Pharmaceuticals: Innovative Interventions Required

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<tr><th colspan="4">Intervention 1 : Focused scheme to improve scale of operations of domestic companies</th></tr>
<tr><th>S.No.</th><th>Tasks</th><th>Key Stakeholder</th><th>Innovation</th></tr>
<tr><td>1</td><td>Policy support from government in the following areas so as to increase scale of operations:

• Incentives to domestic firms who invest more than a threshold amount in fixed assets.
• Formulate direct as well as indirect subsidy schemes for players operating in pharmaceutical clusters. Direct subsidies can be in the form of cash incentives for the reimbursement of direct investment costs, incentives for labor and research and development (R&D) etc.; while indirect subsidies would be in the form of relief from land property taxes, income tax exemptions etc.
• Financial assistance to improve market access:
  • Assistance to domestic firms who wish to acquire international brands, equity holdings, controlling interests, intellectual properties etc.
  • Incentives for improved access to developed markets. Incentives need to be provided for: product dossier development expenses, regulatory filing costs and potential litigation costs.
  • Assistance to domestic firms for participating in international trade events so as to provide them access to export markets.
  • Scheme to introduce ‘Shared Marketing Services’ for the small companies. Facilitate marketing co-operation in destination countries, by having a common entity to market the products for its members at a small marketing fees while remitting the entire revenues to the respective exporting member companies. This will help the co-operative entity enjoy larger product portfolio, large capacity as a backbone, economies of scale in distribution and warehousing, etc. and minimise the overall investments in the marketing.</td><td>Department of Pharmaceuticals</td><td>Knowledge Creation and Commercialization</td></tr>
<tr><th colspan="4">Issues Targeted</th></tr>
<tr><td colspan="4">• Fragmented nature of the Indian pharmaceutical industry means that only few companies are large enough to bear the transactions costs associated with compliances attached with entry regulations of the developed markets.
• Important facets of pharmaceutical industry such as intellectual property creation, facility design and maintenance, global regulatory affairs, legal compliances, etc. are being conducted by limited players</td></tr>
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Intervention 2 : Improve raw-material competitiveness of the bulk drugs industry			
S.No.	**Tasks**	**Key Stakeholder**	**Innovation**
1	Policy support from government in the following areas so as to resolve raw-material issues faced by Indian bulk drugs industry: • Subsidized access to sugar should be provided to Pen-G manufacturing fermentation units so as to improve their cost structures. Providing subsidized sugar at INR 20/Kg for the industry will help reducing the costs by at-least 7-8%. • Reduction in excise and customs duty of chemicals and raw materials that are imported for biotech products is very important to reduce the manufacturing costs. • Reduction in import duty for intermediates/fine chemicals like urea, hydrazine hydrate etc. currently not available in India to solve short term raw-material issues for bulk drugs industry.	Ministry of Commerce, Department of Pharmaceuticals	Knowledge Creation and Commercialization
2	Focused scheme for encouraging domestic manufacturing of critical raw-materials and intermediates/inputs for bulk drugs. The scheme will supplement the objectives of the Cluster Innovation Centres to bridge the demand-supply gaps in multiple aspects of a business and drive need-based innovation in the industry clusters in a localized manner, by prioritizing the needs of the industry and enable agencies like the Government and others in directing their efforts for increased efficacy. Some of the steps that may be adopted are: • Designate an agency to identify prospective international partners who are pioneers in manufacturing of inputs like: non-agricultural urea, hydrazine hydrate etc. • Provide tax holidays for wholly-owned subsidiaries, JVs & overseas companies setting up production base in India. • Leverage access to domestic raw material sources to global majors willing to transfer technology to the Indian companies interested in setting up the manufacturing capacity. This can be done by – Reducing excise duty on these inputs in case of domestic production or by reducing customs duty in case of imports. – Financial incentives to companies supplying inputs/raw-materials to these units	Department of Chemicals & Petrochemicals, Department of Pharmaceuticals	Knowledge Creation and Commercialization

Issues Targeted
• Lack of availability of petrochemicals used for manufacturing of bulk drugs in India resulting in reliance on imports. • Rising prices of sugar leading to overall increase in production costs.

Intervention 3 : Foster technology up-gradation in the overall pharmaceuticals value chain			
S.No.	**Tasks**	**Key Stakeholder**	**Innovation**
1	Set up an implementing agency to enable Indian small scale units to adopt 2D barcoding which has been made a regulatory requirement for export of medicines by DGFT to prevent fake medicines and mis-representation of Indian exports in the name of other countries like China etc. The agency may increase awareness about the methodology as well as relevance of this technology. Further, financial subsidy needs to be provided to SSI for adoption of 2D barcoding technology	Ministry of Finance, Department of Pharmaceuticals	Knowledge Diffusion & Absorption
2	Set up a national implementing agency to undertake project of planning, implementing and monitoring the program for incorporating RFID in cold chain and logistics to improve the traceability in the pharmaceuticals supply chain. The scheme aims at providing access to knowledge for RFID technology development to modernize the pharmaceuticals supply chain. The implementing agency may focus on the following activities: • Launch a pilot project for enabling RFID adoption in pharmaceuticals supply chain logistics. • Designate one integrated cold chain with own logistics services to champion the technology. For the same, one time capital grant can be provided along with technology & implementation support. • Facilitate training programmes for knowledge transfer on the successful RFID installation • Provide incentives for cold chain and logistics providers to install & implement the technology.	Ministry of Science & Technology	Knowledge Diffusion & Absorption
3	Launch a scheme for supporting cold chain facilities for pharmaceuticals and refrigerated Vehicles. It will involve following activities • Capital grant (% of the project cost) may be provided for setting up cold chain facilities (More grant can be provided for set up in difficult areas) • Provide grant for acquisition of refrigerated vehicles for efficient transportation of pharmaceuticals products.	Ministry of Finance, Department of Pharmaceuticals	Knowledge Creation and Commercialization

	• Provide incentives for conversion of cold storage(s) services into storage cum distribution facilities with refrigerated fleet		
4	Focused scheme to support infrastructure creation for setting up green-field medical devices and equipment parks. These parks would focus on: Testing laboratory and common sterilization facility for medical devices; medical instruments/equipment calibration and validation facility; engineering Services like surface treatment, coating, electrical and mechanical maintenance etc.; training centre to train shop-floor, managers and entrepreneur's level skills for medical devices industry. Various activities involved for the same are: • Identify locations to set up green-field Medical Devices & Equipment Park so that maximum pharmaceutical clusters can be benefitted. • Provide state nodal agency for single window clearance and inter-departmental coordination. • Invite FDIs to set up JV's with domestic companies and encourage technology transfer to these domestic companies. • Easy access to port/air-port, Infrastructure development - land, power etc. (In case, cluster falls in inland areas, provide cash back scheme for expense incurred on shipment to the nearest port) • Set up Technical/Vocational training institutions in the cluster. • Set up Infrastructure for collaborative R&D and Testing, involving stakeholders from various players in the value chain.	Ministry of Finance, Department of Pharmaceuticals	Knowledge Creation and Commercialization
Issues Targeted			
• Inadequate medical devices and equipment industry. Critical equipment like analytical instruments is not indigenously available. • Lack of cold storage space & facilities suited to specific pharmaceutical products, with automated humidity & temperature control mechanisms			

References:

1. **American Academy of Pediatrics & GS1 Healthcare, US - Project on 2D barcoding**

GS1 is a neutral, not-for-profit organization dedicated to the design and implementation of global standards and solutions to improve the efficiency and visibility in supply chains. GS1 is driven by more than a million companies, who execute more than six billion transactions a day with the GS1 System of Standards. GS1 is truly global, with local Member Organizations in 111 countries, with the Global Office in Brussels, Belgium.

GS1 US is the Member Organization of GS1 that serves companies in the United States. As such, it is the national implementation organization of the GS1 System dedicated to the adoption and implementation of standards-based, global supply chain solutions in the United States. GS1 US currently serves over 200,000 U.S. member companies -- 16,000 of which are in healthcare.

The American Academy of Pediatrics (AAP) has chosen to work with GS1 to provide the standards around 2D barcoding because of GS1's experience and involvement in healthcare delivery systems. GS1 has developed standards that are followed throughout the world and recognized by many manufacturers. DataMatrix and GTIN are used as the delivery system for 2D barcoding on vaccines. The GS1 Data Matrix is one type of 2D barcoding. It uses the Global Trade Identification Number (GTIN) which integrates the NDC.

The specific standards referenced in this GSI guideline are listed below, and the relevant provisions of these standards/specifications are to be considered provisions of this guideline:

- GS1 General Specification – Available in the Solutions Center through the GS1 US website at www.gs1us.org/solutionscenter
- ISO/IEC 16022 Information Technology – International Symbology Specification – DataMatrix
- ISO/IEC 15416 Information technology – Automatic identification and data capture techniques – Barcode print quality test specification – Linear symbols
- ISO/IEC 15415 Information Technology – Automatic identification and data capture techniques – Barcode print quality test specification – 2D symbols
- ISO 1073-2 Alphanumeric character sets for optical recognition – Part 2: Character set OCR-B – Shapes and dimensions of the printed image
- AAP Clinician Guidance

Additional considerations and resources specified

- 2D barcodes require camera-based scanners. Traditional laser barcode scanners cannot read the 2D barcode. As a result, it is important for supply chain partners to communicate prior to implementing 2D barcodes to ensure that the appropriate scanners are in place.
- Prior to purchasing barcode scanning equipment, it is recommended that the purchaser consult the Simplified Guide for U.S. Healthcare Barcode Scanner Acquisition Criteria and the AAP Clinician Guidance.
- There are many reasons why a barcode may not scan. Many times it is not the barcode, but the scanner itself. For example, the lens could be dirty or the batteries discharged. GS1 US prepared another document entitled Procedure for Responding to Troublesome Barcodes to help resolve barcode scanning issues. This document offers a simplified process to rectify barcode scanning issues based on the experiences of healthcare users.

Intervention 4 : Foster R&D and encourage new drug development			
S.No.	**Tasks**	**Key Stakeholder**	**Innovation**
1	Launch a national level scheme to encourage both academia & industry to target efforts towards new drug development. The scheme focuses on creating an enabling environment for collaborative research between Industry and Universities/Public Funded Research Institution. The scheme may target to implement the following: • Provision for funding up-gradation of labs in the private and government sector with sharing basis on 50-50 pattern for the lab up-gradation for equipment deployed for drug development under specifically identifiable projects. • Incentive scheme to reward any breakthroughs in drug discovery by academia or industry. • Incubation centres for providing supportive framework for the researcher that enables him to turn a technological idea that has an economical-marketing potential into a product of interest for investors.	Ministry of Science & Technology, Department of Pharmaceuticals	Knowledge Creation and Commercialization
2	Set up a Pharmaceutical Nanotechnology Center to perform focused research on use of nano-materials for emerging industries like medical devices industry and for new innovative drug delivery systems, diagnostic, imaging and biosensor equipment, etc. The centre may perform following tasks: • Perform research work on development of nano-materials, new drug delivery systems based on nanotechnology etc. • Conduct knowledge transfer programs to appraise user industries about applications of nano-technology. • Conduct training programmes on the above mentioned technologies. • Implement incentive scheme for drugs manufacturers to commercialize the research work. • Collect royalties for any income accruing from the successful commercialization of an R&D program, receiving support from the agency.	Ministry of Science & Technology, Department of Pharmaceuticals	Knowledge Diffusion and Absorption
Issues Targeted			
• Low investments in innovative R&D continue to be a major weakness of Indian Pharmaceuticals industry. • Lack of ability to compete with MNCs for discovery of new drugs, research &commercialization of molecules on a worldwide basis. • Lack of proper regulatory framework for bio-similar drugs			

References:

1. **Promoting Pharmaceutical Medicine Training Programme :'PharmaTrain' - Ireland**

The main objective of the PharmaTrain project is to build and implement a new modular Master level programme for advanced studies in Pharmaceutical Medicine and Drug Development Sciences. The programme is based on the Bologna credit and title system and builds on the new PharmaTrain syllabus 2010 of the European Federation of Courses in Pharmaceutical Medicine (EFCPM).

The modular concept of the training programme also provides an opportunity to professionals to select courses for accredited Continuing Professional Development (CPD), as well as individualized training à la carte. The PharmaTrain consortium has identified 6 base courses and 13 master level programmes at European universities that will be standardized at the same quality level. PharmaTrain sets, maintains and constantly improves the standards and quality management of the training schemes and practices for pharmaceutical professionals

The programme will encourage exchanges between the industry, regulators and academia, produce and promote distance e-learning programmes, and will enable increased flexibility, transferability and mobility. A uniform high-level training in Europe will make the drug development process faster, more economical, and more tailored to patients' needs, and will give Europe a global advantage in developing new innovative medicines. PharmaTrain is a collaboration of 20 EFCPM university training programmes, 13 learned societies including 3 competent authorities, several partner training organizations and 15 pharmaceutical companies. One year after its start, May 1, 2009, PharmaTrain has gained full momentum and has met basically all milestone deliverables in the 'Prepare Phase' and now launches the next two years of the Learn/Execution Phase.

First year results include:

- Creation of new postgraduate training curricula with syllabus standardised modularisation and related learning outcomes providing increased mobility
- Unified examination principles
- Different mixes of blended e-learning for comparative testing during the programme
- Combined with a new concept of cooperative training among new EU member states as well as a pan-European accreditation system
- A continuing Professional Development (CPD) Platform and a comprehensive quality management process

Intervention 5 : Strengthen testing & certification infrastructure and encourage adoption of global standards by Indian pharmaceutical units			
S.No.	**Framework for Innovation**	**Key Stakeholder**	**Innovation**
1	Launch a scheme to set up Joint testing and lab facilities for certification of Indian pharmaceuticals products imported into various focus countries in BRIC, ASEAN, CIS, IBSA markets. This will enable Indian products to enable faster registration and later continued exports sustainability due to building of mutual trust in respect of quality of drugs imported as certified by the joint facilities. The scheme aims at creating common facilities that will be utilized by multiple industry stakeholders. The steps to be taken for the same are: • Develop MoUs for mutual partnership at Inter-governmental level. • Designate a SPV for implementation of joint testing labs.	Ministry of External Affairs, Department of Pharmaceuticals	Knowledge Diffusion and Absorption
2	Focused scheme for encouraging SME's to upgrade to WHO-GMP standards. The scheme aims to strengthen the manufacturing standards used by industry by providing access to knowledge for WHO-GMP standards. Various activities that may be performed for the same are: • Creation of document for necessary requirements for WHO-GMP manufacturing standards. • Arrange for training/awareness programmes in all the small & big pharmaceutical clusters targeting all the SSI. • Dissemination of information on WHO-GMP standards for enterprises setting up new units in the sector. • Tie-ups with financial institutions like SIDBI to provide soft loans for SSI units who are willing to upgrade to WHO-GMP standards.	Department of Pharmaceuticals	Knowledge Diffusion and Absorption
3	Launch a programme to make reference standard products available not only for IP but also for other countries where major exports are focused. For the same reason an implementing agency can be made which will perform following tasks: • Create a database of all the reference standards present in export focused countries for India. • Tie-ups with international labs to develop knowledge base on these standards. • Tie-ups with NIPER or other research institutes for development of reference standard products for various countries.	Department of Pharmaceuticals	Knowledge Diffusion and Absorption
Issues Targeted			

• Lack of availability of reference standard products as per Indian Pharmacopeia (IP). Thus while more than 1000 molecules are being manufactured or marketed in the country, IPC has reference standards for about 200 products only, resulting in dependence on imports for these batch specific and time limited reference products. • Lack of advanced lab and related infrastructure for drugs testing, especially in segments like antibiotics. • Lack of ability to compete with MNCs for discovery of new drugs, research & commercialization of molecules on a worldwide basis.

Intervention 6 : Training & awareness schemes targeted towards SMEs for ensuring compliance to testing & manufacturing standards			
S.No.	**Tasks**	**Key Stakeholder**	**Innovation**
1	Set up training centres for "International Manufacturing Standards" at major bulk drug clusters like: Hyderabad, Chennai, Ahmedabad, Mumbai and Kolkata. These training centres may involve trainers from industry as well as academia. Further, trainers from individual countries can also be invited to conduct sessions on country specific standards. The aim of these centres will be to provide access to knowledge required by small Indian firms to be competitive in quality conscious export markets.	Department of Pharmaceuticals, NSDC	Knowledge Diffusion and Absorption
2	Provide database support for SMEs in the following areas: • Technology- and innovation-related international journals from major publishers • Country wise SOPs for testing the products shall be explained in detail. This will include testing labs availability and tests conducted by them, fees for conducting the tests etc. • Industrial status of these countries also needs to be integrated. The software should be integrated with government schemes available as well for enabling SMEs to conform to these standards.	Department of Pharmaceuticals, Ministry of Science & Technology	Knowledge Diffusion and Absorption
Issues Targeted			
• Lack of awareness of global testing standard for drugs among Indian SMEs. • Lack of ability to compete with MNCs for discovery of new drugs, research & commercialization of molecules on a worldwide basis.			