R&D for Development of New Drugs for Neglected Diseases: A Proposal for South-South Cooperation

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Access to Medicines

- Availability
- Affordability
- Appropriateness

Drugs for neglected diseases

- Few or no drugs exist for neglected diseases particularly “very neglected diseases” (African trypanosomiasis, leishmaniasis and Chagas’ diseases etc)
- Some increase in R&D for neglected diseases drug development by some not-for-profit organizations such as Drugs for Neglected Diseases Initiative and by some MNCs such as AstraZeneca and GlaxoSmithKine.
- But it is widely believed that more needs to be done particularly by developing countries themselves

Incentives for new drug development

- "Push" incentives
  - public support (such as direct public spending, R&D grants, tax credits)
- "Pull" mechanisms
  - Product patent protection

Outline of presentation

- Post-TRIPS product patent regime
- Public support and public-private partnerships in India
- Case for south-south cooperation

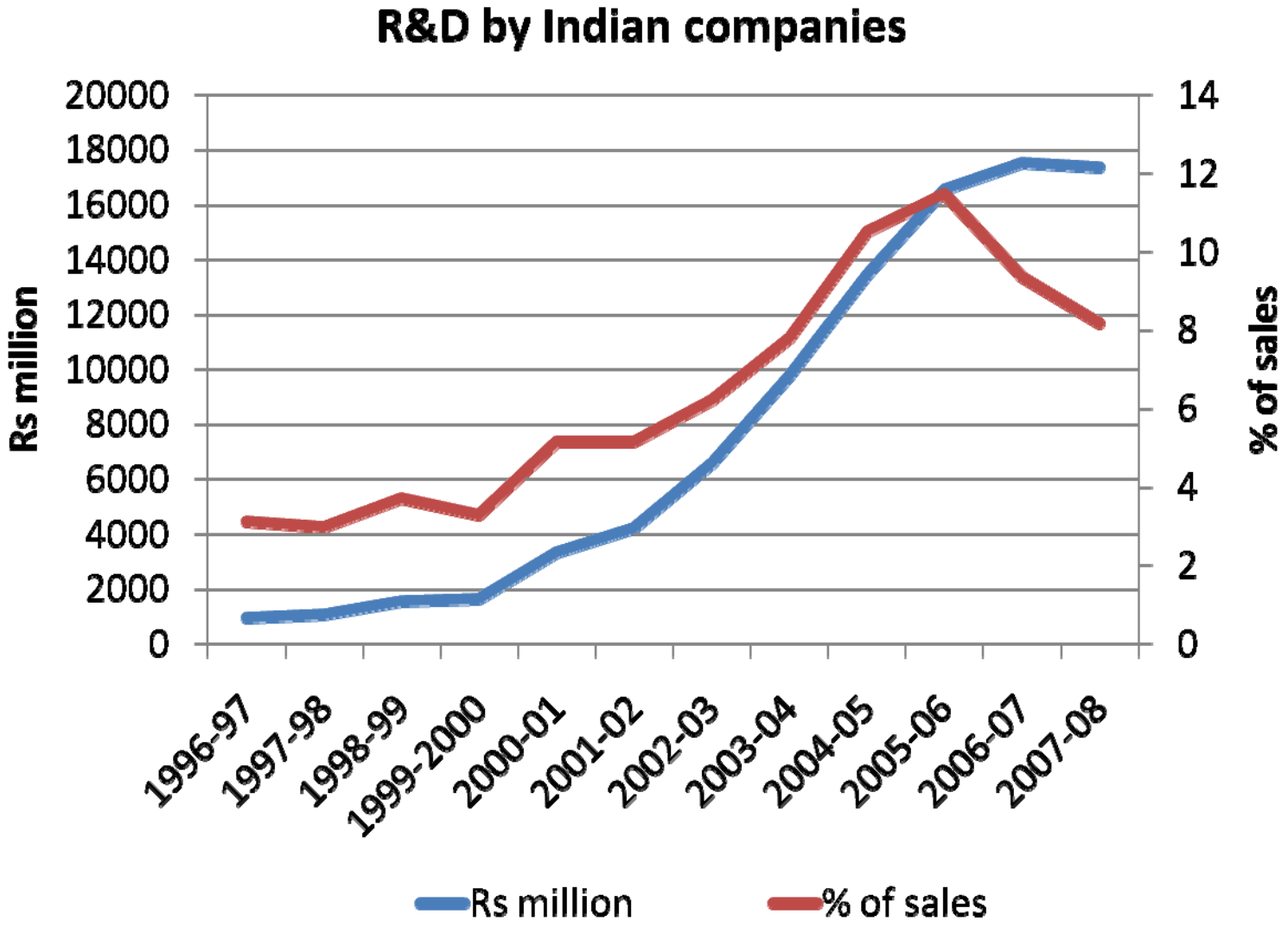
India after TRIPS

- India has introduced a product patent regime in pharmaceuticals from 1 January, 2005
- Arguments:
  - MNCs argued that developing countries too would benefit from stronger patent protection because it will stimulate private R&D investment for developing country diseases
  - It has also been more specifically claimed that local companies will be prompted to do more R&D for the development of new drugs more suited to their needs

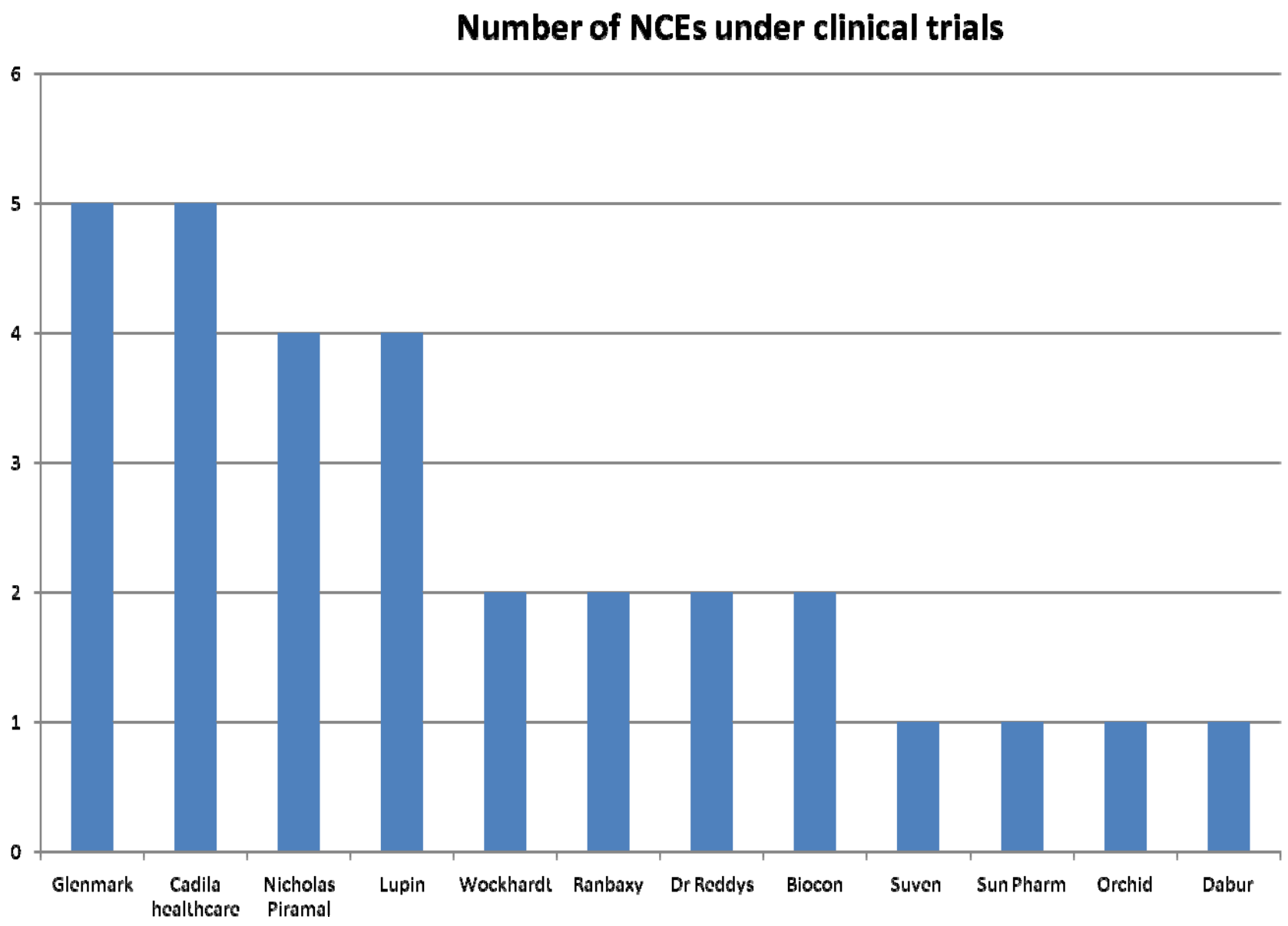
13 Indian companies involved in new drug R&D, 2007-08

	Rs million	% of sales	$ million
Ranbaxy*	4605.1	11.29	114.4
Dr. Reddy's	3334.5	8.82	82.9
Lupin	1933.7	7.52	48.1
Cadila Healthcare	1618	9.43	40.2
Sun Pharm	1443.9	6.27	35.9
Wockhardt	1267.4	10.81	31.5
Torrent Pharm	1131.7	11.37	28.1
Orchid Chem & Pharm	709	5.73	17.6
Glenmark Pharm	659.1	4.89	16.4
Biocon	646.5	7.36	16.1
Piramal Healthcare	352.8	1.86	8.8
Suven Life Sciences	300.6	25.64	7.5
Dabur (Fresenius Kabi Oncology)*	262.3	10.96	6.5
TOTAL 13 companies	18264.6	8.18	453.9

*: Now taken over by foreign companies



Note: For 11 Indian companies involved in new drug R&D


Number of NCEs under clinical trials
6
5
4
3
2
1
0
Glenmark
Cadila healthcare
Nicholas Piramal
Lupin
Wockhardt
Ranbaxy
Dr Reddys
Biocon
Suven
Sun Pharm
Orchid
Dabur

Strategy of Indian companies

- Indian companies are not yet ready for a start-to-finish model in NCE research because of lack of skills and funds
- Model: develop new molecules up to a certain stage and then license them out to partners from developed countries, primarily MNCs
- Not surprisingly NCEs being developed by the Indian companies are related primarily to global diseases such as diabetes, cancer, heart diseases, asthma, and obesity rather than the neglected diseases
- Exception: one anti-TB and one anti-malaria NCE

Other Reasons for MNC collaboration

- In pre-TRIPS process development era:
  - Indian companies not required to promote drugs – only limited phase III clinical trials necessary
- In post-TRIPS new drug development phase:
  - Difficulties of promoting drugs developed independently
  - Not a single instance of a drug developed elsewhere but successfully marketed in developed countries, particularly in USA and Western Europe without the involvement of MNCs

Problems of alliance with MNCs

- Not only inadequate emphasis on drugs for neglected diseases
- Potential conflict of interest
- Indian companies now aware of the conflict

Thus

- New drug R&D has started in India under Indian private initiative
- But Indian private sector not yet ready for independent R&D for new drug
- And difficulties faced in collaborating with MNCs
- Natural Question: what can the government do?

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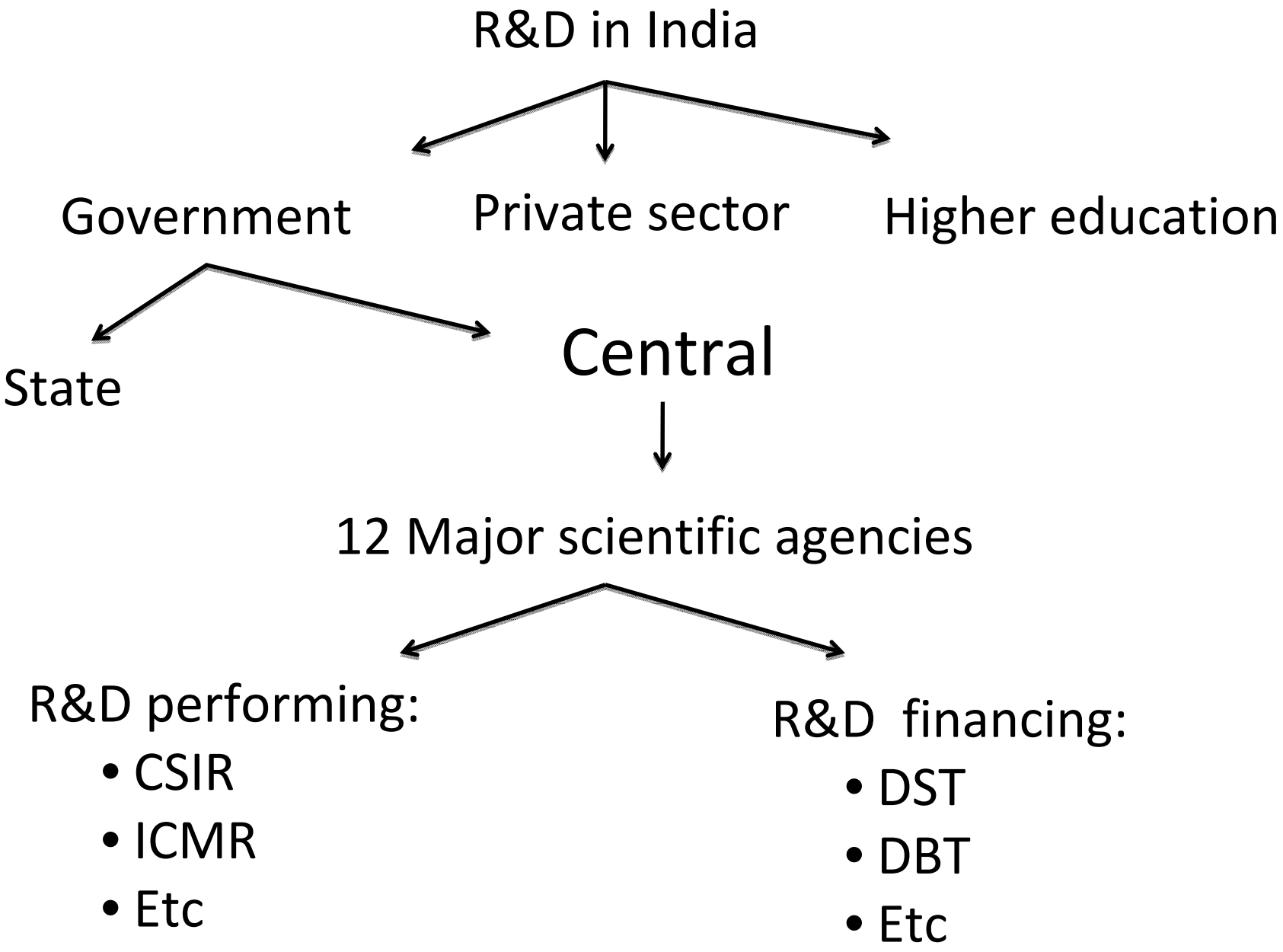
Push incentives of public support

- Direct public spending
- R&D grants and
- Fiscal incentives

India has an elaborate public R&D infrastructure


R&D in India
Government
Private sector
Higher education
State
Central
12 Major scientific agencies
R&D performing:
• CSIR
• ICMR
• Etc
R&D financing:
• DST
• DBT
• Etc

Central Drug Research Institute

- A laboratory under CSIR Involved in new drug development since its inception in 1951
- One of the few public sector organizations in the world which have their own full fledged drug development infrastructure
- Has developed about 10 drugs
  - Not registered in developed countries
  - Not commercially successful
- Hardly any interaction with the pharmaceutical industry
  - Indian companies more keen to collaborate in process development

Significant recent changes

- Public private partnerships
  - DST's Drugs and Pharmaceuticals Research programme
  - CSIR's Open Source Drug Discovery programme
  - CSIR's New Millennium Indian Technology Leadership Initiative (NMITLI)
  - DBT's Small Business Innovation Research Initiative (SBIRI) and Biotechnology Industry Partnership Programme (BIPP)

PPTs

- Basic idea is to synergise the strengths of publicly funded R&D institutions and the Indian pharmaceutical industry
- Provide:
  - Collaborative platform
  - Grants
  - Soft loans
- Major national laboratories and pharmaceutical companies have been involved
- Budget small (though increasing)

But

- Funds not the only problem
- Some of the basic problems which developing countries face have not yet been adequately tackled
- Problem is not only about developing a drug - It is also about how to promote it
- Recall: difficulties of collaborating with MNCs
- Solution:
  - R&D model bypassing the role of MNCs and developed countries

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South-South R&D Model

- Expand the Indian PPPs and include organizations from other innovative developing countries such as Brazil and South Africa
- Conduct clinical trials and get regulatory approvals in these (and other developing) countries
- Marketing focus on these countries rather than on developed countries and MNCs

Advantages

- Costs of clinical trials will be significantly lowered
  - Clinical trials: 40% of new drug development costs
  - Regulatory approvals: another 10%
- Countries such as Brazil, India and China will provide a large enough market for the pharmaceutical companies in these countries to participate in the PPPs
- This provides them an alternative to collaborating with MNCs
- If and when these drugs are successful, efforts may be initiated to get these registered and marketed in developed countries as well.

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For comments and details