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Challenges for Policy Makers –
From Formulation To Implementation
Of
Biotechnology Development Policy

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3rd Asian Conference on Biotechnology Development
9-10, November 2006
Philippines
Shifting thoughts from information technology biotechnology exposes Unique challenges for policy making for biotechnology
<table>
<thead>
<tr>
<th>Attributes</th>
<th>Physical Technology</th>
<th>Biotechnology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capital Investment</td>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td>Product Development Time</td>
<td>Less than 1 year</td>
<td>3-10 years</td>
</tr>
<tr>
<td>Product Development cost</td>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td>Regulatory Control</td>
<td>Few</td>
<td>Many</td>
</tr>
<tr>
<td>Failure Risk</td>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td>Entry Barriers</td>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td>IPR costs &amp; values</td>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td>Market size</td>
<td>Medium to Large</td>
<td>Small to Medium</td>
</tr>
<tr>
<td>VC’s understanding</td>
<td>Good</td>
<td>Poor</td>
</tr>
<tr>
<td>Market Size of Service</td>
<td>$&gt;100$ billion(software)</td>
<td>$&lt;$10$ billion(CROs)</td>
</tr>
<tr>
<td>Cross licensing</td>
<td>High</td>
<td>Medium to high</td>
</tr>
<tr>
<td>Public acceptance</td>
<td>High</td>
<td>Low</td>
</tr>
<tr>
<td>(sensitivities)</td>
<td></td>
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</tbody>
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Need for technology based risk profiling

<table>
<thead>
<tr>
<th>Risk</th>
<th>Core technology interest</th>
<th>Perceived risk factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>CRO, CMO &amp; Diagnostics (Services Business)</td>
<td>Relatively low risk companies</td>
</tr>
<tr>
<td>Med.</td>
<td>Enzymes and Biogenerics</td>
<td>Medium risk</td>
</tr>
<tr>
<td>High</td>
<td>Drug discovery &amp; delivery technologies / Bio-agri/ Bioinformatics / Biomass / Biofuels</td>
<td>Perceived as high risk, nascent business models</td>
</tr>
</tbody>
</table>
The Value Chain of innovation in biopharma

Source: Jone and Hine (2004)
Stages in Research Development and Commercialization of Transgenics

Policy makers face challenges at all major phases of biotechnology development:

- formulation and arriving at a consensus
- translating the policy into schemes
- actual implementation.
Major Challenge I: Policy--formulation and arriving at a consensus

Project affected people
- Individual and families near the project
- Indigenous groups and their leaders

PUBLIC SECTOR
- Local state & National
- Multinational & bilateral development institutions

PRIVATE SECTOR
- Project financiers
- Local business
- Industry
- Associations

ADVOCACY GROUPS
- Local and National grass roots NGO’s
- Religious groups
- University and research centers

Too many new and fresh stakeholders influencing Policy

Thinking in terms of stakeholders than stockholders.
Policy--formulation and arriving at a consensus

Rich In Bioresources And Poor In Productivity And High In Malnutrition

Prevalence of stunting among children under five, in areas of >2 inhabitants/sq km

Public versus Private goods

Goods can be defined along a spectrum from pure "private" goods to pure "public" ones.

Most goods are private in nature, having clear property rights associated with them.

By contrast, the benefits of public goods are enjoyed by all (non-excludable) and consumption by one individual does not deplete the good and thus does not restrict its consumption by others (non-rivalrous). For instance, the Internet is typically open to all (non-excludable) and downloading information does not deplete the information (non-rivalrous).

Global public goods are simply public goods that possess such properties of public-ness across national boundaries.
while the proportion of the world’s population living in poverty declined slightly, the number of people living in absolute poverty – on less than a dollar a day – remained constant at about 1.2 billion. So the challenge is not just about new technologies and their adaptation or dissemination– it is about access to established and useful and proven technologies by the whole of the world’s population and not just a few

Policy–formulation and arriving at a consensus
Communicating and educating biotechnology to the policy makers is one of the great challenges. Achieving better co-ordination and division of labour between the actors involved in formulation or implementation is another great challenge.
Major Challenge II
Translating policy into innovative and pragmatic schemes/programs and/or governmental notifications
The strength of a biotechnology development lies in upscaling a number of proven technologies – diagnostics, vaccines, products, and processes – for fine-tuning and large-scale production. While industry is strong in product development and marketing for commercial benefits, biotechnology in country still lacks the infrastructure for R&D in molecular modeling, protein engineering, drug designing, immunological studies, pre-clinical studies, clinical trials, etc.

Depositories of biological materials will be created in partnership with industry on IDA model for agriculturally and medically important organisms, plasmids, cosmids and constructs of special nature. State-of-the-art large animal house facilities with GLP will be created for testing candidate vaccines and biotherapeutics.
Stem Cell Research – Strategy

Basic Stem Cell Research

Stem Cell Bank

Stem Cell Therapy production unit

Stem Cell Clinical Trials

Licensed Product Manufacture

Cell Biology

Immunology

Animal Modeling

Bioengineering

Research grade cell banking and Characterization

Clinical grade cell banking and Characterization Research

Production process Development

Pilot scale Capacity to supply stem cell for clinical trials

Safety and efficacy

Stem cell Therapy Commercial or Public sponsored
There is a need for better inter-departmental co-ordination in policy formulation, better management and evaluation at the implementation stage and streamlining of the existing set of instruments. Yet harmonize with international protocols / commitments.
Post marketing regulatory awareness to meet EU requirements even though there is no domestic law as yet
Scientific and Public good Perspective for informed Regulatory Decisions
most challenging task: III is implementation of the strategy of actions evolved from the policy

Developing new Biotechnology is not cheap, however. Most current research is being carried out by private sector companies and in the developed world.

### Distribution of Total R&D Expenditure in Science and Technology

<table>
<thead>
<tr>
<th></th>
<th>Public</th>
<th>Private</th>
</tr>
</thead>
<tbody>
<tr>
<td>India</td>
<td>95</td>
<td>05</td>
</tr>
<tr>
<td>Mexico</td>
<td>88</td>
<td>12</td>
</tr>
<tr>
<td>Indonesia</td>
<td>96</td>
<td>04</td>
</tr>
<tr>
<td>Zimbabwe</td>
<td>86</td>
<td>14</td>
</tr>
<tr>
<td>USA</td>
<td>30</td>
<td>70</td>
</tr>
<tr>
<td>Switzerland</td>
<td>26</td>
<td>74</td>
</tr>
</tbody>
</table>
Typical Developments in knowledge industry

- 1980
- 2000
- Human resource Development
- Joint R&D
- Equipment and infrastructure
- Mutual benefit
- IPR
- Sharing benefits
- Technology licensing
- Safety
Lack of adequate human resources

- Quality education and numbers wanting at Masters and Ph.D Level,
- Need for trained teachers, technicians to handle facilities / laboratories
- Lack of human resource with skills and expertise to take various tasks from discovery to market like bioprocessing, biodesign, clinical trials, technology transfer, IPR management, regulation and Interdisciplinary training
- Inadequate strategy for Scale – up of technologies through linkages with private sector, developmental agencies
- More emphasis on individual investigator projects than Network or coordinated projects along the value chain from discovery – technology development-validation-delivery.
- Number of programmes have increased and close monitoring has not been possible.
Research Skills are essential than degrees/certificates
Convergence of Technologies – Need task based human resources --
A biotechnology finance life cycle
PARTNERSHIPS:
FUTURE MODELS

Alliance Model

Industries Market Intelligence
Lab’s Domain Knowledge

Part flows back as Royalty
Wealth Creation by Industry

Alliance

Co-development of projects executed by industrial partner
Increase of New Process/ Product

Human resources absorbed by Industry

Industry Marketing

CSIR Report 2005
PARTNERSHIP:
FUTURE MODELS

R&D Service Model

Industries Marketing Skill, Manpower and Operating Expenses

Lab’s Domain Knowledge

Part flows back as Royalty

Alliance

Knowledge Based Service centres Managed by Industries with Lab’s equity in IPR/Services

IPR Generation

Industries in Core Sectors: Pharma, Genomics, Bioinformatics etc. benefit

Marketing of IPR for Wealth Generation

CSIR Report 2005
World is becoming small and markets are growing - Ramanujam

Product, expertise

Success criteria
Socio-economic factors
farmer, consumer,

Delivery systems and network

National governments

Public

International agencies

Financial/consultancy agencies

Policy, Time, Cost -benefit, Policy, Investment

Private

NGO

Options and alternatives
Precision

acceptance,
**Developed countries**

Transnational knowledge transference enablers (MDBs, NGOs, MNCs, Regional Groups)

Trans-national ways means for knowledge transference: Skills, technology, partnerships

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**Role of Government**
- Establish a stable and predictable political and macroeconomic environment
- Issue transparent policies and enforce legal & property rights
- Facilitate cluster development
- Create a business environment with low transaction costs
- Support incentive creativity & innovation

- Build strategic alliances with the private sector, unions, trade associations, universities and research institutions

PUBLIC SECTOR

**Role of Enterprises**
- Mount competitive strategies
- Develop network and clusters for achieving efficiency
- Increase technological effort (R&D)
- Build new capabilities and skills
- Develop modern infrastructure
- Build strategic alliances with public sector, unions, universities and research institutions
- Meet international standards of costs, quality and delivery

PRIVATE SECTOR

**UNIVERSITIES & RESEARCH INSTITUTIONS**
- Align curricula to business’ needs
- Crafts public and private partnerships to develop new capabilities and skills

**Non-Governmental Organizations**
- Serve as enablers, catalysts and accelerators of public and private partnership

Institutions for collaboration

Inter-organizational learning
CLEAR OUT COME - Performance Indicators

- Greater enrolment of students in life sciences;
- Increase in the number of persons with higher levels of education and skill in life sciences and biotechnology;
- Greater contribution of research to economic and social development
- Increased contribution of university system to basic life science as well as translational biotechnology research
- Strong international partnerships linked to national goals.
- Increased number of new companies and increase in SME’s engaged in R&D, and
- Finally, the Indian biotech industry generating revenue to the tune of at least US $ 10 billion annually and creating substantially more jobs by 2010.
Innovative performance

Factors affecting performance

Organizational Environment

People

Technology

Market

Tasks

Processes

Suppliers

Task.

Leadership

Public/private

Strategy

Technology

Customers

Regulations

Political and social Environment

Economy
TO CONVERT CHALLENGES TO OPPORTUNITIES

- POLICY MAKERS
- FORMULATION
- ACTION PLAN
- IMPLEMENTATION
- STAKEHOLDERS
- HUMAN
- INTERNATIONAL
- INFRASTRUCTURE
- PHYSICAL
- FISCAL
Political will
Planning,
Coordination
communication
Integration
Are must
if the the policy has to succeed
If not ......................
Dilemma of hunger and malnutrition

Collaboration & Partnerships

Pragmatic & inclusive policy for all

Proponents ↔ Opponents

TECHNOLOGY

WTO
CODEX
CBD
TRIPS
PVP
PBR--Treaties
conventions

Dilemma of hunger and malnutrition