FICCI's Wish List

Healthcare and Life Sciences

India is at the cusp of a major healthcare system transformation with several initiatives on the anvil to address the accessibility, affordability and quality issues of healthcare in the country. Similarly, medical technology and the life sciences sector including pharmaceuticals, bio-pharmaceutical and clinical trial sector is going through a reform process to further strengthen and retain our global competitiveness.

Sixty seven years since independence with two National Health Policies in 1983 and 2002 in place, quality 'Healthcare for All' remains a distant dream. Our health outcomes continue to lag behind developing countries and world averages; collaboration between the public and private sector fail to reach scale and trust; inspite of being the pharmacy of the globe, our poor do not have access to basic medicines and there is hardly any research on new drugs addressing tropical diseases prevalent in our country. Further, absence of local manufacturing of medical technology makes access to locally relevant devices and equipment unavailable and healthcare inaccessible and unaffordable for our people.

FICCI believes that during the Twelfth Plan period, along with strengthening the initiatives undertaken in the Tenth and Eleventh Plan period, we must bring in appropriate reforms in policy and regulatory framework to realize our aim of achieving universal health coverage (UHC) in the country in next ten years. Some of the immediate tasks which can be looked at in the 100 days time frame are the following-

I. Create a new health policy for 2015-2025

- As Health has been a priority sector for the past decade and the 12th Five Year Plan is often referred to as the 'plan for health', it is the right time to set up a committee to draft the new National Health Policy for 2015-2025.
- The new health policy should look at the 'healthcare for all' holistically
  - ✓ Ensure availability of clean drinking water and sanitation across the country
  - ✓ Develop specific policies for dealing with issues of nutrition , NCD, communicable diseases/epidemic outbreak, health technology, devices, affordable and accessible medicines, medical education and CME, School health, innovation in healthcare, Occupational health, PPP, MCH, social media
  - ✓ Focus on implementation of the policies in a professional manner taking into consideration the rural urban divide.

II. **Create a roadmap towards increasing Government expenditure on Health from 1.1 percent of GDP to 2.5 percent in next five years.**

- **Universal Health Coverage**: FICCI recommends a blended approach, one that strengthens the links of government health insurance to healthcare providers (both public and private) but ties funding to performance. This approach is well grounded in current Indian reality and also draws on international experience. While there is a huge role for the public delivery system in promotive, preventive and primary care in India, health insurance could be a key enabler in terms of both financing and incentives for improved performance. *(FICCI- EY: Universal Health Cover for India: Demystifying Financing Needs, 2012)*

- Introduce National Telemedicine Network linking 500 high end public and private hospitals with 500,000 rural health centers.

HEALTH SERVICES

III. **Focus on Prevention for a Healthy India:** As India undergoes a rapid demographic and epidemiological transition, investments in preventive and promotive health have becomes quintessential.

[Appropriate interventions in health can give returns nine times the investment (Lancet Commission on Global Health 2035; India is estimated to lose 1.3% of GDP annually by 2015 due to chronic diseases (Abegunde and Standiole (2006); Companies lose approximately 14% of their annual working days due to health-related reasons (ICRIER, 2008)]

Hence, it is important to leverage the health and health insurance industry in these efforts for a healthy and productive India.

- An additional provision in section 80D should be added to incentivize the insurance industry as well as policy holders for health insurance products with preventive and promotive coverage. It is proposed that an additional Rs.10000/ paid as premium for a preventive and promotive cover or add-on cover be eligible for section 80D and eligible for 150% of the premium paid.

- Incentivize employers and individuals by providing tax rebates to undertake preventive health checkups; the current tax rebate of Rs.5000 available for preventive checkups within the health insurance exemption limit should be increased to Rs.15000 and not clubbed with the health insurance limit as they serve different purposes.

- Develop a framework to institutionalize healthy practices in various social settings including communities like urban slums, rural settings, etc.

IV. **Increase focus on Non Communicable Diseases (NCDs): awareness, prevention and management-** NCDs are estimated to account for nearly 53% of all deaths in the country (WHO, 2011). The National Programme for the Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) was initiated in 100 selected districts in 21 states during the 11th Five Year Plan. However, less than 1% of the population has been screened for diabetes and hypertension as per the 12th plan document. The following needs immediate attention:

- Leverage the private sector expertise (in diagnostics, radiology & medicine domain expert companies in preventive healthcare, integrators, health services companies etc.) for implementation of NCD strategy in line with the NPCDCS operating guidelines.

V. **Promote health insurance** in the country to improve affordability of healthcare especially targeting the youth to reduce overall health related financial distress.

The government must aim at achieving universal health coverage over the next decade enabled by social, government-sponsored, employment-based, community-based or private voluntary health insurance. Key enablers towards this change are-

- Strategic initiative by the Government to enlarge the scope of health insurance schemes sponsored by it purely from an economic and social criterion to that of age. As the Indian population ages, the need to provide the elderly with easy access and affordable healthcare would become an impending necessity.

VI. **Quality Assurance:** Both the private and the public sectors lack adequate provisions for standards and accreditation, with only ~220 NABH accredited hospitals and ~400 NABL accredited labs till date. The Accreditation movement in Health needs to be given a big fillip.

- Adoption of evidence based National Standard Treatment Guidelines and Electronic Health Record Standards (facilitated by FICCI on behalf of MoHFW) and tariff determination based on National Costing Guidelines to usher in transparency in diagnosis, treatment and costs.

- NABL and NABH should fall under one umbrella i.e., the MoHFW, GoI instead of NABL falling under the Dept. of Science and Technology, GoI and NABH under the Ministry of Commerce and Industry, GoI.

- Incentivise accredited hospitals by providing 2.5% increase in the reimbursement rates and fast tracking of reimbursement claims

- Ensure all government healthcare facilities like PHC, CHCs, district hospitals etc. go through the accreditation process

- Public and private hospitals and healthcare facilities adopting Electronic Health Record Standards should be provided funding for IT infrastructure up-gradation.

VII. **Passage of the Indian Medical Council (Amendment) Bill, 2013** which would help in reducing the resource crunch of trained medical professionals in the country by the following provisions-

- to amend section 13 of the Act relating to recognition of medical qualifications granted to a citizen of India by medical institutions not included in the First or Second Schedule so as to extend the benefit to the overseas citizen of India; and thereby allowing such professionals to practice post their screening test in India.

- to amend section 14 of the Act which would allow overseas experienced individuals to be employed through specific employment; (process being employer approaching medical council for time bound registration of an individual with defined clinical privileges).

VIII. Medical Education:

- Develop PPP models for district hospitals where the private sector may be permitted to use them to set up medical colleges to enable better dispersion across the country and address regional disparities.

MEDICAL DEVICES AND TECHNOLOGY

IX. **Separate Chapter on Medical Devices in Drugs and Cosmetics Act, 1940**- Medical Devices are fundamentally different in pith and substance from pharmaceutical formulations, which has been realized by the Government. Deliberations on a separate regulatory regime for medical devices thereby differentiating them from drugs under the schemes of Drugs and Cosmetics Act 1940 has been ongoing. In line with this, we recommend:

- A regulatory structure for technologies under Department of Science and Technology and in accordance of global practices wherein medical devices are governed by different sets of rules and regulations from drugs and pharma products.

X. **Developing the Ecosystem of Indigenous Manufacturing-**_There is a need to incentivize local manufacturing of medical technology sector to provide customized indigenous products for the Indian population in the long run. However, the import of lifesaving products and equipment should not be disincentivized by imposing taxes and duties. This could adversely affect the access and availability of resources to patients as most hi -tech Innovative products and technologies originate from a well – developed ecosystem and innovation cycle, which is not available in India yet and will take time to evolve. We recommend the following to stimulate local manufacturing:

- **Creation of exclusive dedicated medical technology parks** where there is a cluster of manufacturers of medical technology products with basic infrastructure to support these and the inclusion of benefits for customs duty on raw material, excise duty concessions, vat holidays, it holidays, etc.

- **Single Window and 35 working day clearance through a nodal agency for procedural simplification and effectiveness**: FICCI recommends formation of a single nodal agency and a central clearance system for all the compliances to be met. The single nodal body will be a one point contact for the investors, manufacturers, importers, exporters in the medical technology sector and it will collate the efforts of various departments of ministries and other agencies.

XI. Non Adversarial Tax Regime for Devices

- NIL Customs duty to be specified for the import of raw Material/ Parts/ Sub-Assemblies required for ultimate local manufacturing of Medical Devices and Electronics.
- All critical care medical devices, consumables used with devices in the specific critical treatment procedure and their spare parts should be exempted from Custom Duty.
- Excise duty on medical equipments be reduced significantly and may be prescribed at the lowest slab to enable the domestic industry to find a foothold.

XII. Healthcare Innovation Policy Framework

The Medical Technology Industry continues to battle with a lack of regulatory awareness and attention from the governments in order to achieve scale. More than 80% of all medical technology and devices in the country are imported. Other BRIC economies have initiated specific actions to build a self-sufficiency in this industry; not only as a knowledge industry but as an industry of strategic importance.

An integrated National Health Innovation Policy Framework needs to be rolled out to promote & support innovative products and practices and integrate all current initiatives under various departments and ministries.

- Initiate a policy direction to spur Research and Development in both University and Institutions of higher learning to produce tangible outcomes for social impact. 40% of public funding for research should be earmarked for impact research and grants should be made available to recipients who demonstrate both capability and capacity to innovate. Report successes and failures in public domain so that professionals and entrepreneurs can identify gaps and take appropriate steps to bridge them.
- Make it mandatory to recertify Medical Graduates and Post Graduates. ICMR to recast a curriculum for translational research for 3rd year MBBS and make it mandatory for Post Graduates to engage in translational research project for credits in recertification.
- Create a special bridge program to enable and encourage engineers to enter into clinical disciplines and vice versa
- Create a national entrepreneurship policy to encourage the investor community to participate in early stage investments. Capital gains exemption for angel and venture capital investors should be provided.
- Institute a High Priority Technology Assessment Board to identify areas of high priority for funding, tax exemptions and other fiscal incentives
- Institute a quality management systems in governance and quality improvement programs
- Formulate and adopt a measureable index for innovation
- Offer income tax rebate up to 250% of the value investment for R & D and innovation of Medical Instruments, Diagnostics Instruments, Consumables, Devices, etc.

XIII. **Review MCI Guidelines on Devices:** The development of healthcare services is greatly dependent on the industry who impart continuous medical education (CME) to the Healthcare practitioners and keep them abreast of the latest technology. There is a need to review the MCI guidelines and incorporate necessary changes to address the need for medical technology industry.

XIV. **Review Pricing of Medical Devices:** In the case of Pharmaceuticals, one molecule is the same irrespective of manufacturers. However in the case of medical technologies, there are no two similar technologies. Each has a different design and also in the same product there are different codes having different sizes. Hence the formula being applied on Pharma pricing cannot work in Medical technology. Any act to control prices in the Pharmaceutical way will affect the industry adversely and in turn will lead to non-availability of the technologies to the patients.

XV. **Clinical Trials for Medical Technology**

The medical technology trials are distinctively different from the pharmaceutical trials as the device trials do not have systemic/ genotoxic effect on the body. Hence the regulation on medical technology trials needs to be rationalized so that development is encouraged.

PHARMACEUTICALS

XVI. Create an ecosystem for spurring R&D and innovation

The global industry is highly research intensive and spend around 15% turnover in R&D, however, in India it's still low with less than 2% spending. Although the Indian private players have increased investments in R&D, the focus is on the thriving generics business instead of new drug discovery. As a global player we need to remove this weakness in the system by-

- Setting up a "National R&D Observatory" in India, which will provide technical support to establish a system to monitor R&D investments and pipelines and recognizing the considerable gaps that exist.

- Ensuring flow of funds by raising the weighted tax deduction from 200%-250% and extending it to clinical trials as well.

- Extending exemption from excise/custom duties on raw materials, capital goods and diagnostic kits.

- Building synergy with industry and major government institutions and universities for technology transfer and Intellectual Property Right for research and innovation.

- Encouraging innovation on continuous basis in order to create a favourable environment for incubation of new and unique recombinant Biologics that will address the three issues of affordability, availability and quality in overall healthcare scenario.

XVII. Create a common understanding of Clinical Trials landscape in India

From 2010 onwards India has witnessed heightened activism and media sensationalism targeting clinical research resulting in a slew of new regulations. While these regulations have been well-intentioned, they have proved to be disastrous for clinical research in the country and the long-term future of pharmaceutical innovation in India. There is an urgent need to revive the sector to address the burden of existing and new diseases. This would include recasting of adverse regulations introduced in 2013-14. In this regard, we propose the following:

- A framework of internal operating procedures should be put in place for the efficient functioning of the regulatory authority in order to maintain a high level of documentation, probity, and transparency. The functioning of the regulatory authority should be subject to regular audits. Summary audit data in appropriate format should also be available in the public domain.

- The regulatory authority should function at a high measurable standard of customer service with regards to research applicants. This should include time-bound review and disposal of applications. Customer service metrics should be available in the public domain in a timely manner.
- The CDSCO should be strengthened through a comprehensive program of up-gradation of qualifications, skills and experience of personnel dealing with the review of research applications within the regulatory authority.
- Several issues pertaining to BA-BE studies, compensation packages, long processing time due for approvals etc. needs to be streamlined for reviving Clinical Trials in the country.
- Create awareness amongst judiciary, media and civil societies in order to enable them to take informed decisions.

XVIII. Foster the quality agenda for API manufacturing: Some of the recent events have brought forth the need for incentivizing and promoting quality practices in the API manufacturing in India. We propose the following:

- Encourage development of innovative API technologies and promote indigenous manufacturing of APIs
- The existing Indian GMP (schedule M + guidelines) should meet the international standards.
- The existing clusters in the sector need to have common facilities for testing etc.
- Expedite the setting up of mega parks and new clusters in the API segment with common facilities
- Focus capacity building endeavors for both regulators and manufacturers in India.

XIX. Issues related to Drug Price Control Order 2013

There is a lot of issues in implementation of DPCO 2013 and there is no clarity on inclusion of different dosage and different delivery system in the NLEM List. Slow process of price approval of new drugs and retail and wholesale margins to trade etc. is also an issue. NLEM list is expected to be further expanded which will create conflicting situations for drug manufacturers, importers, marketers and retailers and potentially lead to lack of access of medicines to the community at large. We propose the following:

- Device different guidelines for biopharmaceuticals that involve formulations based on biological products from chemical drugs.
- Exclude brands with less than 1% market share from ceiling price calculation.
- Apply price fixation formula only to products, dosages and strengths specified in Scheduled I of DPCO, 2013.
- Revise trade margin for retailers to compensate loss under DPCO 2013.
- Price implementation in 45 days of notification/order from prospective batches.

XX. **NPPA's order no. S.O. 1157 (E) regarding fixing of ceiling prices for 12 formulations.** Dexamethasone and Gentamicin Injections are being marketed in 2 ml (single dose vial) and bigger vials of (multi dose) 10ml, 20ml and 30ml packs. The ceiling prices of these formulations

have been worked out by averaging the prices of different packs to retailer (PTR) as per MAT value as on 30th September, 2013. Averaging prices of different packs to arrive at ceiling price for all packs would not be in the interest of the manufacturer as it will not only impact the reduction in the ceiling prices but will also cause loss to the industry and impact the availability of these formulations in the market as the manufacturer will be forced to discontinue these products due to negative/low margin.

- There is a need to reconsider the notification issued by NPPA and issue guidelines to calculate and notify separate ceiling prices for different packs in case of injections, liquids and ointments. This will also be in line with notification on fixation of prices on pro-rata basis as per DPCO, 1995 which was applicable to only tablets & capsules.

XXI. Foreign Direct Investments

Currently, India permits 100% FDI in the pharmaceutical sector through automatic approval route in greenfield projects and on a case to case basis for brownfield projects. The DIPP had sought reduction of FDI limit for brownfield pharma projects from 100 per cent to 49 per cent in "critical'' areas as it feared that acquisition of Indian companies could vitally affect availability and affordability of generic (off-patent) medicines.

- We recommend that the Government should continue with the present policy on FDI in Pharma (uncapped). The free market should be allowed to prevail.

XXII. Ecosystem for Biotechnology

Since biopharma sector is one of the largest components of the Indian biotech industry and the most promising, India needs to maximize its presence in this space. This sector invests substantially in innovative product development and clearly a lot of companies see more value in ramping up their service offerings even as they try to overcome the technological, financial and regulatory challenges. To help streamline the issues, we propose the following:

- Promote Biopharmaceutical clusters for comprehensive indigenous manufacturing of similar biologics and vaccines.
- Revive export incentives/BTP Schemes for this sector to realize its full potential. Since, R&D in biotech, especially the Biopharma sector is highly capital intensive, export tax benefits are required to de-risk and fund original research. The increased number of BTP schemes would also ensure provision of financial and logistical support for establishment of biotechnology parks and pilot projects in various states.

XXIII. **Over the Counter Drugs**

There is a need to have separate regulation for OTC sector as there is no legal recognition in Drugs and Cosmetic Act, definition of OTC drugs and positive list of OTC medicines. (*FICCI had submitted a Concept note on Over the Counter Drugs to the Drug Controller General of India as enclosed*)