World Health Organization
COUNTRY OFFICE FOR India

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

FICCI



Position Paper

Enhancing India's Global Role in Supply of Generic Medicines

"Focus on Strengthening Domestic Landscape of APIs, Regulation of Drug Trials and Fostering Innovation"

India Pharma Summit 2013-14

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Overview of the Indian Pharmaceutical Sector

Overview of the Indian Pharmaceutical Sector

The Indian Pharmaceutical industry has been witnessing phenomenal growth in recent years, and is estimated to be approx. US$ 26 billion industry. India exports around US$13 billion of pharmaceutical products, including vaccines, to most countries in the world. Pharmaceutical market in India is ranked third globally in terms of volume and thirteenth in terms of value, accounting for about 10 percent of the world's production by volume. The pharmaceutical industry in India is estimated to be growing at an annual rate of 14%. The industry has seen tremendous progress in terms of infrastructure development, technology base and the wide range of products manufactured. India possesses about 360 US FDA approved manufacturing units and over 150 EDQM approved drug manufacturing units in the country. India is emerging as a world leader in generic pharmaceuticals production, supplying 20% of the global market for generic medicines. India accounts for 8% of global production, and is exporting to over 200 countries.

Indian pharmaceutical industry has been playing a pivotal role in supply of affordable and quality vaccines to the developed and developing countries. India is a major vaccine producer that has 12 major vaccine manufacturing facilities. These vaccines are used for the national and international market (150 countries) which makes India a major vaccine supplier across the globe.

According to the latest data, the cumulative drugs and pharmaceuticals sector has attracted USD 11,304.91 million worth foreign direct investments (FDI) during the period 2000 to 2013. Our industry would continue to experience strong growth as structural growth drivers continue to remain impervious. The Indian Pharma sector exports target has been set to US$ 25 billion by 2016. Generics will continue to dominate the market while patent-protected products are likely to constitute 10 per cent of the pie till 2015. Global demand for generic drugs from Indian companies is booming as developed nations battle rising healthcare costs. As a result, generics companies are increasingly focusing on expanding presence in relatively under-penetrated markets (i.e. France, Spain & Italy), branded generic markets of East Europe and niche areas like complex generics, OTCs etc.About 40% of the generic and over-the-counter drugs sold in the U.S. are from India.



CAGR: Compounded annual growth rate E: Estimated; P: Projected
Source: CRISIL Research, Directorate General of Foreign Trade



Domestic Landscape of Active Pharmaceutical Ingredients (API)

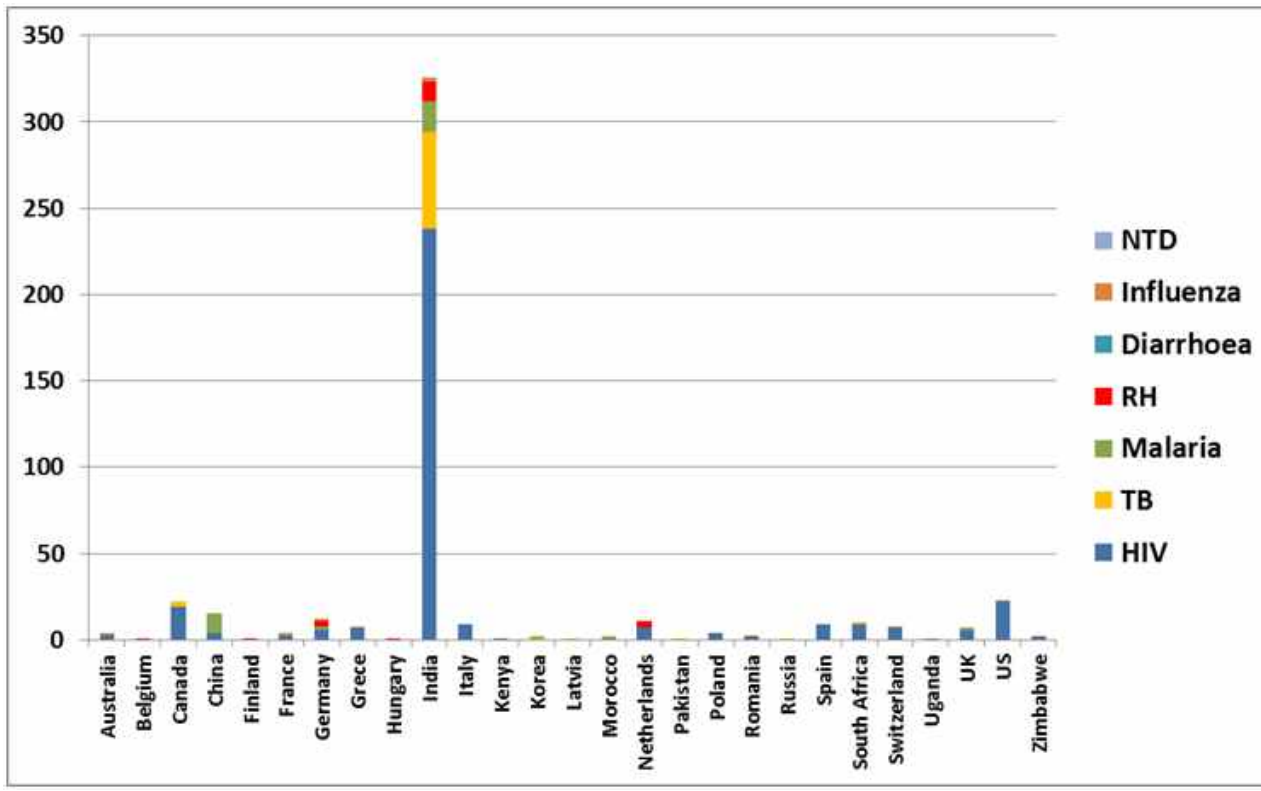
Domestic Landscape of Active Pharmaceutical Ingredients (API)

Quality in medicines is one of the cornerstones of health care and has a major impact on access and cost. Medicines of good quality improve the chances of successful treatment for individual patients and promote better outcomes for public health in general.

Good-quality Active Pharmaceutical Ingredients (APIs) are inevitable for the production of good-quality medicines. This has been emphasized further when studies conducted in different regions of the world revealed that medicines (particularly antimalarial, anti-tuberculosis and antiretroviral therapies) failed to meet quality standards and began to pose safety threats to patients in developing countries by delivering faulty and inefficient drugs. One of the important components of a pharmaceutical product is the active pharmaceutical ingredient (API). Ensuring the quality of the API greatly contributes to achieving the objective of building the quality, safety and efficacy into the product. Despite being one of the fastest growing markets in the world, lower ranking in terms of value results in significantly low prices of medicines in the country. Although India's strides to establish itself as a dominant force in the global pharmaceuticals marketplace are noteworthy, certain issues require urgent attention before it can stake its claim as being the global leader in API manufacturing.

The pharmaceutical sector is undergoing rapid development and one of the key priorities is ensuring quality, safety and efficacy medicines and medical products. Indian manufacturers are the most important suppliers of generic medicines to countries of need and the most relevant contributor to WHO Prequalification Programme. More than 65-70% of medicines in the WHO Prequalified List of Medicinal Products belong to Indian manufacturers in the segments of HIV-AIDS, Tuberculosis, Malaria, Reproductive Health, and other categories.

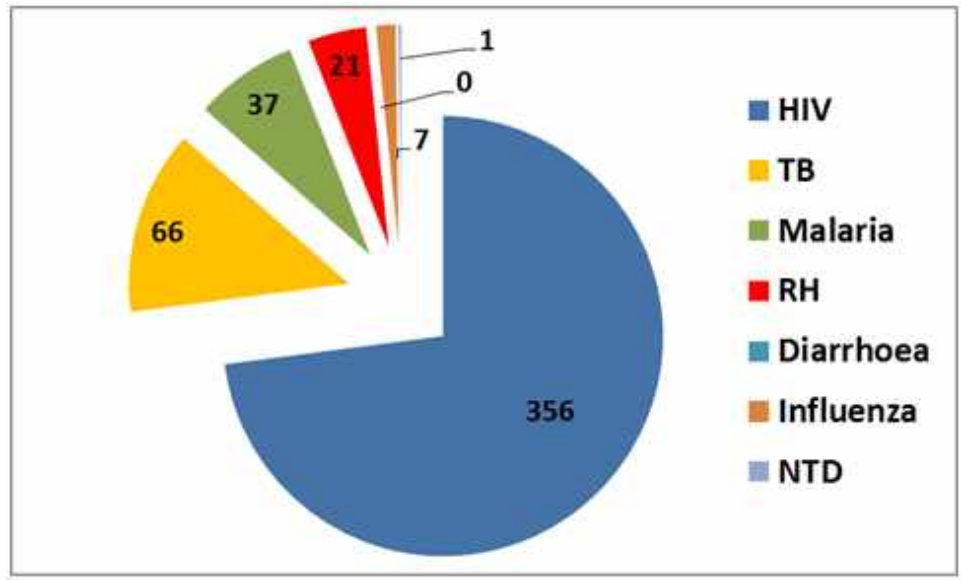
Figure 1. WHO Prequalified Finished Pharmaceutical Products Manufacturers. Adapted from WHO Prequalification of Medicines Programme



World Health Organization's Prequalification of Medicines Programme (PQP) was launched in 2001 to ensure the safety and efficacy of medicines. Its objective was to fulfill the work of regulatory authorities in resource poor countries, by setting and holding standards for generic medicines that could then be administered and save lives on a mass scale. PQP made a comprehensive evaluation procedure that had two components: API master file (APIMF) to verify compliance with WHO norms and API manufacture sites to verify compliance with WHO GMP requirements. API prequalification provides an assurance that the API concerned is of good quality and manufactured in accordance with WHO Good Manufacturing Practices (GMP).

India has shown a commitment and a strong political will to strengthen and build capacity of the National Regulatory Authorities (NRA). There is provision of large funds for strengthening drug regulatory authority and drug testing laboratories in the 12th Five Year Plan of the GOI and funds have been allocated appropriately. In the recent WHO NRA Assessment of the National Regulatory Authority, conducted in December 2012, India has been declared as 'functional' against the indicators. With a regulatory system for vaccines assessed as functional by WHO, vaccine manufacturers in India continue to remain eligible to apply for prequalification of specific products.

Figure 2. Medicines Prequalified by WHO in India. Adapted from WHO Prequalification of Medicines Programme



Key challenges in the Domestic API Landscape in India

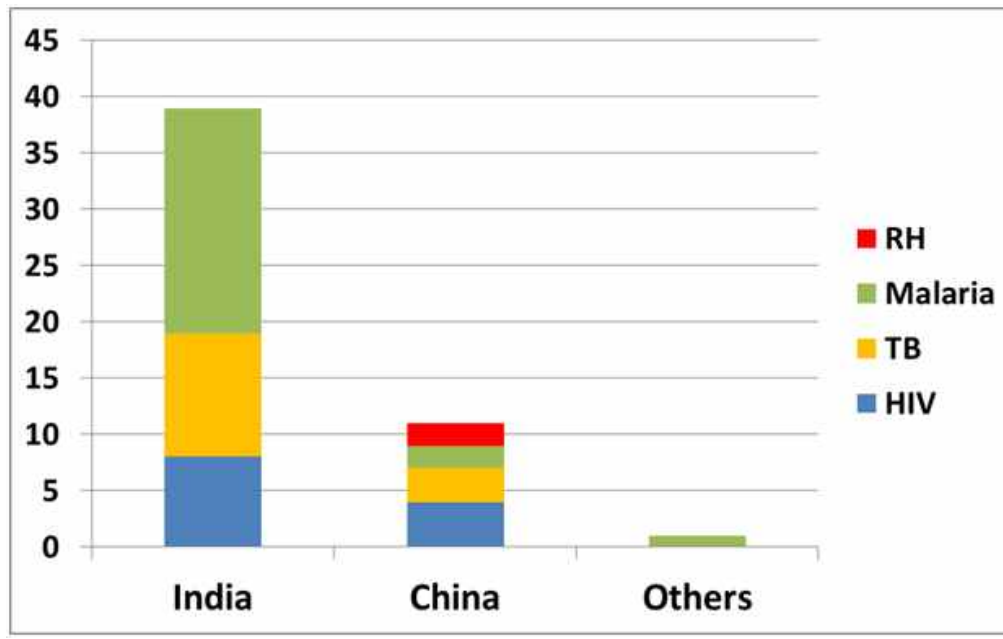
Indian manufacturers have several strengths such as availability of qualified personnel, strong R&D capability, strong vertical integration of generic pharmaceutical industry, including R&D and innovation and process design. There is a however a scope for improvement in the areas of GMP systems which might range from several areas like strengthening Quality Management Systems, premises and equipment, control of materials, documentation and laboratory systems etc. The necessary measures that can be taken by providing policies, resources, setting standard protocols, training requirements for the stakeholders and monitoring supply chains for consistency by conducting internal audits.

Purchasers of Indian medicines and importing countries need to be assured about quality in international standards, including GMP. Although Indian medicines are of high quality, some of the recent regulatory actions in against some manufacturing sites in India need deep analysis.

The domestic drug manufacturing industry should also consider to transition from the current scenario of import dependency to self-sufficiency with respect to active pharmaceutical ingredients. The government is actively seized of the situation and working out strategies so that Pharmaceutical units in the country manufacture quality and cost-effective APIs. There is a need for up-gradation of SMEs to WHO - GMP, USFDA/EDQM/PICs and other International Standards. CGMP requirements serve as the primary regulatory safeguard over drug manufacturing and must be followed by companies to ensure manufacturing quality.

The pharmaceutical industry has been incentivized to promote higher spending in research and development and in form of lower taxes and duties on life saving drugs and active pharmaceutical ingredients (API) to provide a fillip to its growth. However, there is need for more emphasis on Public Private Partnership, industry-academia collaboration.

Figure 3. WHO Prequalified Manufacturers of Active Pharmaceutical Ingredients (Adapted from WHO Prequalification of Medicines Programme)



Government Initiatives

The cluster development scheme in Pharma sector, started recently by the Department of Pharmaceuticals is for upgrading the existing common facilities and also for setting up new common facilities in clusters. The details of the scheme are available on the website www.pharmaceuticals.gov.in.

Key Recommendations

- The existing clusters in the sector need to have common facilities.
- Mega parks and setting up of new clusters in the API segment are the need of hour.
- There is a need to focus capacity building endeavors for both regulators and manufacturers in India.

- Review of existing Indian GMP (schedule M + guidelines) and risk-based suggestions for most urgent additional guidelines to converge interpretation and practice to international standard should be considered.

- Creation of a Pan- Indian database of approved products and licensed manufacturers.

- Promote greater engagement in international programmes of inspection, organize joint inspections and promote sharing of inspection reports among international and national inspectors.



The Changing Regulatory Landscape for the Conduct of Clinical Trials in India

The Changing Regulatory Landscape for the Conduct of Clinical Trials in India

Clinical trials are regulated by Central Drugs Standard Control Organisation (CDSCO), Directorate General Health Services, Ministry of Health & Family Welfare. Clinical trials are required to be carried out in accordance with requirements and guidelines specified in Rule122DA, 122DAA, 122DB, 122E and Schedule Y of Drugs & Cosmetic Rules. Some of the key provisions of the Drugs & Cosmetics Act such as Schedule K, Schedule M, Schedule Y, etc. have been already amended and elaborated over the years considering the growth needs of this industry. The government is setting up a centralized drug licensing authority (CDA) across the country to bring uniformity in rules and regulations governing the healthcare sector.

According to Schedule Y, for new drug substances discovered in India, clinical trials are required to be carried out in India right from Phase I (b) for new drug substances discovered in countries other than India. After submission of Phase I data generated outside India to the Licensing Authority, permission may be granted to repeat Phase I trials and/or to conduct Phase II trials and subsequently Phase III trials concurrently with other global trials for that drug. Phase III trials are required to be conducted in India before permission to market the drug in India is granted; Amended Schedule Y[i] has laid down the Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy (General considerations for conducting Clinical Trial as per Drugs and Cosmetics Act 1940 and Rules 1945).

India has been a favored hub for clinical trials primarily due to a large patient pool, trained physicians well versed in English language, larger patient recruitment rates, communication network's presence, infrastructure & expertise, GLP (Good Laboratory Practice) accredited laboratories, large hospitals with infrastructure to recruit large number of patients, lower costs & timelines. A favorable regulatory landscape in harmonization with the U.S. and International Conference on Harmonization (ICH) standards had facilitated the clinical trials conducted and outsourced to India. However, clinical trials are on a decline over the past year.

Over the past few years – the regulatory authorities in India - Central Drugs Standard Control Organization (CDSCO) - have taken several initiatives to streamline clinical research in the country, viz. publication of Indian Good Clinical Practice (GCP) Guidelines, amendments to Schedule Y, BA-BE study guidelines, regulatory inspections of clinical trials, introduction of Clinical Trial Registry (India), and implementation of the WHO Good Manufacturing Practice Certification Scheme. The introduction of

the Clinical Trials Registry in India (CTRI), launched in 2007, in harmonization with the WHO International Clinical Trials Registry Platform (ICTRP), encourages all clinical trials conducted in India to be prospectively registered before enrollment. The prospective registration of clinical trials in India was made mandatory by Drugs Controller General India (DCGI) since 15th June, 2009, which has led to an exponential increase in the number of registrations of trials over the last few years. In addition, some recent regulatory reforms/initiatives include the introduction of a robust review process for clinical trial proposals, harmonization of regulations on toxicity, definitions of Phase 1 consistent with ICH guidelines, implementation of Common Technical Document (CTD) Format for Biologicals, and introduction of CTD Format for New Chemical Entities. The Draft guidelines and requirements for registration of Clinical research organizations (CRO's) in the country have been developed, which will be incorporated as new Schedule Y1 in Drugs and Cosmetics Rules, 1945.

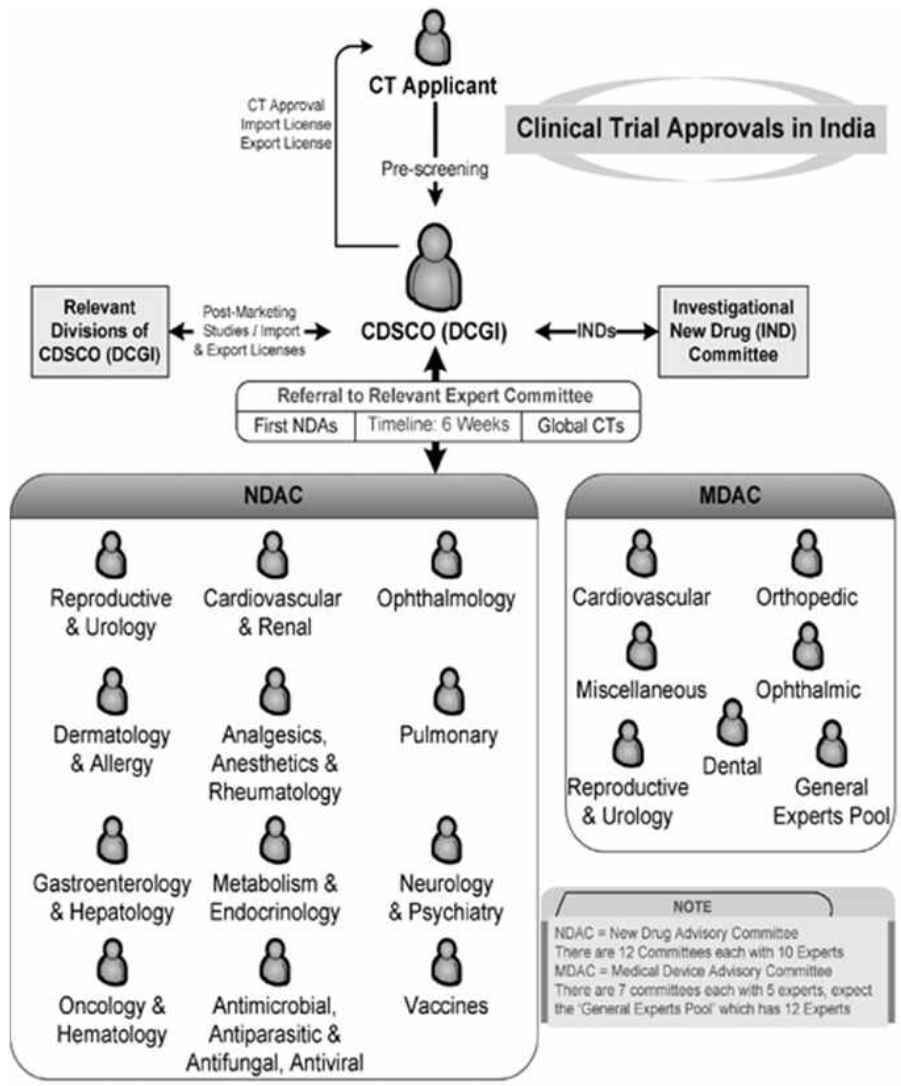
With introduction of Rule 122 DD in Schedule Y, prior registration of Ethics Committees with DCGI is mandatory to review and accord its approval to a clinical trial protocol. The registration is given for a period of three years to the committees from the date of issue, unless suspended or cancelled. Now all BA/BE study protocols need to be reviewed and approved by a registered Independent EC from same location as that of the BA/BE center. Of the additional responsibilities given to the Ethics Committees, one of the major responsibility is forwarding it's report on the serious adverse event of injury, after due analysis with causality assessment and opinion on financial compensation to the licensing authority within twenty one calendar days of the occurrence of the event, and in cases of SAE of death report should also be sent to Chairman of the expert committee[ii]. Prior consent of the subject should be taken for *audio-visual recording of informed consent* process and the same should be documented by the Investigator. Such consent may be taken orally. Only those subjects who give the consent for the AV recording shall be included in the clinical trial. During the video graphy process, care should also be taken not to include unrelated persons/patients at the hospital within the field of vision[iii]. This issue is posing multiple challenges for the stakeholders in India, including Institutional Ethics Committees and clinical investigators participating in clinical trials in India.

The issue of compensation to participants for research related injury is variably addressed globally. The Indian law for clinical trials i.e. the amended Schedule Y of 2005, the Indian GCP Guidelines for Clinical Trials (in Clause 2.4.7) and the ICMR Ethical Guidelines for Biomedical Research on Human participants, 2006 (in Chapters III & IV) have specified the need for provision of compensation of participants for research related injuries. As per Indian Council of Medical Research (ICMR) Ethical Guidelines for Biomedical Research on Human Participants (2006), research participants who suffer physical injury as a result of their participation are entitled to financial or other assistance to compensate them equitably for any temporary or permanent impairment or disability. Recently, ICMR has developed the Draft Guidelines on Compensation for research related injury in India. There have been some recent initiatives taken by the regulatory authorities vis-à-vis compensation issues for subjects enrolled in clinical trials in India. In November 2011, the Govt. of India published a statutory Gazette notification to bring an amendment in the Drugs & Cosmetics Rules, 1945, after consultation

with the Drugs Technical Advisory Board (DTAB), for medical treatment as well as financial compensation in case of injury to the clinical trial subject or his death during the participation in clinical trials in India. There have been several deliberations around the compensation formula proposed by the regulators, including discussions with industry and academia in this regard. However, there are on-going deliberations to resolve the challenges of operationalizing this amongst the stakeholders.

In addition, due to the increasing stifling regulations and growing uncertainty, outsourcing of clinical trials to India has declined over the past months. There is a need for bringing clarity among stakeholders, including pharmaceutical industry, and expedite the processing time of clinical trial applications which are now undergoing multiple levels of review by technical committees of CDSCO.

Figure 4: Clinical Trial Approval Processes at CDSCO(Ref: www.cdsco.nic.in)



Challenges in Clinical Trials Landscape in India

There are several challenges and issues in conducting clinical trials in India, and along with the optimism for growth in this industry, is the concern that vulnerable populations may be exploited. This has been reaffirmed by the recent Parliamentary Standing Committee Report of unethical drug trials having been conducted, with gaps in the informed consent process and procedures. There is a need for building capacity of institutional ethics committees, along with the registration of these committees for enhanced oversight of clinical trials. There is a lack of information about the institutional and independent ethics committees, their roles, responsibilities & functioning, and other ethical aspects of clinical trials like the rights and voluntariness of subjects, compensation and/or treatment(s) available to the subject in the event of a trial-related injury, benefits to patients including post-trial access to trial medication, and issues regarding informed consent, the process, extent of its comprehension by subjects/patients participating in clinical trials in India. Enhancing subject protection, addressing compensation issues in case of a trial related injury, monitoring clinical trial sites for Good Clinical Practice compliance, and building more capacity in terms of trained and certified clinical trial investigators, are some of the challenges in the conduct of clinical trials in India.

Prof Ranjit Roy Chaudhury Committee Report

Subsequent to the Parliamentary Standing Committee Report on CDSCO, Prof Ranjit Roy Chaudhury Committee was constituted to review the clinical trials landscape in India. In July 2013, Prof. Ranjit Roy Chaudhary report was released. This report lays down policies and guidelines for approval of new drugs, clinical trials and banning of drugs. The report also stresses on the importance of transparency during trials and mentions it needs to be shared through information technology services. The report highlights the need for clinical trials to be conducted in accredited sites by accredited Investigators with the oversight of accredited Ethics Committees (ECs).The draft rules have already been published for making mandatory audio / video recording of informed consent process. After acceptance of the Ranjit Roy Chaudhury Report by the Government, detailed presentations and discussions were held with OPPI, IPA, ACRO, FICCI and CII and other industry bodies and stakeholders. The Supreme Court of India waists the compliance of these recommendations by Government of India. The Report has not evinced any adverse comment from members of the Parliamentary Committee on Health. Apaper of the components of the Report and its follow –up is currently under preparation.

Key Challenges and Way Forward

There is a need for bringing clarity among stakeholders, including pharmaceutical industry, and expedite the processing time of clinical trial applications which are now undergoing multiple levels of review by technical committees of CDSCO. There is a need for increased transparency in CDSCO and a need a to increase and maintain credibility with the public. This can be achieved by having proper E-Governancesystem in place. This has also been recommended by the Working Group for the Drugs and Food Regulation of the 12th Five Year Plan 2012-17.

In the changing regulatory landscape, there is a need to strike balance in the regulatory regime and the growth of clinical trial industry, keeping in view the need for closer cooperation for ethical and transparent conduct of clinical trials in India. In addition, there is a need to address other challenges as well, like harmonization of regulatory requirements for clinical trials including capacity building of the regulators, registration of clinical research organizations as well as clinical trial sites in India, certification of Good Clinical Practice benchmarked clinical investigators, strengthening of clinical trial inspections, registration of Institutional Ethics Committees, and strengthening of Clinical Trials Registry of India.



Fostering R & D and Innovation in India: Challenges and Opportunities

Fostering R&D and Innovation in India: Challenges and Opportunities

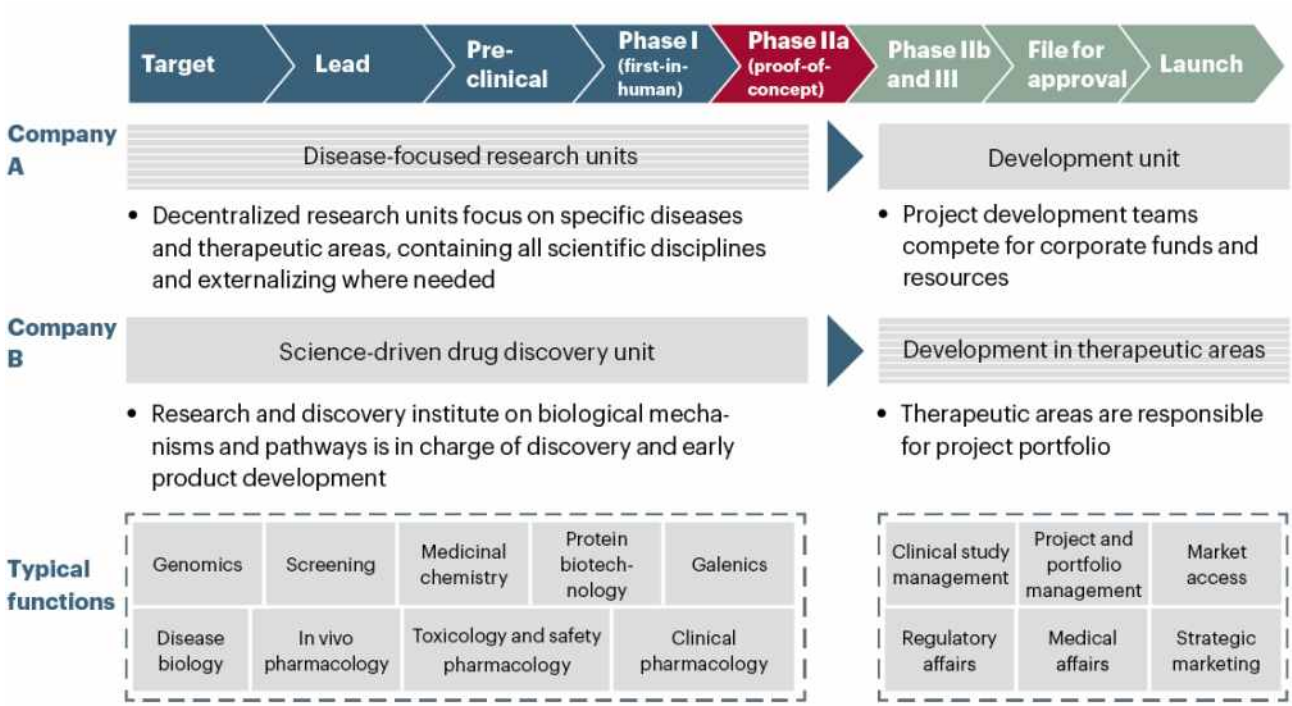
India is experiencing a rapid health transition, with increasing burdens of non-communicable diseases. According to the Global Burden of Disease study non-communicable diseases accounted for 53% of all deaths and 45% of disability-adjusted life-years (DALYs) in 2010 in India[iv]. Earlier estimates, from the Global Burden of Disease Study, projected that the number of deaths due to chronic diseases would rise from 3·78 million in 1990 (40.4% of all deaths)[v] to 7.63 million in 2020 (66.7% of all deaths). Of the estimated 9.6 million deaths that occurred in India in 2008, 53 percent (5.1 million) were due to non-communicable diseases and 10% were due to injuries[vi]. There is growing recognition that the current research-and-development (R&D) and innovation-regulation ecosystem could be made more efficient to stimulate and support access to innovative therapies for Indian population. The non-communicable diseases, such as cardiovascular diseases, diabetes, asthma and cancer, take a bigger toll on developing countries, affordable access to user-friendly versions of existing generic medicines, and to low-cost versions of newly-developed medicines, for treating those diseases, will be needed. The quality of all these products will have to be assured.

Medicines are a major component of modern health systems today and have helped to significantly reduce the burden of deaths and disease the world over. Despite the availability of adequate knowledge, technology and skills to innovate and develop new drugs, the global community faces tremendous challenges in prioritizing and delivering essential medicines to vulnerable populations who are in urgent need of them, while limiting the consumption of non-essential and expensive medicines by those who do not need them. The country not only produces enough drugs to meet domestic consumption, but as one of the largest exporters of generic and branded drugs, is also known as the 'global pharmacy of the south.' India exports life-saving drugs to developing countries and also supplies quality drugs to the rich nations at affordable prices.

The global pharmaceuticals industry is highly research intensive and innovative firms spend on average about 15 per cent sales turn over in R&D. However, R&D expenditure as percentage of sales turnover (R&D intensity) of Indian pharmaceuticals industry remained less than 2 per cent throughout the period till the beginning of the new millenniums. The report of the Hathi Committee (Government of India 1975) observed that R&D intensity was only 1.1 per cent in 1973. Perhaps the low R&D intensity is explained by the fact that Indian companies were engaged primarily in the manufacture of generics and development of non-infringing processes and not in new drug development, which involves huge investments. The leading private sector firms have increased investment in R&D in the past decade,

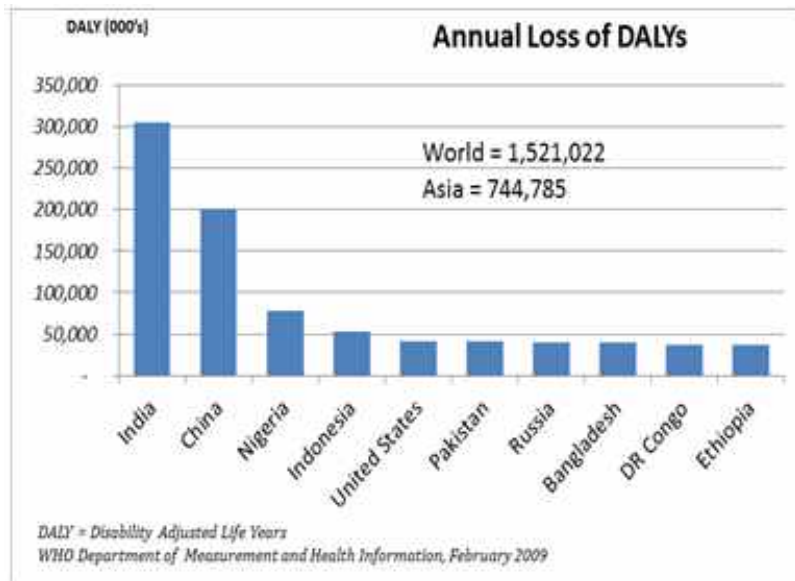
though levels of investment remain relatively low, averaging 8% of sales, compared with 10 to 20% of much larger sales for the big multinationals. Moreover, most firms have stepped back from new drug development, focusing instead on R&D related to their already thriving generic businesses. The Indian drug industry is making a significant contribution to global health through the provision of low-cost generic antiretrovirals (ARVs), antimalarials, antibiotics, and other important medicines to aggregated markets like the Global Fund and the Global Drug Facility, as well as directly to developing countries. At the same time, a contract research industry focused primarily on process and analytical chemistry and on clinical trials had grown rapidly in recent years.

Figure 5: Today's R&D organizations in major pharma companies suggest a breakpoint in the value chain



Sources: Fierce Biotech; A.T. Kearney analysis

With more than 300 million[vii] disability adjusted life-years (DALYs) lost due to disease and premature death, India has, by far, the highest disease burden in the world – China is a distant second with about 200 million. The country has a responsibility towards the health of its citizens that translates to creating an enabling environment for investments in healthcare and goal-directed research in health technologies. With its track record of recent successes, the domestic pharmaceutical industry, together with foreign investment in this sector, can play a pivotal role in turning the situation around if given the right incentives and a favorable regulatory environment.



In 2004, Member States requested WHO to task an independent commission to analyse the relationship between intellectual property rights, innovation and public health. WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) published a report in April 2006, raising global awareness of the existing problems and challenges around innovation and access to health products in the developing world. Following the report of the Commission, the World Health Assembly (WHA) adopted resolution WHA59.24 in May 2006 requesting the Director-General to establish an Intergovernmental Working Group (IGWG). Member States adopted the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) at the 61st WHA 2008 (Resolution WHA 61.21) and established consultative expert working groups (CEWG) on research and development, financing and coordination (Resolution WHA 63.28). The aim was to devise a global strategy on public health, innovation and intellectual property that aims to promote new thinking on innovation and access to medicines, as well as, provide a medium-term framework for securing an enhanced and sustainable basis for needs-driven essential health research and development relevant to diseases which disproportionately affect developing countries, proposing clear objectives and priorities for R&D, and estimating funding needs in this area. The global strategy was designed to promote innovation, build capacity, improve access and mobilize resources. Further the specific needs of developing countries for innovation, technology transfer and access to medical products for essential health R&D for diseases which disproportionately affect developing countries, precise definition of objectives and priorities for R & D, estimation of funds and coordination for promoting health R&D have been emphasized. Member states needed to strengthen heath R&D capacities for Type II, III and specific R & D needs of developing countries for Type I diseases by enhancing financial resources from existing government budgets and private sources and explore new sources for heath R & D.

A study by WHO-India of the Indian landscape, in this context, was conducted wherein fund allocation and expenditure of the Indian government in health R&D is reported and the Indian perspective discussed. Analysis and comparison of resource flow on R&D by two principal Indian biomedical funding agencies (ICMR and DBT) helped to identify the critical needs and gaps important for implementing the specific actions and recommendations. From this analysis, it became evident that disbursement of funds was insufficient in Type II and III diseases; the quantum of funding in the areas

of medical devices and biologics was lowest amongst the interventions that were considered in the analysis; the emphasis on translational research was inadequate and funding for health R&D was not focused to deliver an impact[viii].

Key Recommendations

- There is a growing need to promote research and innovation in India with focus on assuring treatment access at affordable prices for diseases prevalent in our country.

- Impetus for creating clusters of innovation for both pharmaceutical and biologic segments and reducing regulatory complexity for biosimilars & vaccines.

- Policies to encourage innovation need to reflect 'technology push' (advances in Knowledge and their applications) or 'market pull' (social or economic market opportunities Incentivizing innovation).

- Building R&D excellence and accelerating commercialization of research by developing regional industry clusters, encouraging and raising the quality of R&D through public investment and encouraging public private partnerships including product development partnerships (PDPs).

- Ensuring access to financial capital for companies: This includes private investment in investment funds and companies, especially in innovative, technology based companies

- The challenge for the development of biosimilars arises from the fact that biologics are more complex than small molecules and chemically synthesized drugs. Regulatory pathway to be more focused and aligned to scientific basis for vaccines and biosimilars registration in the country.

- Several initiatives have been launched by the Government to give impetus to the thriving biotech industry. Department of Pharmaceuticals is working on several projects through National Institutes of Pharmaceuticals Education and Research. The Biotechnology Industry Partnership Programme (BIPP) has been launched by the Department of Biotechnology (DBT) to support high-end biotechnology research programmes capable of generating globally recognized intellectual property. It specifically focuses on transformational research and development. The DBT has also drafted the National Biotechnology Regulatory Act in order to set up the National Biotechnology Regulatory Authority (NBRA) to regulate the biotechnology segment and reduce regulatory overlap. Biotechnology Industry Research Assistance Council (BIRAC) a Section 25 'Not-for-Profit Company' of Government of India has been set up as Department of Biotechnology's interface agency, which serves as a single window for the emerging biotech industries.



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About Organizers

Department of Pharmaceutical
Ministry of Chemicals & Fertilizers
Government of India

The Department of Pharmaceuticals was created on 1st July 2008 to be a focused Department of Government of India for fostering growth of the Indian Pharmaceutical Industry. The Department has been assigned several functions including inter-alia promotion of Research, Education and Training, Public Private Partnership, international Cooperation, Inter- Sectoral cooperation, Industrial Cooperation, Environment and Hazard Management and Pricing and Availability of Medicines. The Department of Pharmaceuticals discharges their functions through active consultations with stakeholders to formulate new schemes/ proposals/ strategies for promoting growth of the Pharmaceutical Industry

Established in 1927, FICCI is the largest and oldest apex business organisation in India. Its history is closely interwoven with India's struggle for independence, its industrialization, and its emergence as one of the most rapidly growing global economies. FICCI has contributed to this historical process by encouraging debate, articulating the private sector's views and influencing policy.

A non-government, not-for-profit organisation, FICCI is the voice of India's business and industry.

FICCI draws its membership from the corporate sector, both private and public, including SMEs and MNCs; FICCI enjoys an indirect membership of over 2,50,000 companies from various regional chambers of commerce.

FICCI provides a platform for sector specific consensus building and networking and as the first port of call for Indian industry and the international business community.

Our Vision: To be the thought leader for industry, its voice for policy change and its guardian for effective implementation.

Our Mission: To carry forward our initiatives in support of rapid, inclusive and sustainable growth that encompass health, education, livelihood, governance and skill development.

To enhance efficiency and global competitiveness of Indian industry and to expand business opportunities both in domestic and foreign markets through a range of specialised services and global linkages.

World Health Organization is the United Nations' specialized technical agency for Health. It is an inter-governmental organization and works in collaboration with its member states. WHO's objective is the attainment by all people of the highest possible level of health. Equitable access to essential medicines for priority diseases is one of the requirements for fulfilling the fundamental right to health. WHO's Medicines' Strategy is based on four key objectives: strengthening national medicines policy, improving access to essential medicines, the quality & safety of medicines, and rational use of medicines.

WHO India Country Office collaborates with the Government of India and relevant stakeholders within the framework of the collaborative Country Cooperation Strategy (CCS), to actively support the development and implementation of national health policies, strategies and plans in the area of Essential Medicines & Pharmaceuticals, including access, quality and safety of medicines and impact of intellectual property rights on public health.

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