidence of TB was 111 per 100 000 and prevalence 378 per 100 000 population**
- 2003 the prevalence of TB remained at a high of 284 per 100 000 population
- According to the *World Health Report 2004*, India ranks highest in terms of total number of estimated cases of TB

* Indian Council of Medical Research, 1960, WHO, 1967; ** WHO, 1988

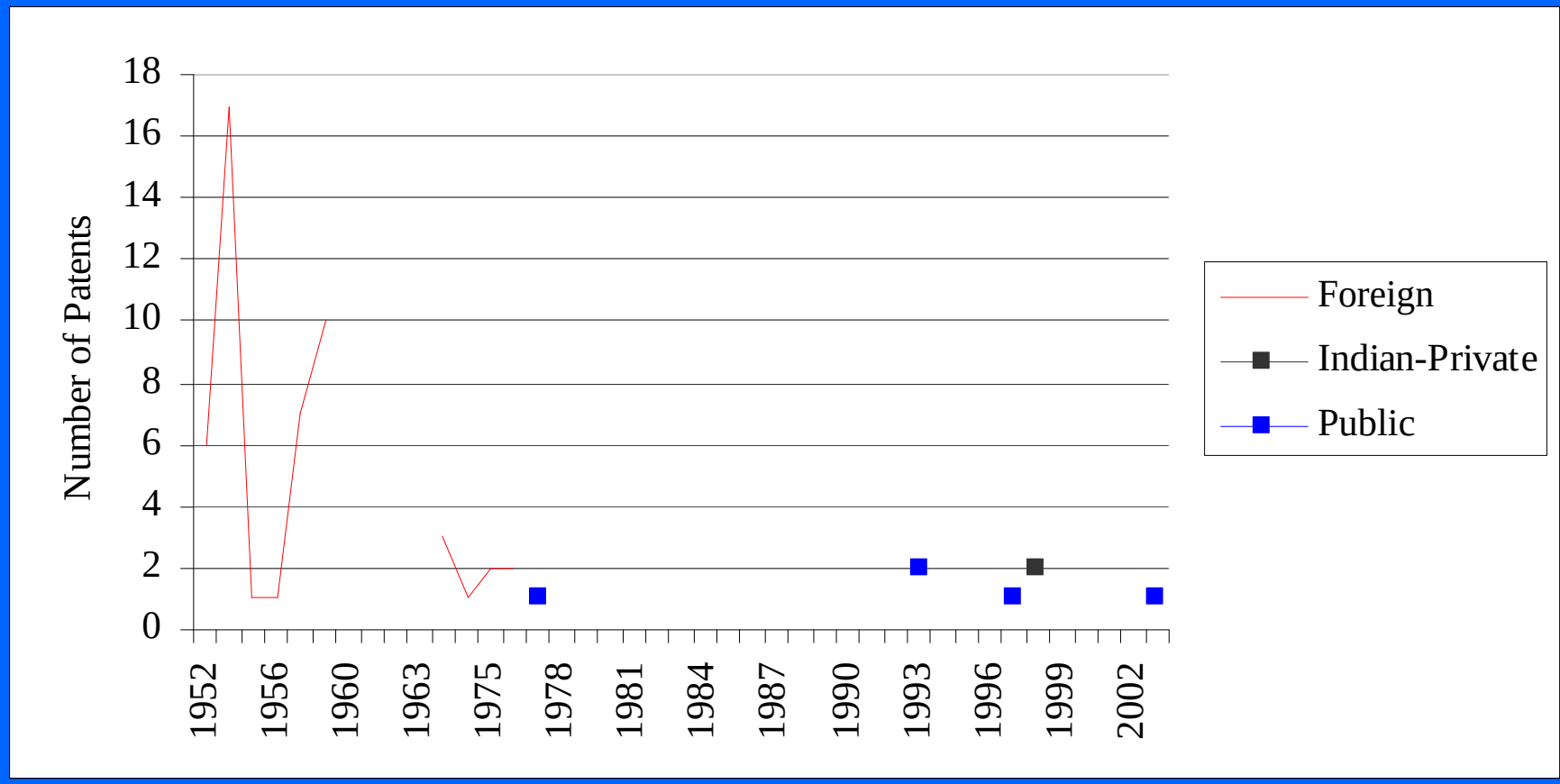
Market Segments with Low or Negative Growth Rates

- Prominent are antimycobacterials: antitubercular and drugs for leprosy.
- Since 1997, antimycobacterials have exhibited a negative growth rate since 1997-1998.

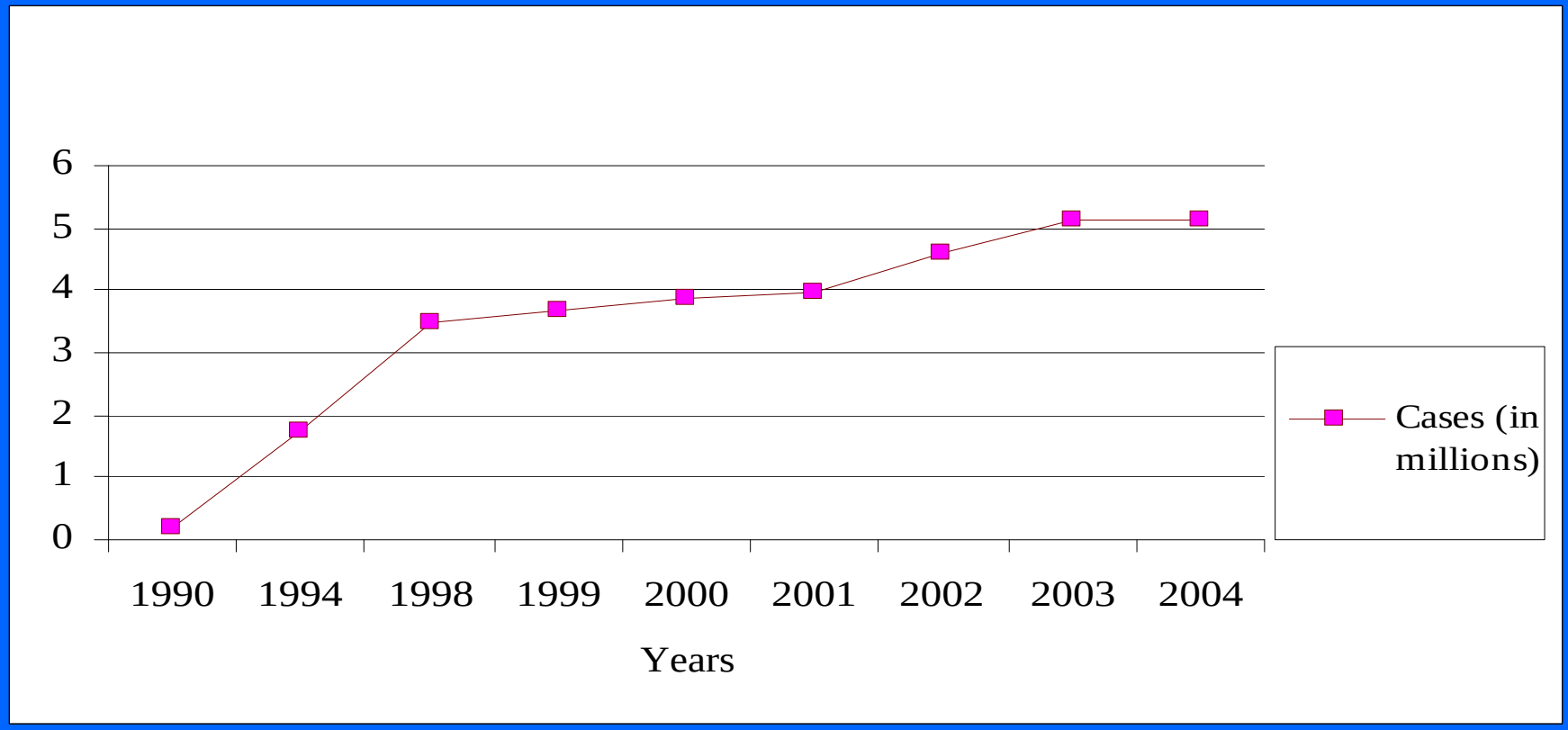
Market Segments with Low or Negative Growth Rates

Therapeutic Group	*1977-1992*	*1992-1994*	*1994-1997*	*1997-1998*	*1998-1999*	*1999-2000*	*2000-2001*	*2001-2002*	*2002-2003*
Antimycobacterials	2.82	4.31	12.32	-3.42	-4.92	-1.97	2.22	-10.5	-10.17

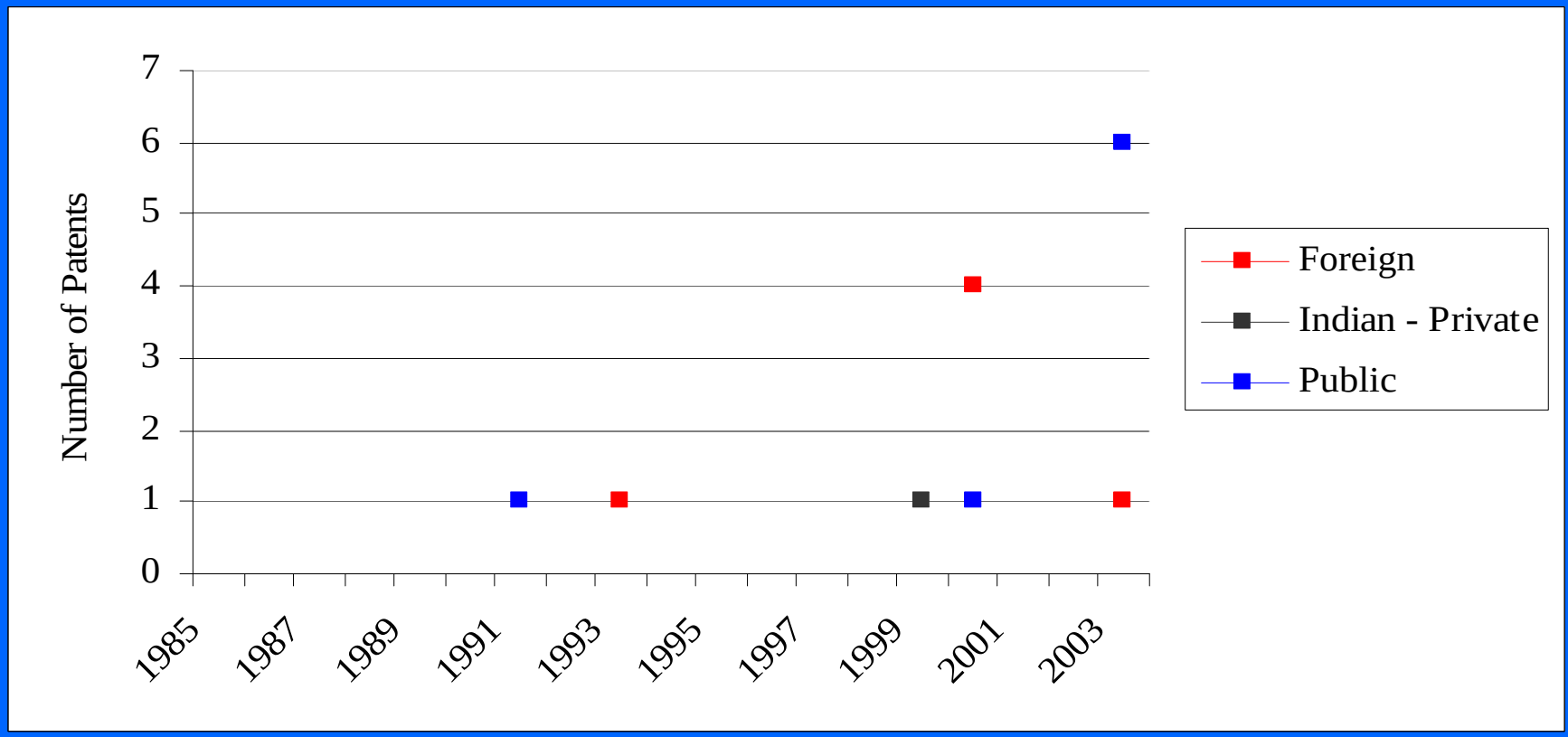
Public Private Patents Mix: Antimycobacterials



HIV


6
5
4
3
2
1
0
1990
1994
1998
1999
2000
2001
2002
2003
2004
Years
Cases (in millions)

Public Private Patents Mix – Antivirals (HIV)



Patterns of Patenting, Market Sales Data and the Disease Incidence (VII)

	1952-1962		*1963-1995*		*1996 -2003*	
Therapeutic Class	**Private (% of total)**	**Public (% of total)**	**Private (% of total)**	**Public (% of total)**	**Private (% of total)**	**Public (% of total)**
Alimentary Tract and Metabolism	100.0	0.0	91.0	9.0	82.1	17.9
Cardiovascular System	100.0	0.0	89.4	10.6	73.9	26.1
Central Nervous System	100.0	0.0	87.5	12.5	72.4	27.6
General Anti-Infectives Systemic	98.6	1.4	94.5	5.5	64.9	35.1
Parasitology	99.0	1.0	66.2	33.8	12.8	87.2

***Source*: Author's analysis of patent record data**

Conclusion

- The Indian pharmaceutical industry has recorded fast growth as a result of government policies.
- According to WHO figures (2004), 65% of the Indian population (approximately 640 million) lacks access to essential medicines.