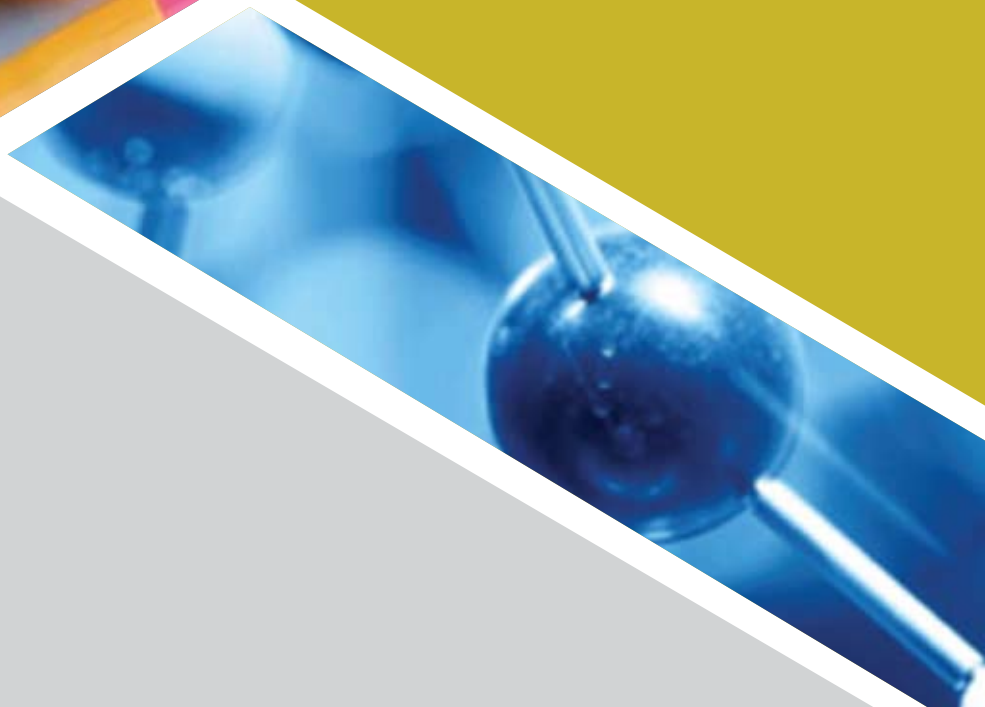
Recommendations of the Task Force on Enabling Private Sector to Lead the Growth of Pharmaceutical Industry



सत्यमेव जयते

Department of Pharmaceuticals
Ministry of Chemicals and Fertilizers
Government of India

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Acknowledgements

This report has been accomplished with the support of various concerned government and private industry bodies as listed below and others who contributed during multiple meetings and interactions:

1. Department of Pharmaceuticals (DoP)
2. Ministry of Health & Family Welfare (MoHFW)
3. Drugs controller (DCGI)
4. Department of Commerce (DoC)
5. Department of Industrial Policy and Promotion (DIPP)
6. Department of Biotechnology (DBT)
7. Department of Science and Technology (DST)
8. Niti Aayog (formerly Planning Commission)
9. Indian Pharmaceutical Alliance (IPA)
10. Indian Drug Manufacturers Association (IDMA)
11. Association of Indian Medical Devices Industry (AIMED)
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13. Federation of Pharma Entrepreneurs (FOPE)
14. Organization of Pharmaceutical Producers of India (OPPI)
15. The Federation of Indian Chambers of Commerce and Industry (FICCI)
16. Confederation of Indian Industry (CII)
17. PHD Chamber of Commerce and Industry
18. The Associated Chambers of Commerce of India (ASSOCHAM)
19. IMS Health and Consulting Information Services (IMS Health)

Background

Pharmaceutical industry is a multi-product industry, producing wide range of products. Manufacturing and trade in Pharmaceuticals is also growing quite steadily. Double digit growth rates indicate its importance in health care. Most hi- tech innovative products and technology originate from a well developed eco-system and innovative cycle which needs to be developed in India to promote indigenous industry and to reduce our dependence on imports.

The 'Make in India' campaign of the Government of India has a mandate to boost the indigenous pharma manufacturing sector in India. To implement the initiative, a Task Force was constituted under the chairmanship of the Secretary, Department of Pharmaceuticals (DoP) to address issues relating to the promotion of domestic pharmaceutical manufacturing in the country. The Terms of Reference (ToR) for the Task Force is attached at Appendix 1.

The first meeting of the task force on 'Enabling the Private Sector to Lead the Growth of Pharmaceutical Sector' was held under the Chairmanship of Secretary (Pharma) on December 10, 2014. The meeting was attended by the representatives of concerned Departments/ Ministries and Various Industry Associations. Secretary (Pharma) emphasized the need to facilitate and promote the growth of the Pharma sector by creating a conductive policy and operating environment. The Task Force decided to constitute three sub-groups on procedural constraints, industry-government linkage and industry-academia linkage. The respective ToRs of different sub-groups are attached at Appendix 2-4. The sub-groups presented its recommendations before the Task Force in its meeting held on April 16th, 2015. The Task Force deliberated on these inputs and observations and finalized its recommendations.

Pharma Sector Overview

The Indian pharmaceutical market size is driven by knowledge, skills, low production costs and quality. Due to this, there is demand from both domestic as well as international markets. This has resulted in a robust sustained double digit growth for the sector. The industry is ranked 3rd globally in volume and 14th in terms of value, supplying around 10% of the total global production. This also amounts to around 20% of the total volume of global generics. Thus every 5th Tablet, Capsule and Injection in generic drugs consumed anywhere in the world is manufactured in India. In fact, India manufactures 30% of the world requirement of Anti-HIV drugs. This growth has been with affordable price to the common man – one of the lowest in the world. The industry is quite fragmented and comprises of nearly 10,500 units with majority of them in the small sector. Of these, about 300-400 units are categorized as belonging to medium to large organized sector.

The Domestic Pharmaceutical Market is skewed towards cities with the top 23 cities accounting for almost 25% of pharma sales of which the Tier-I towns account for one-third of sales and Tier-II cities (population less than one lakh) including the rural market accounting for about 40% of market share. This is for the obvious reasons of better health care accessibility and purchasing power of the resident middle class income group. However, due to shifting rural and semi-urban economic status as well as life styles, the rural areas are witnessing a market increase growth of more than 30% annually. This increase in the growth is catching the attention of the major companies who are now focusing on them for future growth. India is largely self-sufficient in case of formulations, though some life saving, new-generation-technology-barrier formulations continue to be imported.

India is among the top 20 pharmaceutical exporting countries globally and has shown commendable export performance with continuous positive balance of trade. Exports constitute a major part of the Indian pharmaceutical industry and at present it is around 50% of the total turnover of the industry. Indian drugs are exported to around 200 countries in the world including to the highly regulated markets like USA, Russia, Germany, Austria and UK with USA alone accounting for almost 25% of total export. The sustenance in export growth rates will be driven by three factors – increased dependence on generics production due to patent expiries by 2017, estimated at some US $300 Bn of conventional and biopharmaceuticals; slowdown in discovery/ invention of new molecules in developed countries; and pressure on the developed country governments like US, Germany, Japan etc. to contain their healthcare expenditure.

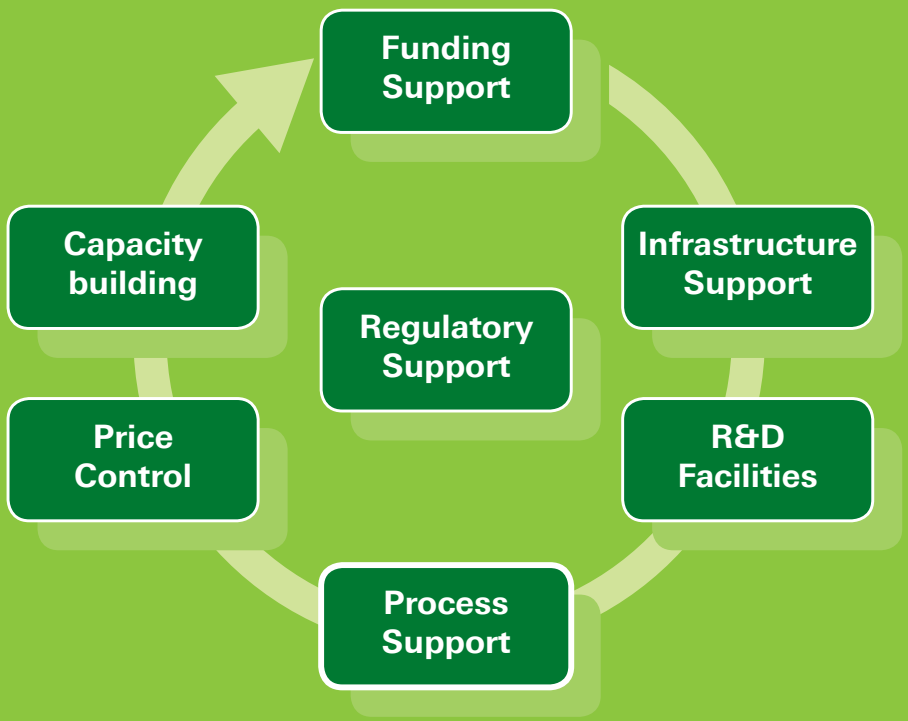
The Indian pharma industry has evolved around industrial development clusters set up by various state governments. In the earlier years, most of the manufacturing and R&D units could take benefit of the then prevalent environmental laws. But now international customers from developed nations are becoming more stringent on ensuring local environment compliance standards and want companies to adhere to these standards. This has led to a big challenge for the Indian pharma industry, particularly small scale units, which either have investment concerns or limitations of growth beyond their allocated unit areas in the industrial clusters set up earlier with antiquated environment standards compliance potential.

Although the Indian pharmaceutical industry is large by Indian standards, on the world market its share is merely 2.4%. The estimated investment in R&D by major Indian pharma companies is around 8.68% of their sales turnover. As a percentage of total production this works out to only 4.4% of the total sales turnover. Compared to the R&D investment in the developed markets of around 8% the Indian investment is quite low.

Recommendations

For strengthening the Indian pharmaceutical sector, the taskforce recommended a better industry-government linkage with respect to coordination and consultation, which would enable the private sector to lead the growth of pharmaceuticals sector. In addition, a strong focus would be required on the following levers, in order to maximize use of resources, generate adequate funding for development of facilities, infrastructure and promote R&D facilities.

These will not only facilitate growth of the pharmaceutical industry but also help build synergies among various stakeholders working across the system and strengthen our pharmaceutical sector. The themes for the recommendations are depicted in the diagram below:



1. REGULATORY SUPPORT

Recommendation 01: Setting up a High Level Coordination Committee

❖ **Objective**

- To periodically review the constraints and issues faced by the Pharmaceutical sector
- To coordinate/ facilitate resolution of these issues/ problems on a periodic basis

❖ **Representatives**

- Secretary, Department of Pharmaceuticals (Chair)
- Ministry of Health and Family Welfare
- Ministry of Environment, Forests and Climate Change
- Department of Industrial Policy and Promotion
- Department of Commerce
- Department of Science and Technology
- Department of Biotechnology, etc.
- Other invited members may be decided by the Chairman which may include Chairman, NPPA, DCGI, Pollution Control Board etc.

Recommendation 02: Constitution of a promotional corporate body/registered society

❖ **Objective**

- Act as a facilitating and promotional body for the Indian Pharmaceutical industry
- Hold periodic seminars/ workshops, Indian Pharmaceutical Summit, sponsor studies, brand-awareness campaign about various concerns raised in media, collect data about the various parameters of industrial activity in pharmaceutical sector and implement promotional schemes
- This body may be modeled on the lines of Pharmexcil (which is related to pharmaceutical exports only)
- Identify redundant processes and bring it to the notice of the concerned agencies to simplify the approval process(es)
- Create a single unified electronic platform for facilitating clearance to reduce time and efforts

❖ **Representatives**

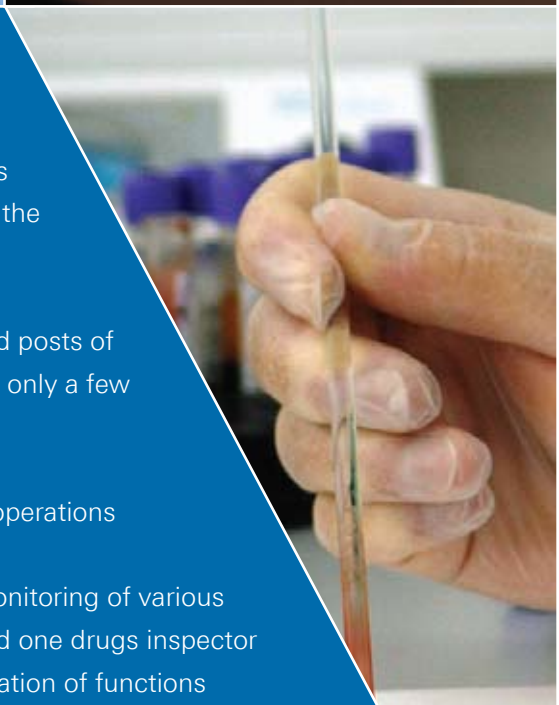
- Constituted under DoP in which all the stakeholders (Government and Industry) may be represented as members

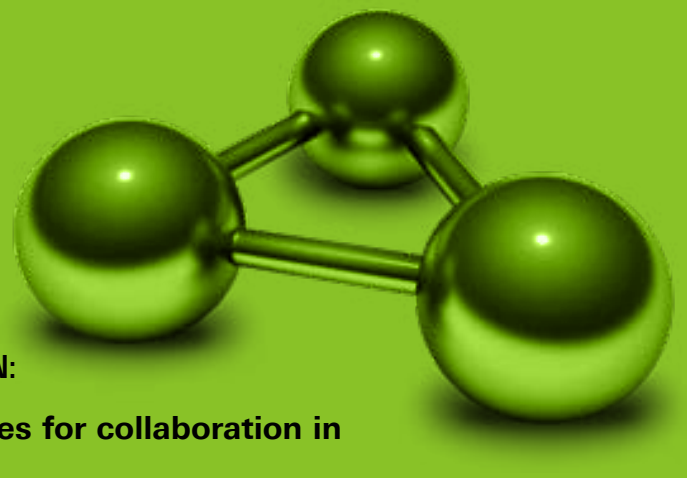
Recommendation 03: Create a Regulatory Cell in NIPERs and other Institutes

- To support the Indian pharma sector understand the global regulatory landscape
- Should have working relationships with other regulatory Institutes like Centre for Innovation in Regulatory Sciences UK, DIA (USA), Centre for Regulatory Excellence at the Duke- NUS Graduate Medical School (Singapore) etc.
- The Regulatory cells in NIPERs will play a key role across the functionalities of process support, capacity building and infrastructure support

Recommendation 04: Strengthening of CDSCO

- The CDSCO needs to be strengthened and empowered both in terms of providing infrastructure support, capacity building etc. to address the growing challenges and demands of the Pharmaceutical industry.
- As on 2013-14, CDSCO has only 340 sanctioned posts including administrative personnel as compared to USFDA's 13,000 sanctioned posts of technical and administrative staff . Moreover, out of these 340 seats, only a few have been recruited so far. Henceforth, CDSCO needs to:
  - o Recruit manpower at various levels/designations
  - o Increase the number of sanctioned posts to manage the daily operations efficiently.
- The drug inspectors need to be recruited for effective control and monitoring of various units and outlets. One drug inspector per 50 manufacturing units and one drugs inspector per 200 sales/distribution outlets is required for effective implementation of functions assigned to state drug regulatory authorities. There are approximately 600,000 retail sales outlets and around 10,500 manufacturing units in the country, which require over 3,200 drugs inspectors. However, in reality, there were only 846 drug inspectors in place against 1,349 sanctioned posts in the states





2. FUNDING SUPPORT

A) EXPORT-IMPORT TRADE FACILITATION/ PROMOTION:

Recommendation 01: Joint funding of schemes for collaboration in pharmaceutical sector

- ❖ DoP may come up with a scheme for new drug development for diseases prevalent in countries importing Indian drugs.

Recommendation 02: Financial Assistance in form of soft loan/ interest subsidy

- ❖ DoP may launch a scheme for giving financial assistance which may be provided for upgradation of selected pharmaceutical manufacturing facilities including bio-pharmaceuticals to the Highly Regulated markets of:
  - US (US FDA)
  - Europe (European Directorate for the Quality of Medicines, EDQM)
  - Australia (Therapeutic Goods Administration TGA, Australia)
  - United Kingdom (Medicines and Healthcare Products Regulatory Agency , MHRA)
  - Other international markets to enable global generics and biosimilars capabilities

B) DOMESTIC

Recommendation 01: Increase funding support to early stage entrepreneurs in Pharma sector

- ❖ DoP may come up with a scheme to provide seed capital and facilitation with other financial institutes to the MSME sector

Recommendation 02: Financial Assistance in form of soft loan/ interest subsidy

- ❖ Financial assistance may be provided for upgradation to WHO-GMP and higher international standard requirements which are now increasingly required for making the SME's sustain in an increasingly competitive and demand driven manufacturing environment

Recommendation 03: Financial and technical assistance to improve financial sustainability of SMEs

- ❖ Cluster scheme may provide financial assistance to SME sector in PPP mode for creation of common facilities and also safeguard the environment from the hazards associated with the unplanned growth of the industry

Recommendation 04: Pharmaceutical Venture Capital Fund

- ❖ The growth of the Indian pharmaceutical industry over the past few decades has predominantly arisen from manufacturing generic drugs for exports and domestic use. DoP may come up with a pharmaceutical specific venture fund, for channelizing public resources into drug design, discovery and development

3. INFRASTRUCTURE SUPPORT

A) EXPORT-IMPORT TRADE FACILITATION/ PROMOTION:

Recommendation 01: Establish required cold chain facilities

- In order to enhance export capability for high end drugs requiring exact cold chain standards till the time they are exported from the country in light of stringent developed market requirements, there is a need to establish cold chain facilities

Recommendation 02: Provide common infrastructure

- National Biosimilar Center and Regional Biosimilar Centers to undertake consulting activity and consider providing common infrastructure to facilitate the growth of biosimilar industry

B) DOMESTIC

Recommendation 01: Establish Formulation Development Centers

- Formulation Development Centers may be set up which would assist the SME Pharmaceutical unit for development of new formulations from patent products (small and big molecules); with a view to tap/ explore the vast opportunities opening up due to off patenting of a number of molecules valued at about US$ 300 billion (traditional generics and bio-similars) in the next few years

Recommendation 02: Set-up a mega complex for production of identified drug intermediates and raw materials

- Provide one-time support to revive the production of identified drug intermediates

4. R&D SUPPORT

A) DOMESTIC

Recommendation 01: Formulate the national innovation strategy

- Identify and create a think tank to foster the spirit of innovation
- Roll out the strategy towards drug discovery and development process with specific targets defined for each stakeholder involved

Recommendation 02: Create and fund an organization to support and promote biopharmaceutical innovation, R&D and national and international academia-industry partnership

- Create a common platform to connect all dots pertaining to R&D and innovation

Recommendation 03: Create multiple Centers of Excellence (CoE)

- Create CoEs to promote industry – academia partnership for focused applied innovation

Recommendation 04: Academic institutes to undertake research related to technology transfer

- In collaboration with R&D units in the industry

Recommendation 05: Promote interactions of experts between academia and industry

- Government may provide flexibility in service conditions of academia to work in industry for short periods
- Industry representations in the academic institutions as faculties, academic councils, advisory boards etc.

Recommendation 06: DoP may coordinate with all government schemes supporting R&D in Pharma

- Availability of comprehensive information at a single point linking with relevant government schemes would help the domestic industry in getting timely access, clearances and development support.

Recommendation 07: MoH&FW may institute an appellate mechanism for domestic as well as global clinical trials at one level above the delegated authority

5. PROCESS SUPPORT

A) EXPORT-IMPORT TRADE FACILITATION/ PROMOTION:

Recommendation 01: Support for dossier preparation for SMEs in registration of their products in targeted countries

- Providing market opportunities and approval process of various countries through the facilitating body (Pharmexcil)

Recommendation 02: Make necessary changes in the documentation process (es)

- Government may streamline the process for grant of Certificate of Pharmaceutical Producer (CoPP) so that exports are not affected due to non renewal of CoPP on time. Currently, the CoPP is granted for 2 years and extended upto 3 years, beyond which the exporter cannot export till the renewal of certificate
- The application forms for CoPP, WHO-GMP etc. may be made bilingual (instead of being in vernacular language) and also may be allowed to be filed in English
- Provide better regulatory infrastructure and faster clearances at the ports for exporting pharmaceuticals products along with adequate cold chain facilities

Recommendation 03: Support for studies and reports of pharmerging countries on their pharmaceutical industry development and opportunities

- Identification and analysis of the healthcare market and the related pharmaceutical opportunities in pharmerging countries vis-à-vis capabilities and gaps of Indian pharmaceutical industry

Recommendation 04: Create special cells within the facilitating body for generic segment

- ‘Joint Partnership Programs’ may be promoted for development of generics for the developed markets such as US, EU and Japan
- Support for filing of generic drugs in the concerned markets in terms of dossier filing, clinical trials support and other support as required to gain access to the high value markets in US, EU and Japan

Recommendation 05: Promote mutually beneficial capital investment projects with the importing country (ies)

- Example: Joint testing and lab facilities for certification of Indian pharmaceutical products imported into BRICS, IBSA, CIS, EE, WA, Africa and ASEAN markets will help in appreciation of the dossier submitted by Indian companies and the quality standards followed by them

B) DOMESTIC

Recommendation 01: Simplification of the approval process for clinical trials

- Create simplified and streamlined process alongwith with well defined timelines for approvals of clinical trials. Currently, the industry is faced with a 3 tier structure for permitting clinical trial of a new drug with the chain of Expert Committee → Technical Committee → Apex Committee; having overlapping mandates

Recommendation 02: Rationalization of environmental clearances

- The process of environmental clearance may be rationalized and made time-bound e.g. a company already having Pollution Control Board clearance need not apply again in case of change in product mix as the total effluent discharge remains the same. In this connection it may be noted that the pharmaceutical industry is innovation driven and better processes or substitutes are employed to increase the competitiveness

Recommendation 03: Provide flexibility to the pharmaceutical companies to file for test licensing

- Companies may be granted flexibility to file its application from Central Office or the Zonal Office. Moreover, the infrastructure capacity at the Zonal Offices need to be strengthened to help companies applying for license and getting the treasury challan verified by the Inspector before filing

Recommendation 04: Digitalization of clinical trial, licensing and quality control processes

- The entire clinical trial, licensing and quality control processes etc. may be computerized and made online to speed up the process and increase transparency. In addition, the Ministry should also create a single window medicine monitoring IT system to link the headquarters, state offices and government hospitals to seamlessly communicate drug related information

Recommendation 05: Parallel processing of regulatory clearances for imported drugs

- The time taken for obtaining regulatory clearances for launch of a new imported drug may be reduced from current duration of 3 to 4 years; if the clearances like marketing approvals, site registration etc. can be processed in parallel, instead of sequential processing being done presently

6. PRICE CONTROL

A) DOMESTIC

Recommendation 01: Review the implementation of DPCO, 2013

- There is a need to review the implementation of DPCO, 2013 to resolve the genuine practical problems of implementation. Government may implement predictable & stable price control mechanisms through consultative approach with the industry

Recommendation 02: Rationalization of Inverted duty structure on APIs and exemption from excise duty for production of APIs

- The excise duty rate of API may be rationalized and made at par with Pharma goods i.e. excise duty on the inputs (API) may be reduced from current 10%. Alternatively, Government should introduce a refund mechanism to enable Pharma manufacturers to avail refund of excess cenvat credit especially in case of such an inverted duty structure

Recommendation 03: Revise the list of R&D equipments exempted from customs duty

- To be revised in consultation with NIPER

7. CAPACITY BUILDING

A) EXPORT-IMPORT TRADE FACILITATION/ PROMOTION:

Recommendation 01: Capacity building of regulators of the importing country (ies)

- Educating, training and laying down lean processes, benchmarks and frameworks for the regulators of the importing country(ies). This would help Indian regulators to augment a mutual interaction and improved communication/ relations with the importing countries

B) DOMESTIC

Recommendation 01: Skill development of personnel required for upgradation to WHO-GMP and higher International standards

- Workshop seminars/ short-term training courses may be beneficial for continuous training and development of industry personnel in order to address the short supply of skilled and trained personnel

Recommendation 02: Start scholarship programs for getting "industry-ready" skilled manpower

- Pharmacy Council of India may create a systematic partnership with Industry to support students of B Pharm/ M Pharma courses to undergo internships in the industry for 3-6 months

Recommendation 03: Promote Continuous Medical Education (CME) programs in Pharma sector

- Promoted by educational institutions like NIPER to upgrade the knowledge and skills of existing work force in pharma sector

APPENDIX

Appendix 1 | Terms of Reference (ToR) for the Task Forcefor e-Samiksha on Enabling the Private Sector to lead the growth of Pharmaceutical Sector

(i) Identifying the challenges before the Indian Pharmaceutical Industry pertaining to various government departments and agencies

(ii) Identifying ways to ensure better coordination among various Government Departments and Industry to facilitate the Industry

(iii) Identifying areas of duplication, if any, among different Government agencies and departments on issues relating to Pharmaceutical Industry including research

(iv) Suggesting suitable changes in the administrative arrangements or administrative mandate of Government agencies and Departments to enable better and coordinated facilitation and support to the industry

(v) Exploring the possibility of having a single window clearance type of facilitation for the industry for the required regulatory approvals

(vi) Working out the mechanism for a regular and institutionalized forum for Government Industry partnership where the industry issues can be redressed periodically and in a time bound manner

(vii) Exploring the possibility of linking the Indian Pharmaceutical Industry with various educational and research Institutions in the Government Sector like NIPERs, Research Institutes under Department of Health Research, Department of Bio Technology, Department of Science and Technology and others

Composition:		
1.	Secretary, D/o Pharmaceuticals (DoP), Government of India	Chairman
2.	Representative of D/o Health & Family Welfare, GoI (Not below the rank of Joint Secretary)	Member
3.	Drug Controller General of India (DCGI) or his representative	Member
4.	Representative of D/o Commerce, GoI (DoC) (Not below the rank of Joint Secretary)	Member
5.	Representative of D/o Industrial Policy and Promotion , GoI (Not below the rank of Joint Secretary)	Member
6.	Representative of D/o Bio-Technology, GoI (Not below the rank of Joint Secretary)	Member
7.	Representative of D/o Science and Technology, GoI (Not below the rank of Joint Secretary)	Member
8.	Representative of Planning Commission (Not below the rank of Joint Secretary)	Member
9.	Representatives of Indian Pharmaceuticals Alliance (IPA)	Member
10.	Representatives of Indian Drugs Manufacturers Association (IDMA)	Member
11.	Representative of Association of Indian Medical Devices Industry (AIMED)	Member
12.	Representative of Bulk Drugs Manufacturers Association (BDMA)	Member
13.	Representative of Federation of Pharma Entrepreneurs (FOPE)	Member

Appendix 2 | ToR for Sub group 1 on Procedural constraints and ways to address them for promotion of pharmaceutical industry

Terms of Reference of the Sub-group:

(i) Identifying the challenges before the Indian Pharmaceutical Industry pertaining to various Government Departments and agencies

(ii) Identifying ways to ensure better coordination among various Government Departments and Industry to facilitate the industry

(iii) Identifying areas of duplication, if any, among different Government agencies and Departments on issues relating to Pharmaceutical Industry including research

(iv) Suggesting suitable changes in the administrative arrangements or administrative mandate of Government agencies and Departments to enable better and coordinated facilitation and support to the industry

(v) Exploring the possibility of having a single window clearance type of facilitation for the industry for the required regulatory approvals

Composition:

The Sub- Group was chaired by Shri Sudhansh Pant, Joint Secretary, DoP. The Sub-group consisted of representatives from the following department/organization

(i) Ministry of Health & Family Welfare (MoHFW)

(ii) Drugs controller (DCGI)

(iii) Department of Commerce (DoC)

(iv) Indian Pharmaceutical Alliance (IPA)

(v) Indian Drug Manufacturers Association (IDMA)

(vi) Association of Indian Medical Devices Industry (AIMED)

(vii) Bulk Drug manufacturers Association (BDMA)

(viii) Federation of Pharma Entrepreneurs (FOPE)

(ix) Organization of Pharmaceutical Producers of India (OPPI)

(x) The Federation of Indian Chambers of Commerce and Industry (FICCI)

(xi) Confederation of Indian Industry (CII)

(xii) PHD Chamber of Commerce and Industry

(xiii) The Associated Chambers of Commerce of India (ASSOCHAM)

Appendix 3 | ToR for Sub group 2 on Industry Government Linkages

Terms of Reference of the Sub-group:

Working out the mechanism for a regular and institutionalized forum for Government-Industry partnership where the industry issues can be redressed periodically and in a time bound manner

Composition of the Sub-group:

The Sub-group was chaired by Shri Shailendra Singh, Joint Secretary, Department of Industrial Policy and Promotion. In consisted of representatives from the following Departments/Organizations:

(i) Ministry of Health & Family Welfare (MoHFW)
(ii) Department of Biotechnology (DBT)
(iii) Department of Science and Technology (DST)
(iv) Niti Aayog (formerly Planning Commission)
(v) Indian Pharmaceutical Alliance (IPA)
(vi) Indian Drug Manufacturers Association (IDMA)
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(x) Organization of Pharmaceutical Producers of India (OPPI)
(xi) The Federation of Indian Chambers of Commerce and Industry (FICCI)
(xii) Confederation of Indian Industry (CII)
(xiii) PHD Chamber of Commerce and Industry
(xiv) The Associated Chambers of Commerce of India (ASSOCHAM)

Co-opted members:

The following officers have been included as co-opted members:-

(i) Smt Chandni Raina, Director, DIPP
(ii) Sh Awadhesh Kumar Choudhary, Director, Deptt. Of Pharmaceuticals

Appendix 4 | ToR for Sub group 3 on Government Academia Linkages

Terms of Reference of the Sub-group:

Exploring the possibility of strengthening the linkages of the Indian Pharmaceutical Industry with various educational and research Institutes in the Government Sector like NIPERs, Research Institutes under Department of Health Research, Department of Bio-Technology, Department of Science and Technology and others, for R & D and other relevant matters

Composition:

The Sub- Group was chaired by Dr. Sanjay Mishra, Adviser, DST. The representatives from following Department/organization participated in the Sub-group:

(i) Department of Pharmaceuticals (DoP)
(ii) Department of Biotechnology (DBT)
(iii) DS (NIPER)
(iv) Indian Pharmaceutical Alliance (IPA)
(v) Indian Drug Manufacturers Association (IDMA)
(vi) Association of Indian Medical Devices Industry (AIMED)
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