Policy, Markets and Knowledge: Strategic Synergies in Indian Pharmaceutical Firms

The Open University, Milton Keynes

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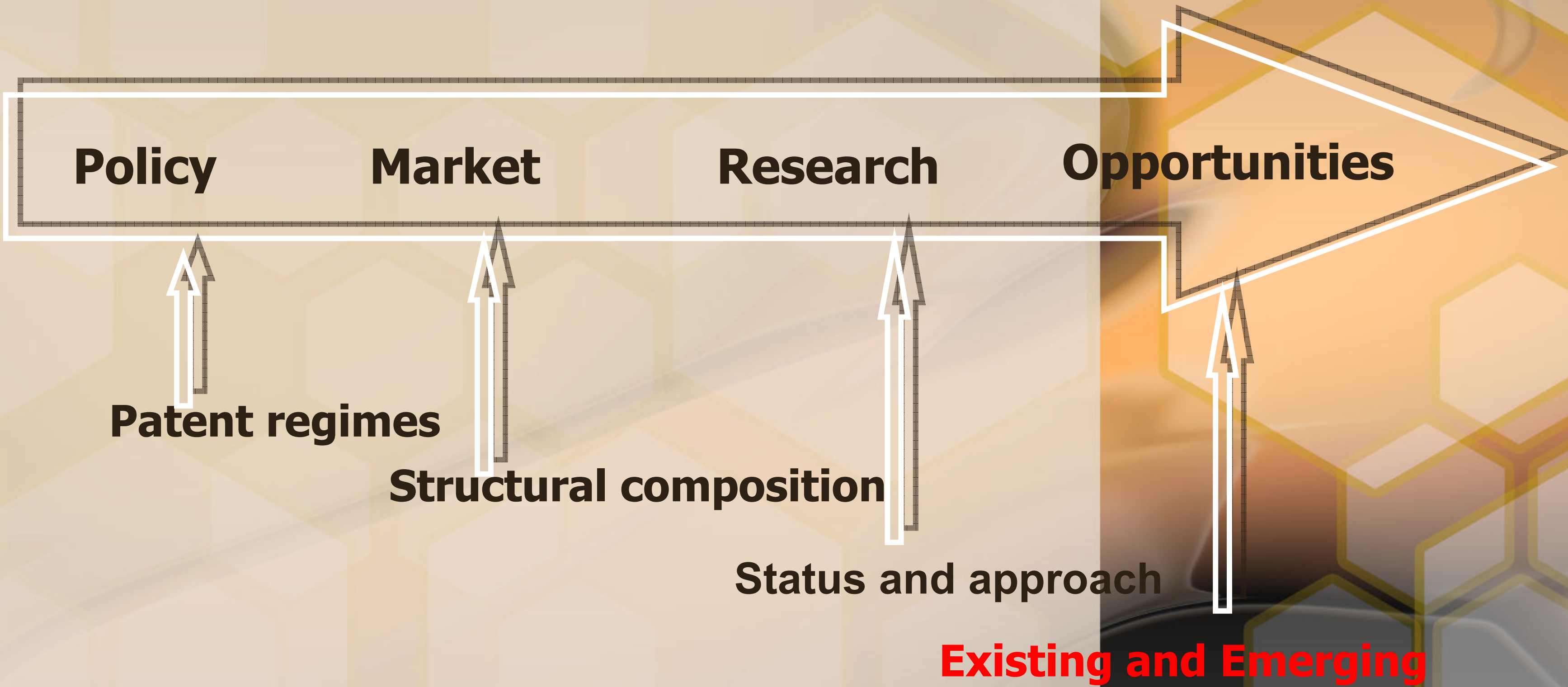
Agenda



Policy
Market
Research
Opportunities
Patent regimes
Structural composition
Status and approach
Existing and Emerging

Phase I (1950-1970)

•The Patents & Design Act 1911
•Industrial Policy 1948
•First DPCO 1970

Policy

•Foreign Ownership
•Drug Prices high
•High import for essential drugs

Market

•Technology import
•Industrial know-how & Capital import
•No bulk production
•Research non-existent

R&D

The PDA 1911 and Industry Growth

CSIR Labs
State-owned (6)
IDPL
HAL
Tech-Institutions
Public

25-30
Chem Pharma
Indo Pharma
Unichem
Sarabhai
IPCL
Zandu
CIPLA
East India
Bengal Immunity
Alembic
Bengal Chemicals
Private

Pfizer....80 MNCs
Wyeth
G.Remedies
Abott
Smithkline
Boehringer
Ciba-Geigy
Merck
Sandoz
Rhone
Nicholas
Roche
Bristol Myers
Hoechst
Burroughs
Parke Davis
Boots
Glaxo
FERA

Phase II (1970-90)

The Patents Act 1970
New Drug Policy 1978, 1986
Revised DPCO 1979, 1987
Hatch Waxman Act 1984
NIP 1991 (Liberalization)

Policy

Emergence of domestic sector
(small, medium and large Pvt. sector)
Public Sector decline
Increased production
Import substitution-self sufficiency
Lower Drug prices
Exit of MNCs

Market

Reverse Engineering
Large scale production capacities and capabilities (generics)
Non-infringing processes

R&D

Process patent regime & industry growth

Dynamic Changes

Nature of Firm	1970	1982	1993
Western Multinationals	80	50	39
Indian Public Sector	10	2	1
Indian Private Sector	10	48	8000+

- In 1976, among the top 20 firms, (which held 57.19% of the pharmaceutical market in India) , there were only 4 Indian firms.
- By 1995, only 7 MNCs (including their subsidiaries) figured among the top 20 pharmaceutical firms in India.
- Among the top 50 in 1995-96 only 12 MNCs figured in the list.

Phase III (Since the 1990s)

TRIPs Agreement 1995
DPCO 1995
Schedule M enforcement
Schedule Y amendments
National Pharmaceutical Policy 2006 draft

Policy

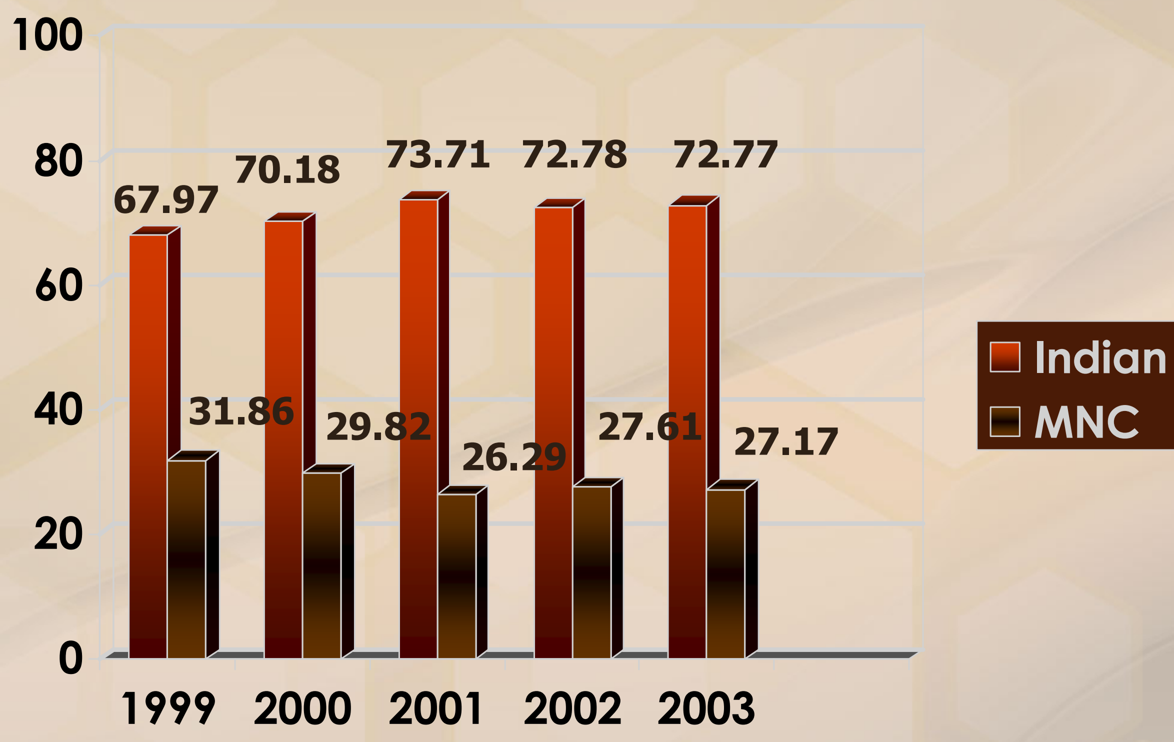
Continued growth of the domestic Sector
(Mainly large pharma)
Net exporter of low-cost, high-quality generics
Entry in regulated markets
Reawakening of PRIs, Laboratories
Return of Western MNCs

Market

Innovative R&D (NCEs, NICEs)
(greater investment, patent filings)
Greater Innovation in generics
(branded and bio-generics)
Science based in-house infrastructure

R&D

Product patent regime and industry growth



Market share of local Indian companies and MNCs

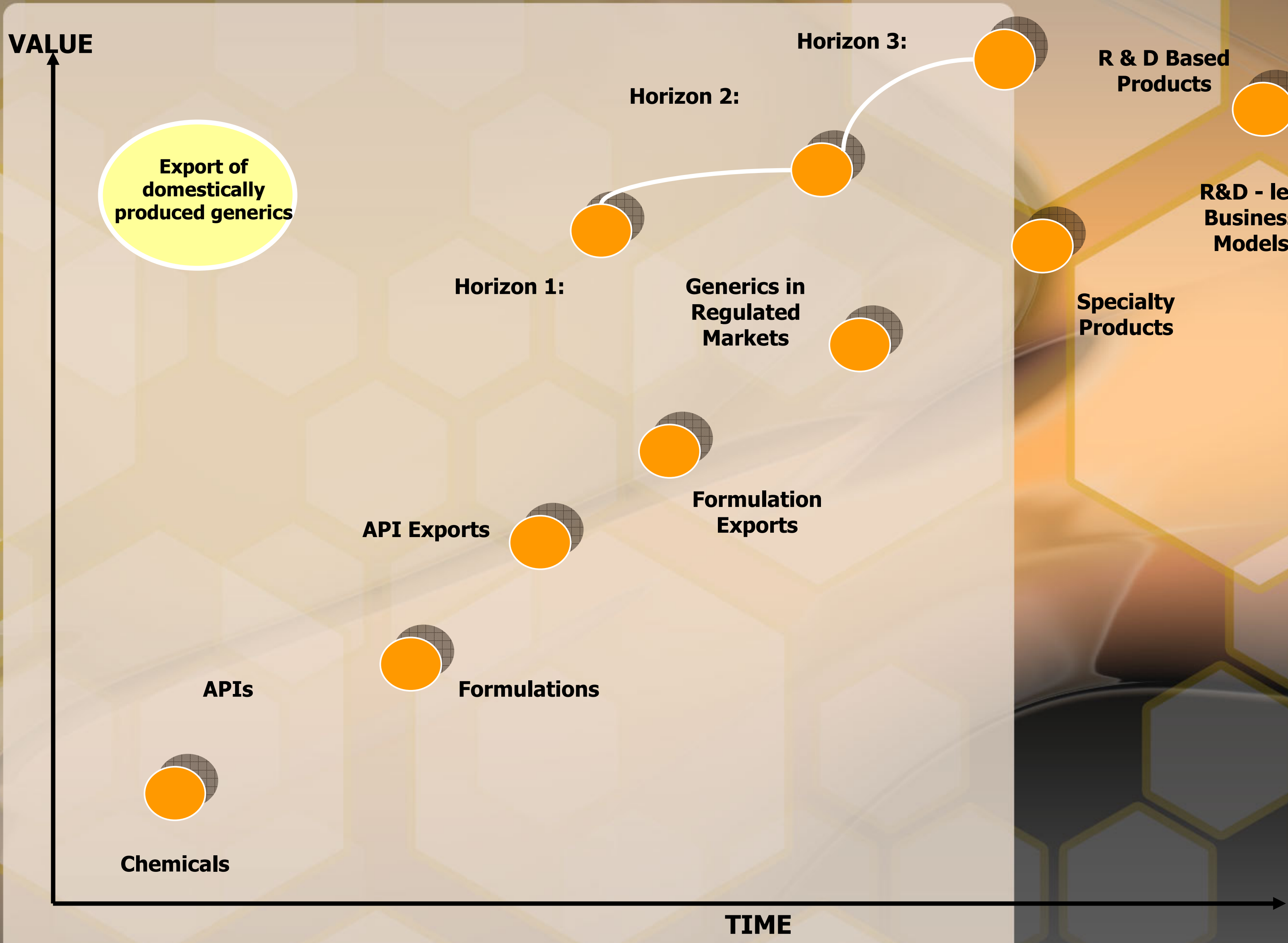
Phase I+II+III (1950-2000...)

•The PDA 1911 •Industrial Policy 1948 •First DPCO 1970	The Patents Act 1970 New Drug Policy 1978, 1986 Revised DPCO 1979, 1987 NIP 1991 (Liberalisation) Hatch Waxman Act	TRIPs Agreement 1995 DPCO 1995 Schedule M enforcement Schedule Y amendments NPP 2006 draft
•Foreign Ownership •Drug Prices high •High import	Emergence Pvt. Sector Public Sector decline Increased production Import substitution Lower Drug prices Exit of MNCs	Domestic Sector (Mainly large pharma) Net exporter Entry in regulated markets Reawakening of PRIs, Return of Western MNCs
•Technology import •Capital import •No bulk production •Research non-existent	Reverse Engineering Large-scale production capacities (generics) Non-infringing processes	Innovative R&D (NCEs, NICEs) Greater Innovation in generics (branded and bio-generics) Science based infrastructure

India's capability creation and value progression chain

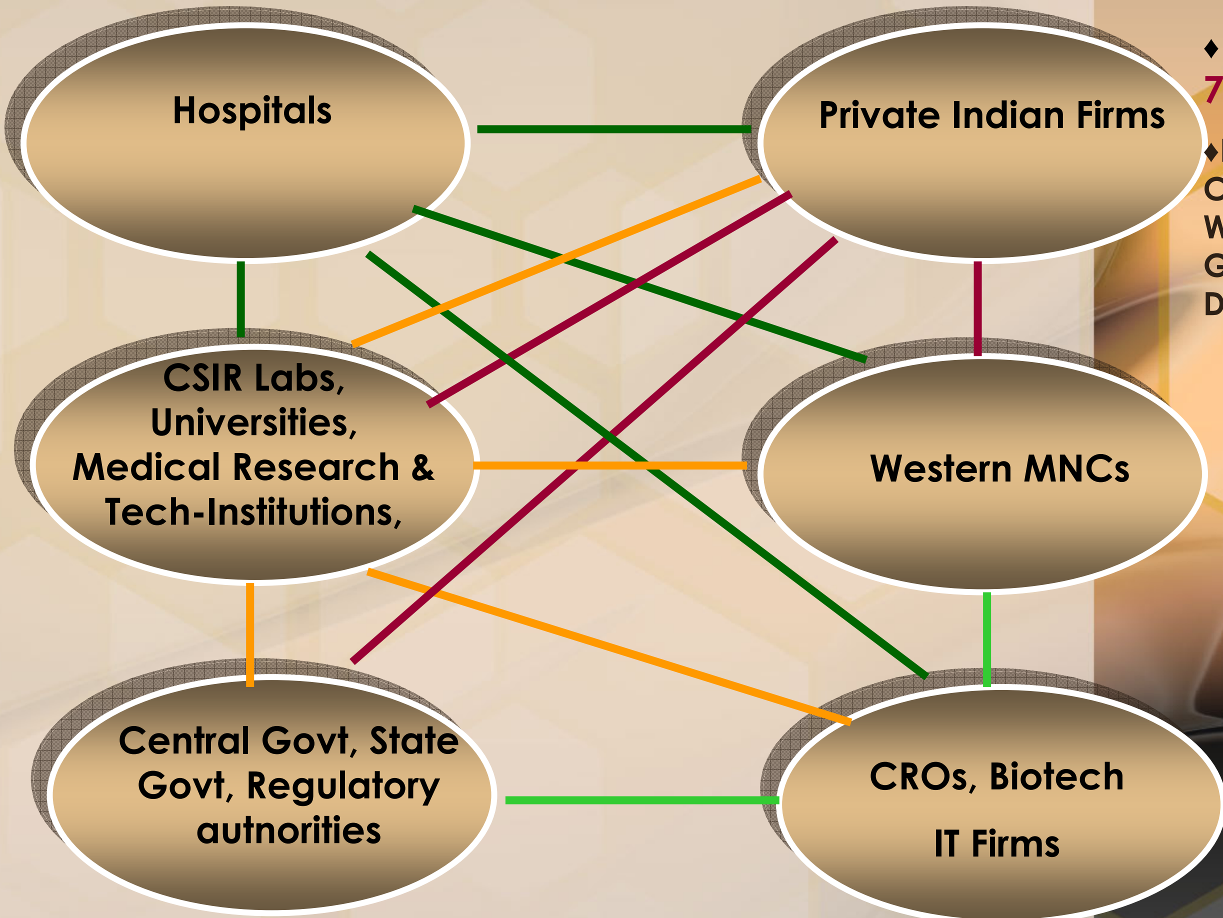
Paradigms	Shifts			
Knowledge Base	Minimal Information Minimum Knowledge (Explicit)	Increasing Knowledge		3D-Information Complex - Knowledge (Tacit)
Research	Duplicative Imitation R&D: Reverse Engg Process Development	Creative Imitation R&D: Generics, Chiral Synthesis	Incremental Innovation R&D: NDDs and Analogue Research	New Innovation R&D: NCEs
Drug Development Capabilities	Primitive Formulations- Manufacturing	Intermediate Chemical Synthesis Skills	Semi-Advanced Complex technologies	Advanced New Knowl -edge fields
Timescale	15 – 24 yrs	Decreasing Cycle Time		10 – 12 yrs

Leveraging strengths to move up



Research Networks

Top 10 corporations = 37 % market share, 8 out of 10 are Indian Firms



- 250-300 firms account for 70% of products

♦Ranbaxy, DRL, NPIL, Sun, Lupin, Cadila, Zydus,, Cipla, Wockhardt, Torrent Aurbindo, Glenmark, Matrix, Alembic, Divis, Sarabhai, Dabur ……..

♦ GSK, Novo Nordisk, Astra, Pfizer, Merck, Eli Lilly, Roche ……..

♦ Siro-Clinpharm, lambda ,i-Gate, Aurigene, Wellquest, Syngene….200

♦Biocon, Bharat Serum &vaccines, Panacea, Shantha Biotech, …..200

♦Wipro, TCS, IBM, ORACLE, Accenture, Satyam, Intel…..

MOH, ICMR, DCGI, DBT, DST, Maharashtra, Karnataka, Andhra-Pradesh, Gujarat,

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Public

25-30
Chem Pharma
Indo Pharma
Unichem
Sarabhai
IPCL
Zandu
CIPLA
East India
Bengal Immunity
Alembic
Bengal Chemicals

Private

Pfizer....80 MNCs
Wyeth
G.Remedies
Abott
Smithkline
Boehringer
Ciba-Geigy
Merck
Sandoz
Rhone
Nicholas
Roche
Bristol Myers
Hoechst
Burroughs
Parke Davis
Boots
Glaxoaxo

FERA

Research Findings: Industry Landscape

- Emerging Innovation Model
  - Technology push + Market pull
  - Generics + NDD (hybrid models)
  - R&D led Service business models
- Guiding Principles
  - knowledge integration
  - Cooperate where cannot compete

- In Transition

  -Process to Product regime (Policy)

  -Imitation to Innovation (Research)

  -Non to semi-regulated markets (Market)

  -In-sourcing to out-Sourcing, Captive investment, partnerships (Strategy)

Three Act Play

(Beginning of advanced R&D in India)

- First Act

advanced development for products

- Second Act

Basic research

- Final Act

R&D Power house ??

Where will Indian drug companies be in 5 years?
Everywhere – if they innovate!!
(Knowledge @ Wharton)

Thank You

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