

National Workshop
Patent and Public Health – Addressing
the Future Imperatives of Health
Security in the Post – TRIPS Era,
11th April 2005, New Delhi

‘THE WAY FORWARD’

***By Ashwini Kumar
Drugs Controller General (India)***

An Act of Genocide



New IPR Regime

Boon to Indian Pharma Sector

Patents Act amendment

‘will put Life-Saving Drugs out of reach’

“.....grand design of the developed world and multinationals to kill local industries.....”

“Patents Law Favorably Amended”

---- IDMA

.....drug pricing issues in product patent....

---Chronicle Pharmabiz

INTERVIEW | *Y.K. Hamied*

Patents law will lead to MNC monopoly



THE CHAIR-
MAN of Re...

What has changed now for In...

----Hindustan Times

नई पेटेंट व्यवस्था में दवाओं के दाम नहीं बढ़ेंगे : कमलनाथ

नई दिल्ली (बा.सं.)। नई व्यवस्था पेटेंट व्यवस्था से दवाओं के दाम बढ़ने की बात को नकारते हुए सरकार ने कहा है कि नए कानून में उसके पास आवश्यकता पड़ने पर किसी कंपनी के पेटेंट अधिकार को अधिकतम करने का पूर्ण अधिकार

आयोजित एक परिषद के लिए भेजे गए संदेश में कहा कि नए कानून में ऐसी पर्याप्त सुरक्षात्मक प्रावधान किए गए हैं ताकि जल्द ही दवाओं की कीमतें न ही और दाम न बढ़ें।

मानव एवं उद्योग संवर्धन तथा उत्पाद एवं विकास पर संयुक्त

कार्य, समानांतर आपस, सरकार द्वारा पेटेंट अधिकार के अधिग्रहण, जनहित में पेटेंट अधिकार रद्द करने और आन्तकालिक स्थितियों से निपटने के पर्याप्त प्रावधान किए गए हैं।

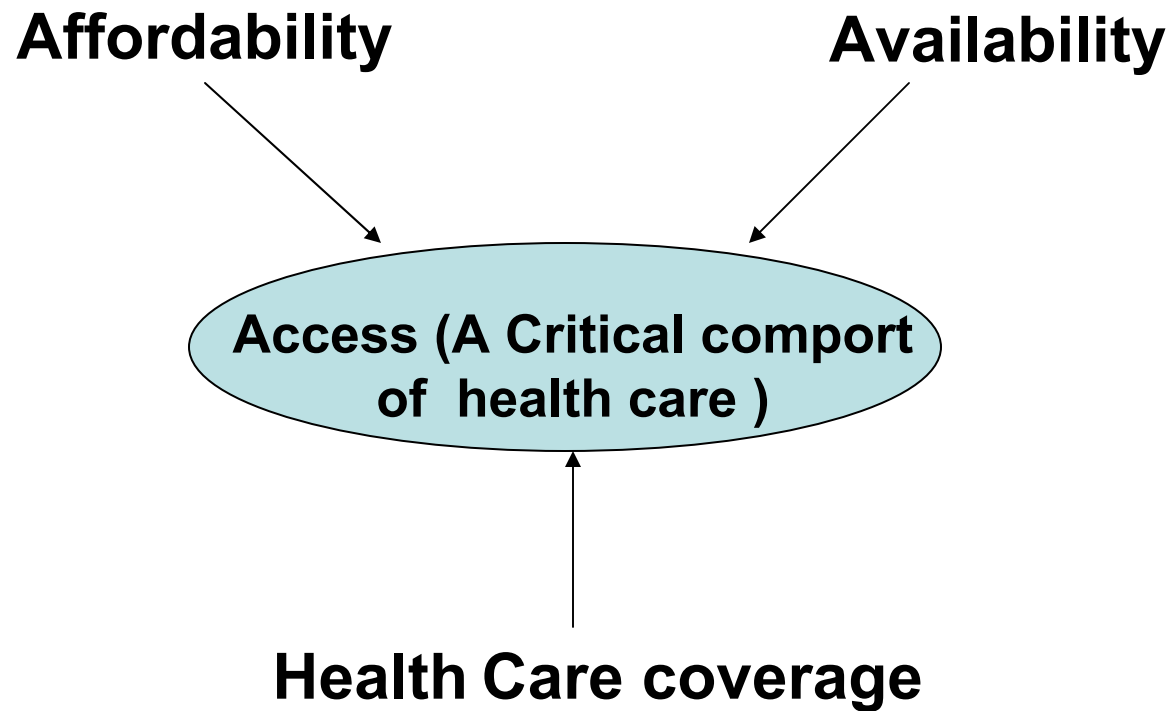
इस अवसर पर जारी संकेत

पेटेंट से हिल सकती हैं राष्ट्रीय स्वास्थ्य सेवाओं की चूल्हे

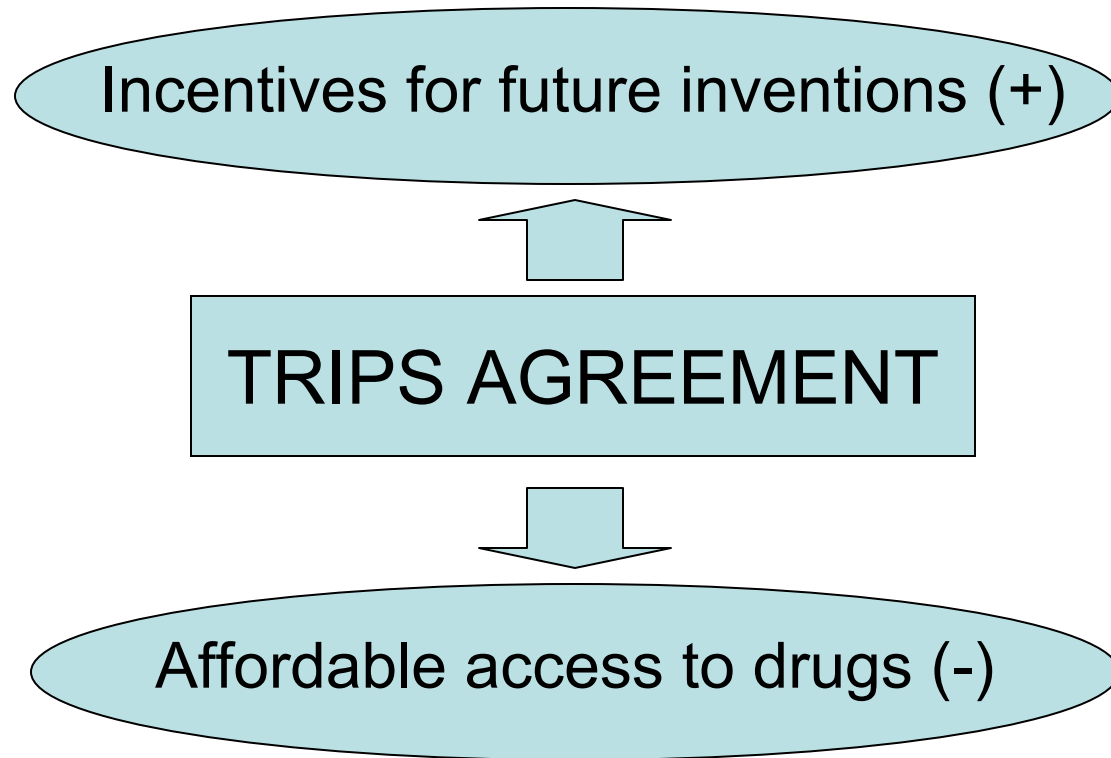
शैलवाला

नई दिल्ली। ईस्ट इंडिया कंपनी के बाद अब वैद्युत इंडिया कंपनी प्रोडक्ट पेटेंट के माध्यम से भारत में घुस कर यहां की अर्थव्यवस्था को संभालने की तैयारी में है। वर्तमान समय में प्रोसेस पेटेंट के माध्यम से अधिकांश भारतीय फार्मास्यूटिकल कंपनियां विदेशी नई खोज पर यहां अन्य तकनीक का इस्तेमाल करके हवाएं बनाती हैं। अमेरिका आदि में हुई नई खोज पर बनी हवाएं अधिक

Health – A life time concern

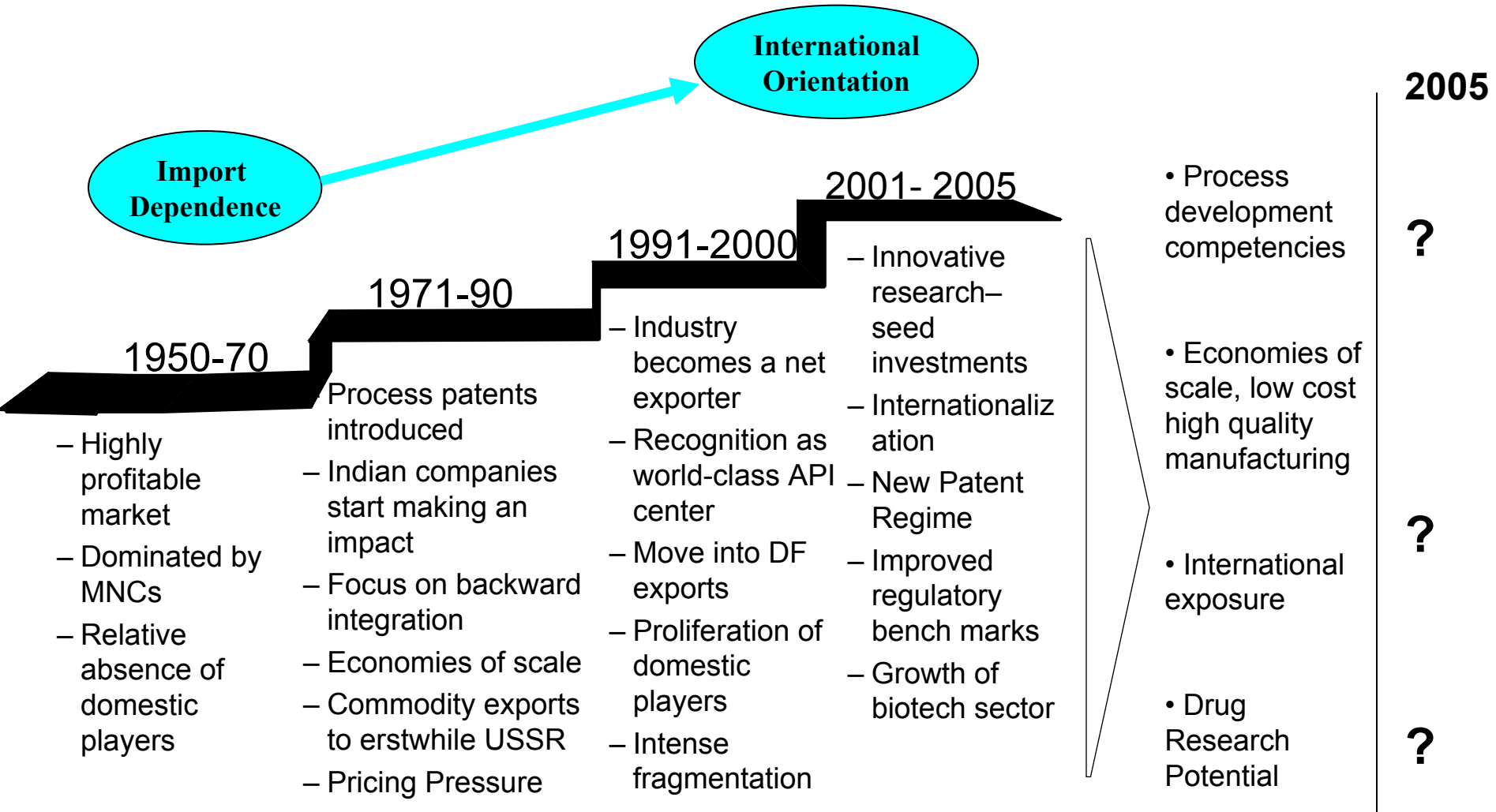


DRUGS AND PHARMACEUTICALS



- Complementary public health goals
- Balance is required
- Flexibility for public health needs

Indian Pharma Industry - A Historical Perspective



Changes in Disease Profile



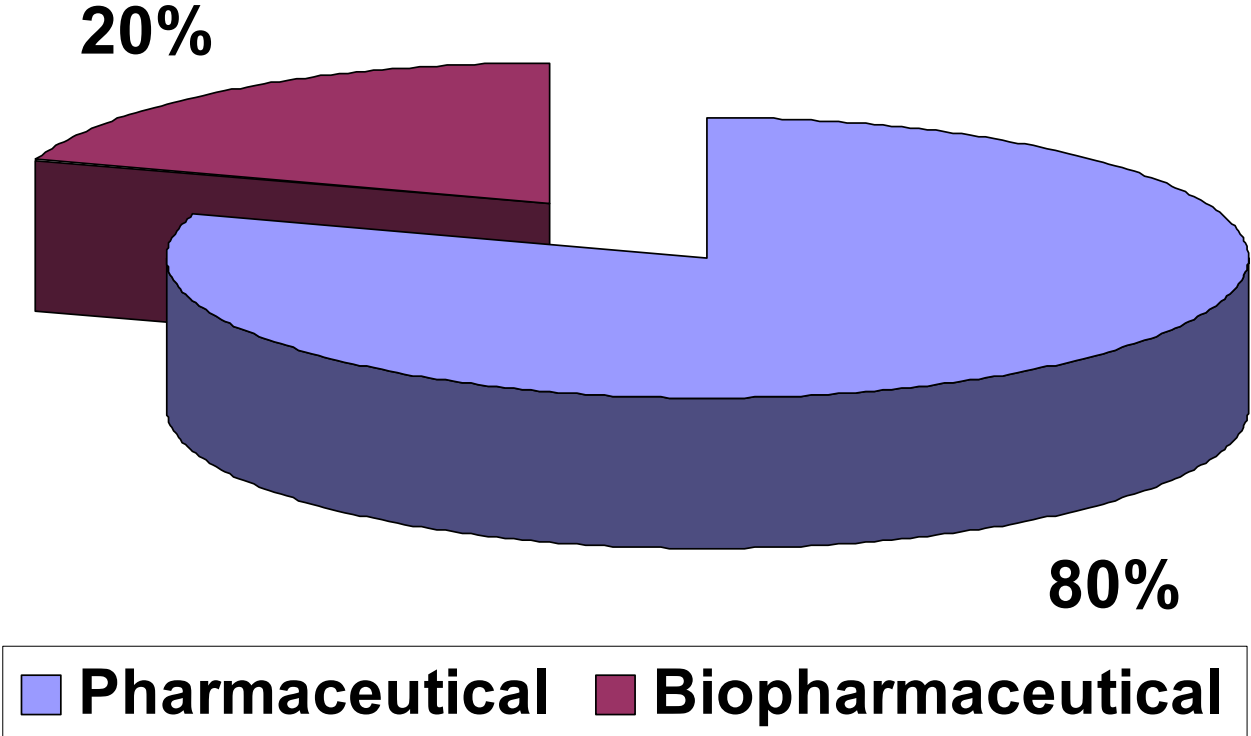
Increased life expectancy due to better control of infections leading to western disease patterns.

INDIA - COMPETITIVE ADVANTAGES

- **Quality Producers (many approved by US-FDA)**
- **Competitive cost base (Plant/Development/Labour costs)**
- **Scientific talents**
- **Educated and English speaking) work force**
- **Managerial/Technical competence**
- **Excellent record of improved cost – beneficial chemical synthesis**
for various drug molecules
- **Wide variety of “Bulk Actives”**
- **Rich Biodiversity**
- **Presence of National Laboratories**
- **Regulatory norms in place**
- **Increasing pressure in biotech therapeutics**

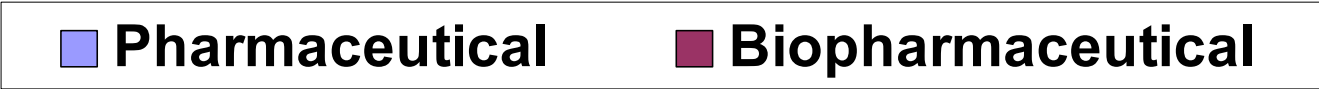
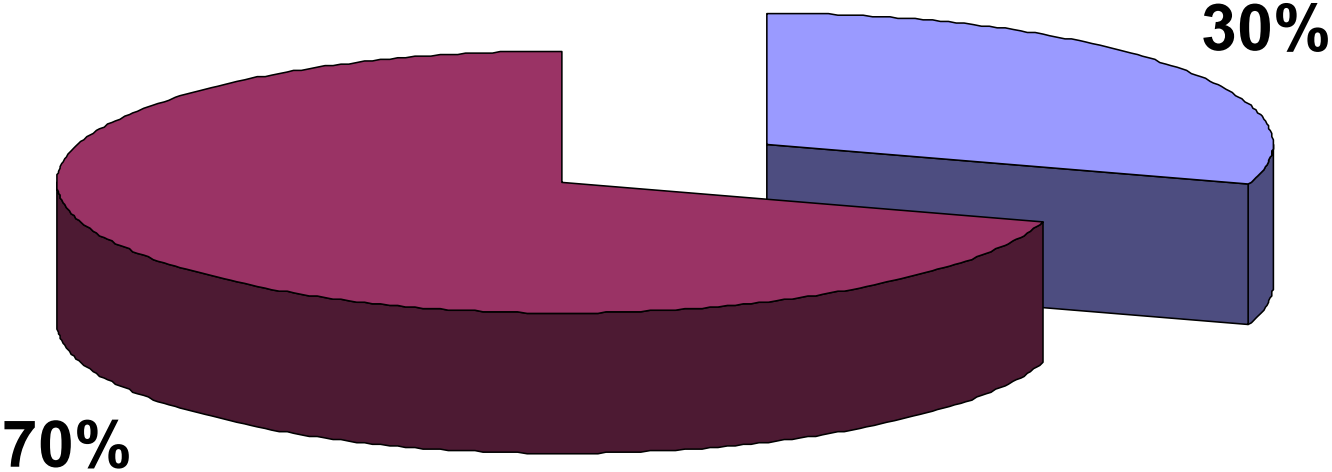
PHARMA MARKET SEGMENTATION

BIO-PHARMACEUTICALS MARKET SHARE - 2001



PHARMA MARKET SEGMENTATION

BIO-PHARMACEUTICALS MARKET SHARE - 2025



VISION 2010 STATEMENT FOR THE PEOPLE OF INDIA

- **To Build a “Healthy India’ by 2010 with :-**
- **To achieve world class quality and create world class manufacturing facilities, backed by contemporary regulatory work.**
- **To achieve the highest market-share of production in the Global Generic Pharmaceutical Market (more specifically, by 2010 to reach a size of 16 % of global volume and a turn-over of \$ 15 billion with export of \$ 8b)**
- **To create for India a strong brand image as the ‘least cost-highest quality’ supplier of pharmaceuticals to anyone, anywhere, anytime.**
- **Become a preferred global destination for clinical research, custom synthesis and genomic research, including bio informatics.**

Pharmaceutical R&D

Current R&D spend of Rs. 320 Cr - 2% of sales

Against an all industry average of 0.3%

R&D spending in the world

MNCs in US / Europe > 15 %

Japanese Companies 9-10 %

Mid-Sized European Cos. 7-8 %

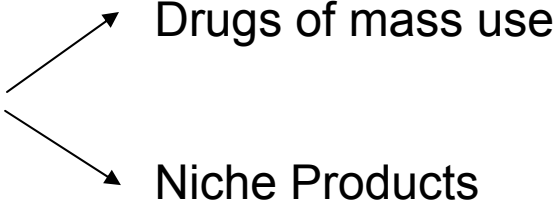
International Generic Cos. 6 %

Need to raise R&D spend

Future Scenario - a distinct possibility

- A significant R&D player
- Indian companies go international
 - Exports Growth : \$ 8 bn (2010)
(From 7,200 Cr to 22,500 Cr to 40,000 Cr)
- Domestic Prices continue to be affordable
- Better health for masses
 - Access to Modern Medicine for 90 % of people (2010)
 - Weaker Section needs met
 - Elimination of spurious medicines
 - Strong regulatory frame work

The Way Forward

- Likely impact – by 2009
- Pricing of patented drugs 
 - Drugs of mass use
 - Niche Products
- Vast local market for existing drugs
 - Wider reach of health care
 - Per capita expenditure on medicines (about \$5) is likely to increase

The Way Forward

- Shifting disease pattern (life style diseases and geriatric care drugs to grow)
- Introducing Indian traditional plant-based medicines into mainstream
- Contract (manufacture, market, and R & D) opportunities
- Increase in patent filing by Indian Pharma sector
- Increasing Govt. support for drug research

Thank You

