Date

Catalyzing the Pharma innovation ecosystem in India

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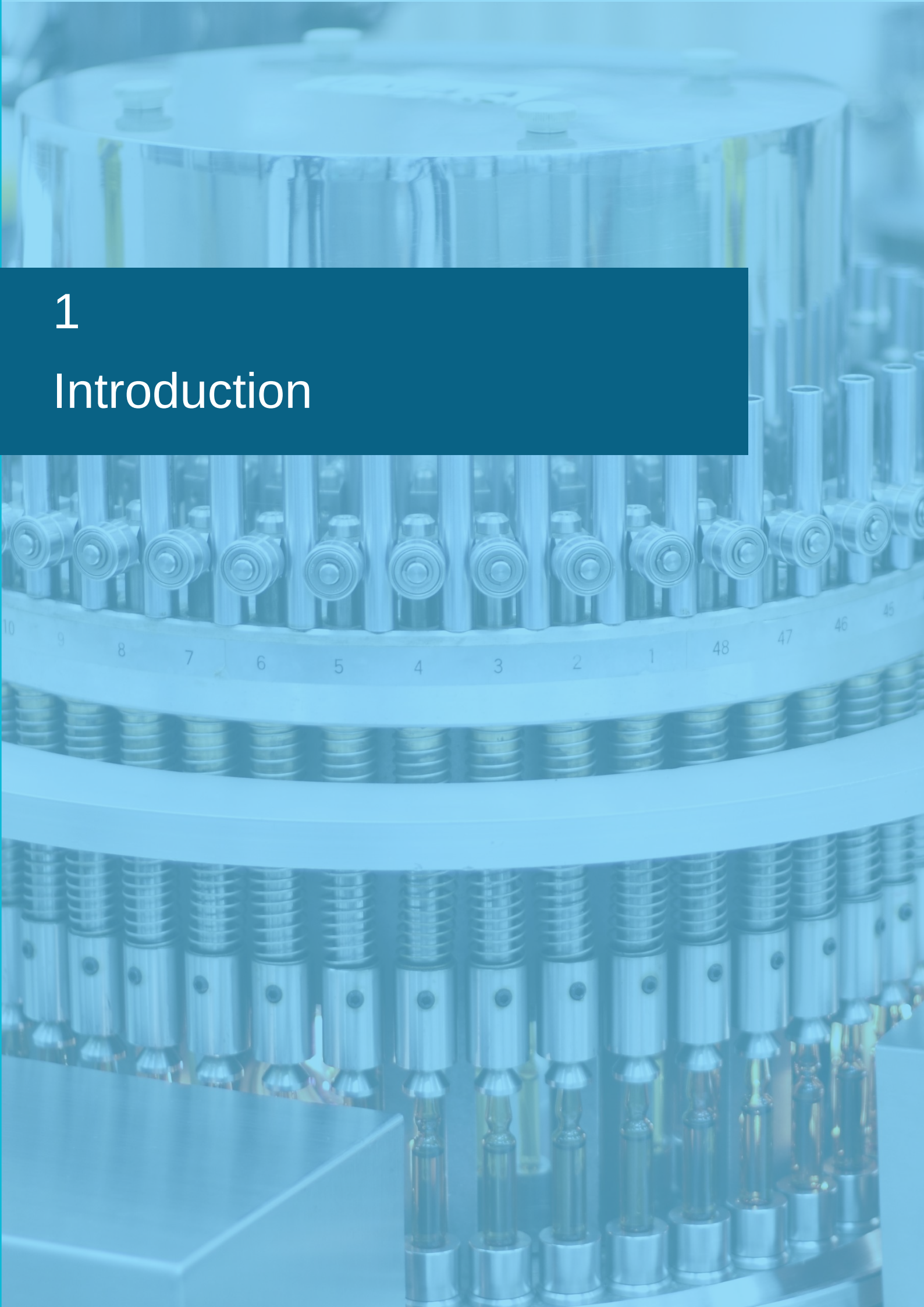

1 Introduction

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1.1 WHY INNOVATION IS CRITICAL FOR INDIAN HEALTHCARE SYSTEM

Starting from a nascent position in 1960s, Indian pharmaceutical industry has emerged as the pharmacy of the world. The industry has played a key role in driving better health outcomes across the world through its affordable and high-quality generics drugs. Increased accessibility to affordable drugs has helped reduce disease burden in the country by 36 percent[1] between 1990 and 2016 and has also brought down treatment cost for several life-threatening diseases to <5% of its original cost[2]. India has also improved access globally by supplying ~60% of global vaccine supply[3], enabling access to AIDS treatment to 37% of patients in Africa in 2009 compared to just 2% in 2003[4] and by being the 2nd largest exporter of Ayurveda and alternative medicine in the world. The industry has also contributed significantly to India's economy by providing employment to 2.7 Mn people[5] , generating USD 13 Bn in trade surplus every year[6], and USD 2 Bn in FDI inflows to pharmaceutical industry from 2015-18[7]

Indian pharmaceutical industry's contribution has become even more prominent in 2020 as India has supported the global battle against COVID-19 pandemic through

- High-level of collaboration with the Government of India to ensure uninterrupted supply of medicines during the National Lockdown of 90+ days and coordination with industry associations in India and with WHO, IGBA, AAM and others
- Supply of COVID-19 medicines (e.g. HCQ, Itolizumab, Lopinavir-Ritonavir, Remdesivir, Favipiravir, Dexamethasone etc.) to multiple countries across the world strengthening India's position as the 'Pharmacy for the World'
- Supply of Covid related medical devices & diagnostic kits e.g. Ventilators, RTCPR kits, IR Thermometers, PPE Kits & N-95 masks
- Initiation of multiple trials for COVID-19 vaccines (e.g. Covaxin, ZyCov-D) and medicines in India, as well as registration of multiple clinical trials by AYUSH CTRI (Studies registered 43, products 30, Centres 88) e.g. Guduchi (Tinospora cordifolia)/ Samshamani Vati, Ashwagandha (Withania somnifera), AYUSH 64

Going forward, Indian pharma industry could potentially grow to USD 120-130 Bn[8] over the next decade, increasing its contribution to GDP by 100 basis points. One of the key drivers for this growth would be expansion of the industry's presence in the innovation space which continues to account for 2/3rd of the global pharmaceutical opportunity. Building this presence can generate substantial health benefit for India by enabling development of drugs for India-specific ailments which do not get adequate attention globally (e.g., drug-resistant infections like NDM-1; oral cavity cancer, where India accounts for ~30% of

1 Measured as Disability Adjusted Life Years (DALYs) after adjusting for changes in population age structure; ICMR, Public Health Foundation and Institute of Health Metrics and Evaluation

2 Includes cost for Hepatitis-C and Chronic Myeloid Leukaemia: Access to Costly New Hepatitis C Drugs: Medicine, Money, and Advocacy, Oxford Journals, Vol 61, Issue 12; Changing the cost of care for chronic myeloid leukaemia, PMC, October 2015

3 Press Information Bureau; IDMA report

4 Pharmaceuticals: India's generics flow to Africa, African Business Magazine, 19 January 2012

5 Includes direct and indirect employment: Indian life sciences: Vision 2030, FICCI Jun 2015, Growth est. by IHS Market

6 Export Import Data Bank, Department of Commerce, PHARMEXCIL, IDMA report on "Journey towards Pharma 2020 & beyond", Statista

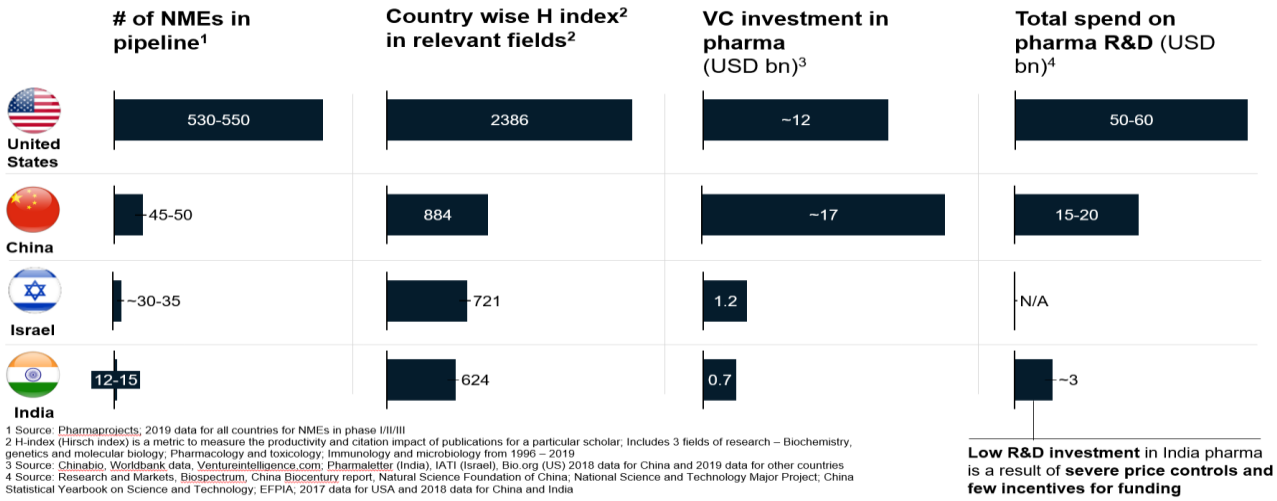
7 RBI Database on Indian Economy, Department of Industrial Policy and Promotion

8 IQVIA, AIOCD, Pharmexcil, IPA team analysis, secondary research

diseases burden[9]). It will also enhance industry's contribution to India's economy (additional USD 10-12 Bn in exports every year) and create large pool of white-collar jobs to enhance India's differentiation vs. other developing economies.

It is however critical for India to move fast on this innovation journey as it currently runs the risk of being left-behind by countries such as Israel and China, which have been progressing rapidly to capture this opportunity. Exhibit 1 captures the performance of US, China, Israel and India on various innovation metrics.

EXHIBIT 1: PERFORMANCE OF US, ISRAEL AND CHINA VS. INDIA ON VARIOUS INNOVATION METRICS



1.2 PROBLEM DEFINITION

While India has witnessed some early success with 5+ NME launches already and 12-15 assets in pipeline, overall scale of innovation continues to significantly lag other markets, driven by a need for improvement across four key areas

- **Regulatory:** While several improvements have been made over last few years (e.g., new clinical trial guidelines etc.), there is potential to further enhance the regulatory framework so as to provide impetus to innovation in the country

- **Incentivizing and funding research:** Level of funding for pharma innovation in India continues to be lower than other markets (~USD 3 Bn for India in 2018 vs. ~USD 15+ Bn in China and ~USD 60+ Bn in US)

- **Industry-academia linkages:** Collaboration between industry and academia has been limited and fraught with several challenges thereby impeding industry relevant innovation in academia

9 Cancerindia.org

- **Policy and programmes:** There is room to further strengthen the current policy landscape to catalyse innovation at scale in the country

Improvements across these areas will spur innovation and provide a fillip to the Indian pharmaand traditional medicine industry

1.3 OBJECTIVES AND APPROACH

Given the above context and problem definition, a Committee was constituted by the DoP to draft and propose recommendations for building a strong R&D and innovation ecosystem for pharma[10] in India. The Committee then set up a core committee and five sub-committees. Four of the sub committees were created in line with the four key areas of focus. The fifth sub-committee was created to help draft and propose recommendations in the space of traditional medicine (AYUSH). The objectives of each of the sub committees are detailed below –

- **Regulatory:** Simplify regulatory processes to enable rapid drug discovery and development
- **Incentivizing and funding research:** Explore mechanisms to incentivize private sector investment in research and evaluate various funding mechanisms – Budgetary support, Venture capital, CSR funding etc. and fiscal incentives
- **Industry Academia linkages:** Identify mechanisms to strengthen the R&D ecosystem through increased collaboration between Industry and Academia
- **Policy and programmes**: Study policies and programs of various departments/ agencies/ institutes, and suggest mechanisms to dovetail research as per requirement of Industry
- **Traditional medicine (AYUSH)**: Identify areas of improvement in traditional medicine across regulatory, incentivizing and funding research, industry-academia linkages and policy and programmes, and draft relevant recommendations

Committee and sub-committee constitution is available in *Annexure 1*

In addition to the committee and sub-committee deliberations, several external experts and publications were leveraged to gather insights on the relevant issues. The list of the same is available in *Annexure 2*

The core committee and sub committees followed a four step process to create the report –

- **Incorporate learnings from global leaders in innovation** - studying the journey of countries that have built a strong innovation ecosystem for pharma and distilling best practices and key learnings
- **Assess the current innovation ecosystem in India** - studying and analyzing the key challenges impeding innovation, keeping in mind the current context of the country and defining the objectives accordingly
- **Draft recommendations across key dimensions**, and propose specific interventions for each recommendation
- **Propose target outcomes and governance framework** - defining specific outcome metrics to be targeted, and proposing a governance framework to review progress against these metrics

[10] Includes traditional medicine

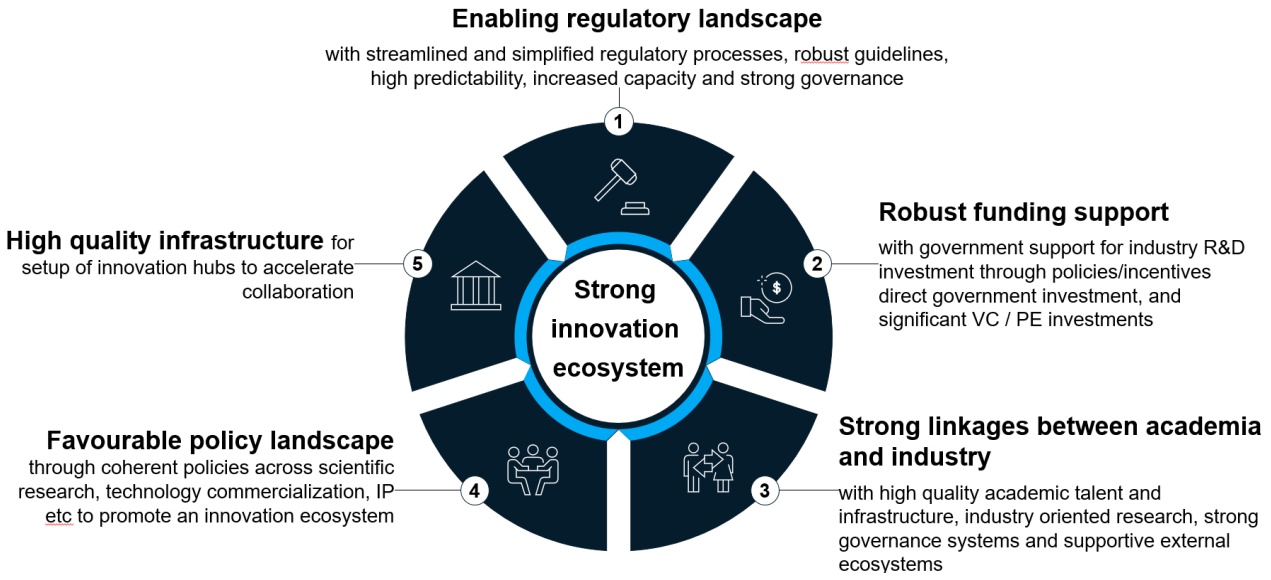
2

Learnings from global innovation leaders

2 Learnings from global innovation leaders

Several countries such as the US, UK, Israel, Switzerland and China, among others, have built a strong innovation ecosystem for pharma. Five building blocks of innovation emerge from the journey of these countries. *Exhibit 2* captures details of these essential building blocks of innovation.

EXHIBIT 2: 5 BUILDING BLOCKS OF INNOVATION



Key learnings from the best practices of global innovation leaders across each of the five building blocks are detailed in the sub sections below.

2.1 REGULATORY: LEARNINGS FROM GLOBAL BEST PRACTICES

Key learnings from countries with enabling regulatory landscapes designed tp accelerate innovation such as US, EU and Israel have been distilled below

i. **Streamlined regulatory processes:** duration of approval 30-50% less than India driven by well-defined timelines (e.g., EMA takes ~210 days), parallel processing of approval steps, and single body for submission (e.g. USFDA)

ii. **Robust process guidelines :** 600+ (in FDA) detailed guidelines and checklists across several key areas (e.g., guidance on clinical study design). US FDA has also introduced guidelines for Nwe Age technology backed by Artificial intelligence (e.g. Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)

iii. **High predictability :** USFDA (i) ensures detailed report sharing publicly and with applicant post approval/hold of a submission, (ii) enables sponsor to track application with defined process to engage at every step

iv. **Large regulatory capacity:** (i) USFDA and Food & Nutrition Services (Israel MoH) have dedicated project managers as single point of contact for industry (ii) USFDA/EMA has therapeutic area wise in-house evaluation offices (iii) US FDA has ensured programmatic capability building on Artificial intelligence to reduce errors and increase efficiency

v. **Strong governance and program management:** Commitment to defined timelines with provision for a recourse (e.g. automatic approval) in case of no/delayed response, defined metrics for performance management (e.g., EMA provides procedural calendar)

2.2 FUNDING: LEARNINGS FROM GLOBAL BEST PRACTICES

Best practises from global leaders driving innovation-specific funding such as US, UK, Israel, China, Russia and Taiwan have been detailed below

i. **Government support for industry R&D investment through policies/incentives to improve RoI of innovation :** Leaders in innovation globally provide multiple tax incentives/low cost debt to industry (e.g. 230% R&D super deduction in UK, 0% tax on patented products in China) . Additionally, reimbursement policies are adopted to provide access and improve uptake (e.g. Russia launched 7 Nosologies – A state driven re-imbursement program to provide universal medical insurance)

ii. **Increased government funding through direct investment for R&D :** Taiwan invests 0.5% of GDP in pharmaceutical R&D, UK Invests 0.3%, US invests 0.6% with government contributing 40-70% of this. In Israel, companies can get up to 85% of qualified research expenses as a R&D grant via the Track 35 program

iii. **Significant VC and PE investments :** Relaxed tax norms for foreign investors: Israel restructured its legal, accounting and regulatory framework to mimic that of the US, with the new Israeli framework guaranteeing US investors parity with US tax rates

iv. **Capital co-funding**: Israel Govt's Yozma initiative involved fronting up to 40% capital in a joint fund with insurance (capped returns for Govt.) against down-side risk for foreign investors

v. **Govt. created deep ecosystem for risk based financing** through active outreach programs e.g., annual BioCentury China summit

2.3 INDUSTRY ACADEMIA LINKAGES: LEARNINGS FROM GLOBAL BEST PRACTICES

Learnings from countries with strong industry academia collaboration such as US, UK, Israel, China, Switzerland and Germany have been detailed below

i. High quality academic talent and infrastructure through development of "anchor institutes" to pursue long-term research projects on themes of strategic importance with support of special resources and funding (e.g. NCCR Switzerland, C9 China)

ii. Promotion of industry oriented research through industry's support in development of curriculum, setup of technology transfer offices in universities with expertise in IP management, marketing, and industry outreach, with specific focus on future ready technologies such as AI, automation and digital (e.g. GE Heathcare's Edison AI platform in China)

iii. **Strong policy framework for collaboration** for moving academic discoveries into the commercial landscape (e.g. Bayh Dole US, Inventor's law Germany)

iv. **Setup of strong governance framework** to build accountability through strong program management, and stage gated outcome based funding

v. **Development of conducive external ecosystem** through setup of independent bodies to catalyze collaboration (e.g. A*STAR Singapore, CTI Switzerland)

2.4 POLICY: LEARNINGS FROM GLOBAL BEST PRACTICES

Policy-relevant best practises from global leaders in innovation such as US, and EU have been distilled below

i. **Coordination of disparate policies** for scientific research, technology commercialization, IT investments, education and skills development, tax, trade, IP, in an integrated fashion to drive innovation

ii. **Monitoring and analyses of research and innovation developments through setup of an observatory** to support better policy making (e.g. RIO in Europe)

iii. **Support for design, implementation and evaluation of reforms** through dedicated facilities (e.g. PSF Europe)

2.5 INFRASTRUCTURE: LEARNINGS FROM GLOBAL BEST PRACTICES

Learnings from countries that has setup best in class innovation hubs such as US, UK, and Singapore have been detailed below

i. **Setup of innovation hubs** housing a network of academic institutions, start-ups, clinical settings, funding agencies etc to enable high impact collaboration (e.g. Oxford Science Park UK, Scripps Research Institute, University Hub MIT, US, ASTAR Singapore)

The committee has leveraged the learnings from these global innovation leaders and tailored the same to the Indian context while drafting the recommendations for building a strong innovation ecosystem in India

3

Assessment of current innovation ecosystem in India

3 Assessment of current innovation ecosystem in India

As mentioned earlier in the report, while India has witnessed some early success with 5+ NME launches already and 15+ assets in pipeline, overall scale of innovation continues to significantly lag other markets, driven by need for improvement across all five elements of the innovation ecosystem. The current gaps and areas that need improvement are detailed in the sub sections below.

3.1 ENABLING REGULATIONS TO SPUR INNOVATION

While some improvements have been made over last few years, there is room for improvement across various elements of the overall regulatory framework including:

i. **Process:** Multi-ministerial rounds of regulatory approvals are currently leading to inordinately long timelines, and there is a need for defined timelines for regulators to review and respond

ii. **Guidelines:** There is need for defined guidelines across drug classes (e.g. Biosimilar Guidelines were well thought out based on risk rationalization and key clinical & quality criteria)

iii. **Predictability:** There is need for Improved visibility (real time tracking) of applications through online submissions at various stages

iv. Regulatory capacity: Capacity in regulatory bodies needs to be strengthened to augment current capabilities and consistency in expert guidance and regulatory processing needs to be improved

v. Governance: There is need for dedicated project management capacity for new drug applications to optimize review and approval timelines

3.2 AUGMENTED FUNDING AND INCENTIVIZATION TO DRIVE INNOVATION[11]

Level of funding for pharma innovation in India can be augmented, including

i. Incentivizing investment by pharma cos - There is a need to enhance support for private investment in innovation which is currently significantly lower as compared to other leading hubs globally, given 200% tax super deduction for R&D expenses has been rolled back, there is no specific low interest loans available for innovation, the scope of patent box is limited as it includes only royalty income on patents registered in India, and taxation of research grants received from outside India as income

Revenue uptick for innovative drugs in India is significantly lower (>95% lower) compared to US thus limiting the incentive to invest. This is driven by challenges of access, which gets addressed in other markets through Govt. sponsored reimbursement e.g., public procurement in Russia coupled with 70% trial reimbursement, direct grant up to 85% of research expenses in Israel

ii. Direct government support for innovation - There is a need to increase overall funding by GoI which is currently lower (<$1Bn)[12] than global leaders in innovation. Specifically there is a need for a single body or central agency with consolidated funding pool to invest through the research life cycle, consistent policies across schemes for assessment of innovation, schemes with

11 Products developed in India or where Global IP is held in India; Based on secondary research, expert inputs, team analysis, BIRAC website

12 Including projected increase through National Biopharma mission

meaningful scale for late stage research (e.g. phase 2 and 3) e.g., BIRAC funding on an average is ~$200 K per case1 (compared to $750 K+ in Israel and $500K+ in Brazil) with 80% of funds being utilized for early stage research only. Overall funding from BIRAC is only ~USD 30 Mn / Yr supported through BioNEST, BIPP, SBIRI and BIG like programs

Currently limited outcomes have been achieved from the funding e.g., only 21 IPs filed through BIRAC funding in 2017-18

There is also a need to focus on creating well-developed research ecosystem (Currently No institute in top 200 globally, H-index rank of 21)

iii. **External investment in India (e.g. PE/VC) -** There is a need to increase investor confidence in the Indian pharma and biotech innovation ecosystem due to limited demonstrated 'success stories' as opposed to hubs like China where Government created deep ecosystem for risk based financing through active outreach programs (e.g., annual BioCentury summit) and structured engagement (e.g., invited VCs for screening of startups to incubate)

There are several challenges in regulatory, tax and legal environment for external funding with multiple regulations across SEBI, FEMA and ambiguity in implementation, and no tax concession for investments by VC/PE or angel investors

There is also a need to ease stringent listing norms to increase listing and exit opportunities

3.3 IMPROVED INDUSTRY-ACADEMIA LINKAGES

There is scope for strengthening the collaboration between industry and academia, including

i. **Quality of talent and infrastructure -** There is a need to improve research talent through increased funding and collaboration with industry, and to strengthen current research infrastructure and orientation (e.g. lack of anchor institutes in the country)

There is also a need to draft policies to attract back high-quality global talent to India

ii. **Industry orientation of academic research –** Industry input in design of university curriculum needs to increase, along with increase in representation of industry in academia (e.g. as part of board of governors etc) and vice versa.

There is also a need to setup more functional research and incubation centers in universities, with tech transfer and marketing expertise

Additionally, Indian academia's familiarity with latest regulations can be improved

iii. **Accountability and trust –** trust and accountability between industry and academia need to be forged on the back of success stories of collaborations. Harmonized frameworks for project management and governance need to exist enabling alignment of objectives, timelines and metrics of success (e.g., publishing papers vs. commercialization)

iv. **External enablers for collaboration –** an enabling ecosystem needs to be setup e.g., market place / platform for matching academic institutes and industry projects, providing a platform to showcase innovations etc

v. **Robust policy framework for collaboration -** Current patent policy framework is not adequate to ensure fair reward sharing except in a few leading institutes (e.g. CSIR, IISc). There is a need to increase policies to incentivize industry investment into academic research programs

3.4 POLICY LANDSCAPE TO ENCOURAGE INNOVATION AT SCALE

There is scope for strengthening the current policy landscape for R&D innovation in India, including

i. **Policy coherence:** Currently there are numerous policies leading to incoherence and making articulation as well as the implementation challenging across the policies

ii. **Export/import balance:** There is a need to reduce the disparity between import and export that is currently leading to an imbalance

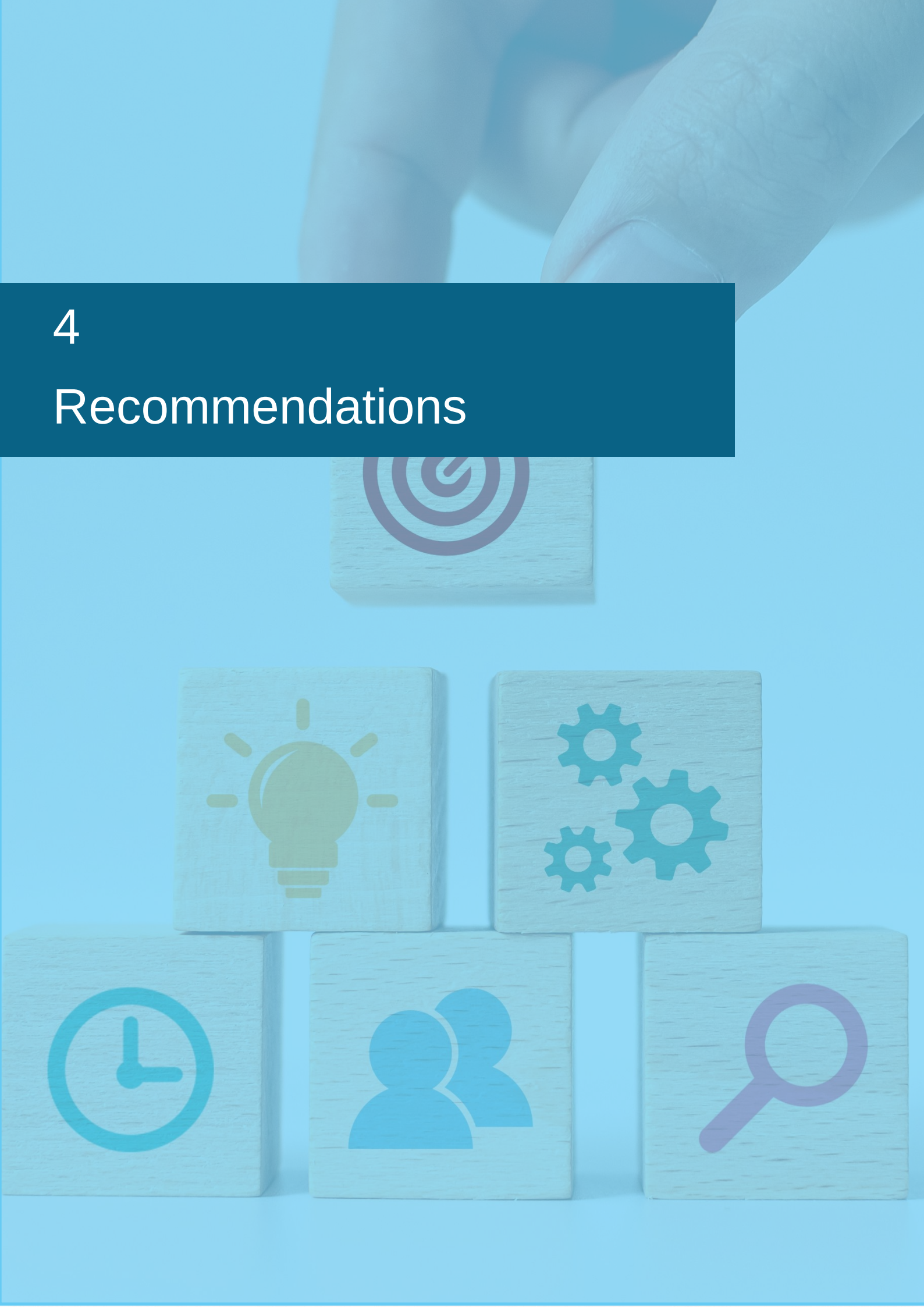
iii. **Disease burden:** There is also a need to align current pharmaceutical R&D focus in line with the disease burden of the country

iv. Industry academia collaboration: Linkages between scientific research institutes & industry need to be strengthened

3.5 CREATION OF DEDICATED 'INNOVATION' HUBS WITH BEST IN CLASS INFRASTRUCTURE

While few innovation clusters exist in India, the current infrastructure is limited and concentrated in a few nascent innovation hubs in the country, emphasizing the need for more high quality infrastructure.

4 Recommendations

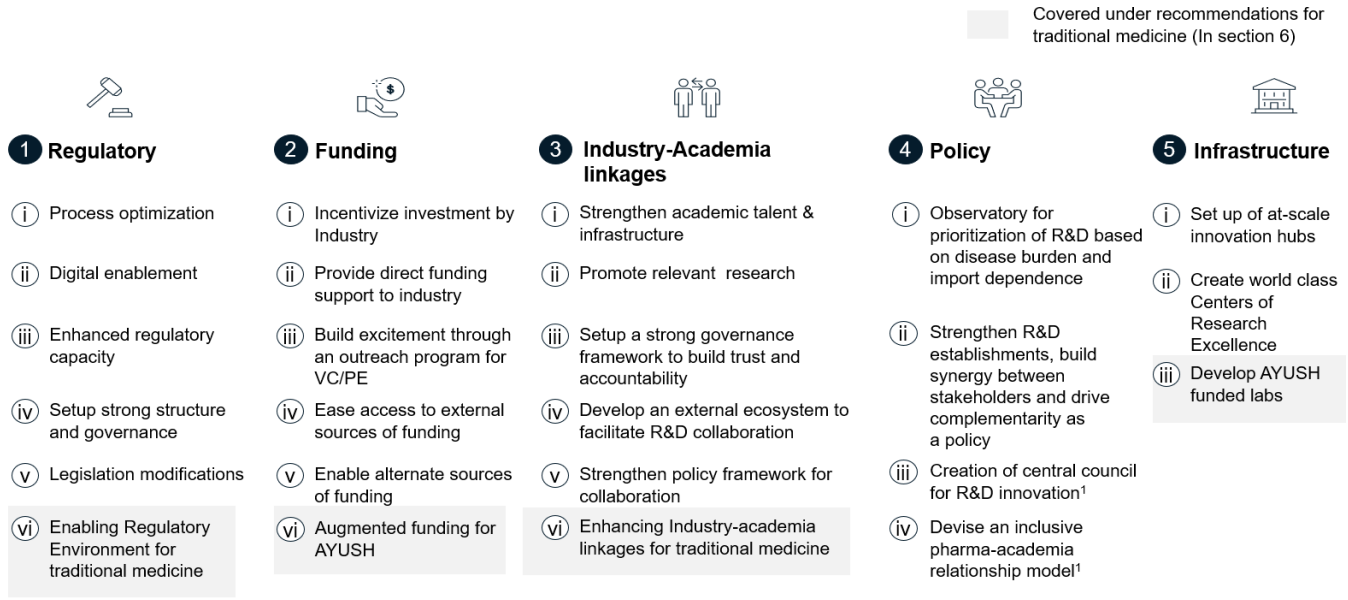


4 Recommendations

Although challenges exist, several enablers including a strong local industry and depth of technical capabilities can help India work towards the vision of "Discover in India" and build a strong ecosystem for healthcare innovation. Achieving this vision will not only help India maintain its global relevance but also drive several health and economic benefits (detailed earlier) for the country

The committee studied global best practices and took into consideration existing enablers as well as areas that need improvement to draft and tailor 25 over-arching recommendations spanning the five building blocks of innovation. Exhibit 3 captures a summary of these 25 recommendations.

EXHIBIT 3: SUMMARY OF RECOMMENDATIONS



1. Also covered as part of industry academia linkages

Specific interventions have been put forth against each of the recommendations across the five building blocks of innovation and the same have been detailed in the sub sections below.

4.1 REGULATORY: KEY RECOMMENDATIONS

5 recommendations and 17 interventions have been put forth to enable a regulatory environment that can spur innovation

i. Process optimization

a. Initiating parallel processing of critical steps that are not dependent on each other to reduce the critical path for approval timelines e.g. Parallel to MAA, completion of Joint Inspection (if required) and submission of CTDL/NIB Testing report to CDSCO, HQ infrastructure bond)

b. Reduction of overlapping approvals e.g. For granting approval for initiation of research of biologics – Approval by IBSC and notification to RCGM

c. Enabling deemed approval of steps post completion of pre-defined timelines i.e., certain steps to be made deemed approval unless regulatory body finds an issue with the submission

within stipulated time limit e.g. CLA approval for RLD in 7 days; Clinical trial initiation by CDSCO in 30 days

d. Automated (immediate approval) for specific steps using risk based approach specially upto clinical trials stage. Product already approved by Global regulator such as USFDA, EMA, PMDA, HC and TGA should be approved in India via automatic route

e. Creation of detailed checklists for each submission step with digital capability to check completeness at the time of submission

ii. Digital and Artificial Intelligence Enablement

a. Creation of a single end to end digital portal used by different departments to be hosted by CDSCO through (i) setup of an interconnected portal with automated transfer of data across departments and sub-departments (e.g. all data pertaining to RCGM would flow there, and automatic/deemed approval would be generated), (ii) enabling upload of all documents on the integrated portal (some of the documents in particular sections cannot be uploaded. In SUGAM e.g. BE protocol - CRO center approval, Ethics Committee approval)

b. All submissions to be made online with pre-defined checklists with (i) live online tracking of status of application through password protected access, (ii) generation of requisite certificates post completion of different stages on the online portal , and (iii) publishing of the summary of approval with inputs from SEC, DSMB

c. Detailing of scientific reason/s for additional requirement through online portal with clear commitment on timelines

d. Leveraging virtual platforms for all sponsor meetings

e. Artificial intelligence backed dossier review and deficiency identification using natural language processing (NLP) and automated document management workflows to enhance efficiency and reduce human errors

iii. Regulatory Capacity

a. Set up of project management roles in the regulatory body to act as single-point-window for industry (for NCEs and NBEs)

b. Building specific capacity through empanelment of labs for Diagnostics and Medical devices. Class A & B Medical devices may be certified by accredited labs notified by NABCB (both private & public) for approval by CDSCO

c. Dedicated capacity building program (e.g. Center for regulatory excellence at NIPER's) and increased collaboration with international agencies to enhance experience (/exposure) of Indian regulators on new drug approvals

iv. Structure and Governance

a. Pre-defined procedural calendar for each approval step with clear timelines for each stage of process (e.g., responding to queries or protocol amendments) and performance management on the agreed timelines to ensure no slippages. IND and SEC calendar to be published on the website, while ensuring adequate meeting frequency to meet approval timelines

b. Enhanced predictability and collaboration by creating visibility on the review status across the approval steps on the online portal, and actively engaging with industry to collect feedback

c. Identification of key performance metrics, with continuous tracking and periodic (quarterly) publishing of results

v. Legislation

a. Products that are cultured and cultivated artificially under controlled conditions are essentially not impacting natural resources and effectively the biodiversity of the country and hence should be exempted from The Biological Diversity Act

b. Empower institutional bodies for approving pre-clinical protocols e.g. Institutional Animal Ethics Committee (IAEC) to be on par with Institutional Bio- Safety Committee (IBSC) to permit regulatory approvals for pre-clinical activities

c. In case of vaccines and biologics for a particular class of product, enable joint inspection by CDSCO and State FDA (which should be conducted only once), as running the activity for marketing authorization parallelly

d. Legislation enabling regulation of all medical devices in a phased manner is recommended with lead time of 12 months to manufacture for each category of medical device - Class A, B, C & D

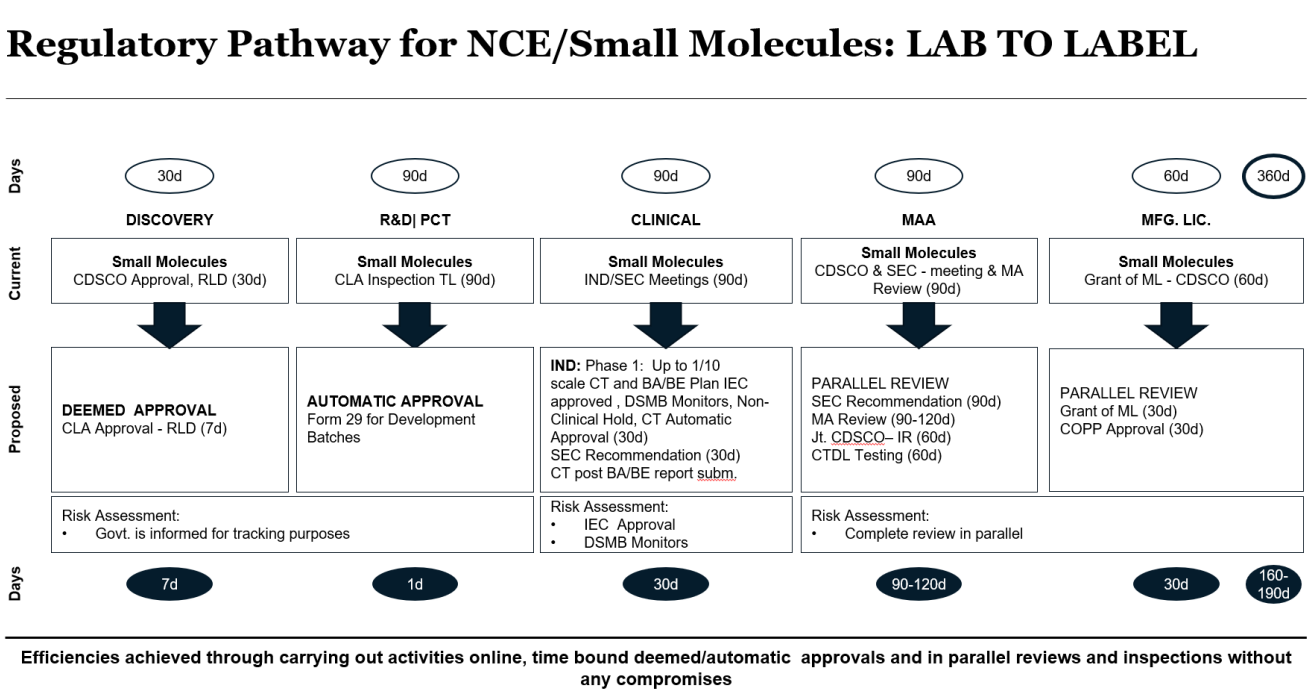
e. Create dedicated licensing authority for ASU drugs. Explore providing Ayurveda WHO licensing authority to have the power to issue WHO GMP certificate

EXHIBIT 4: PROPOSED REGULATORY TIMELINES FOR APPROVAL POST IMPLEMENTATION OF RECOMMENDATIONS

Product/ Permission type	Existing duration of Approval in India (in days)	Target duration of Approval in India (in days)
NCEs/ Small Molecules	360	160-190
r-DNA products	660	160-190
r-DNA Vaccines	1,600	160-190
Non r-DNA Vaccines	1,000	160-190
r-DNA/NCE/Small molecules in Orphan/ Rare diseases	r-DNA : 157 NCE/Small molecules : 127	r-DNA : 80 NCE/Small molecules : 70
Additional indication of r-DNA/NCE/Small molecules	90	After Innovator : 7 Before Innovator :45
r-DNA/NCE/Small molecules in Restricted Emergency Use Authorisation (EUA)	r-DNA: 157 NCE/Small molecules : 127	r-DNA: 80 NCE/Small molecules : 70
Stem Cell, Cell Therapies Regenerative Medicines	360	160-190

Deemed/automatic approvals from all departments up to preclinical stage will help achieve these timelines

EXHIBIT 5: PROPOSED PATHWAY FOR NCE/SMALL MOLECULE TO OPTIMIZE TIMELINES OF APPROVAL



4.2 FUNDING OF INNOVATION: KEY RECOMMENDATIONS

5 recommendations and 10 interventions have been put forth to augment incentives and funding to drive innovation

i. Incentivizing investment by pharmaceutical companies

a. Schemes/tax policies to support investments into R&D/innovation

- Bring back super deduction of 200% on R&D expenses (Section 35(2AB) of Income Tax Act to be amended)
- Introduce special (lower) corporate tax rates of 10-15% for companies set up in Innovation hubs/ for pharmaceutical as a priority sector (Similar to 15% tax rate u/s 115BAB for new manufacturing companies)
- Increase scope of patent box (10% tax rate u/s 115BBF) to include income other than royalty (e.g. self-use income) and income from India based R&D, leading to global patents (held in India)
- Introduce tax exemption on research funds (e.g. Angel investment for startups and research grants received from outside India)
- Tax credits for donors which are subtracted directly from a person's tax liability
- Launch long term, secured "Innovation bond" with income tax concessions (in line with infrastructure bond)

b. Ensure improved ROI for innovation through reimbursement

- Inclusion of innovator drugs in public health schemes (Aayushman Bharat, State insurance programs) at appropriate price to increase access

- Patient assistance program for diseases with India specific burden e.g., 50% of Colorectal cancer treatment cycle cost co-paid by Govt.
- Direct subsidy to compensate for lower price e.g. 50% of the differential between India and others (e.g., US, China) directly paid back

ii. Providing direct funding support to industry

a. Increase scale of funding

- Use of INR 20,000 Cr outlay for research through NRF to augment the existing funding for pharmaceutical innovation – potentially from current INR 1500-2,500 Cr to INR ~7500 Cr (USD 1 Bn) immediately (to take overall spend on Pharmaceutical R&D to 0.2% of GDP[3]) to be in line with global
- Create a special fund for promoting Innovations in Ayurveda and
- Create a special fund for promotion of Health tech startups focusing on Digital and Analytics (including Artificial intelligence) in Pharmaceutical research and innovation

b. Harmonize policy and streamline process

- Expand existing schemes to increase funding at advanced stages and for complex innovation (e.g. Drug discovery) - e.g. expand scope of National Biopharmaceutical Mission to include small molecules or set up a new "innovation fund"
- Define consistent policy framework for evaluation of projects and disbursement of funds (e.g. Definition of innovative products to be common as products with global IP held in India)

c. Scale-up and redesign nature of direct support to industry

- Extend milestone based payments (with indigenous R&D centers approved by DST) to support late stage (phase 2 and 3 clinical trials) research e.g., Reimburse up to 70% of trial cost incurred

iii. Build excitement about India innovation through an outreach program

a. Create a compelling 'Discover in India' vision and actively disseminate messages across community

- Setup innovation forums and awards to enable investors to have visibility to and actively interact with local innovation community
- Indian innovation leaders to participate in Global Forums to highlight progress in Innovation in India

iv. Easing access to external sources of funding

a. Play an enabling role through streamlining regulatory, tax and legal environment

- Harmonize multiple regulations for hassle-free single window clearance for external funding e.g. streamline regulations of SEBI AIF, GOVCI by Dept. of Economic Affairs, and CBDT Guidelines
- FVCIs to be registered with SEBI and be allowed to freely invest and disinvest without any requirement for approval from FIPB / RBI (similar to FIIs)

b. Relaxation in listing/IPO norms, e.g.

- Relax norm of 3 years track record of profit for companies backed by registered VC Funds
- Allow direct listing of companies (backed by VCFs) with shares/securities listed in other countries
- Allow listing of pre-revenue companies to encourage VCs to invest

c. Encourage investment in innovation through matching funds

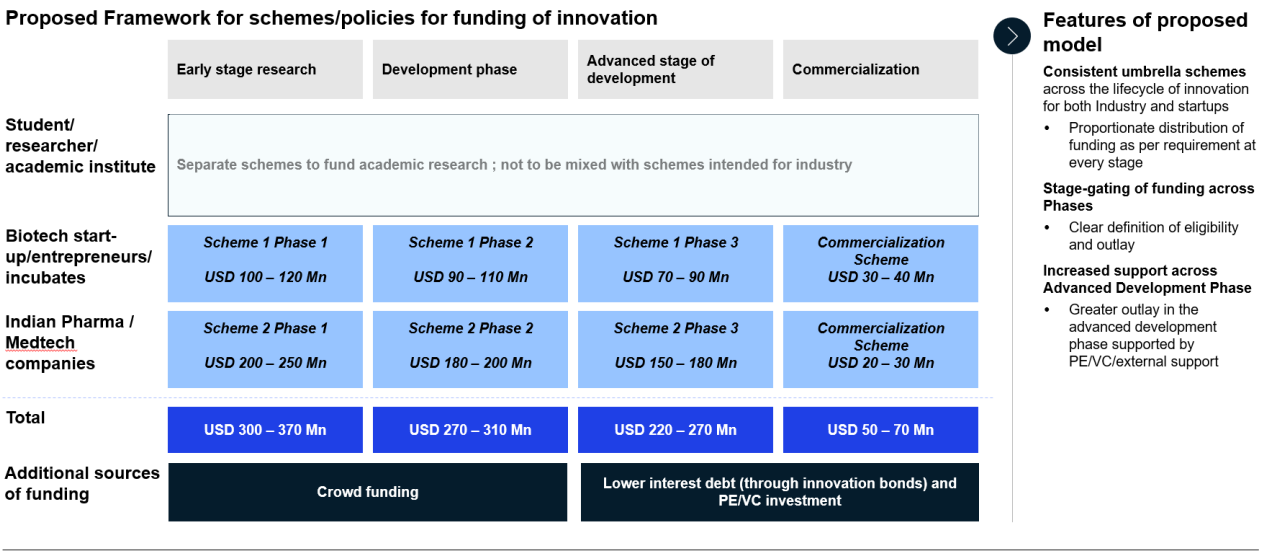
- Co-invest as an LP for VC funds with capped returns (e.g., buy out Govt. staked at cost) to build investor confidence
- Expansion of Fund of Fund Biotech Innovation Fund – AcE (INR 2500 Cr) to co-invest in AIFs to catalyze 2x Venture funding of upto INR 25 Cr each in 250 Biotech Startups, Medium scale companies

v. Enable alternate sources of funding

a. 3 distinct models of crowd funding that can be explored

- Donation / Reward Crowdfunding
- Debt Crowdfunding (also called Peer-to-Peer or 'p2p' lending):
- Equity Crowdfunding

EXHIBIT 6: PROPOSED FUNDING FRAMEWORK FOR USD 1 BN INTEGRATED MODEL OF FUNDING FOR SCHEMES AND POLICIES



4.3 INDUSTRY-ACADEMIA LINKAGES: KEY RECOMMENDATIONS

5 recommendations and 23 interventions have been put forth to strengthen industry-academia collaboration to further catalyse innovation

i. Strengthen academic talent and infrastructure

a. Attract global educational institutions of eminence to create centres in India, leveraging the provision in the National Education Policy (NEP) allowing foreign universities to open campuses in India

b. Purposeful investment in few priority institutes to build 'Centres of excellence' focussed on innovation and R&D in the country that

- drive focused research and active global collaboration on key themes of relevance for India (e.g. API, Discovery Research)
- drive continuous focus on strengthening faculty (through collaboration with foreign professors, adjunct faculty from industry) and upgrading infrastructure
- get significantly high levels of funding with per capita funding close to western university levels
- are granted government accreditation to serve the objectives of building world-class institutions and attract global faculties
- have decided future technology (e.g. Artificial intelligence, automation, digital) focused CoEs to improve utilization of such technologies for pharmaceutical innovation
- play a leadership role in an outreach program to bring smaller institutes under their wing
- help in quality testing, bioequivalence studies and/or phase I clinical trials of drugs with help of technology from industry

c. Industry sponsored at masters and PhD level in academic institutions

d. Early exposure of pharmaceutical graduates and post graduates to industry under formal arrangement (e.g. industry internships) and deputation of academicians or scientists to industry

e. Adjunct faculty / visiting / honorary professor from industry, national laboratories and institutions of repute, in academic institutions

f. Programs to attract global talent and incentivize local talent in research areas through recognition (President's Award and equivalent), monetary awards, fellowships & grants, etc

ii. Promote relevant research

a. Strengthening academic curriculum to make it dynamic and contemporary to meet current needs of pharmaceutical sector, with increased focus on future ready technologies (e.g. Artificial intelligence, automation, digital)

b. Regulatory bodies and industry led training on various regulations including CMP, GLP, GCP to the academia

c. Industry representation in academic institution body or function, e.g. as part of board of governors / board of management, academic committees, research committees, panel of examiners

d. Industry Chair in academic institutions

e. Early involvement of experts from industry in academia to promote 'meaningful, market ready research' with clarity on go-no go criteria for various stages of drug development

f. Active promotion of 'future ready' research in academia, with thrust on artificial intelligence

g. Setup of entrepreneurship incubation centers in academic institutions

h. Industry housing a laboratory setup in academic institution i.e. use of centralized institutional facility for a specialized industry laboratory

i. Setup of an external cell in academic institutes to assist with tech transfer, marketing and to further attract industry collaboration

j. Encourage industry to appoint outstanding academicians on industry boards

iii. Setup a strong governance framework to build trust and accountability

a. Encouraging industry to fund research in academic institutions with outcome based funding i.e. stage gate funding with pre-defined milestones

b. To ensure accountability, setup a strong program management to monitor and report progress, robust performance framework with upfront alignment of objectives and funding linked to outcomes, and a well-defined conflict escalation and resolution process managed by a central body

c. Trust and transparency between academia and industry through strong IP protection, contractual design, and enabling higher flexibility between scientists and industry partners

iv. Develop an external ecosystem to facilitate R&D collaboration

a. Setup an independent council to catalyze, facilitate and promote industry academia and regulatory linkages and international collaboration

b. Increased emphasis on strong and impactful alumni associations with representation in the institute management to attract investments and improve placements

v. Strengthen policy framework for collaboration

a. Design a Bayh Dole like policy to encourage academicians to setup independent companies (spin offs) to move academic discoveries into the commercial landscape, and ensure fair reward sharing between innovators, institutes and industry

b. Provision for companies to setup "research fund" for supporting research programs at academic institutions and laboratories with tax incentives

EXHIBIT 7: SETUP OF INDEPENDENT COUNCIL FOR PROMOTION OF INDUSTRY ACADEMIA LINKAGES

Objective

To catalyze, facilitate and promote industry academia and regulatory linkages and international collaboration

Responsibilities

Serve as a nodal point for linking industry-academia linkagess in government initiated programs of relevance

Serve as **an advisory council for major funding agencies such as DBT, DST, ICMR etc** in **designing bilateral or industry relevant schemes**

Serve as a 'patron' board for solving any disputes/disagreements between industry-academia linkages.

Optimally match industry projects with academic partners

Periodically **hold R&D symposiums to showcase latest innovation**

Continuously monitor key outcome metrics e.g. % total academic patents utilized by industry, number of academic projects in commercial collaboration with companies etc

Co-funded by industry and government for facilitating activities for stronger industry academia linkages

Board composition

Co-chaired by a leading academician and a leading industry representative

Representative from all funding agencies (DST, DBT, DoP, ICMR, Regulator, FICCI, CII, IPA, OPPI, IDMA etc)

Board of Governors comprising of **representatives from academia, industry and regulatory**

4.4 POLICY: KEY RECOMMENDATIONS

4 recommendations and 6 interventions have been put forth to strengthen the current policy landscape for innovation

i. **Observatory for prioritization of R&D based on disease burden and import dependence**

   a. Creation of Observatory for R&D prioritization in both communicable and non-communicable diseases areas through

      – Evaluation of disease burden and identification of knowledge gaps in disease areas : Bring together diverse agencies to gather data and provide inputs/reports on:

         □ Disease burden (ICMR, PHFI and others)

         □ Knowledge and gaps in disease areas (ICMR, CSIR, DBT, DST-SERB)

         □ Pharmaceutical gaps (where treatments either do not exist or are inadequate, or where existing treatments are likely to become ineffective in the future, such as those for AMR; ICMR, CSIR, DBT, DST-SERB , Pharma)

      – Observatory to work with regulatory agencies and keep them updated on new developments across disease areas

ii. **Strengthen R&D establishment, build synergy between stakeholders and drive complementarity as a policy**

   a. Strengthen R&D establishments and build an ecosystem model that acts as a unique platform for innovation, integrates diverse skill sets, and brings together stakeholders of bio-pharmaceutical / biomedical innovation landscape, while ensuring synergy between stakeholders across the drug discovery pipeline

b. Create a combined vision across departments and ensure complementarity of policies enacted by these departments targeted towards common goals and outcomes

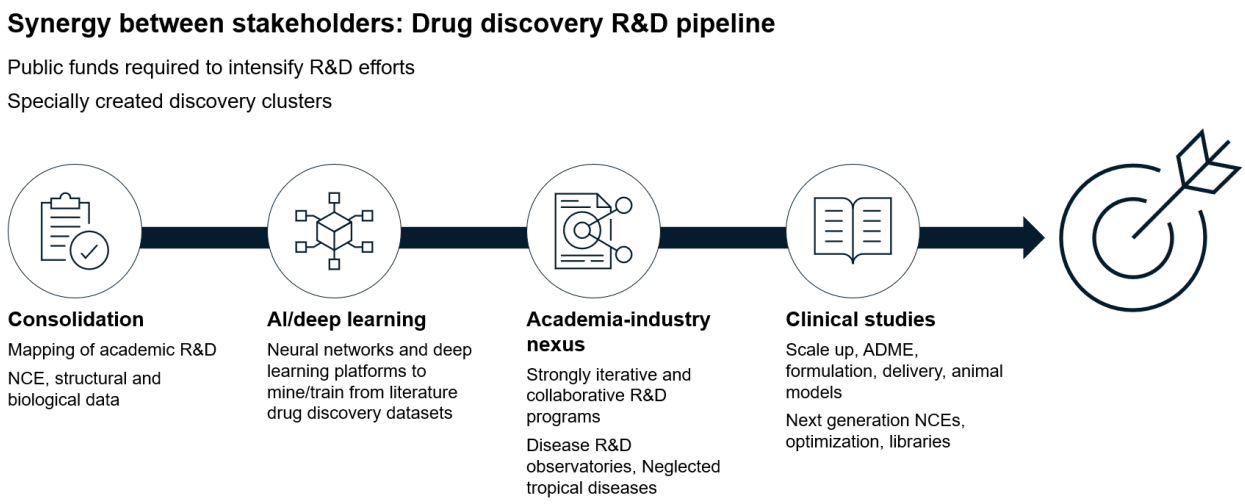
iii. **Creation of central council for R&D innovation[13]**

a. Creation of council[13], with strong project management structure, with representation from industry, academia and government to (i) focus on industry relevant research areas, (ii) decide priority areas such funding and incentives, and (iii) continuously monitor the program and project implementation. Corpus fund for the council has to be created jointly by government and industry

iv. Devise an inclusive pharma-academia relationship model[13]

a. Devise an inclusive pharma-academic relationship model, which brings in funds for scientific research that has promise for practical applications and translation, leveraging provisions in current policies (e.g. National Education Policy)

EXHIBIT 8: BUILD SYNERGY BETWEEN STAKEHOLDERS ACROSS THE DRUG DISCOVERY PIPELINE



4.5 INFRASTRUCTURE : KEY RECOMMENDATIONS

2 recommendations and 4 interventions have been put forth to create best in class infrastructure for innovation in the country

i. Set up of at-scale innovation hubs

a. Scale up 1-2 existing hubs to maturity (e.g. Hyderabad, Bangalore for pharma) ensuring co-location of academia, public R&D Centers industry, startups, incubators; provide "plug and play" infrastructure and ensure requisite financial and regulatory support

b. Establish sub-sector specific new hubs as a consortium / network of academic institutions, universities, start-ups with industries, business schools, clinical settings, funding agencies (including VCs) to provide an integrated thrust to research in the country in 3-5 years' time frame

13 Also covered as part of industry academia linkages

c. Promote establishment of health-tech ecosystem within the innovation hubs with high end capabilities merging healthcare with the new age technologies such as artificial intelligence, digital and analytics

ii. Create world class Centers of Research Excellence

a. Create a matrix of Therapeutic Segment, like Respiratory Track-Gynaecology-Digestive System etc and give each of these segments to one of these institute which solely focusses on this vertical and becomes a Centre of Excellence in that segment

EXHIBIT 9: PROPOSED MODEL OF 'INNOVATION HUB' FOR INDIA

Setup as an **independent science park**

Leverage existing facilities in major cities to create the ecosystem

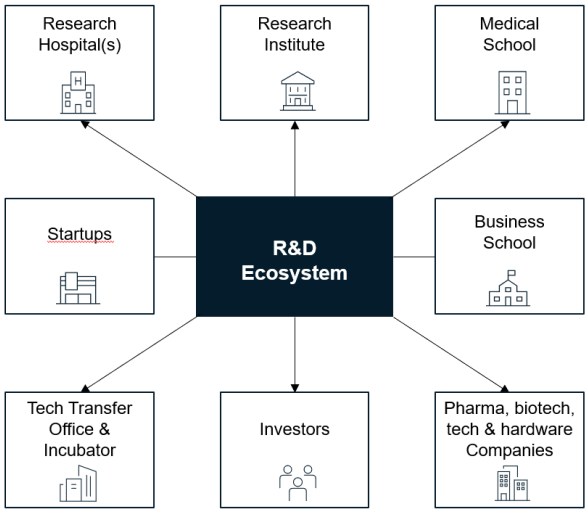
Researchers from the institute and the hospitals can collaborate

Clinical studies of discoveries from research institute can be done **at the research hospital**

New inventions can be protected by a **central tech transfer office and companies incubated in the incubator, funded by on site investors**

Industry partners to have space in the science park for direct collaborations and M&A

Business school for recruitment for companies and start-ups



4.6 TRADITIONAL MEDICINE: KEY RECOMMENDATIONS

4 recommendations and 10 interventions have been put forth to drive innovation in traditional medicine

i. Enabling regulatory environment

a. Enabling provision for seeking approvals for pre- clinical and clinical development of AYUSH medicines should be developed with Central Ministry i.e. Min. of AYUSH (on lines of CDSCO) for R&D institutes / company willing to go through the process for new drug development in the sector

b. Introduce the concept of providing Data Protection for 5 years as an alternative to Patents to Ayush Industry. This is in line with the recommendations in the report of Satwant Reddy Committee dated 31st May 2007 . Note: Currently As per the Indian Patents Act Patents are not granted to ASU Products

c. Create dedicated licensing authority for ASU drugs and Ayurveda WHO licensing authority to have the power to issue WHO GMP certificate

ii. Augmented funding for Ayush

a. The budget allocation to AYUSH sector by the Government of India should be adequately raised to increase investment in programs and activities that promote innovation

b. Investment in standardization of single herbs and identifying molecules / actives to validate claims scientifically + allow standardised doses to be available

c. Government to create a special fund for promoting Innovations in Ayurveda, where certain basic research on identified potential herb candidates is sponsored

d. Evidence based Ayurveda through Government funding clinical trials in Ayurvedic formulation

iii. Develop Ayush funded labs

a. Ayush funded labs for marker compounds for classical herbs that can benefit Indian industry at large

   - EU Observership to be utilised to gain Market Access for Ayurvedic products in EU
   - India to get monographs of 50 important herbs created and validated in the EU, which European commission will be paying for

iv. Enhancing Industry-academia linkages for traditional medicine

a. Enabling to set up All India Institute of Ayurveda (AIIA) Institute in Other parts of the country to have the access for the Research

   - Industry Linkage Cell to be made mandatory in each college
   - Industry Academia research a must for each college to maintain their UGC accreditation
   - UGC to give a high weightage to Industry Academia Research in their evaluation of an institute. Curriculum to include a mandatory 12 months of Industry Research

b. SERB-PM Research Fellowship for students wherein Industry sponsoring 50% of fellowship already available

5

Implementation plan and outcome metrics

5 Implementation plan and outcome metrics

5.1 IMPLEMENTATION PLAN

Successful implementation of recommendations will require concerted efforts from all key stakeholders, along with a suitable governance and monitoring mechanism. Government can help setup such a governance and monitoring framework with

- Smart cross stakeholder committee with representation from industry, academia and government
- Strong project management structure for continuous monitoring of the program and project implementation
- Regular cadence of reviews with quarterly review meetings to assess progress and online publishing of the results of quarterly review

5.2 KEY OUTCOME METRICS

Outcome metrics will need to be defined across major building blocks to measure the success of the implemented recommendations. Exhibit 10 captures proposed outcome metrics along with proposed targets for FY25 and FY30

EXHIBIT 10: PROPOSED OUTCOME METRICS

Proposed performance metrics

(Period of measurement, Unit of measurement)

Outcome metrics	Target (FY25)	Target (FY30)
New molecular entities (NMEs) [1] registered from India *(annual, number)*	>3	>10
Regulatory approval of different molecules within target timelines *(annual, %)*	>90%	>95%
Direct government funding across schemes to Industry and Startup by Central and State govt. *(annual, USD Bn)*	2 (USD 1 Bn immediate target for FY22)	5
Industry academia (or research lab) collaborations *(annual, number)*	2X[2]	5X[2]
At Scale Life science Innovation hubs *(cumulative, number)*	>5	>10
Contribution of domestic production in Indian Medical Devices industry *(annual, percentage)*	25% (Market size USD 15 bn)	35% (Market size USD 30 bn)

1. Includes both NCEs and NBEs
2. X indicates the current baseline – to be established

5.3 INNOVATION INDEX

The idea behind the formulation of the Innovation Index is to create a holistic view of the Indian Innovation Ecosystem for pharmaceuticals in comparison to global peers. The Index will be computed on a yearly basis and will set a comprehensive mechanism to measure actual performance against the roadmap of Vision 2030 defined in this whitepaper. The Index identifies quantitative metrics across the five key building blocks and enables comparison and benchmarking with other global ecosystems. The Innovation Index will be augmented through insights from key stakeholders from the government, industry, academia, investors and researchers based on a survey questionnaire.

The final output would be a score on a scale of 1 – 10 across the identified five key building blocks of the innovation ecosystem in comparison with global peers. Exhibit 11 captures an illustration of the quantitative indicators and survey questions.

EXHIBIT 11: ILLUSTRATIVE BUILD OUT OF THE INNOVATION INDEX

Dimension	Quantitative Indicator	Survey Questions
Regulatory landscape	• Regulatory approval of different modalities (e.g. Small molecule, biosimilar) within target timelines	• How effective is the current regulatory system in the review and approval of new drugs?
Policy		• How effective are current pricing, reimbursement and procurement policies in encouraging innovation?
Funding	• Total private capital for R&D • Direct Govt funding • Primary funding through VC/PE	• Rate the ease of funding from each of the following sources – Indirect Government incentives for R&D investment, Debt financing, Primary market financing, Direct Government funding, Secondary market financing (e.g. IPO)
Capabilities - Infrastructure and talent	• # of at-scale Life science Innovation hubs in global top 100 ranking • # Publications in international journal, average citations	• How do you rate quality of R&D talent in India in the following fields - Drug discovery, clinical development and CMC • How would you rate India's infrastructure for innovation today (e.g. Innovation hubs)
Collaboration Industry- Academia and Global collaboration	• # of Industry academia (or research lab) collaborations • # of cross border deals on Drug R&D • # of global trials	• How would you rate the quality of collaboration between Academia and Industry • How do you rate India's collaboration with global industry and stakeholders for innovation?
Output Dimension	• # of New molecular entities (NMEs) registered from India • # PCT patents filed	• What's the level of novelty of innovative pipeline from local Indian companies

6
Impact

6 Impact

6.1 QUANTITATIVE AND QUALITATIVE IMPACT OF INNOVATION IN INDIAN PHARMACEUTICAL INDUSTRY

The 25 recommendations proposed can help catalyze innovation and accelerate growth of the Indian pharmaceutical industry. Innovation will drive the next wave of growth for the industry with potential to propel projected growth rate from 7-8% to 11-12%. This will help deliver both 'Qualitative' as well as 'Quantitative' impact for the country

Quantitative Impact of Innovation

- **Higher Contribution in the GDP of the 5 Trillion economy:** This will increase the Industry's contribution to GDP by 100 basis points from 1.5% to 2.5% through increase in output from USD 28 Bn in 2018 to USD 120-130 bn by 2030

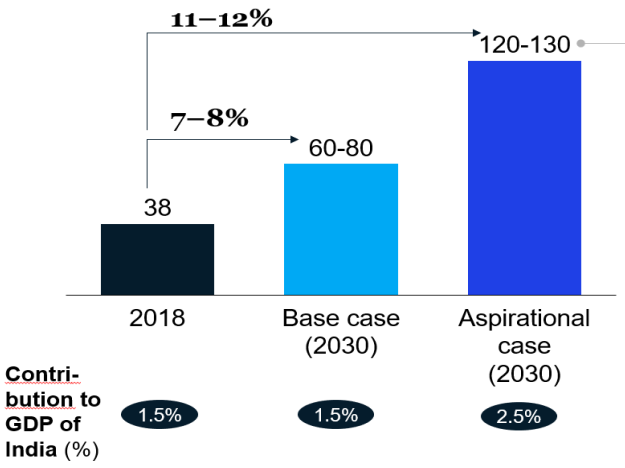
- **Increased exports and Forex inflow:** Total exports by the industry in FY20 were USD 20 Bn growing at ~5% between 2015-20. This can be increased to USD 50Bn + by 2030 with 10%+ growth rate. This will help the industry to push the net foreign exchange earnings to around USD 40 billion to 50 billion annually by 2030 from current levels of ~USD 10 billion

- **Increase in Global market share:** Achieving these goals will mean Indian pharmaceutical industry can improve its global market share by value to ~7.0% by 2030 from current market share of 3.6% . It will enhance Indian pharma's significance beyond generics, to biologics, new drug development and incremental innovation thus positioning India as the true "Pharmacy of the World" . It will also mean the Indian pharmaceutical market will break into top 5 markets by value globally, from its current rank of 11th and become world's largest supplier of drugs by volume

EXHIBIT 11: ESTIMATED INNOVATION LED GROWTH IN INDIAN PHARMACEUTICAL INDUSTRY

The 25 recommendations will help catalyze innovation and accelerate growth of Indian Pharmaceutical and Med-tech industry

Projected size of the Indian pharma industry, USD billion



Key catalysts required

- Enabling regulations to spur innovation
- Augmented funding and incentivization to drive innovation
- Strong industry academia linkages
- Dedicated 'Innovation' hubs with best-in-class infrastructure
- Strong policy landscape that is conducive to innovation at scale

Source: IQVIA, AIOCD, Pharmexcil, IPA team analysis, secondary research

Qualitative Impact of Innovation

- **Import Substitution and self-reliance:** Reduce dependence on imports for Medical devices, Formulation, API, intermediates and KSM . In FY 20, pharma imports amount to ~USD 10 Bn, of which medical devices account for ~52% and bulk drugs and intermediates account for ~31%.

- **Improvement of overall healthcare index and reduced disease burden for India and other emerging economies:** The Indian pharma industry can support Government of India's vision of providing universal healthcare by providing access to quality medicines at affordable prices. As more and more patients come under treatment, this could help reduce the disease burden in the country substantially. Thrust on innovation will help increase the DALY (Disability Adjusted Life Years) in India and other emerging markets to levels comparable to that of developed economies such as the US and UK by 2030 (currently India's DALY is 72 percent higher than China's)

- **Creation of high end jobs in R&D and Innovation:** Setup of dedicated innovation hubs and a broader innovation ecosystem will enable creation of more high end jobs with in-demand skillsets across the innovation value chain (e.g. scientists, regulators, biotech experts, health-tech experts)

- **Opportunity to attract back Indian talent with expertise in R&D and Innovation :** A strong innovation ecosystem will help attract back high quality talent from across the world, further catalysing R&D and innovation in the country

6.2 POTENTIAL TO REPLICATE SUCCESS OF THE INDIAN IT INDUSTRY POST 1991, WITH GOVT. SUPPORT

Successful implementation of the proposed recommendations can help the India pharmaceutical industry replicate the success that the Indian IT industry has seen post 1991

Government initiatives contributed to rapid growth of Indian IT sector between 1990-2001, leading to a self-sustaining ecosystem that continued the growth momentum. The share of IT sector in Indian GDP increased from 0.1% in 1991 to 7.7% in 2020 as output increased from USD 1 bn to USD 180+ bn

Increased incentivization and set-up of ecosystem from 1991-2001 helped create a self-sustaining ecosystem for IT industry to grow beyond 2001.

- **Incentivizing investment by IT industry through improving RoI:** Preferential Tax Policies led to high non-operating income and increased margins making the sector attractive for investments . Building domestic demand through Government led spending- In 1999-2000, Government spending constituted more than one-third of overall domestic IT spend (compared to 23% in the US in the same year)
- **Direct funding and infrastructure support:** Software Technology Parks of India (STPI) initiative set up in 1989. Ecosystem creation which enabled the sector to move up the value chain. By the end of 1999-00, STPI accounted for ~63% of the overall software exports from India . 6-8 at scale parks emerged (e.g. Bangalore, Hyderabad, Noida, Pune)

- **Ease of external financing:** Ease in equity financing for IT sector – Relaxation in the IPO requirement for IT firms (Relaxed Criteria: Knowledge-based firms qualified for listing IPOs must meet the paid-up capital of not less than Rs50 million and capitalization of not less than Rs500 million)

Precedence of attractive returns have catalyzed investment in IT/ BPO sector in India leading to a large universe of scaled up IT/BPO companies (total 10K companies, ~800 Nasscom registered). This also led to USD 2bn+ PE/VC investment in IT services sector annually from 2015-20

□ □ □

Building presence in the innovation space is now a critical priority for India in order to both address the needs of the healthcare system in the country, as well as maintain relevance in the global pharma space. India has several strengths to leverage, and a strong starting position to build on, as it looks to evolve beyond its successful journey of "Make in India" towards the vision of "Discover in India". Successful implementation of proposed recommendations, with concerted efforts from the industry, academia and government can help unleash India's innovation potential and position India as the future "Pharmacy of the World".

Annexure

ANNEXURE 1: COMPOSITION OF COMMITTEE AND SUB - COMMITTEE

ANNEXURE 2: EXTERNAL EXPERTS AND PUBLICATIONS LEVERAGED TO GATHER INSIGHTS ON THE RELEVANT ISSUES

NOT EXHAUSTIVE

List of Experts

Finance expert
Ramesh Swaminathan
CFO, Lupin

Industry Association Expert
Harish Mehta,
Founder, NASSCOM

Pharma VC Expert
Prem Pavoor
Head of India, Eight Roads

Market listing Expert
Sanjay Singh Bhati
DGM IMD, SEBI

Regulatory Expert
Sundar Ramanan
Global Regulatory Affairs, Biocon

PE Expert
Shashank Singh
Partner and India Head, APAX Partners

Regulatory Expert
Ravindra Mittal
Regulatory & Medical Advisory, Cadila Healthcare

Regulatory Expert
Suresh Anekal
National Regulatory Affairs, Biocon

List of Publications

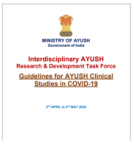
Framework of industry-university linkage in research - Department of scientific and industrial research, Ministry of science and technology, Government of India

6th Annual Report , BIRAC India

CII Note on Inputs to Simplify and Expedite the Drug Approval Process in India

Science, Technology, and Innovation in Indian Systems of Medicine: An Exploration in the Context of COVID-19 Pandemic

Year-end review 2019 Ministry of AYUSH



Interdisciplinary AYUSH R&D Task Force – Guidelines for AYUSH Clinical Studies