सत्यमेव जयते
Government of India
Department of Pharmaceuticals
Ministry of Chemicals & Fertilizers

Confederation of Indian Industry

12th National Pharmaceutical Conclave

Make, Develop and Innovate in India

12-13 December 2014

Identifying key growth imperatives

Foreword

अनंत कुमार
ANANTH KUMAR
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सत्यमेव जयते

रसायन एवं उर्वरक मंत्री
भारत सरकार
MINISTER FOR
CHEMICALS & FERTILIZERS
GOVERNMENT OF INDIA

FOREWORD

The pharmaceutical sector of the country has the joint responsibility to improve the healthcare scenario of nation as well as to drive economic growth through exporting quality products and showcase India as a Pharma destination for the world. A paradigm shift is required in the pharmaceutical sector-A shift in policy, governance, regulation which is already taking place and Department of Pharmaceuticals is in a transition to fulfil the need of making quality medicines available to public at affordable costs.

I am privileged to note that the Department of Pharmaceuticals has worked together with CII on their joint initiative "12th National Pharmaceutical Conclave-Make, Develop and Innovate in India" to understand the issues faced by the industries and discuss the way forward to look for viable solutions and means for working together to bring stability in the sector.

India has played a leadership role in pharmaceutical manufacturing and the present gaps in the area of bulk drugs, clinical research, etc. are to be sorted out together as the sector is fragmented and there are different regulatory agencies playing different roles.

On behalf of my Ministry, I welcome the initiative taken and look forward to promote the growth of the sector and will explore through the salient recommendations evolved out of this conference.

(ANANTH KUMAR)

March 16, 2015

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HANSRAJ GANGARAM AHIR

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FOREWORD

Mr Hansraj Gangaram Ahir, Hon'ble Minister of State for Chemicals and Fertilizers

It was a pleasure to attend the "12th National Pharmaceutical Conclave-Make, Develop and Innovate in India" and collaborate with CII to bring all the stakeholders of this fragmented sector together in single platform. Government is keen and open to work with the industry and make suitable amendments in policies to spur Pharmaceutical manufacturing activity, also there is a need for industry to focus more on research and ensure a fuller utilization of the country's technically trained manpower.

The CII conclave was an important step in facilitating a dialogue between various stakeholders to work towards identifying key imperatives to facilitate industry growth. The discussion with the experts from various session on the issues faced by the pharmaceutical sector will charter the way forward on how to breach the gap of accessibility.

The Ministry looks forward to the compiled recommendation from all the stakeholders present with their ideas on how to revive the pharmaceutical sector especially in the areas of API, Bulk Drug Manufacturing, R&D and Clinical Research. The inputs given will help the government to work towards the growth of the sector to make India a hub for pharma and will also help us in taking policy related measures wherever required.

(Shri Hansraj Gangaram Ahir)

March ,2015

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Dr. V. K. SUBBURAJ
Secretary

सत्यमेव जयते

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Foreword

The Department of Pharmaceuticals is working together with the industry and the various other stake holders to make affordable and good quality medicines available within the country. At the same the Department is keen to position India as a pharmaceutical hub for the entire globe.

It gives me immense pleasure to note that the entire pharmaceutical industry joined together in this 12th National Pharmaceutical Conclave-Make, Develop and Innovate in India jointly organized by CII with the support of our Department. And representatives from the entire pharmaceutical sector has joined hands to discuss on the issues affecting the Pharmaceuticals Industries as we aspire to achieve success in "making", "developing" and "innovating" in India to turn Make-in-India in the Pharmaceutical Sector to a reality.

Pharmaceutical industry has brought pride to the country; it has been a healer to the entire nation, a revenue earner and big tool to project a positive image of India as a destination for quality and affordable medicines. Today our medicines are exported to more than 220 countries. Many developing and under developed countries are entirely dependent on us for vaccines and lifesaving medicines.

There is a huge potential in the sector and we have to substantially increase our manufacturing capabilities to meet the requirements. Also, the pharmaceutical sector, as well as the Medical Devices sector should travel together to make India self-dependent.

We take this opportunity to thank the organizers for such a platform where we can hear from the entire Industry on their views and recommendations to have enabling policies which facilitates growth and make medicines accessible to all.

16/3/2015

(V.K.SUBBURAJ)

The pharmaceutical industry in India occupies a place of pride in not just the Indian, but across the global. The impact transcends the value chain with Indian pharmaceutical companies leading in APIs, formulations and even in emerging areas like contract research. The numbers further strengthen the story- the industry ranks third - in terms of volume and fourteenth - in terms of value amongst all countries today.[1]

The growth of the industry has been backed by robust drivers- on the demand side and supply side. The need for cheaper quality drugs in the developed world and improving healthcare access in the developing world has been a key driver. On the supply side, India's inherent strength in chemistry and the ability to research and manufacture quality medicines at a lower cost has been a major advantage.

However, the industry has faced several challenges in the last couple of years. On the exports front, several instances of non-compliance of quality norms resulted in loss of revenue and credibility. China's increasing prowess in certain APIs and intermediates and resulting import dependence have emerged as a significant threat. Complex approval procedures and lack of clarity in regulations have led to a considerable slowdown in clinical trials .Increasing price control and lack of predictability and stability on various industry related policy issues resulted in shrinking of the domestic industry in value terms. In a nutshell, for the first time, industry observers became sceptic of its growth prospects- a feeling hitherto unknown to the industry stakeholders

With an objective of bringing all stakeholders together and facilitating meaningful discussions on the challenges and possible mechanisms for countering it, **the Confederation of Indian Industry (CII) had organised a two-day - 12th National Pharmaceutical Conclave - from 12 - 13 December, 2014 at New Delhi, in partnership with the Department of Pharmaceuticals, Ministry of Chemicals & Fertilisers, Government of India as the Anchor Ministry. The Conclave was supported by all major industry associations including Indian Pharmaceutical Alliance, Indian Pharmaceutical Association, Indian Drug Manufacturers Association, Bulk Drug Manufacturers Association, Organisation of Pharmaceutical Producers of India and the Federation of Pharma Entrepreneurs.**

The theme of the conclave – make, develop and innovate in India – aimed at creating a healthy India by focusing on manufacturing, formulation development and innovation in India.

To improve access to medicines in India, and to healthcare more broadly, the conclave deliberated on much needed collaborative multi-sector approaches that meet both the Government's health policy objectives and ensure patient access to medicines. It was also felt that policy, regulatory and legal reforms could substantially improve the business environment for the pharmaceutical sector in India, in addition to supporting the new Government's goals of bringing growth to India through manufacturing, pharmaceutical development and innovation.

In order to sustain competitive edge of the pharmaceutical industry, Government must encourage policies that support manufacturing, formulation development and which are conducive to fostering a research & innovation environment in India. It is also important for the Government to create an enabling environment for clinical research in the Country to facilitate access to newer therapies for patients.

The Conclave witnessed enthusiastic participation from senior executives of major pharmaceutical companies, key people from the ministries, regulatory bodies, academia and IP bodies. The conclave helped in identifying various issues as well as some possible solutions through seven dedicated plenary sessions.

This document essentially aims to capture the key observations in each of the sessions, present some ideas on possible actions which promise the highest favourable impact on the industry and identify key stakeholder groups which would then help chart the next steps through further discussion.

CII is grateful to the Department of Pharmaceuticals, Ministry of Chemicals and Fertilisers, all other relevant Ministries and all Associations of the Pharma sector that came forward and lend their participation and inputs to make it truly a representative platform for the industry.

CII hopes this document, will help both government and the industry drive a focussed growth agenda for the sector through further consultation on each of the ideas presented

Dr. Rajiv I Modi
Chairman
CII National Committee on
Pharmaceuticals

K G Ananthakrishnan
Co-Chairman
CII National Committee on
Pharmaceuticals

Chandrajit Banerjee

Director General

Confederation of Indian Industry

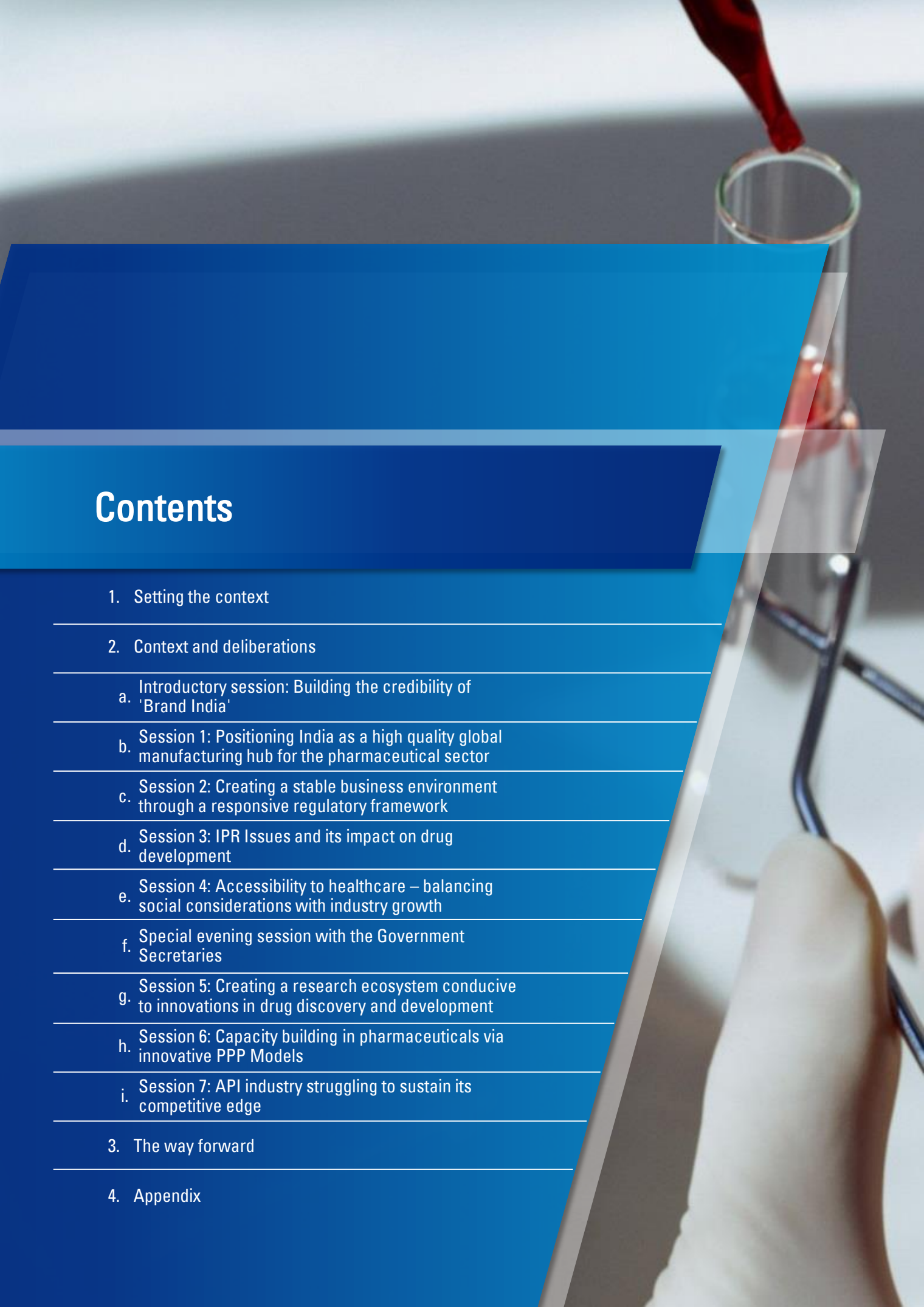
The Pharmaceutical sector comprise a very important segment of CII's membership in which we see a great promise. This is one sector that truly lends itself to be a thrust sector under the Government's "Make in India" programme.

Amid all speculation revolving around the credibility of "Brand India", a lot needs to be done to make India a cost effective and high quality global Pharma manufacturing hub. This Conclave was a defining step in the direction of taking this vision forward and discussing with the different stakeholders on the need to build on and find some robust and actionable solutions.

I would like to extend my special thanks to the Department of Pharmaceuticals as the anchor Ministry and the source of guidance for organizing this initiative. This milestone initiative of CII is envisaged to set a corner stone to bring all stakeholders together in a single platform to initiate discussion on the key requirements.

My sincere thanks to the Organizing Committee members, all the partner Associations-Indian Pharmaceutical Alliance, Indian Pharmaceutical Association, Indian Drug Manufacturers Association, Bulk Drug Manufacturers Association, Organisation of Pharmaceutical Producers of India and Federation of Pharma Entrepreneurs.

I hope that the observations that emanated from these two days deliberation will be a fruitful vision for the policymakers for the conducive growth of the Pharmaceutical sector.



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Context and Deliberations

The inaugural session of the Conclave served as a platform for the Government to discuss and deliberate on issues plaguing the Pharmaceutical industry in India

The 12th National Pharmaceutical Conclave's visionary theme 'Make, develop and innovate in India' enabled multiple stakeholders to discuss and deliberate on changes that are considered necessary for unlocking the true potential of the Indian pharmaceutical industry. [1]

The Inaugural Session of the Conclave witnessed strong participation from industry captains and key government officials including, Mr. Hansraj Ahir, Hon'ble Minister of State, Ministry of Chemicals and Fertilisers, Dr. V K Subburaj, Secretary, Department of Pharmaceuticals, Mr. Navreet Singh Kang, Additional Secretary, Ministry of Health and Family Welfare. [1]

All the delegates lauded the accomplishments of the Pharmaceutical industry and addressed it as the 'pride of the country'. Hon'ble Mr. Hansraj Ahir together with the Secretaries acknowledged the commendable work done by the Pharmaceutical industry in exporting drugs to more than 200 countries across the globe, which would not have been possible without manufacturing of high quality products at an affordable price.

The Minister and Secretaries, during the course of the Conclave also acknowledged that over the last couple of years, Indian pharmaceutical industry has faced various challenges which has affected the growth as well as impacted the image of 'Brand India'. The Government's willingness to discuss and deliberate on issues to create a conducive, stable and predictable atmosphere, was the highlight of the session.

> "Government is keen and open to work with the industry and make suitable amendments in policies to spur Pharma manufacturing activity. Also there is a need for industry to focus more on research and ensure a fuller utilization of the country's technically trained manpower"
>
> **Mr. Hansraj Ahir** | Minister of State for Chemicals and Fertilizers | Government of India

> "I think this is the time to act and government is determined. Suitable suggestions should get converted into action. It requires coordinated action by various ministries to ensure that we create the right atmosphere for the growth of the industry"
>
> **Dr. V K Subburaj** | Secretary | Department of Pharmaceuticals

> "I would like to assure you that we have no intention of causing obstacles or hurdles in the way of development of the industry. We would like to be partners in this"
>
> **Mr. Navreet Singh Kang** | Additional Secretary | Ministry of Health and Family Welfare

Context to introductory session: Building credibility of 'Brand India'

'Brand India' has several tests to pass before it is able to rebuild its image as a favourable destination for the pharmaceuticals industry

Exports have always remained a key growth driver for the Indian Pharmaceutical industry. Pharmaceutical companies have capitalised on export opportunities, both in regulated and semi-regulated markets, which helped exports from India grow at a CAGR of more than 20 per cent from 2006 to 2012. In the long term, Indian Pharmaceutical industry aspires to be the 'Pharmacy of the world' by supplying APIs and finished formulations to global markets.

While on one hand the Indian Pharmaceutical industry aspires to be the largest pharmaceutical manufacturing hub, on the other hand, it is facing several compliance and regulatory issues, which is tarnishing image of 'Brand India'. Such a situation demands a holistic approach towards protecting the reputation of the industry.

Few incidents of noncompliance, that have been highlighted in the media, have gained considerable attention. More than the monetary considerations, such incidents have far more serious impact on the credibility of 'Brand India'.

Further, regulatory issues pertaining to clinical trials seem to have impacted India's reputation of being research friendly. The government's actions on price controls have also been seen with a lens of scepticism, both by domestic and international companies.

Key Concerns

- Shortage of experts to manage regulatory needs of the pharmaceutical sector
- Inordinate delays in clearances for clinical studies
- Indian companies are yet to cope-up with the changing global manufacturing norms (slowly transforming)
- Sub-optimal infrastructure such as laboratory space, sea ports, industrial parks, roads and cargo zones at airports for the import and export of pharmaceutical products
- India ranks low on 'ease of doing business' index, driven by long processes and multiple clearances required to start a new business[4]

This introductory session aimed to set the context for all other sessions in the conclave. Specific focus of this session was to highlight various issues and challenges encountered by the Pharmaceutical industry which has created a possible dent to the reputation of 'Brand India'.

Context to introductory session: Building credibility of 'Brand India'

The introductory session helped in setting the context for the conclave by identifying key areas of interventions to rebuild 'Brand India'

Quality of medicines

•Need for a proactive approach by the industry to ensure consistent quality of medicines, irrespective of exports or domestic consumption and follow same standards for manufacturing. Investments in terms of empowering employees, auditors and building a quality culture may go a long way in curbing compliance issues.

•Capacity building of Drug Controller's office to ensure that quality is not compromised and officers act with utmost integrity.

Innovation & IPR

•Need for a policy framework and transparent, predictable enforcement of IPR law is required to boost investments in innovation.

•Lack of data exclusivity and challenges faced by patent holders is likely to impact FDI by Global players.

Price control regime

•Need to have a transparent and predictable pricing regime. Adhering to the DPCO for longer periods rather than changing it on an ad hoc basis creates enormous uncertainty and distrust. This creates confusion whether price control genuinely addresses the accessibility and affordability issues.

•Industry is willing to partner with Government to tackle accessibility issue and equally concerned about it.

Regulatory challenges

•Industry is facing issues with drug approvals and inconsistencies in approvals. The number of approvals of generics and biosimilars has decreased and the ambiguity over fixed dose combinations are adding to a lot of concerns.

•Clinical trial approvals is another challenge which need to be resolved to boost product launches and attract investments.

Infrastructure development for revival of API industry

•India's dependence on China for raw materials required to manufacture APIs is acknowledged by the industry. In order to tackle this issue, the industry is emphasising on development of clusters, common facilities and support to SMEs to upgrade their facilities and manufacturing standards.

•Consultation with all the stakeholders while creating policies is another important aspect that the government should probably consider.

> "Quality is not just the responsibility of one department. Each and every person in the organisation is responsible for it"
>
> **Dr. Shailesh Ayyangar** | President OPPI and MD | Sanofi India

> "Various clusters are required in our country in a big way if we have to take pharmaceutical development to further growth. We will be coming out with a cluster development program soon"
>
> **Dr. V. K. Subburaj** | Secretary | Department of Pharmaceuticals

> "Compromised drug regulatory regime, challenge from China, unpredictable pricing regime are some of the major threats that the Indian pharma industry faces today"
>
> **Mr. D.G. Shah** | Secretary General | IPA

> "We need to iron out the real as well as perceived differences to rebuild brand India. In case of quality compliance, there is a need for a proactive approach instead of reactive"
>
> **Mr. S.V. Veeramani** | President | IDMA

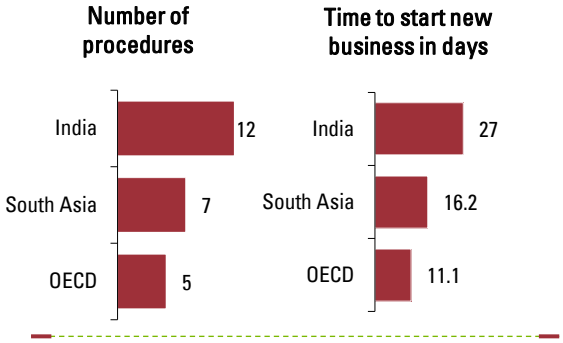
Compliance to quality, complex regulatory mechanism and sub-optimal enabling infrastructure are key challenges faced by manufacturers

To remain a globally competitive player in the field of Pharmaceutical manufacturing, India needs to remain competitive on many aspects, such as the scale of production, quality standards, innovations, technological advancements as well as cost.

Competitiveness is derived from all steps in the pharmaceutical manufacturing value-chain – including setting up the manufacturing unit, making it operational and complying with the global quality standards, etc.

In order to successfully implement the 'Make in India' campaign for the Pharmaceutical sector, there are a few concerns that need to be addressed. These include tougher regulations related to land acquisition, restrictive labour laws, delays in environmental clearances, sub-optimal infrastructure, limited cluster-based development and stricter enforcement of regulation and quality measures

Ease of establishing new business in India



Source: 'The Make In India opportunity in five charts', Live Mint, 25 September 2014

Key Concerns

•Tough regulations and complexities related to land acquisition serve as a deterrent to the growth of the manufacturing segment

•Slow decision making and delay in environmental clearances

•Unethical administrative clearance/inspection also acts as a hurdle for the manufacturing sector

•Sub-optimal infrastructure such as roads, railways, airports and ports discourage investors from establishing manufacturing units in India

•Power shortage is a long standing issue

•Limited cluster-based development in the Pharmaceutical sector

•Lack of strict enforcement of regulations and quality measures for high quality product output

•Lack of incentives to encourage setting up world class manufacturing units

Key points of discussion at the panel:

•Simplifying regulatory approvals for setting up the plant

•Cluster-based development for the Pharmaceutical industry to enhance cost advantages and linkages

•Right set of measures that need to be put in place to ensure quality of the products

Enhancing the business and regulatory environment will help position India as a leading manufacturing hub

Challenges	Suggestions
Complex process to set up manufacturing units •Lack of a single window clearance mechanism makes the process of setting up a manufacturing plant in the country tedious and complicated •Involvement of multiple Ministries makes the process time-consuming. For instance, land and environment clearances required for establishing manufacturing units are governed by two separate bodies in the country	**Government to simplify processes to set up and run business in India** •Setting up single window clearance mechanism can be the way forward •Doing away with redundant processes and making use of online portals, wherever feasible. (*The Government has already undertaken some steps in this regard to provide clearances through a web-enabled system)*
Infrastructural issues to operate a manufacturing plant •Lack of infrastructure in terms of availability of adequate power, water and shortage of common effluent treatment plants are some of the deficits	**Reducing operational hurdles by providing robust infrastructure and policy initiatives** •Inducing cluster development can help ensure infrastructure, resource and knowledge sharing, leading to lower economic costs of utilities and facilities •Simplifying financial and tax compliances will help in easing the business environment.
Less emphasis on quality culture in manufacturing •Export is a major revenue generator for pharmaceutical companies. Difference in quality norms for different geographies (such as the U.S, E.U, etc.) may have led to quality challenges •The industry is yet to reach a level that promotes quality as a universal culture in each of its operating departments.	**Industry should focus on inculcating 'high quality output' culture** •Promoting quality across the company with strong endorsement from leadership levels. The senior members of industry should take responsibility of focussing on quality control processes •Strive for consistency in quality protocols across different departments within the company

"I think all these challenges and issues need to be addressed in a very time bound efficient manner so that we can turn around this wonderful industry to go on a faster growth pace and also attract global giants to establish world scale manufacturing facilities in India"

Dr. Rajiv Modi | Chairman & Managing Director | Cadila Pharmaceuticals

"We need to focus on … first, a policy and regulatory framework in place to build a robust competitive environment for promoting manufacturing and R&D. Secondly, having cross-fertilization and linkages with the global counterparts to bring best practices from all over the world"

Mr. Sudhanshu Pandey | Joint Secretary | Department of Commerce

"The onus of ensuring high quality standards does not lie on the inspectors alone, system should be in place so that everyone at each stage in the pharma value chain is bound to be compliant."

Mr. Shailendra Singh | Joint Secretary | DIPP

Creating a stable business environment: The context

Multiplicity of regulatory bodies has adversely impacted the effectiveness of policy formulation and implementation

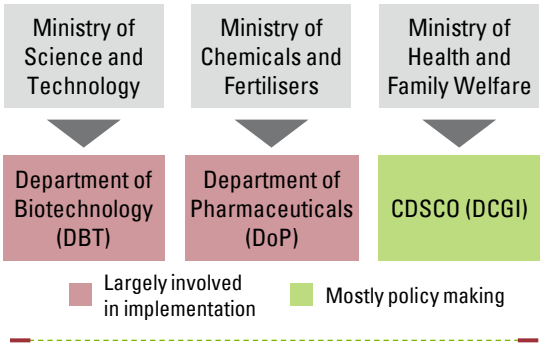
Policy making in life sciences including clinical research and pharmaceuticals is a distributed responsibility—the Department of Pharmaceuticals (DoP) under Ministry of Chemicals & Fertilizers focusses on pharmaceutical policy making while implementation is largely driven through a different Ministry - Ministry of Health and Family Welfare.

Moreover, health is a state subject, and therefore, the State Government also plays a vital role. The policy for bio-pharmaceutical products and other research driven aspects are driven by Department of Biotechnology.

This multiplicity at the policy making level can result in inefficiencies in allocation of resources and creation of divided agendas. The issues pertaining to regulations, at times, take longer to resolve than the industry may desire.

Lessons can be learnt from other countries that have unified bodies for policy making for the Pharmaceutical sector

Multiplicities in policy making in India



Learnings from the U.S.

In the U.S., a single agency 'FDA' regulates the drugs sector and is responsible for all regulatory tasks such as approval of new drugs, issuing license for manufacturing units, etc.

Learnings from China

In 2013, China restructured its food and drug regulatory body to form a single agency with ministerial level powers. The new agency called, 'China Food and Drug Administration' replaced a large cluster of overlapping regulators to streamline regulation processes for drug and food safety

The complex disciplines in Pharmaceuticals, Clinical Research and ethics need expertise and skilled human resource to review and validate proposals, lay down SOPs, etc. for which timely training and capacity building is necessary. Regulatory authorities such as CDSCO and DCGI are working towards building capacity of regulatory offices in terms of number of drug inspectors as well as training the staff for speedy approvals and timely feedback to address various challenges faced by the industry.

Key Concerns

- Multiplicity in policy making delaying timely approvals and resolution mechanisms
- Sub-optimal capacity of regulatory offices delaying approval processes

Key points of discussion at the panel:

- Current regulatory challenges governing the Pharmaceutical sector in India
- Leading industry practices and lessons learned from other international regulatory systems which can be leveraged to overcome the challenges.
- The optimal options to overcome these challenges in a regulatory environment

Creating a stable business environment: The deliberations from the conclave

A single consultative platform involving multiple stakeholders may be the first step towards a unified regulator; greater transparency and autonomy is desired

Challenges	Suggestions
Multiplicity in policy making leads to delay in decision making •Policy making is a distributed responsibility in the life science sector •It is also likely that inefficiencies occur during prioritisation of sector initiatives and allocation of funds due to the presence of multiple decision makers	**Single consultative platform should be created to reduce multiplicity** •Unified ministry with policy making and implementation powers can reduce multiplicity in policy making. This should be a long-term aspiration •Single consultative platform with representation from all stakeholders can be the way forward, including representation from all ministries, fixed frequency of meetings and discussions with industry and academia
Limited autonomy and compromised regulatory structure delays decision making •In regulated markets such as the U.S. and E.U., regulators have additional autonomy to drive a policy more independently. However, this is not the case in India. Its position from a bureaucratic stand point dilutes the decision making power, which might lead to inefficiencies and delays	**Autonomy of CDSCO to create robust regulatory structure** •Head of CDSCO should be elevated to an appropriately senior level position and powers should be vested in this role to ensure independence
Low transparency in regulatory system is a key hurdle for the industry •Presence of multiple bodies and numerous regulatory stakeholders creates a confusion in terms of allocation of responsibility •The lack of defined guidelines for approval drug of applications leads to approval delays •Limited use of IT platforms leads to data overload, loss and leakage	**Policy makers should define roles and responsibilities for increased accountability** •Roles and responsibilities of the stakeholders should be clearly defined for improved accountability •SOPs and SLAs should be put in place •Processes via online portals should be implemented for ease in carrying out business

> "Opportunity cost incurred because of disharmony within the regulatory setup, when benchmarked with international regulations, is too high to be ignored"
>
> **Mr. Sudhanshu Pandey** | Joint Secretary | Department of Commerce

> "Head of regulatory body should be elevated to 'Secretary' level position in order to ensure quick decision making"
>
> **Mr. D A Prasanna** | Chairman & MD Ecron Acunova & Chairman Acro

> "There is an urgent need to develop a transparent regulatory system to improve the regulatory environment in the country. Increasing communication and collaboration between stakeholders will go a long way in ensuring an evolved regulatory environment."
>
> **Prof. Ranjit Roy Chaudhury,** | National Professor of Pharmacology and Chairman Committee on Reform of the Drug Regulatory System

Strengthening regulatory capacity will be imperative to make review process efficient and reduce approval time

Challenges	Suggestions
Low capacity and skill-gap within the regulatory system is delaying approvals •There is a need for significant ramp up in the number of drug regulators to meet the current demand •There is a gap in the know-how and technical expertise of drug regulators to assess complex drug approval cases •Testing laboratories are not equipped with advanced equipment for testing and analysing complex formulations	**Government needs to strengthen regulatory capacity and upgrade skill sets within the system** •There is a need for a clearly defined plan to aid implementation. An expert committee can be constituted to oversee the same •Manpower strength needs to be increased •Upgradation of existing testing laboratories is required *Steps already taken to address the existing challenge include:* –The government is planning to increase the number of drug inspectors at the CDSCO to 1,000 from the current 500 –It also plans to increase the number of officials in state regulatory departments to 3,000 from the current 800
Stringent laws in clinical trials are hindering industry growth •The guidelines laid down by the Supreme Court to conduct clinical trials in the country are difficult for the companies to follow, leading to a process that is not only time consuming but also tedious •Lot of misconceptions among media and NGOs related to clinical trials	**Regulatory policies should be clearly laid down to ensure high quality clinical trials** •The regulatory body must suggest a time bound plan to resolve the clinical trial issues •Compensation provided in case of negligence during clinical trials should be increased •Media and NGOs need to be educated on facts and procedures related to drug discovery and clinical trials to get their support •Clinical trials should be conducted only at accredited clinical sites by accredited principal investigators after approval by accredited ethics committee

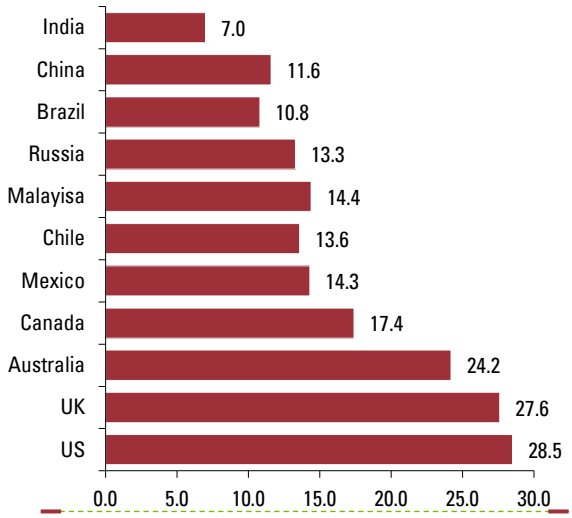
"Review process during patent application needs to be streamlined; questions should be shared well in advance so that companies can provide scientific evidence to support their products."

Ms. Suneela Thatte, | Vice President, Quintiles

While India aspires to be a key player in drug discovery and development space, uncertainties in the IPR environment hinders this vision

Over the last few years, issues of honouring patents vs. India's attempts to protect and manage healthcare needs of its population, has caught the attention of intellectual property observers globally and the Pharmaceutical industry in particular. The Indian government has already decided to moot a strong and comprehensive policy on IPR to boost R&D, drug development and exports.

International IP index scores, 2014



Source: "GIPC International IP Index", Global Intellectual Property Centre website, December 2014

Key Concerns

• Debates and concerns around the incidence of patent denial and Compulsory Licensing

•Absence of a proper structured independent body (with expertise and infrastructure) to look into intellectual property issues, initiate policy dialogues for timely and effective resolution

•Delay in redressal of IP matters

Key points of discussion at the panel:

- Regulatory challenges faced by patent holders
- Practical issues in implementation of the current IPR regime
- Ways to strengthen the IPR environment in India, helping ensure that the interests of patients and the industry are balanced
- Examination of a speedier redressal mechanism

An evidence based approach towards IPR will create greater clarity and predictability; focus on capacity building and leveraging technology can drive efficiencies

Challenges	Suggestions
Negative perception towards the IPR regime •There is a perception among stakeholders and foreign investors around unpredictability in the realm of IPR which may have a negative impact on the investment climate in the country	**Clarity and predictability in policies can help improve the image of India globally** •Robust IPR ecosystems bring a high level of clarity and certainty to the market, enabling innovative ideas to be scaled up
Lack of skilled examiners has led to patent hurdles •The industry has not succeeded in building a pool of examiners and controllers of high quality who are equipped with specialised or adequate IP skills (like performing prior art search, etc.) •Laws in the country need to be strengthen to empower the employer enough to stringently penalise employees who do not adhere to data confidentiality protocols	**Nurture a talent pool by creating specialized courses in IPR to bridge the gap** •Identification of the skill gap and designing academic courses (Certificates & PG Diplomas) in line with the industry requirements (specialized in IT, Bio-tech, etc.) •For a patent examiner, training forms a vital part, as it enables delivery of high quality products and services consistently. Collaborations and imbibing leading practices from global counterparts may be beneficial
Sub-optimal efficiencies of patent office operations hinder timely approvals •The four patent offices in the country may have inconsistencies between each other in terms of examination of applications, making the process of examining patent applications complicated •There is a delay in publication of patent application and pendency of about 4-5 years •There is absence of a transparent online database where all patent documents are stored, leading to data gaps	**Leverage technology for better coordination amongst patent offices** •The four patent offices of the country need to be e-connected to help ensure that they work in tandem so that there is consistency •There is need to develop a robust online search engine for all Indian patent documents to avoid any duplication •The number of patent examiners hired in each office should be increased to tackle the issue of delays and pendency in reviewing patent applications

"Unless there is investment and protection of Intellectual Property, investors will be discouraged"

Mr. Ranjit Shahani | Vice Chairman and MD, Novartis

"… we need a strong and transparent IPR policy and regime to attract investment"

Dr. Malathi Lakshmikumaran| Director and Practice Head, Lakshmikumaran & Sridharan Attorneys

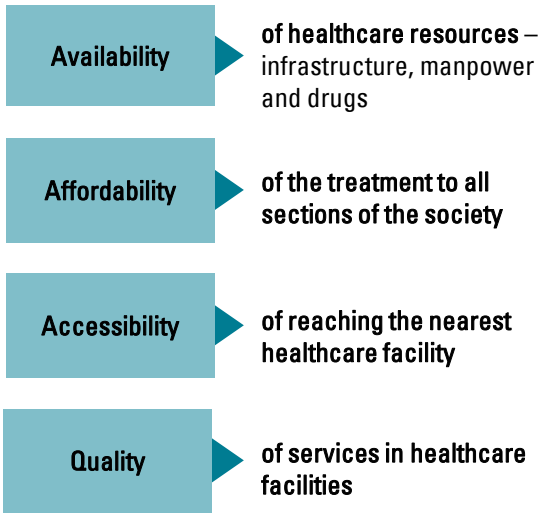
"It is a myth that just because a drug has patent protection, it will have a high price associated with it"

Mr. Sharad Tyagi, | Boerhringer Ingelheim India Pvt. Ltd.

Accessibility and availability of healthcare resources are major issues plaguing the Indian healthcare sector

Unified vision of universal healthcare

Key pillars of universal healthcare



Nearly seven decades post independence, access to quality healthcare for all has remained a key challenge for the Indian government. Access to universal healthcare is interdependent on various factors, which include awareness, availability, affordability, accessibility, acceptability and quality of care. The government has initiated many measures in the past to improve each of these aspects of healthcare, but a lot more needs to be achieved.

Affordability has always been cited as one the major factors impacting access to healthcare. The government has been working in this area by taking initiatives such as improving healthcare insurance coverage through RSBY, implementing programmes to enable availability of free medicines in government healthcare centres in Tamil Nadu, Rajasthan. These steps have helped improve access to healthcare.

Drug price controls is a mechanism through which the government is trying to make drugs affordable. While it may tend to improve affordability, it also adversely affects the pharmaceutical industry and thus, may limit access in the longer term.

The Indian pharmaceutical sector is gripped with an arduous task of balancing accessibility and availability together with innovation, and increasing investment in the sector especially to enhance the healthcare scenario.

Key Concerns

•Arbitrary inclusion of products under price control brings uncertainty, lack of stability and transparency in the process

•Expansion of list of drugs under DPCO impacting growth of the industry

•Inadequate focus on other healthcare levers to improve access in India, while addressing affordability as the only way to improve access to healthcare

Key points of discussion at the panel:

- Ways to find the best possible approach to provide access to medicines
- The relevance of pricing policies in India and its effectiveness
- Identifying specific roles the government and industry need to play to ensure accessibility

Accessibility to healthcare: The deliberations from the conclave

A multi-pronged focus on improving infrastructure and enhancing capacity will be key to providing universal access to quality healthcare

Challenges	Suggestions
Weak infrastructure in rural areas have led to decreased accessibility •Health infrastructure is largely concentrated in urban areas making healthcare accessibility a challenge in rural areas. Further, the under development of roads and other logistics, compounds issues of accessibility •Shortage of primary health care centres and community health centres in India is limiting access to healthcare	**Focus on adding healthcare infrastructure is need of the hour to increase accessibility** •Increase public expenditure on primary healthcare infrastructure improvement in rural areas and semi-urban areas •Encourage private hospitals' networks to establish basic health infrastructure in rural areas. Promote PPP models
Manpower shortage limits accessibility in healthcare •Shortage of doctors and para-medical staff limits the reach of health care delivery in India •Only one doctor for 1,700 people in India whereas the World Health Organisation guidelines stipulate a minimum ratio of 1:1,000	**Step-up investments in setting up medical training institutes** •Increase investment in setting up medical colleges and nursing schools in the country •There is a need to empower and train paramedical staff to provide emergency medical care
Focus only on the drug prices may not suffice •While it is essential to ensure affordability, price alone cannot drive accessibility. Focus on availability of diagnostic services, technical staff, etc. should be a priority	**Universal health insurance should be implemented** •Focus needs to be shifted from price to other areas such as insurance. Increase penetration of health insurance schemes as out-of-pocket expenditure is among the highest in the world. State driven insurance models that top-up the centrally driven insurance schemes in terms of re-imbursement can be a viable option •Promote private sector participation in community health insurance area

> "Innovative models for sourcing drugs can be looked at …therefore reduces cost"
>
> **Mr. Rajeev Sadanandan** | Joint Secretary, Ministry of Labour and Welfare

> "… empower paramedical staff with some rights to provide emergency medical care, especially in a nation where 70 per cent of rural population does not have access to affordable healthcare"
>
> **Dr. Shubnum Singh,** | Dean Max Healthcare institute

The special dinner session on day 1: The deliberations

Some of the important issues – a perspective of the policy makers and the industry leaders

Succinctly, the delegates had a vision for the Indian pharmaceutical sector- of being global leader in Pharma production by establishing India as a Pharmaceuticals manufacturing hub using our inherent strengths as drivers and addressing the existing challenges.

Creation of a conducive environment for making, developing, and innovating in India, with an active and equal participation from the private sector has the potential to enable the Indian Pharmaceuticals industry to rise up to the top and re-emerge as a leader in the pharmaceutical arena.

The session drew participation and sharing of perspectives from highest level of policy-makers on strategic interventions to take Pharmaceutical Industry on a higher growth plan.

Key suggestions made and the initiatives discussed at the session includes- India to be self reliant on the raw materials required for the pharmaceutical manufacturing to drive industry to succeed. Performing robust Research and Development, is one of the ways to address the disease burden and ensure access to medicines to the citizens. The nodal Government agency-Department of Pharmaceuticals mentioned that it has taken a step further and have introduced three Task Forces and thus have a created channel to take up issues of the sector and initiate development and ensure ease of doing business gets implemented through the provisions being made with DIPP. The other area which was discussed was on traditional medicines which has remained India's forte for thousands of years. Certain areas of traditional medicines has come out to be a holistic way of curing ailments. Newer dimensions in AYUSH system of medicine such as phytopharmaceuticals are the newer forms of traditional medicine which deserves a fresh-look as a potential area and should be encouraged with new investments in this area for development.

> "R&D is the only route through which we can ever address the disease burden of India and provide access to the best medicine to our citizens"
>
> **Mr. Amitabh Kant** | Secretary | Department of Industrial Policy & Promotion

> "There would be someday, maybe 10 or 20 years later, when the world has to substantially fall back upon these traditional sectors particularly because of the rising costs of healthcare and changing disease profile"
>
> **Mr. Nilanjan Sanyal** | Secretary, Department of AYUSH

> "Becoming world leaders in pharmaceuticals is possible for India, provided all of us work with the re-doubled vigour"
>
> **Dr. V. K. Subburaj** | Secretary | Department of Pharmaceuticals

> "The entire tonality of the bureaucracy in terms of supporting the industry and changing the entire system of operation is music to ears"
>
> **Mr. K.G. Ananthakrishnan** | Co-chairman, CII National Committee on Pharmaceuticals | VP and MD, MSD Pharmaceuticals Pvt. Ltd.

The special dinner session on day 1: The deliberations

Some of the important issues – a perspective of the policy makers and the industry leaders

The key discussion themes highlighted during the power-packed dinner session by the policy makers, Mr. Amitabh Kant, Secretary, DIPP, Mr. Nilanjan Sanyal, Secretary, Department of AYUSH and Dr. V K Subburaj, Secretary, Department of Pharmaceuticals were in coherence with other sessions in the conclave. The delegates were of the view that the Indian pharmaceutical industry has come a long way in the last few decades, witnessing a transformation from being a predominantly generic manufacturer to partnering with major pharma MNCs in their drug discovery efforts.

However, with multiple systemic challenges and increasing competition from other countries in the manufacturing space, the Indian pharmaceutical industry is expected to be faced with the ardent task to retain its competitive edge. All delegates established the challenge of creating a sustainable environment and the need to realign focus on key imperatives for the industry to propel its growth.

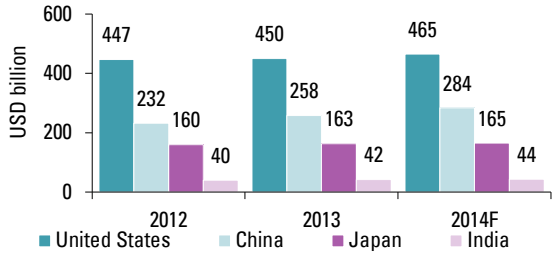
Key discussion points	Takeaways
Manufacturing of pharmaceuticals in India •Need for creating a business friendly environment and enhancing ease of doing business by simplifying operational procedures and approval processes •Government has already started taking steps by enabling online clearances and removal of human interventions, integrating all clearances under the E-biz platform to create a single approval platform	Need to have simplified polices and processes to attract investments in pharmaceuticals manufacturing
Self-sufficiency in drugs and intermediates •High dependence on intermediates and APIs imports from China is being viewed as a cause of concern •This import dependence is likely to impact India's ability to meet its healthcare needs for critical diseases	Impetus to make API industry competitive to reduce import dependence
Focus on R&D •With all the essential ingredients in place, laying emphasis on R&D could not only help address the growing disease burden of India, but also help India place itself amongst other global innovators •R&D conducive environment will attract MNCs to invest in India	Need for greater focus on R&D to further move up the value chain
Making quality control a top priority •Following GMP guidelines by ensuring compliance with the quality regulations has become essential, especially in the wake of non-compliance events in the recent past •Strict discipline and commitment will be required from all stakeholders for implementation of quality norms in pharmaceutical manufacturing	Ensure focus on high quality standards to reinstate image of Indian drugs among global players
Inclusion of traditional medicine •There is a need for infusion of talent, capital, ideas and science, and recognition of the potential of the traditional medicine sector •Requirement of experimenting and validating research in traditional medicine in a much more elaborative way was also discussed	Need to recognize relevance of traditional medicines along with mainstay pharmaceuticals

Creating a research ecosystem: The context

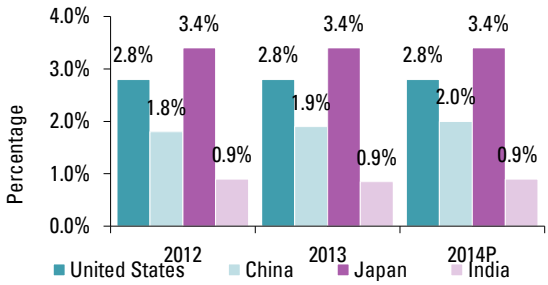
Sub-optimal R&D ecosystem in India is adversely impacting innovation in the pharmaceutical sector

In order to create a robust research ecosystem in India, the country must address some key issues such as quality of academic research output, limited industry-academia collaboration, multiplicity in policy making and low support from the government in the form of direct incentives.

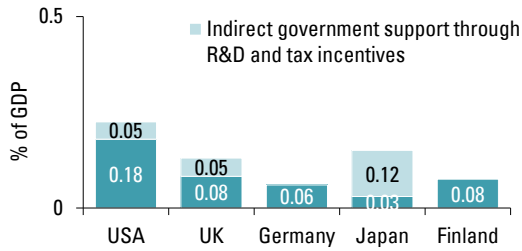
R&D expenditure by country



R&D expenditure as a % of GDP



Government support to R&D



Indirect incentives such as 200 per cent weighted tax deduction is generally provided India. Direct funding is not a commonly used instrument in India

Source: "Stimulation of Investment of Private Sector into Research and Development in India", Report of The Joint Committee of Industry and Government, May 2013;

Key concerns

•Low R&D expenditure and limited private funding towards drug discovery

•Low support by the Government for R&D in the form of direct incentives

•Lack of schemes and funding programmes to incentivise Indians, carrying out research elsewhere, to take up leadership roles in India

•Quality of research output is low as the research is not industry focussed and measurement standards for research output are not very well defined

•Limited industry and academia collaboration as academic institutes in the country have largely maintained a focus on publications whereas businesses are looking for innovative solutions from academia to help meet patient needs

•Limited model agreements that help ensure IP protection so that rights of both the parties are safeguarded and collaboration is fruitful

•Lack of a single consultative platform in policy making to facilitate efficient policy making and avoid conflict in agenda

•Gaps exist in terms of incubation support and mentorship as limited occupancy in incubators has been observed owing to the limited facilities/support provided by incubators

Key points of discussion at the panel:

- Ways to improve the quality of research coming from academia which would be relevant and commercially viable
- Approaches to build trust between industry and academia to foster collaboration
- Way to resolve issues related to regulatory/ IP framework
- Methods to channelize private funding towards R&D

Creating a research ecosystem: The deliberations from the conclave

A clearly defined roadmap, encompassing collaboration, funding and capacity building, will help boost innovation (1/2)

Challenges	Suggestions
Lack of well-defined innovation strategy leads to low R&D output •As it exists in developed economies, India does not have a well-defined innovation strategy in place •Even the government's role in the field of drug discovery remains unclear	**Devising robust innovation strategy will enhance R&D** •Having a planned approach towards drug discovery and development process, with clear accountability, is bound to reap benefits •It is equally important to identify personnel who will take responsibility and have the ability to drive it. Establishing a 'Think Tank' (with participation from industry, academia and government) will go a long way in facilitating the process of innovative thinking in the industry
Lack of funding has led to slowdown in innovation •There is limited venture funding in both the pharmaceutical and biotech space. Small biotech companies, that have come up with excellent targets, are shelving their discoveries as they are unable to take their targets from discovery stage to Phase-I due to lack of funding and government incentives •Some government schemes that have been initiated to foster early stage research, while useful, are not monitored adequately to gauge the impact	**To boost R&D innovation, a dedicated fund should be created** •Creating an innovation fund for targeted R&D in therapeutic areas of choice could also be useful The Department of Biotechnology has taken significant measures in this direction through schemes like Small Business Innovation Research Initiative (SBIRI), Biotechnology Ignition Grant (BIG) scheme for igniting new ideas. The new Government has announced plans to set up an INR10,000 crore fund for start-ups and entrepreneurs in the Union Budget 2014-15. Similar funding for R&D in the sector can help encourage firms to undertake higher levels of research and innovation and create products of tomorrow

"It would help enormously if there was more scientific input and greater degree of leadership that the industry can rely on"

Mr. Christopher Stirling, | Global Head Life Science | KPMG - United Kingdom

"Synergy between the laboratories and the industry is required to be leveraged… it is important that the stage of engagement with R&D is done at an appropriate time"

Dr. P S Ahuja | Director General | CSIR

A clearly defined roadmap, encompassing collaboration, funding and capacity building, will help boost innovation (2/2)

Challenges	Suggestions
Limited industry-academia collaboration have left a gap in development of talent pool •Despite the strong base of nationally recognised academic set-ups with adequate research infrastructure and thriving life sciences companies, the low levels of industry-academia linkage is a cause of concern	**Greater industry-academia collaboration will ensure high quality work force** •Clear trust issues by creating model agreements that help ensure IP protection so that rights of both parties are safeguarded and collaboration is fruitful •Norms for professional exchange between industry and academia to be eased- e.g. 10 years of research focused work in a life sciences company can be treated at-par to a post-doc qualification •Co-locate academia and industry to promote research
Deficit at leadership levels in the pharmaceutical sector is a major challenge •While the industry focusses more on meeting the demand for talented personnel at the entry and mid-levels, gap in resources at the leadership levels continues to increase. There is a lack of right candidates at the leadership levels to drive research toward commercial innovation and train employees in skills needed to sustain growth of the industry	**Reversing the brain drain may help in bridging the talent gap** •The concept of reverse brain drain, prevalent in China, has been missing in India. Indians undertaking research elsewhere should be incentivised to engage in leadership roles in India. This could be done by apportioning part of the enhanced innovation funding on a structured programme to bring such Indians into applied and basic research in India

"The net result of unstructured plan in India is that there are pockets of brilliance which has not led to meaningful drug discovery"

Mr. Sudhir Nambiar | Senior Vice President & Global Head, API R&D, Dr. Reddy's Laboratories

"The concept of creating a venture fund supported by the government for innovative drug discovery would something which will be path breaking for the country and we need it at this stage"

Dr. Mukta Arora | India Head – Global External R&D and Global Sourcing | Eli Lilly & Co.

The demand supply gap in skilled resources can be a potential challenge to industry's growth

One of the critical challenges being faced by Indian pharmaceutical industry today is the lack of employable manpower. Simultaneously, an evolving pharmaceutical sector calls for changing skill set requirement. In such a scenario, it is important that the government, academia and private sector need to bear the onus of developing skilled manpower for the sector. The private sector has an equally important role to play here, especially in terms of bringing clarity around the exact skill sets/training in demand.

PPPs can potentially be a way to facilitate this process by factoring in viewpoints from the public and private perspective. Adequate training and skill development will not only help increase the employment levels in the country but also enhance the efficiency of the sector on the whole.

Varied skills needed to cater to every aspect of the pharmaceutical value chain

R&D

Diploma, Graduates, Post Graduates, Doctorates and Post Doctorates in pharmaceutical and Science

Production

Diploma and Graduates in pharmaceutical and Science

Marketing and sales

Graduates from all disciplines, MBAs, CAs

The situation so far…

- Pharmaceutical companies in expansion mode, demanding greater need for technically skilled and knowledge workers
- Lack of employable manpower with skill deficit a major challenge
- Skill requirements not fulfilled by the existing talent

Key concerns

- Limited employable pool of skilled manpower
- Limited collaboration between all stakeholders to facilitate upgradation of skill sets
- Brain drain to lucrative destinations like the U.S.
- Pharmaceutical education is seemingly less attractive financially than the IT industry, which limits talent attraction to the sector

Key points of discussion at the panel:

- Perspectives on creation of innovative PPP models for strengthening the pharmaceutical industry
- Ways to boost the capacity for churning out skilled professionals who can add value across the value chain including regulatory, quality and compliance areas
- Examples of new and innovative PPP models to manage shortage of skilled manpower

Targeted skill building, with active participation from private sector, is required to ensure trained manpower availability

Challenges	Suggestions
Skill deficit manpower at entry level creates challenges for the industry •Lack of practical, industry relevant skills, these employees require significant training which incurs capital investment and time from the employers, making these employees less attractive for hiring •The Indian skills report 2014 suggest that a large portion (66 per cent) of the manpower is not industry ready	**Improving skills training to manpower will help fill the gap** •The industry should take initiatives to get more involved with the academia and design industry-relevant courses so that they are able to produce the required workforce for them •Having well structured, industry specific training programmes in finishing schools for fresh graduates to prepare them to do their jobs more effectively •The PPP business model can be instituted and followed where the government provides the basic infrastructure and the private players meet the operating expenses through fees
Relatively lower remuneration packages for pharmaceutical jobs has attracted less talent •In India, IT and finance professionals likely to make more than their pharmaceutical counterparts in terms of remunerations	**Incentivising pharmaceutical professionals is important to attract talent** •Remuneration package in the pharmaceutical sector should be comparable to their global counterparts (factoring in the purchasing power parity) •Incentivise NRIs working abroad to work in India as they can bring advanced technology knowledge and skill sets required at senior level positions
Lack of structured on-the-job training programmes have led to slow growth of talent •No provision for providing allied skills like IT, data analytics, etc.	**Robust and well defined on the job training programmes can ensure skill advancement** •Devise robust training programmes for on-the-job training of professionals at regular junctions •Identify skill gaps and promote skill advancement of employees so that they remain globally competent and motivated

"Students usually lack skills required at the entry level and companies incur humongous costs in training them"

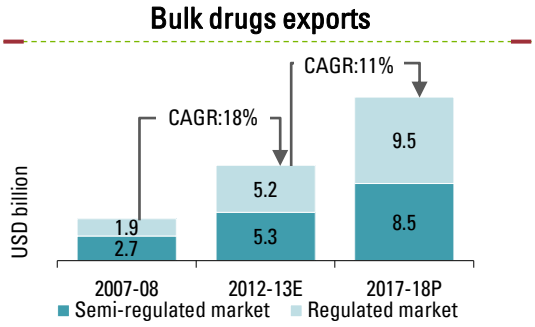
Mr. Ranjit Madan, | CEO, Sector Skill Development Council

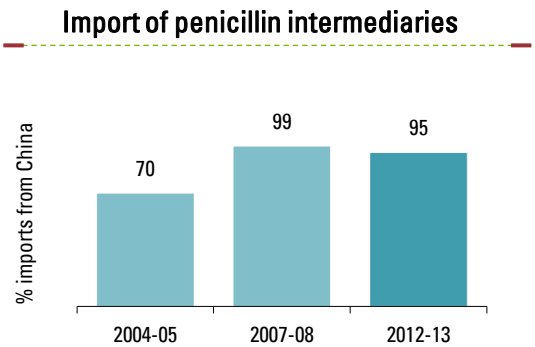
"Pharma Industry should partner with NIPERs to transform them as innovation hubs"

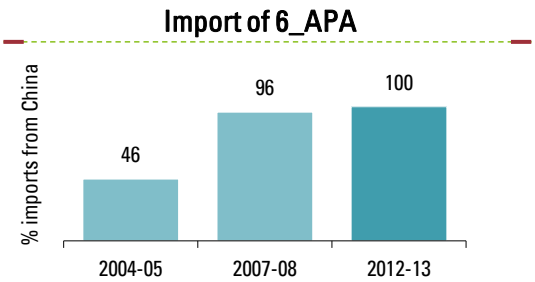
Mr. Ariz Ahammed, | Joint Secretary, Department of Pharmaceuticals

High dependency on API import from China has strategic implications on the Indian economy

Despite an attractive value proposition, the Indian API industry is plagued with issues revolving around increased dependence on Chinese API imports and a few non-compliance incidents. This calls for an urgent need for India to have a re-look at its API strategy. The Government of India is keen to address the above challenge in its new API policy. It becomes imperative for all stakeholders to suggest corrective measures.







Source: "Export import data bank", Ministry of Commerce; KPMG in India analysis, 2014

Strengths

- Fully integrated manufacturing
- Global recognition to Indian API manufacturers
- Cost arbitrage
- Strong manufacturing capabilities and globally compliant manufacturing plants
- DMF filings by India currently more than China
- Increased participation in the supply of late stage intermediaries to innovator companies globally

Key Concerns

•Considerable increase in API imports from China

•Losing cost competitiveness to Chinese APIs, which are understood to be 15-20 per cent cheaper

•Increasing report of compliance related issues impacting credibility of 'Brand India'

•Inadequate government intervention in terms of infrastructure and regulatory support to domestic players

Key points of discussion at the panel:

- Factors that drive China's competitiveness in APIs- cluster-based development, better integration with chemicals industry, dependable supply of factor inputs such as power, water, labour
- Short term vs long term strategic interventions available for India to manage current API situation

API industry struggle: The deliberations from the conclave

Cluster development and fiscal incentivisation will be the key steps to help India achieve self-sufficiency in APIs

Challenges	Suggestions
Lack of cluster-based developments has resulted in inefficiencies in API production and has resulted in import dependence on China •High import dependency on China for APIs and advanced intermediates such as 6-Aminopenicillanic acid, 4-amino phenol and dicyandiamide •Small and medium enterprises have been rendered unviable given the significant scale built by China in select products	**Promote integrated manufacturing facilities to reduce import dependency** •Facilitate setting up of vertically integrated manufacturing facilities for essential medicines •Fiscal incentives such as subsidised debt, tax and duty breaks can be provided by the government to facilitate setting up of integrated manufacturing units
Inadequate government support has been a major factor for poor API sector growth •Inadequate government subsidies and incentives to domestic API manufacturers •High utilities cost as compared to China •Low investment in process and chemistry innovation •Limited policy support for pharmaceutical cluster development	**Cost-competitive utilities will help** •Government to ensure that cost of utilities are low •Investments in power plants and other enabling facilitators •Strengthening and upgrading large scale government pharmaceutical production facilities **Invest more in newer technology** •Increased investment in R&D and technology can facilitate improvement in manufacturing processes •Incentivise key technologies such as fermentation, bio-catalysis and chiral chemistry **Focus on cluster development to boost manufacturing** •Encourage setting up of chemical and pharmaceutical clusters in close proximity to each other. This will enable companies to build scale and reap benefits of vertical integration •Investments in uninterrupted and low cost power availability and common effluent treatment plants in pharmaceutical clusters

"The government is thinking of prioritising APIs because bulk of it is being imported from one particular country (China)"

Mr. Sudhansh Pant | Joint Secretary, Department of Pharmaceuticals

"While China takes 4-5 years to register our products, we do it in 3-9 months……..why this discrimination exists is a question that remains unanswered"

B.R. Sikri | Co-Chairman, Federation of Pharma Entrepreneurs

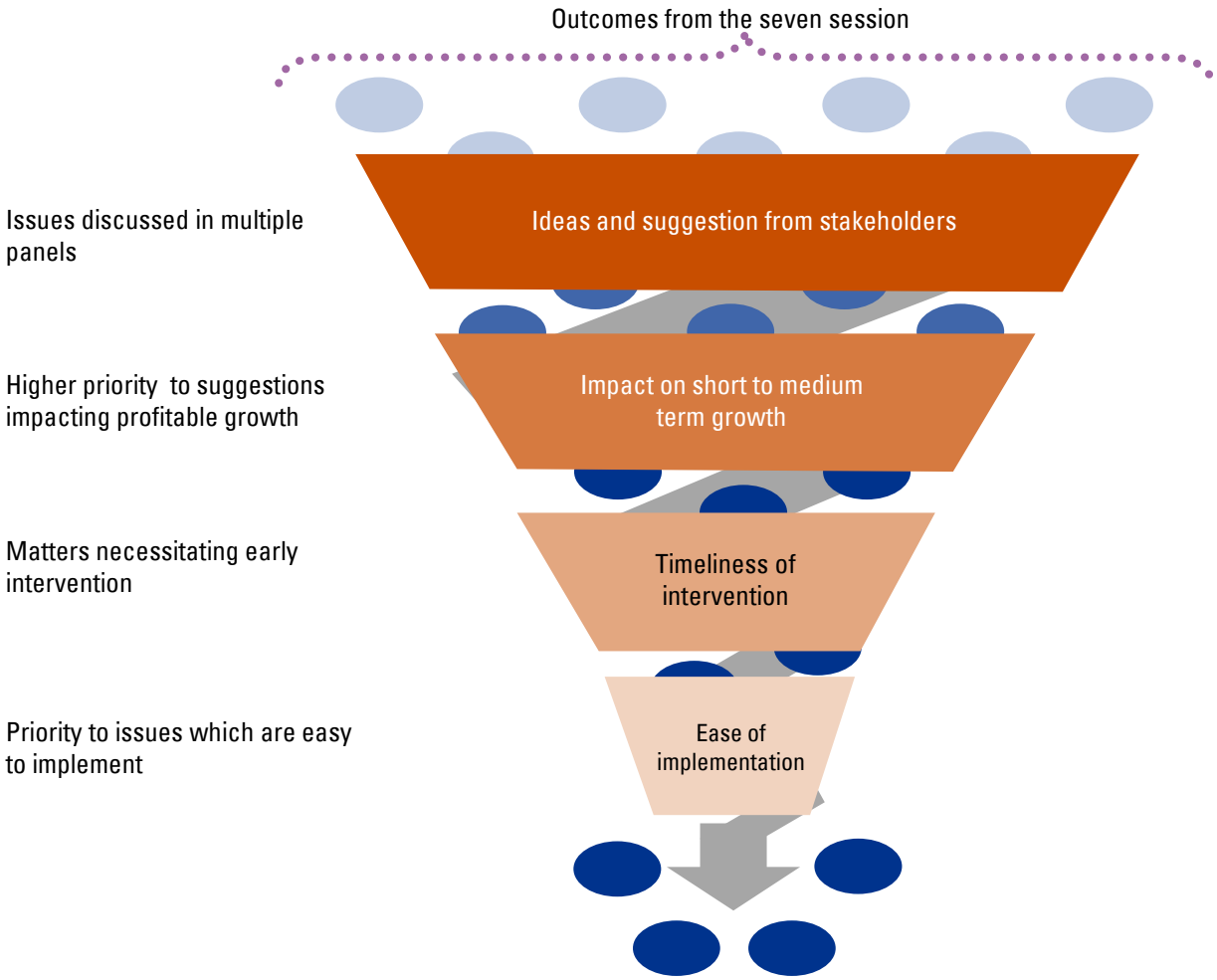
"Due to more cost-efficient manufacturing in China, we have been priced out by about 15-30%. The government is…working towards resolving it by a way of setting up clusters to ensure economies of scale and providing fiscal incentives"

Mr. Sudhansh Pant | Joint Secretary, Department of Pharmaceuticals

The way forward

A structured approach was followed to help prioritise the deliberations presented at the conclave

The seven sessions across the two-day conclave were successful in throwing up a multitude of suggestions. While all of these suggested actions were useful, it was imperative to prepare a targeted list to facilitate implementation. The framework below outlines these targeted list of suggestions.



Course of action discussed:

- Common themes across sessions such as skill building were naturally given preference
- The overall short-term and medium term impact of successful implementations of these suggestions were also considered.
- Suggestions that pertain to issues that require urgent intervention such as import dependence of critical APIs were also accorded higher priority
- Ease/difficulty of implementation was also considered. Hence, while having a single regulatory body for the entire industry is extremely desirable, the same could not be given high priority because of the practical difficulties in the short term for effective implementation

Key suggestions emanating from the conclave have thus been identified based on intervention timeframe for implementation and responsible stakeholders (1/3)

suggestions	Suggested actionable interventions	Timeframe & responsible stakeholders		
Single window clearance mechanism	• Identify & reduce redundant processes to simply the approval process	DIPP, State		
	• Establish empowered nodal agency both at central & state levels for speedy clearances and permits required to set up manufacturing plant		DIPP, State	
	• Single unified body providing clearance and permit from a single location/entity can help reduce time and efforts			DIPP
Inducing manufacturing clusters	• Evaluate the status of the existing Pharma clusters and identify areas for improvement and upgradation	DoP		
	• Identify location for new cluster development in the close proximity of academia, research institutes & industry	DoP		
	• Identify public & private sector stakeholders for the development of new cluster		DoP, State	
	• Development of chemical & pharmaceutical clusters at identified locations			DoP, State, Private partners
Unified policy mechanism	• Creation of a single consultative platform with adequate representation from all stakeholders to ensure efficiency in policy making and avoid conflict in agenda		DoP, MoHFW	
	• Empowerment of regulatory authorities for quick decision making and efficient functioning		DoP, MoHFW	
	• Creation of single regulatory body governing pharmaceutical, biotechnology & medical devices sector			DoP, MoHFW

Immediate Within 6 months | Short term 6-12 months | Medium term 1-3 years

Key suggestions emanating from the conclave have thus been identified based on intervention timeframe for implementation and responsible stakeholders (2/3)

suggestions	Suggested actionable interventions	Timeframe & responsible stakeholders		
Capacity building across functions	• Identify skill gaps in the quality, research & development, regulatory & IP functions which has high requirement	LSSSDC		
	• Development of structured skill development program to address the skill gaps		LSSSDC, Industry	
	• Roll out the program through institutes like NIPER to impart industry relevant training		LSSSDC, DoP	
	• Upgradation of drug testing laboratories, both in terms of infrastructure and manpower, to strengthen regulatory system		DoP	
Developing a national innovation strategy	• Identify and create think tank to formulate the national innovation strategy to foster the spirit of innovation	MoS&T, CSIR, ICMR, Industry		
	• Roll out the strategy towards drug discovery and development process with specific targets defined for each stakeholder involved		MoS&T, CSIR, ICMR, Industry	
Creating innovation fund targeted towards specific therapy areas	• Creating an innovation fund for targeted R&D in therapeutic areas of choice, to help develop new treatments for complex and rare diseases		MoF, MoS&T, MoHFW	
Streamlining IP operations	• Create robust IPR policy which will bring clarity and predictability	DIPP		
	• Link IP offices and build IP database for efficient patent search	DIPP		
	• Strengthen operations of patent offices by capacity building of patent examiners to reduce timelines for granting patents		DIPP	

Immediate
Within 6 months

Short term
6-12 months

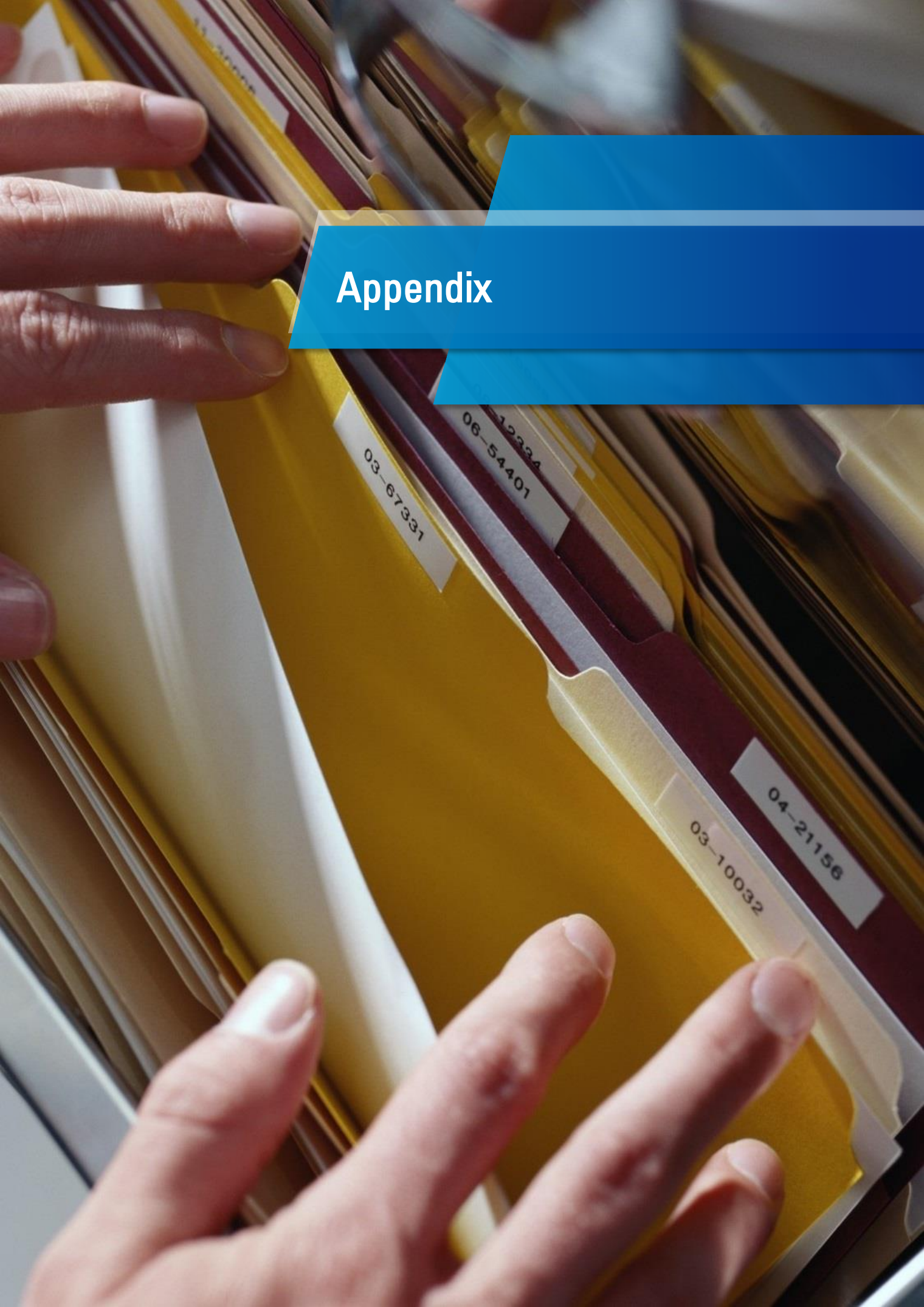
Medium term
1-3 years

Key suggestions emanating from the conclave have thus been identified based on intervention timeframe for implementation and responsible stakeholders (3/3)

suggestions	Suggested actionable Interventions	Timeframe & responsible stakeholders		
Evidence based price controls	• Implement mutually agreed, predictable & stable price control mechanism through consultative approach with the industry	MoHFW, DoP, NPPA		
Greater industry-academia collaboration	• Foster the culture of translational research to attract industry	MoS&T		
	• Create an autonomous and independent agency which will be an industry academia interface		MoS&T	
	• Infuse the culture of transparency to build the trust with industry		MoS&T, Industry	
	• Replicate the 'pocket of brilliance' which are successful with industry collaboration across the nation			MoS&T
Streamlining Clinical Trials	• Institute a single broad expertise-based Technical Review Committee to ensure speedy clearance of applications	DoP, MoHFW		
	• Implement online system to file, track & trace the applications	DoP, MoHFW		
	• Need for time bound action plan to implement key suggestions of Prof. Ranjeet Roy Chaudhury		DoP, MOHFW	
Ensuring quality compliance	• Investment in quality management systems, laboratory controls, training & implementation	Industry		
	• Identify and address the gaps required to be compliant with manufacturing standards	Industry		
	• Financial assistance to SMEs for infrastructure & quality standard upgradation	MoF, DoP		

Immediate Within 6 months | Short term 6-12 months | Medium term 1-3 years

Collaboration between stakeholders, with a unified vision towards growth, is of utmost importance today, a point deliberated upon during the sessions. Implementing these suggestions will require a collaborative effort from all stakeholders at varied levels. To foster collaboration, panellists highlighted the need for creating a platform for regular dialogue with industries and various ministries.



Appendix

Session title and panellists

Session	Panellists
Introductory session: Rebuilding 'Brand India'- industry perspective	Dr. V.K. Subburaj, Secretary, Department of Pharmaceuticals
	Dr. Shailesh Ayyangar, President OPPI and MD, Sanofi India
	Mr. D.G. Shah, Secretary General, IPA
	Mr. S.V. Verramani, President, IDMA
Session 1: Positioning India as a high quality global manufacturing hub for the pharmaceutical sector	Dr. Rajiv Modi, Chairman CII National Committee on Pharmaceuticals and CMD, Cadila Pharmaceuticals Ltd.
	Mr. Shailendra Singh, Joint Secretary, DIPP
	Mr. Sudhanshu Pandey, Joint Secretary, Department of Commerce
	Mr. Arun Mishra, Director- Regulatory Affairs, Abbott
Session 2: Creating a stable business environment through a responsive regulatory framework	Prof. Ranjit Roy Chaudhury, National Professor of Pharmacology and Chairman, Committee on Reform of the Drug Regulatory System
	Mr. Shoibal Mukherjee, Co-founder and Chief Medical Officer, Appletai
	Dr. G.N. Singh, Drugs Controller General of India, Central Drugs Standard Control Organisation
	Dr. Kiran Marthak, Director and Head Global Clinical Development, Lambda Therapeutic Research
	Ms. Suneela Thatte, Vice President, Quintiles
	Mr. Apurva Shah, Group MD and Co-founder, Veeda Clinical Research Pvt. Ltd.
	Mr. D.A. Prasanna, Chairman and MD, Ecron Acunova and Chairman Acro
	Mr. Imtiyaz Basade, Senior VP- Regulatory Affairs, Mylan Pharmaceuticals Ltd.
Session 3: IPR issues and its impact on drug development	Mr. D.V. Prasad, Joint Secretary, DIPP
	Mr. Ranjit Shahani, Vice Chairman and MD, Novartis India
	Mr. Alok Sonig, Senior Vice President and India Business Generic, DRL
	Mr. Sharad Tyagi, MD, Boehringer Ingelheim India Pvt. Ltd.
	Dr. Malathi Lakshmikumaran, Director and Practice Head, Lakshmikumaran & Sridharan Attorneys

Sources: 12th CII National Pharma Conclave 2014

Session title and panellists

Session	Panellists
Session 4: Accessibility to healthcare – balancing social considerations with industry growth	Mr. Sudarshan Jain, MD, Abbott Healthcare Solutions
	Mr. Rajeev Sadanandan, Joint Secretary (RSBY), Ministry of Labour and Employment
	Mr. Amit Backliwal, MD, IMS
	Dr. Y.K. Gupta, Professor Pharmacology, AIIMS
	Dr. Shubnum Singh, Dean, Max Healthcare Institute
	Dr. P. Senthilkumar, IAS, Special Secretary, Health & Family Welfare Department, Government of Tamil Nadu
Session 5: Creating a research ecosystem conducive to innovations in drug discovery and development	Dr. P.S. Ahuja, Director-General, CSIR
	Mr. Christopher Sterling, Global Head, Life Sciences, KPMG
	Mr. Sudhir Nambiar, Senior VP and Global Head, API, R&D, DRL
	Dr. Mukta Arora, India Head- Global External R&D and Global Sourcing, Eli-Lilly and Company
Session 6: Capacity building in pharmaceutical via innovative PPP models	Mr. K. G. Ananthakrishnan, Co-chairman, CII National Committee on Pharmaceuticals and MD, MSD Pharmaceuticals Pvt. Ltd.
	Dr. Ariz Ahammed, Joint Secretary, Department of Pharmaceuticals
	Mr. Ranjit Madan, CEO, Sector Skill Development Council
	Dr. T.P. Ahluwalia, Ph.D., D.Sc, Scientist-G (Sr. DDG) and Head, Division of Health Systems Research, Indian Council of Medical Research
	Mr. K.L. Sharma, Joint Secretary, MoHFW
Session 7: API industry struggling to sustain its competitive edge	Mr. Sudhir Nambiar, Senior VP and Global Head, API, R&D, DRL
	Ms. Priyanka Aggarwal, Partner, Boston Consulting Group
	Mr. Sudhansh Pant, Joint Secretary, Department of Pharmaceuticals
	Mr. B.R. Sikri, Vice Chairman, Bulk Drug Manufacturers Association and Co-Chairman, FOPE
	Mr. Vijay Kumar, President, API marketing, Ind-Swift Laboratories Ltd.

Sources: 12th CII National Pharma Conclave 2014

Abbreviations

6-APA	6-Aminopenicillanic acid
API	Active Pharmaceutical Ingredient
BIG	Biotechnology Ignition Grant
CA	Chartered Accountant
CAGR	Compounded Annual Growth Rate
CDSCO	Central Drugs Standard Control Organisation
CEO	Chief Executive Officer
CII	Confederation of Indian Industry
CMD	Chairman and Managing Director
CSIR	Council of Scientific and Industrial Research
DBT	Department of Biotechnology
DIPP	Department of Industrial Policy and Promotion
DMF	Drug Master File
DoP	Department of Pharmaceuticals
DPCO	Drug Price Control Order
DRL	Dr. Reddy's Laboratories
EU	European Union
FDA	Food and Drug Administration
GDP	Gross Domestic Product
GIPC	Global Intellectual Property Centre
ICMR	Indian Council of Medical Research
IP	Intellectual Property
IPR	Intellectual Property Rights

LSSSDC	Life Sciences Sector Skills Development Council
MBA	Masters of Business Administration
MD	Managing Director
MoF	Ministry of Finance
MoHFW	Ministry of Health and Family Welfare
MoS&T	Ministry of Science and Technology
NGO	Non Governmental Organisation
NPPA	National Pharmaceutical Pricing Authority
NRI	Non Resident Indian
OECD	Organisation for Economic Co-operation and Development
OPPI	Organisation of Pharmaceutical Producers of India
PPP	Public Private Partnership
R&D	Research and Development
RSBY	Rashtriya Swasthya Bima Yojana
SBIRI	Small Business Innovation Research Initiative
SEZ	Special Economic Zone
SLAs	Service Level Agreements
SOPs	Standard Operating Procedures
U.K.	United Kingdom
U.S.A	United States of America
VP	Vice President

Sources: 12th CII National Pharma Conclave 2014