## 12. Key Recommendations

Following paragraphs summarise the key recommendations made in earlier sections,

## I. Accelerating the Growth of Generic Pharmaceutical Industry

**1. Building Portfolio for Untapped Highly Attractive Opportunities**

Prioritised funding by institutions like EXIM Bank through Special Purpose Vehicles (SPVs) has to be pursued aggressively. Such SPVs shall contract product development work for excellent but high initial cost opportunities such as specialty generics, topicals, steroids, hormones, biopharmaceuticals, non infringing process based DMFs/formulations, ANDAs, etc. Obviously, such funding is not a loan stretching the balance sheets of companies nor an equity dilution in the current company. An agreed percentage of revenues from the SPV funded projects will go back to the funding bank towards the investment and Internal Rate of Return (IRR). Once the funding BANK recovers its investment and IRR, the ownership of the products will flow back to the company without complications. Public and private initiative on a mega scale in this area is essential for jumpstarting India's pharmaceutical industry into a higher orbit achieving quantum growth. (Short Term)

**2. Engineer Alliances to Protect Strategic Interests of the Country**

Alliance initiatives between domestic companies funded through a venture capital concept by Exim bank, etc., should be promoted. Prioritizing funds to promote internal M&A is necessary in creating large Indian companies to counter the increased bargaining power of consolidated buyers.

3. **Enhancing Pool of Trained Professionals**

The country has to facilitate Learning and Development vigorously through public initiatives in enlarging the pool of skilled population in the areas of:

- Law
- Regulatory affairs
- Knowledge of market environment at the global level
- Patent procedures & filing
- Non Infringing Processes -concepts & strategies

Government should facilitate L&D for pharmaceutical professionals to enhance the learning opportunity and available pool of talent. (Medium Term)

4. **Treat Investments in Quality on Par with R&D to Enhance Quality and Skilled Scientific Personnel**

Insisting on stringent cGMP (current GMP) and bioequivalent drugs for key drugs can turn the table in enhancing the skilled population. Only when organizations have a need for higher quality, employees in

such organizations will have incentive to learn, update and join the elite trained pool of scientific personnel. While it directly benefits in increasing the skilled population, it also benefits in assuring quality drugs to Indian population. This is also a progressive step in controlling spurious drugs. Considering investments for Quality Control equipment at par with R&D capital goods purchases is a crucial step in rejuvenating Indian quality environment. (Short Term)

5**. Reviving Indian Drug Intermediate Industry**

The energy and labour costs differential has virtually eroded. In the past intermediate industry migrated to China due to these reasons. India is emerging as a significant supplier of finished APIs and formulations to regulated markets and ROW. China can capture our market with the strength in intermediates if India does not pay attention to building intermediate industry. Every year, several new chemical entities loose patent protection and the corresponding opportunity for several intermediates and finished APIs emerge. Government should setup an expert panel to study the potential intermediates that can come back to Indian manufacturing arena. Genuine foreign site inspections, analysis of imported samples of every consignment, in-depth review of regulatory submissions will put Indian industry on par with imports at least in strategic intermediates. (Medium Term)

6. **Looking At Narcotics Formulations as an Important Opportunity and Not Just a Menace**

In view of the above, it is therefore necessary, to simplify the procedure and to capture the global narcotics business in certain classes of narcotics. The entire process of approvals from multiple agencies such as DCGI, INCB, Ministry of Finance, State Narcotics Boards, the quota systems and canalization should be relooked at for promoting export production. The genuine manufacturer exporters may be permitted to directly import narcotic substances based on risk profiling and past records doing away with GOAW & ministry of finance approvals.

The quota system should be done away for export production as it is difficult to assess import requirements one year ahead especially when the country desires to capture a bigger share.

Obtaining INCB permission for each consignment of the same material for same importer and by the same vendor for certain classes of narcotics is not present even in developed countries such as Europe where the regulation is very stringent and must be done away with.

Online submissions, approvals and clearances should be considered. (Short Term)

7. **Reviving Fermentation Capabilities of India**

As the cost disadvantage is disappearing between China and India in energy and labour, the country should relook at fermentation R&D, Lyophilised pharmaceuticals, etc., Soft funding for fermentation projects as a kick off to bring back select intermediate industry especially in biopharmaceuticals and certain recent fermentation based intermediates/ APIs may be considered. (Medium Term)

8. Attracting Talent to Chemistry, Biology and Law

An integrated postgraduate course in chemistry could be offered in NITs, IITs, NIPER, and leading universities at the 10+2 level. Most bright students prefer engineering streams. Pure science in local colleges has become an unattractive destination. While chemistry is fancied to some extent, biology has much less attraction. Integrated courses in biology could be introduced at leading institutes focusing on microbiology, biotechnology and pharmacy. The quality of education in some of the private institutions offering these courses requires in-depth examination.

Integrated courses in law and life sciences should be introduced in premier law schools and universities.

A legal frame-work should be developed for tapping and developing the student potential while employing them for project works. However, as industry is not willing to offer projects in view of confidentiality issues, the legal framework should provide for confidentiality agreements by students and professors of universities. The confidentiality agreement should carry particulars such as passport details, permanent address of the student, etc. to trace them in the event of violations of such confidentiality agreements. Further, government should also make it mandatory for University Professors to produce a minimum number of projects/research works each year. Patentable research should drive these Institutions and universities. Increments and promotions may be linked to the research output and industrially commercialisable projects undertaken by their students/ departments. Grants etc. could be linked to the requirements of projects in terms of equipments/ space rather than mere capacity expansion etc. (Medium Term)

**9. Thrust in developing Economies**

Neglecting less developed markets may prove unwise in medium term. We should develop customised promotional programmes for markets in Africa, CIS, South East Asia and Latin America more vigorously. Non tariff barriers are constantly mounting in various parts of world. Although these markets are less regulated, the regulatory requirements and aspirations are escalating. Many current exporters in various countries with compromised infrastructures will find uneconomical to reinvest in businesses paving way for growth of Indian Pharmaceutical industry with high quality investments in manufacturing.

One key barrier is cost of product registration and consequent follow up for our highly fragmented industry. We have to go out of box and facilitate a shared structure to provide skilled registration services for our fragmented industry to capture the skill set, minimise costs through economies of scale. This will provide a breather to SMEs who have already invested heavily in manufacturing and finding it difficult to economically register and reach various markets. Learning the skill set and regulatory compliance issues for each and every country across world are prohibitively expensive for a SME. However such a draw back can be easily overcome with a public initiative in providing such service. The skill set achieved can be available for multiple organisations. Further procuring RLDs (Reference Listed Drugs) or Innovator samples across world is a very expensive and time consuming process for a SME. A shared service set up can overcome this barrier**.** (Medium Term)

**10. Shared Marketing Services**

Where feasible, Pharmexcil can facilitate marketing co-operation in destination countries, wherein a common entity can 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**.** (Medium Term)

**11. Identifying Strategies to Participate In Regional Clusters**

In each regional cluster in the global pharmaceutical trade there exists a country in each cluster which supports all the neighbouring countries. Currently India competes with these regional champions in exports to the countries in the cluster. Over a period of time as regional champions emerge our exports could dry up. Pharmexcil should organise a study with the objective of finding practical strategies in utilizing these regional strengths for the furthering of our exports**.** (Short Term)

12**. Anti-diversion Mechanism in case of exports against compulsory licensing**

Indian companies should be careful to have anti-diversion mechanisms in place i.e. mechanisms to ensure that the medicines are consumed in the market for which they have been manufactured (the market which has declared the national emergency) and are not re-exported, as this would tarnish their reputation irretrievably. Pharmexcil should initiate a system with exporters wherein it creates awareness and promotes compliance. (Short Term)

## II. Enhancing India's R&D

**13. Treatment of R&D Expenditure for Tax Purposes**

Outsourcing done by approved R&D, for example bio-equivalence studies which are integral part of R&D should be considered for weighted deduction. (Short Term)

**14. Permitting Commercial R&D Subsidiaries for Tax Exemption**

Commercial R&D firms promoted by established firms as subsidiaries should be allowed for the purpose of tax holidays in pharmaceutical industry. (Short Term).

**15. Focusing on Immediately Commercialisable technologies By Government Institutions**

One or two Indian scientific institutions should work along with domestic firms to identify target products which can benefit from these new technologies and take up projects. A small percentage of costs should be shared by industry firms and the technology may be licensed by them with out bottlenecks. (Medium Term)

**16. Banks should provide certain capital for taking up commercialisable R&D**

R&D being revenue expenditure, certain new technologies are taking a back seat in corporates that are already struggling for profits. Competing countries are investing in new technologies like biocatalysts, etc. forging ahead of India. Banks should develop SPV concepts to fund these technologies. (Medium Term)

**17. Encouraging Public Private Initiatives in R&D**

Major impetus to R & D should be given through the creation of synergy between the industry and academia where the 'cluster' model of the United States could be adopted. This may be accomplished through policy initiatives which stimulate research partnerships between pharmaceutical industry and academic institutions / publicly funded R&D organisations. Encourage the mobility between personnel from R & D institutions and the private sector. (Long Term)

**18. Intense scrutiny of patentability of research is needed for grant of funds.**

Pharmaceutical Research and Development Support Fund may have to be increased in size and clearer policies governing its application could be helpful. Encouraging tripartite partnerships between corporates, lending banks and the R&D fund may bring in investment in desired direction and its better utilization.

Revenue generating and patentable research should be the focus in research. Ensuring some participation of private sector in each project helps in adherence to time schedules and weeds away unattractive projects. The current global recession is releasing several scientific personnel in western world. Proactive steps in bringing experts to India to lead our projects or help us as consultants can bridge the vast gap in drug discovery value chain. Procedural issues in Visas etc can be resolved for specialists building our national projects. (Long Term)

**19. R&D Incubators to Promote Entrepreneurship and New Ventures**

BOT (Build operate Transfer) model in the lines of public private partnership could be considered to create a conglomerate to have 20 to 25 workstation in each incubation cell in each incubator. Such incubators in all major science cities such as Hyderabad, Bangalore, Pune, Chennai, Chandigarh, etc. under the aegis of NIPER may be promoted. Common storage, air handling, water, effluent management, analytical support is part of infrastructure. Depending on the location a capital out lay of Rs.5- 10 Cr may be required to revolutionize this concept. (Medium Term)

**20. Enhancing Availability of Clinical Investigators/Researchers**

India should attract Indian scientists to set-up service centres in India and provide Venture Capital funds on some prioritization basis. Efforts should be made to coordinate with medical colleges and pharmacy colleges to enhance focus and seats in clinical pharmacology. A study may be initiated for examining the

opportunity to set up a discipline for clinical research or a special training to become clinical investigators. **(**Medium Term)

**21. Enhancing Capacity for Clinical Trials, Animal Toxicity/BE centres**

Standardised project reports on building service centers should be developed and current medical institutions and hospitals should be motivated to evaluate setting up of such infrastructure. (Medium Term)

Clinical trials, bioequivalence studies, various toxicity study centers contributing in drug discovery work could be unambiguously termed as R&D investment eligible for tax holidays and weighted deduction.

Drug discovery firms cannot do all work in house and they need to outsource some of work like testing, etc., to third parties. Such outsourcing portion by a government approved R&D facility should be considered for weighted deduction. In the absence of this, each firm has a miniature service center for its own purpose and the sector can not develop and skills required can not be institutionalized.

**22. Government Body Should Facilitate Learning and Legislation with Respect to IRBs**

A course familiarizing Institutional Review Boards (IRBs) could be designed and the information should be communicated to eminent eligible people retiring from various service sectors. By attracting them to understand the opportunity and familiarizing them with the subject, the country can enhance pool of available experts to help these boards. (Short Term)

23**. Service Tax Exemptions for Pharmaceutical R&D**

R&D services may be exempted from service tax for national priority sectors. Providing drugs for Indian citizens is a big priority for nation and this sector could be waived from the net. (Short Term**)**

24**. VC Funding for CROs to Promote Value Chain in Drug Discovery**

Prioritised Venture Capital based funding should be provided to set up large contract research organizations. (Medium Term)

## III. Promoting Contract Manufacturing, Drug Discovery & Clinical Trials

25**. Investing in Key Links to Accelerate Outsourcing Business**

Government should promote capacity building in testing laboratories for stability studies, bioequivalence studies and third party analytical laboratories urgently through policy action, appropriate incentives and venture capital. Such facilities can be made available to SMEs at subsidised rates to reduce entry barriers and encourage competition from start-ups in drug discovery and other key growth segments. (Medium Term)

26**. Promoting SEZs to Accelerate Contract Manufacturing**

SEZs should be promoted consciously in the area of formulations and APIs to ensure that Indian industry compares at par with international locations. (Short Term)

27**. Exemption from Export Duties to SEZ Units**

Export duties applicable to exports should not be charged to SEZ purchases. (Medium Term)

**28. Formulating Practical Norms for Pharmaceutical SEZs**

Domestic sales up to a fixed percentage of capacity installed should be allowed for export oriented pharmaceutical units.

First year of profits should be considered for beginning the tax holiday period**.** (Short Term)

29. **Resolving Hurdles in Contract Manufacturing**

The Government should look at developing a practical and operable system, which should be adopted by contract manufacturers where in the goods come for processing without paying any duty and go back with out any duties except for the processing costs or value addition. The system should have compliance of Drugs and Cosmetics Act as such manufacturing requires lot of documentation meeting the regulatory requirements of various destination countries. Typically, the inputs come from a country and the output will have to go to several countries. Even in standard contract manufacturing, there are issues of free sale certificates, etc. hence there is a requirement for an interdepartmental meet to appreciate the issues involved and develop appropriate departmental notifications. (Short Term)

30. **Pharmexcil's Role in education on Intricate Issues in International Contracts**

In the interest of manufacturers, Pharmexcil should develop standardized agreements and caution on various clauses and their implications to the firm in the long term. A one time effort employing international experts will raise the standards of understanding in this regard. (Short Term)

31**. Intricacies in Negotiation of Contract Manufacturing**

Pharmexcil should organize learning module on contract manufacturing negotiations and help small and medium scale entrepreneurs appreciate the issues of short term and long term. There exists a case to evaluate whether company law provisions have to be amended to bring in exclusive licensing of substantial capacity on par with hiving-off substantial assets. (Short Term)

32. **Incentives to CRO**

The incentives mentioned in the draft National Pharmaceuticals Policy of 2006 such as exemption of service tax for direct investment in the field of clinical development and data management, exemption from import duty, improved regulatory infrastructure and some form of protection for undisclosed test data, etc., ought to be acted upon. (Short Term)

**33. Simplifying approval procedures for Clinical Trials Export/Import Materials**

Established/accredited CROs should be permitted to take one time clearance for import/export of clinical trial materials if the parties to the contract are the same avoiding repeated clearances from various agencies. Based on risk profiling approval from single agency should be considered as time element is most crucial in obtaining and executing of contracts.

Companies engaged in stability testing will have to test large number of samples and import duty on these consignments will severly impact the business. Analytical testing like stability testing etc are good opportunities despite our handicap of distance and transportation. Government should draft necessary legislation keeping the new dimensions and opportunities in the pharmaceutical business. Extensive decentralisation and online approvals are essential. Self approval facility should be given for established corporates based on some risk profiling and audits**.** (Short Term)

34**. Decentralisation of Approval System**

There is a need to promptly decentralize the approval system (e.g., State DCI approval) of T licenses for already approved drugs in India. Automatic approval may be given for new drugs for "invitro testing work'' or if the testing is not in humans (e.g., State DCI). The process of importation of blood samples for analysis has to be simplified. Risk profiling should be done and reputed clients and reputed service centers in India may be given exemptions with obligation to submit annual reports.

Such certificates should be available on line for substantial exporters or a drug control office employee empowered to sign such documents should be posted at corporates with huge requirement of procedural documents. (Short Term)

## IV. Indian System of Medicines & AYUSH

**35. Promoting AYUSH Education**

Greater attention is required to AYUSH education as well as infrastructure in institutions imparting AYUSH education.

A possible way of facilitating exports could be to create a single window for clearances for companies wishing to export ASU products.

There is great potential for AYUSH to flourish regionally i.e., in South Asia where there is an existing culture of AYUSH, as well as South East Asia which also has had traditional medicines of various kinds historically. A great deal, however, depends on private initiative and business methods to create awareness and start marketing in these regions. Negotiations should open up regional cooperation in the

services sector with South Asian countries to allow AYUSH doctors practice across the countries in the region**.** (Medium Term)

36**. Extension of Concessions to AYUSH Products on par with Pharmaceutical Products**

The Foreign Trade Policy allows some concessions for pharmaceutical products but makes no mention of AYUSH products as a distinct category. Remedying this could have a beneficial effect on the industry, which requires assistance for large scale technical up gradation. Fiscal benefits granted to the industry for such up gradation, could also act as incentives to the industry. (Short Term)

37. Focus Product Scheme - Top 25 plants, their products and extracts; and Top 50 Ayurvedic formulations, should be identified for special thrust

37.1. Funds must be provided for compiling internationally acceptable Drug Master Files for these products and there must be a concerted push between various Ministries to ensure that these products are allowed market access in all countries.

37.2. The Vishesh Krishi Upaj Yojana (VKUY) should also include extracts as well as compounds isolated from the herbs so identified under the Focus product scheme.

37.3. These focus products should have a published information on minimum purchase price and minimum quantity for a minimum period of time to encourage reliable cultivation. Produce from both wild sources and cultivated land should be encouraged independently.

37.4. To achieve desired purity level at various micro units spread across the country may not be economically feasible. Hence these have to be bought at a gross level and routed to select central units for purification to bring them to the required quality standards. Processing zones, near important cultivation areas should be developed where the whole process of adding value to the raw medicinal plants takes place.

37.5. Ethanol availability to recognized Ayush industries producing these products should be on a fast track and assured basis.

37.6. These formulations should be given complete tax concession with respect to excise duty/ vat etc. when priced at a predetermined threshold cost of therapy per day at therapeutic doses and having therapeutic claims.

37.7. Identify & promote Agri Export Zones (AEZs) for these plants.

37.8. Encourage clinical trial work to establish efficacy/safety and process standardisation of various formulations. Government should conceptualise a project and approach established pharmaceutical companies or established R&D labs, to conduct necessary research for select Ayurvedic preparations especially analytical research.

37.9. Provide a meaningful financial assistance (for example Rs. 50 laks) as a grant if the product satisfies certain parameters such as:

37.1.1. Complies with guidelines on heavy metal/pesticide/mycotoxin/microbial residues

37.1.2. Efficacy is proven by 2 double blind controlled trials

37.1.3. Analytical/chromatographic methods have been developed which facilitate both qualitative and quantitative estimation of ingredients

37.1.4. Is from sustainably usable plant parts for at least 70% of ingredients.

37.1.5. At least 2 publications in reputed journals of pharmaceuticals on the product. (Medium Term)

38. **Creating National Resources in Herbals**

38.1. Schedule 1 of Drug & Cosmetics act lists 57 official Ayurvedic books. Many are out of print and these should be made available and digitized. List of Ayurvedic herbs of India as mentioned in these books should also be made available.

38.2. Compile a comprehensive national database on the available scientific information about safety efficacy phytochemistry and clinical data on each Indian medicinal plant. Create a national library of primary phytochemical reference standards and cost effective testing of herbal products.

38.3. Government should initiate specific research programs through state agricultural universities aimed at searching, identifying elite species/ varieties/ chemotypes of those medicinal plants whose quality assessment criteria have been standardized. Herbal extract/product manufacturers having access to high quality raw material (elite varieties) become very critical for maintaining economic viability/competitiveness in both domestic and international markets. Elite varieties have been identified for some spices but for medicinal plants this work has not been done yet.

38.4. Establish a national germplasm & seed bank for medicinal plants. Aggressively develop the seed material and make it available for cultivation. Provide subsidies for the cultivation of red listed plants.

38.5. India specific Good Agricultural Practices (GAPs), Good Harvesting Practices (GHPs) could be prepared by National Medicinal Plant Board (NMPB)

38.6. In-vitro pharmacology and analytical phyto-chemistry laboratories are very few in India and are crucial for standardization of natural products. A national long term project can give contracts to various laboratories to facilitate the standardization of natural products. As the labs are very few, the ministry should work with some development bank such as EXIM bank to promote such laboratories in key areas backed up by long term work, which is a national priority.

38.7. There exists a need to create competence in the core areas of molecular pharmacology by updating the academic curriculum and upgrading the learning systems. Training on assay systems development, etc., has to be taken up by CSIR laboratories. Several assays that provide higher content information about the drug substance are becoming increasingly unaffordable as several IPR issues are involved. The subject being important, the country needs to achieve some self reliance and hence the national herbal mission should undertake this task.

38.8. In key states, Ayurvedic/medicinal plant herbarium should be set up to collect, maintain and supply upon request authentic specimens of medicinal plants/ parts in a systematic manner.

38.9. Various government bodies are conducting scores of studies on herbal drugs. The current requirements of international bodies do not accept dated study protocols and demand high standards. Urgent audit is required on all these studies and pursue only such projects which are designed to meet international standards.

38.10. NIPER or a national laboratory should undertake special training programmes to SMEs on phytochemical isolation, molecular pharmacology, analytical testing, etc.

38.11. Pharmexcil or some government body should take urgent initiative in training all such clinical investigators and scientists on the design of clinical trials that are acceptable by international regulatory agencies. The current skill set available in modern medicine should be rapidly used in our traditional systems. (Medium Term)

39. **Regulatory Issues**

39.1. A convenient system to register Indian medicinal plants such as Ayurvedic herbs is required. While about 8,000 plant species are said to be medicinal, the medicinal uses of about 1,800 plant species are described in Ayurved. Many are described in folklore and some are in use. However, such plants which are not officially Ayurvedic/Siddha/ or Unani can not obtain manufacturing license as there is no procedure to add new plants/folklore plants.

39.2. Many of the significant Indian plants do not find place in the list of importable herbs in many countries. For example TGA Australia does not recognize any of the Indian pharmacopoeias while it recognizes Pharmacopoeia of the PRC of China. US FDA/ MHRA of UK, MCC of South Africa, TGA of Australia etc., have their own list of positive drugs which are safe and effective for permitting imports. We do not have such an official list that clearly states the important Indian medicinal plants that are safe and effective with reliable documentation. An urgent need, therefore, exists to compile the required data to enlist a herb in importable lists in various countries and initiate the registration of these herbs.

39.3. A concerted effort by the government is needed and the success has to be monitored. Where applicable they may be classified as dietary supplements and in select cases as drugs.

39.4. Indian Traditional medicine should be negotiated for exclusion from all sensitives lists under various bilateral and regional preferential trade agreements entered into by India.

39.5. Pharmexcil should provide a national registration cell which can provide information about the prevailing global rules and regulations governing natural products.

39.6. A periodic quality audit for AYUSH products exported from India should be undertaken to assure quality of the products. (Medium Term)

39.7. An export certification system for Ayush products in respect to heavy metals, pesticide residues, alfatoxins and other toxic materials should be put in place. To begin with this could be based on a self certification approach.

40. **Excise and forestry Issues**

40.1. 'The intention of use' of a particular substance should govern the classification of a substance as a drug/health food/food. For example ginger can be a food and in some doses becomes an Ayurvedic drug and in another dose and form becomes a beverage. This has to be clarified with excise department as one of the steps to promote herbal sector.

40.2. All herbal raw materials are treated alike at forest check points. There exists a case to treat all cultivated herbal raw material and herbs collected from waste lands with a different perspective. Restrictions should be eased where the collection is from sustainable parts like leaves, flowers, seeds, fruits etc., simplification of transit permit/legal procurement certificate for transportation of raw drugs is essential.

40.3. Forest departments should create a list of plants/ trees where the collection is from sustainable parts, and should encourage herbal collectors to undergo proper training. Such training can help improve the overall quality of herbal raw material and reducing wastage. (Medium Term)

41. **International Opportunity**

The herbal products in demand in various countries have to be researched and suitability & availability of Indian herbals for export production should be assessed. Trends in exports of herbal medicines, classes of herbal products, etc. should be analysed to re-orient Indian production to the requirements of International demand. Similarly, formulations popular in various countries should also be identified for manufacture and export of the same. The exercise would open gates for several opportunities for India in Herbal exports. The exercise requires dedicated and extensive research by various stake holders. (Medium Term)

## V Non-Tariff Barriers & International Co-operation

42. **Automatic Approvals for Indian Facilities Recognised by Countries with Mutual Recognition Agreements**

For products manufactured in USA and Australia there is a mutual acceptance. However, the same US FDA approved product in India will still need a plant inspection by Australian authorities. As Australia accepts US facility with out any inspection the same should be extended to US approved facility in India in a auto mode. We may negotiate for such mutual agreements. Further, we should take up a bilateral discussion to accept Indian facilities approved by US or EU or TGA or HPB Canada or MCA South Africa without further inspections by various countries in the ROW. For example, even Nigeria, Ghana, etc.; want to inspect our facilities although our facilities are already approved by US or EU, etc. There is a justification to inspect if such facilities are not approved by any eminent countries. (Medium Term)

43. **Legislation for Import Permissions should be strengthened**

Indian regulation for drugs & pharmaceutical products for imports is very simple in comparison with many major pharmaceutical markets. There is a case for reviewing the same and to bring it in line with international standards for imports. (Short Term)

44. **Negotiating NTB of Local BE Studies**

India should immediately negotiate with countries such as Japan, Thailand, Mexico to accept Indian bioequivalence studies conducted in BE centres accepted by US FDA, etc. Concerned countries can inspect the bioequivalence centers. If required, we should engage international experts on bioequivalence to make a case for our negotiations. (Short Term)

**45. Realigning Registration Fees for Formulations APIs and Intermediates on par with other countries**

India may realign its drug registration fees in line with other countries and use those funds to beef up its foreign inspection systems, introduce stringent dossier review systems, etc.

As a bilateral point, study the feasibility of a reduced fee for registration of products on a mutual concession basis**.** (Medium Term)

46. **Negotiating for Waiver of Mandatory Local Presence**

While negotiating with countries, India should get a concession to avoid requirements of local presence such as local manufacturer/subsidiary/company for entering the market. A local resident may be appointed as FDA agent to safeguard their concerns. (Medium Term)

47. **Participation in US Government Business**

India should examine the ways whereby agreements that enable Indian manufacturers to supply/bid pharmaceuticals to Government contracts such as Veterans' Administration (VA) procurement, etc. could be negotiated. Such opportunity runs into billions of dollars. (Medium Term)

**48. Negotiating for Resolution of Conflicting Definitions of Counterfeit Drugs**

India should make all efforts to ensure that subterfuges to define 'counterfiet drugs' which will adversely affect Indian interests do not succeed.

India may also extend its co-operation in the fight against counterfeit drugs as this would improve the standards of local drugs as also enhance the image of the country**.** (Medium Term)

A programme to launch specific country based campaigns through our missions should be immediately undertaken with a view to spread awareness about Indian capacities among stakeholder groups and

particularly educate regulatory authorities in these countries about Indian pharmaceutical industry. Special visits of drug regulators from these countries to Indian industrial establishments and regulatory authorities should be organised on priority. (Short term)

49. **Centralised Regulatory Support for Export Promotion**

It is very expensive to undertake drug registration at firm level and the knowledge and skills are generally not available in many firms. There is a compelling case to set up a strong regulatory affairs support cell in Pharmexcil which registers drugs for various firms on a consulting basis in various countries. Such a cooperative effort will help institutionalization of knowledge and hasten the export registration in several countries. A central knowledge base with respect to regulatory matters in each and every country that not only keeps track of all regulations but actually undertakes registration work for Indian firms can be a substantial milestone in the evolution of pharmaceutical industry. Further, this is only way SMEs can afford to penetrate foreign countries faster. Similarly, these countries should be sensitized to accept valid GMP inspection certificates issued by other countries. (Short Term)

## VI. Aligning Internal Regulation for surge in Exports

50**. Allowing for Price Rises to Plough Back Investments into Quality**

India should look at the possibility of allowing companies to charge additional prices to fund their quality investments and research for DPCO products while fixing the overall marketing expenditure and trade discounts as percentage of sales for all existing products. Absence of such mechanism may lead to intense consolidation of drug trade which will cripple the manufacturers and finally end up with out investments in most essential activities required for future. The government can consider a policy of equating investments in quality assurance equipment and related personnel with R&D for the purpose of tax benefits. Such a mechanism will help avoidance of low investments in quality and help industry to reach global standards. (Short Term)

51**. Ensuring Reliable Product Quality**

Bioequivalence and demanding relevant data to prove bioequivalence for any changes in process or change of machineries or change of production sites can guarantee the drug quality. These two measures in addition to strict cGMP inspections will assure the drug quality and safety and are expected to dissuade producers with low commitment to quality. (Medium Term)

**52. Redefining Minimum Investments for Reliable Quality**

Prescribing certain minimum investments in quality and manufacturing keeping in mind the current global regulatory standards will ensure that only quality players would be encouraged. Over a period of time, for certain prescribed products, bioequivalence should be made mandatory whether a product is approved by state or central authorities.

Over a period of time change controls should be rigorously prescribed like SUPAC guidelines of USA which will assure drug quality and safety and avoid unexpected production of spurious drugs**.** (Medium Term)

53**. Campaigning Against Spurious Drugs**

States should constitute legal-cum-intelligence cells for carrying on campaign against spurious drugs. There should be separate legal Departments with State Licensing Authorities (SLAs) as well as Central Licensing Authorities to take care of the issue of spurious drugs. There is a requirement for regular inspections so that quality is maintained. However, as there is a lack of infrastructure states should be funded to take care of this aspect of creation of infrastructure by way of recruiting qualified inspectors and also to set up quality testing laboratories with advanced equipment. There is also a need to train staff i.e., regulatory personnel with advanced techniques both at Center and the state level. (Medium Term)

54**. Foreign Site Inspections & Stringent GMP Audits to Ensure Quality Imports**

Foreign inspections to approve every site/unit/block that exports to India like any international regulatory agency should be made mandatory. In addition regular audits to ensure genuineness of compliance should take place. Also parity in fees charged for drug approvals in India for foreign drugs in with fees charged for approval of Indian drugs in those countries should be brought. (Short Term)

55. **Continuous Training and Up gradation of Officers**

A procedure for training and 'accreditation' on continuous basis should be evolved for officers involved in drug regulatory matters and such officers lacking accreditation may be moved to non regulatory matters. (Medium Term)

56**. Expeditious Process by ADC at Customs & Ports**

The approvals given by state DCIs and central DCGI should be made online for quick verifications by ADCs at customs & ports. In the context of aggressive sourcing of business from global markets, India will have to undertake production of several products and combinations for export purpose which has to be approved by central DCGI and some times by state DCIs as the law requires. Online availability of all approvals of state and central drug controllers should be enabled at customs or ports to enhance efficiencies at customs/ports. (Short Term)

57**. Electronic Submissions & Approvals**

Online submissions, approvals, clearances should be permitted at least for status holder export organizations with time bound mechanisms to create a very business friendly climate. (Short Term)

58**. Equate investments in Quality with R&D to Rejuvenate Indian Manufacturing**

Investments in quality should be eligible for weighted tax deduction like R&D. This is necessary to motivate industry for higher compliance standards assuring high drug safety and higher quality standards. (Short Term)

**59. Creation of Special Wing for Foreign Site Inspections & Audits**

Foreign site inspections and Export quality control should be assigned to a special wing. Ensuring that every import comes from high quality sources and as per documentation helps in a big way as many small scale formulators do not have highly sophisticated instrumentation to fully verify import claims and end up in producing spurious drugs. Further such a wing should collect control samples at regular intervals from exporters and analyse for compliance. Outsourcing of such work to highly sophisticated labs with strict timelines for analysis and results will motivate drug inspectors to do result oriented work. In case of process deviations, the quality mechanisms could be addressed at the company. This will help control production of spurious drugs, if any.

Proposed amendments to the Drugs and Cosmetics Act which will introduce severe penalties against offences relating to production and trade of spurious medicines should be carried out**.** (Short Term)

60**. Creation of Clear Regulation for Bio-Similar Products**

India is becoming a major player in manufacture of bio-similar products for marketing in the EU, Canada and elsewhere. At present bio-similar products are being treated as new drugs on an ad-hoc basis since there are no regulations on bio-similars. Therefore, science based specific regulations should be developed for approval of bio-similar products by Ministry of Health and Drug Controller General of India. (Short Term)