A Strategy to Make India a Biotech Leader by 2025

From saving lives to driving the economy

Takshashila Working Group

Takshashila Discussion SlideDoc

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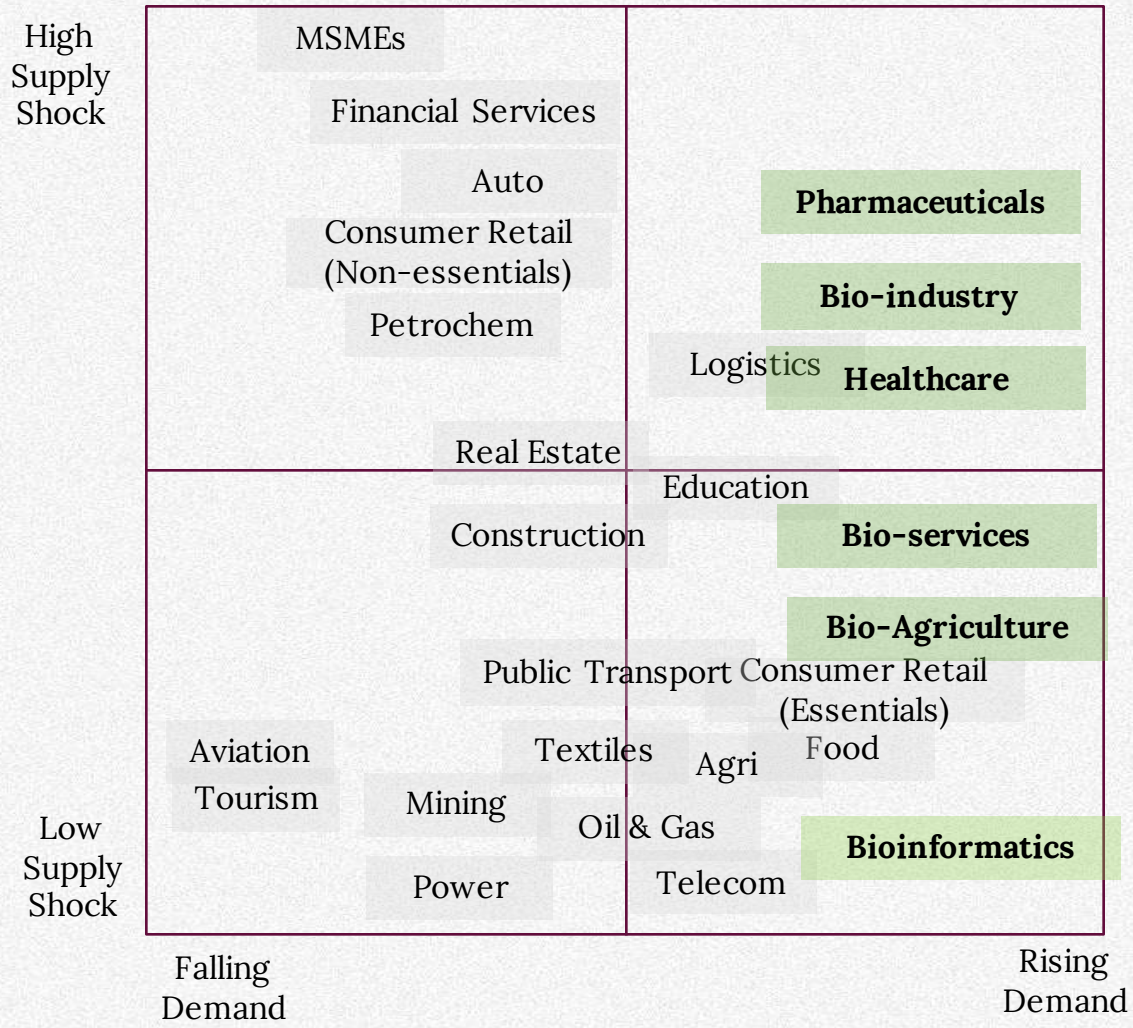
High level strategy

Biotech & healthcare is crucial for economic revival



Global demand for biotech will rise

1. During & after the pandemic, public and private expenditure on healthcare and wellness will drive global demand
2. Biotech is seeing demand surge
3. Healthcare services, pharmaceuticals, diagnostic testing and clinical trials will see high global demand
4. Disruption in global supply chains has created a brief window of opportunity for Indian industry

Necessary to upgrade our industry base

1. Greater investment in R&D, education & skilling necessary to be globally competitive
2. India must create & own key intellectual property across the sector
3. Opportunity to be both self-reliant and a global export house

Green boxes indicate biotech-related sectors and grey boxes are non-biotech sectors.
COVID-19 has increased the demand for biotech and associated services

Biotech helps meet both the health & economic challenge

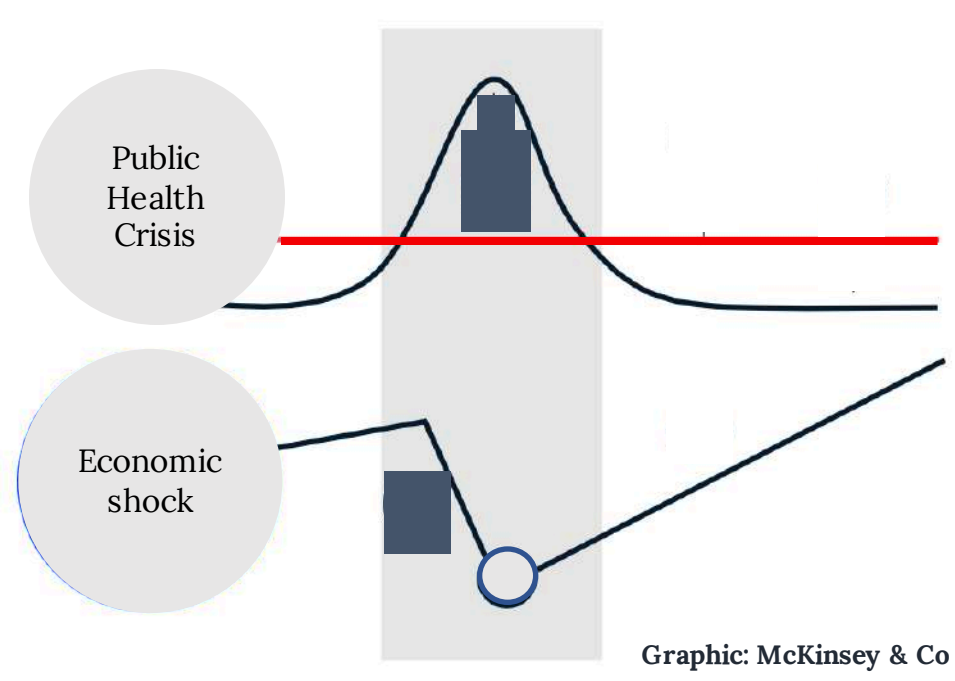


Figure adapted from "Crushing coronavirus uncertainty: The big 'unlock' for our economies" by McKinsey & Company, Published May 13, 2020.

1. Lifeline during the pandemic and fast economic growth engine
2. Capable of quick recovery and growth, if government policies are conducive
3. Industry needs government support during the crisis window
4. Strategic public investment in the sector can make India a global champion

Making India a Biotech Superpower by 2025

1 Biotech for winning the war against the coronavirus

1. Expand production of the anti-pandemic arsenal (drugs, test kits, ventilators, PPE, hospital beds, ICUs & personnel)
2. Expand biotech R&D infrastructure to discover vaccines, therapy and care
3. Strategic changes in trade policy to increase self-reliance and attract global supply chains.
4. Designate biotech R&D as an essential service

2 Biotech for economic revival

1. Immediately raise public expenditure and fiscal incentives for private investment in healthcare have significant multiplier effect
2. Upgrade quality control but simplify regulatory processes to raise private investments
3. Create a special SPV to direct credit to biotech MSMES & startups

3 Biotech for long-term economic competitiveness (global healthcare hub)

1. Create a healthcare city in each major state around a medical college, R&D institution & industry cluster
2. Double the number of biotech parks to 30
3. Create 100 new first-class training institutions
4. Becoming part of the global supply chain is the smart way to become self-reliant
5. Reform industry governance

Opportunity Scan 1/3

COVID-19 Opportunity	Current status	Long term opportunity	Key Challenges	Key Enablers
DIAGNOSTICS Specimen collection consumables - Nasal swabs, throat swabs	Mainly imported from Italy, Germany and US	Any application that requires collection of genomic samples	Patents, specialised manufacturing	• Setting for standards for Indian manufacturers, • Advanced purchase agreements to incentivise new manufacturers • Creation of a strategic stockpile tax exemptions of purchase of equipment
Create and manufacture RT-PCR kits for testing COVID-19 (50% of febrile cases remain undiagnosed - many novel viruses, need test kits)	Imported from US and Germany initially; now South Korea and China; 6 Indian manufacturers approved as of 21	Create RT-PCR kits for other RNA based viral infections	Supply of reagents for manufacturing Cheaper kits available form China Approval processes Access to positive samples	• Easing of approval process: convert more labs into approval testing labs • Reduce/Exempt GST • Removal of price ceilings • Partnerships between research institutions/small to mid-size startups and manufacturers
Antibody tests	Imported from China and South Korea; few kits approved in India	Ready indigenous capability for antibody-based kit production	Access to positive samples Supply of reagents for manufacturing Cheaper kits from China	• Easing of approval process • Increased tax on imported products • Reduce/Exempt GST • Removal of price ceilings • Partnerships between research institutions/small to mid-size startups and manufacturers

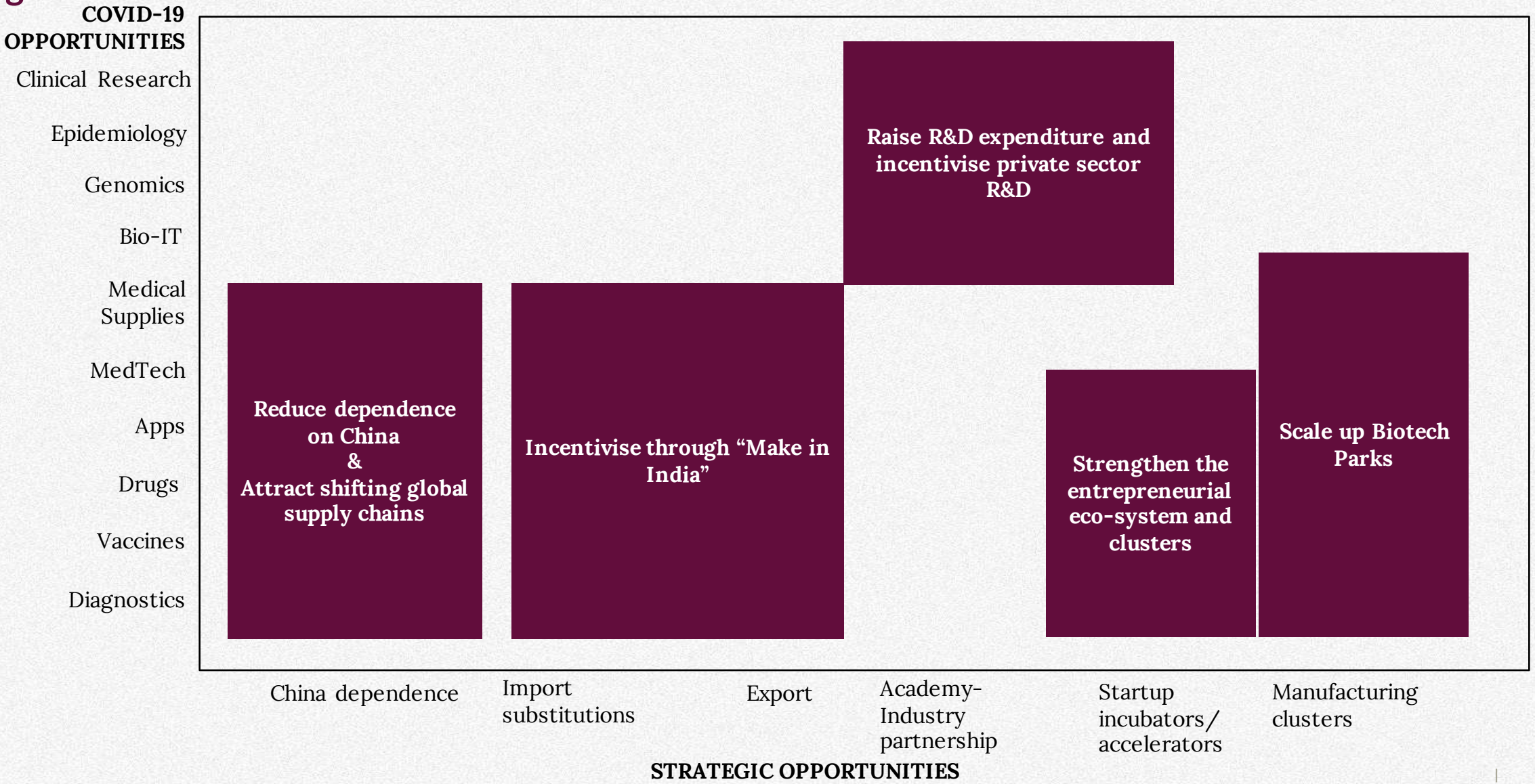
Opportunity Scan 2/3

COVID-19 Opportunity	Current status	Long term opportunity	Key Challenges	Key Enablers
Testing as a service	Allowed in NABL accredited private labs + government labs		Approval process Availability of automatic RNA extraction equipment, Access to RTPCR kits Availability of trained labour	• Easing of approval process; allow industrial organisations to assess and grant testing approvals • Exemption on purchase of specialised equipment • Payment of utilities (short term for COVID-19)
VACCINES Create and manufacture vaccine for COVID-19	5 proposed candidates in development in India	India is already the biggest vaccine manufacturer - a focus on incentivising R&D could help make India the biggest vaccine innovator	Patents, Access to samples Access to BSL2/3 facilities to work with pathogens Capital intensive research with high risks of failure, Access to specialised labour Long approval times	• Fast-track vaccine applications • Build incubators with BSL2/3 facilities for startups • Partnerships between research institutions/small to mid-size startups and clinical trial units/manufacturers

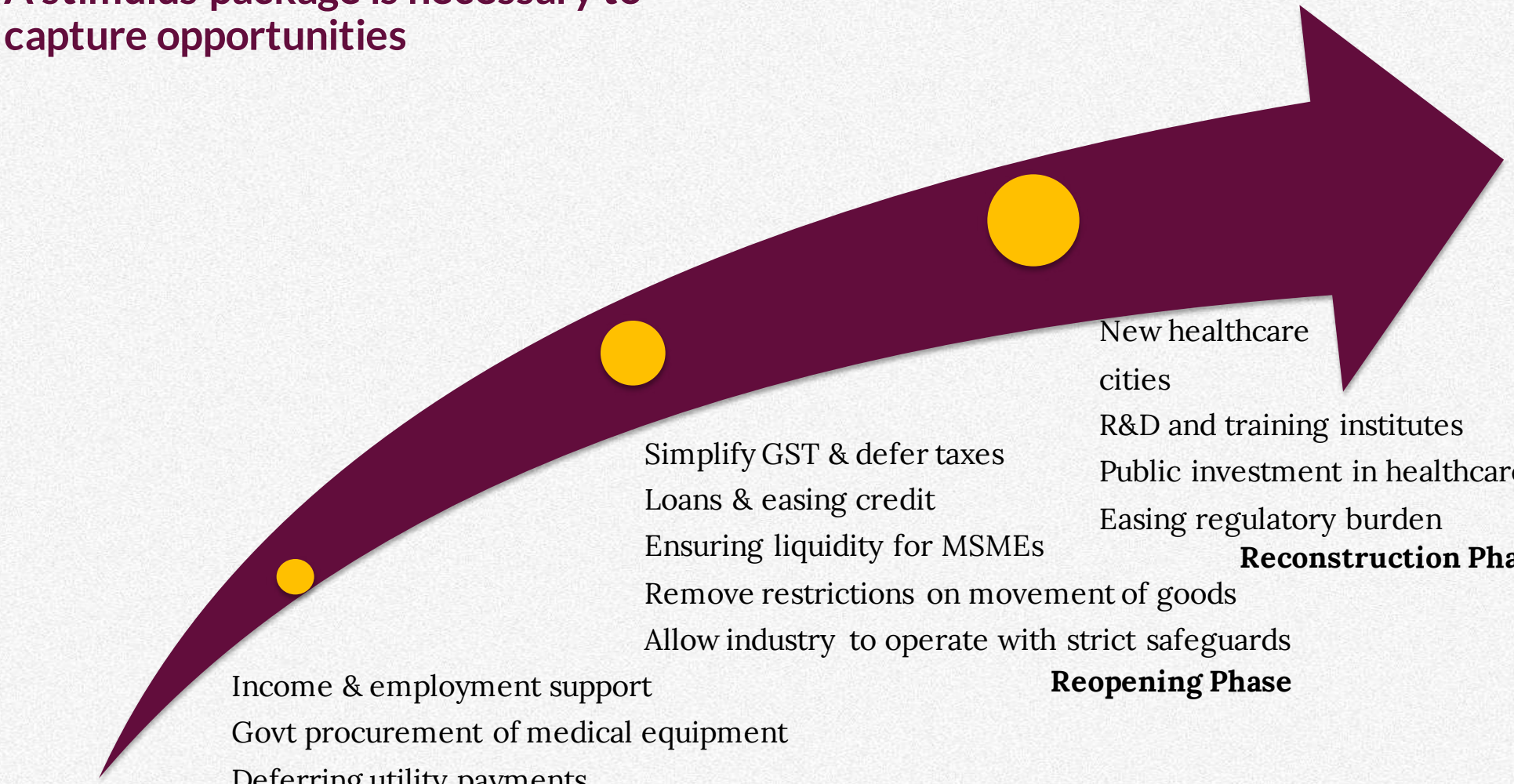
Opportunity Scan 3/3

COVID-19 Opportunity	Current status	Long term opportunity	Key Challenges	Key Enablers
DRUGS APIs - high priority list based on global demand	Drugs currently being trialled	India becomes the main supplier of drugs	Competition with China Patents Manufacturing capabilities Specialised labour Supply chain of raw materials	• Tax breaks for setting up manufacturing units • Import substitution • Removal of price ceilings
MEDTECH Ventilators, ICU equipment, etc	Some indigenous manufacture	India become an important supplier for medtech (eg Pacemakers, X-ray systems, Wearables for telemedicine augmentation, Bionics for disabilities)	High capital requirement, absence of quality standards, complex rules and guidelines, higher duties on raw materials than finished products	• Stockpile key equipment like ventilators • Tax exempt finished products

Emerging opportunities and how to grab them



A stimulus package is necessary to capture opportunities



High Economic Multiplier

New healthcare cities
R&D and training institutes
Public investment in healthcare
Easing regulatory burden

Reconstruction Phase

Simplify GST & defer taxes
Loans & easing credit
Ensuring liquidity for MSMEs
Remove restrictions on movement of goods
Allow industry to operate with strict safeguards

Reopening Phase

Income & employment support
Govt procurement of medical equipment
Deferring utility payments
Govt support for treatment in private setups
Allow private labs to test (govt to bear the cost)

Crisis Management Phase

Low Economic Multiplier

How we can address the internal challenges [1/2]

Issue	Policy Response
Regulatory opacity & effectiveness	• Create a single Ministry of Life Sciences & Health • Separate each governing function (regulatory, policy making, quality assurance, dispute resolution) from production functions (R&D, healthcare, public health management) • Adopt principles-based regulation (instead of rules-based regulation) wherever possible
Supply chain friction	• Prioritise biotech interests in bilateral & multilateral negotiations • Streamline GST regime • Ensure continuity and resilience of the biotech supply chain
Shortage of quality talent	• Expansion of specialized training institutes and fiscal incentives for in-house capacity building/training institutes. • Provide incentives to foreign investors that commit to training & manpower development • Renewed attention to industry-academic/industrial R&D collaborations

How we can address the internal challenges [2/2]

Issue	Policy Response
Intellectual property	• Create a detailed plan to acquire IP/rights in critical technologies and domain areas • Explore negotiations with Western economies on biotech IPR regimes in the post-pandemic world.
Quality control	• Create a National Biotech Quality Council as a PPP - mandate to improve the culture and incentives for radical quality improvement
Clinical trials	• Create a new Safe Clinical Trials Framework to balance scientific advancement and economic interests with the well-being & dignity of people

Recommended Initiatives

New economic value drivers

National fund to promote affordable innovation in biotech and healthcare

- Expected budget Rs 1000 crore over 3 years

Global hub for vaccines, generics, CMO and clinical research

- Make a strategic effort to attract investment, global talent and intellectual property in strategic sectors

Lead a global consortium for infectious diseases

- India to champion a multi-stakeholder forum under G-20 or UN umbrella
- Governments, philanthropies, private sector & civil society groups as participants

Host a pandemic preparedness platform

- Adapt international coordination methods devised for earthquake & tsunami early warning and counter-terrorism/FATF

Make strategic public investments [1/2]

Double the number of biotech parks to 30 under the National Biotechnology Parks Scheme

- Create biotech parks focused on themes - for example, cancer, genetically modified seeds, or renewable energy.
- The biotech park would have facilities to meet requirements for the entire value chain: R&D, training, manufacturing, and performing clinical/field trials.
- Estimated budget: Rs 2000 Crores over 5 years; Rs 200 Crores/year for O&M

Biotech for Pandemic Preparation

- Set up a federated strategic reserve for PPE, ventilators, critical medicines.
- Incentivise indigenous companies through advanced procurement guarantees.
- Use biotech for medical screening, improving diagnosis, solutions to sanitisation, research into vaccines and therapeutics. Set up BSL3 facilities in each state for improved surveillance.
- Estimated budget: Rs 5000 Crores over the next 3 years

Make strategic public investments [2/2]

Invest in new training centres and institutions

- Training centres can offer technical courses preparing students as per industry requirements.
- These centres should become self-sustainable after 3-5 years.
- Courses can include training in biological techniques, ethics and scientific rigour.
- PPP model with industry (where possible)
- Estimated budget: Rs 1000 crores (infrastructure), Rs 100 Crores/year (O&M)

Clear the regulatory decks for growth

Single ministry with structural separation of functional departments/organisations

- Separate policy-making, regulatory, licensing, standards & quality control, and dispute resolution functions (as in the case of telecom)
- Separate funding of R&D from the conduct of R&D
- Create a Life Science Information System that connects government departments, laboratories, academic institutions and industry
- Mandate government-funded research to be published in open/free journals and databases

Review the Biodiversity Act (2002)

- Balance biological diversity and its responsible, sustainable economic use

Create a Safe Clinical Trials Framework

- Policy framework to allow medical advancement while protecting safety, dignity and equity of all citizens
- Encourage investment in campuses, protocols and quality standards for preclinical and clinical trials.
- Emphasise the connection with access to better and affordable drugs within India.
- Estimated budget: Rs 500 crores over 3 years

Key sector-specific proposals [1/2]

Common

- Clear tax refunds and other reimbursements immediately
- Provide wage subsidies to small industries/income support for contract workers to ease liquidity crunch

Bioagriculture

- Declare bioagricuture an essential service
- Incentivise R&D through double tax deduction
- Streamline regulatory processes for a single-window clearance

Bioindustry

- Focus on medtech and telemedicine industries to improve healthcare access
- Ease regulation to incentivise telemedicine and adopt medtech products such as wearables for better monitoring of remote patients

Bioinformatics

- Review global data localisation policies to ensure that Indian bioinformatics companies have access to foreign markets

Key sector-specific proposals [2/2]

Bioservices

- Ease the setting up infrastructure for clinical trials through discounted land offering; increased FDI for cash flow
- Implement global testing standards and cGMP guidelines in order to attract R&D and manufacturing contracts from other countries
- Encourage the setup of accelerators, incubators for bioservices

Biopharma

- Incentivise R&D through double tax deduction
- Clear permissions for manufacturing, transmission of raw materials, etc. to address supply side bottlenecks
- Create biotech-specific in-house global centers, similar to those in the IT sector
- Guarantee fair price through advanced purchase agreements + removal of price ceilings

Appendix: Detailed Recommendations

1. Biotech for pandemic preparation
a. Capacity building 1/2

Sr. No.	Recommendation	Type of recommendation	Nodal agency	Next steps	Budget
1	Expand production of the anti-pandemic arsenal (drugs, test kits, ventilators, PPE, hospital beds, ICUs & personnel) (Slide 6)	Changes to existing programme/project	Govt. and private sector to provide funding Industry partners: Medtech, diagnostics and pharmaceutical industry	• Removal of price ceilings • Incentivise partnerships between research institutions/small to mid-size startups and manufacturers • Tax breaks for manufacturing • Tax exemptions of purchase of equipment and components • Setting for standards for Indian manufacturers (Slide 6) • Set up a federated strategic reserve for PPE, ventilators, critical medicines • Incentivise indigenous companies through advanced procurement guarantees • Set up BSL3 facilities in each state for improved surveillance (Slide 16)	Rs 5000 crores over next 3 years (Slide 16)

1. Biotech for pandemic preparation
a. Capacity building 2/2

Sr. No.	Recommendation	Type of recommendation	Nodal agency	Next steps	Budget
2	Expand biotech R&D infrastructure to discover vaccines, therapy and care (Slide 6)	Changes to existing programme/project	Ministry of Science and Technology (MoST), Ministry of Health and Family Welfare (MoHFW), private sector players	• Fast track vaccine applications • Build incubators with BSL 2/3 facilities for startups • Partnerships between research institutions/small to mid-size startups and clinical trial units/manufacturers (Slide 8)	
3	Testing as a service (Slide 8)	Regulatory change	Indian Council of Medical Research (ICMR), MoHFW	• Easing of approval process; allow industrial organisations to assess and grant testing approvals • Exemption on purchase of specialised equipment • Payment of utilities (short term for COVID-19) (Slide 8) • Allow private labs to test (govt to bear the cost)	

1. Biotech for pandemic preparation
b. Governance changes

Sr. No.	Recommendation	Type of recommendation	Nodal agency	Next steps	Budget
4	Designate biotech R&D as an essential service (Slide 6)	Policy change	Ministry of Home Affairs (MHA), MoST		
5	Host a pandemic preparedness platform	New programme/project	MoHFW	• Adapt international coordination methods devised for earthquake and tsunami early warning and counter-terrorism/FATF	
6	Lead a global consortium for infectious diseases	New programme/project	MoHFW	• India to champion a multi-stakeholder forum under G-20 or UN umbrella • Governments, philanthropies, private sector and civil society groups as participants	
7	Create a healthcare city in each major state around a medical college, R&D institution and industry cluster (Slide 6)	New project	MoHFW, MoST, MHRD, Medical Council of India, private sector, Ministry of Finance (MoF)	• Identify areas in each major state where the healthcare city can be built	

2. Biotech Research and Development
a. Capacity building 1/2

Sr. No.	Recommendation	Type of recommendation	Nodal agency	Next steps	Budget
8	Double the number of biotech parks to 30	Changes to existing programme/project	National Biotechnology Parks Scheme, Dept of Biotechnology (MoST)	• Create biotech parks focused on themes – for example, cancer, genetically modified seeds or renewable energy • The biotech park would have facilities to meet requirements for the entire value chain: R&D, training, manufacturing, and performing clinical/field trials (Slide 16)	Rs 2000 crores over next 5 years, Rs 200 crores/year for O&M
9	Create 100 new first-class training institutions (Slide 6)	Changes to existing project	MoF, MoST, Educational Institutions, private sector	• Expansion of specialised training institutes and fiscal incentives for in-house capacity building/training institutes • Provide incentives to foreign investors that commit to training and manpower development • Renewed attention to industry-academic/industrial R&D collaborations (Slide 11)	

2. Biotech Research and Development
a. Capacity building 2/2

Sr. No.	Recommendation	Type of recommendation	Nodal agency	Next steps	Budget
10	Create 100 new first-class training institutions (Slide 6)	Changes to existing project	MoF, MoST, Educational Institutions, private sector	• Expansion of specialised training institutes and fiscal incentives for in-house capacity building/training institutes • Provide incentives to foreign investors that commit to training and manpower development • Renewed attention to industry-academic/industrial R&D collaborations (Slide 11) • Training centres can offer technical courses, preparing students as per industry requirements • These centres should become self-sustainable after 3-5 years • Courses can include training in biological techniques, ethics and scientific rigour (Slide 17)	

2. Biotech Research and Development
b. Governance changes 1/2

Sr. No.	Recommendation	Type of recommendation	Nodal agency	Next steps	Budget
11	Create a single Ministry of Life Sciences & Health	Policy change		• Prepare a proposal stating the importance of combining life sciences and health under one ministry • Separate policy-making, regulatory, licensing, standards & quality control, and dispute resolution functions (as in the case of telecom) • Create a Life Science Information System that connects govt departments, labs, academic institutions and industry • Mandate govt-funded research to be published in open/free journals and databases (Slide 18)	

2. Biotech Research and Development
b. Governance changes 2/2

Sr. No.	Recommendation	Type of recommendation	Nodal agency	Next steps	Budget
12	Create a new Safe Clinical Trials Framework to balance scientific advancement and economic interests with well-being and dignity of human beings	Regulatory change	ICMR, MoST	• Policy framework to allow medical advancement while protecting safety, dignity and equity of all citizens • Encourage investment in campuses, protocols and quality standards for pre-clinical and clinical trials • Emphasise the connection with access to better and affordable drugs within India (Slide 18)	Rs 500 crores over 3 years
13	Create a National Biotech Quality Council as a PPP (Slide 13)	Policy change	MoST		
14	Review the Biodiversity Act 2002	Policy change			

3. Financing biotech sector development 1/2

Sr. No.	Recommendation	Type of recommendation	Nodal agency	Next steps	Budget
15	Upgrade quality control but simplify regulatory processes to raise private investment	Regulatory changes			
16	Create a special SPV to direct credit to biotech MSMEs and startups (Slide 6)				
17	National fund to promote affordable innovation in biotech and healthcare (Slide 15)	Policy change	MoF, MoST		Rs 1000 crore over 3 years
18	Provide wage subsidies to small industries/income support for contract workers to ease liquidity crunch (Slide 19)	Policy change	MoF		

3. Financing biotech sector development 2/2

Sr. No.	Recommendation	Type of recommendation	Nodal agency	Next steps	Budget
19	Prioritise biotech interests in bilateral and multilateral negotiations (Slide 11)	Policy change	Ministry of External Affairs, MoST		
20	Create a detailed plan to acquire IP rights in critical technologies and domains (Slide 13)	Regulatory change	MoST		

4. Sector specific recommendations 1/3

Sr. No.	Recommendation	Type of recommendation	Nodal agency	Next steps	Budget
21	Bioagriculture		MHA, MoST	• Declare bioagriculture an essential service • Incentivise R&D through double tax deduction • Streamline regulatory processes for a single-window clearance	
22	Bioindustry		Ministry of Electronics and Information technology, MoST, MoHFW	• Focus on medtech and telemedicine industries to improve healthcare access • Ease regulation to incentivise telemedicine and adopt medtech products such as wearables for better monitoring of remote patients	

4. Sector specific recommendations 2/3

Sr. No.	Recommendation	Type of recommendation	Nodal agency	Next steps	Budget
23	Bioservices		MoF, MoST	• Ease the setting up of infrastructure for clinical trials through discounted land offering; increased FDI for cash flow • Implement global testing standards and cGMP guidelines in order to attract R&D and manufacturing contracts from other countries • Encourage the setup of accelerators, incubators for bioservices	

4. Sector specific recommendations 3/3

Sr. No.	Recommendation	Type of recommendation	Nodal agency	Next steps	Budget
24	Biopharma		MoHFW, MoF	• Incentivise R&D through double tax deduction • Clear permissions for manufacturing, transmission of raw materials etc. to address supply-side bottlenecks • Create biotech-specific in-house global centres similar to those in the IT sector • Guarantee fair price through advanced purchase agreements + removal of price ceilings	
25	Bioinformatics			• Review global data localisation policies to ensure that Indian bioinformatics companies have access to foreign markets	

Crisis as an Opportunity

Create a future without some of the constraints of the past

Create a future that is more environmentally sustainable