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CURRENT SCENARIOS ON REGULATORY LANDSCAPE OF INDIAN PHARMACEUTICAL INDUSTRIES

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ABSTRACT: India is the fourth largest generic pharmaceutical market in the world. Indian pharmaceutical industries are very well established in today's world and continuously producing a variety of products, which are useful in the treatment of various diseases and grabbing the market segments. India has a large number of resources to contribute vitality in the research and manufacturing process, and due to its large patient population & genetic pool, now it has become a region for cost-effective and speedy Clinical Trials (CTs) for Investigational New Drugs (INDs). Due to having these significant advantages, India now able to contract multinational pharmaceutical companies (MNPCs) to outsource operations in the fields of drug discovery and also able contract manufacturing and clinical research (CR) to organizations in India. On the other hand, understanding the regulatory scenario is not easy because the rapid and ongoing changes and the burden on the regulatory bodies to ensure a healthy supply of quality drugs at affordable prices to the population. The Indian pharmaceutical industry has shown impressive growth over the last few years and has become one of the sunrise sectors of the Indian economy. Indian generics companies supply 84% of the AIDS drugs that doctors without borders use to treat 60,000 patients in more than 30 countries. This article mainly focuses on the current scenario of various pharmaceutical industries and the different regulatory bodies conducting the Indian pharmaceutical system.

INTRODUCTION: The regulatory framework in the Indian pharmaceutical sector is extremely critical because of rapid and ongoing changes at the global level, largely with reference to good manufacturing practices (GMP), good clinical practices (GCP) and good laboratory practices (GLP) [1].

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The responsibilities of the regulatory bodies to ensure a healthy supply of quality drugs at affordable prices to the Indian masses also make the regulatory framework critical [2].

The Indian pharmaceutical industries are developing day by day and becoming more and more competitive, so the regulatory agencies are also established to ensure the safety, efficacy and quality of drugs and the accuracy and appropriateness of the drug information available to the public [3]. Regulatory bodies provide strategic, tactical, and operational direction and support for working within regulations to accelerate the development and delivery of safe and effective

healthcare products to individuals around the nation [3].

Objective of Regulatory Agencies:

1. Ensuring availability of essential and good quality life-saving medicines for mass consumption; at reasonable prices,

2. Strengthening the system to practice quality control on drag production and promoting the rational usage of drugs in the country;

3. Providing a favorable environment to encourage new investments in the Indian pharmaceutical industry to produce cost-effective technologies and new drags and

4. Strengthening the capability for producing drugs within the country.

Thus, the policy has recognized that the expansion of the domestic pharmaceutical industry will attract more investment from foreign & domestic companies, at the same time maintaining the prices of drugs at an affordable level [4].

Pharmaceutical Regulatory Authorities: Pharmaceutical regulatory authorities or organizations are responsible for effective drug regulation, which is also required to ensure the safety, efficacy and quality of drugs, as well as the accuracy and appropriateness of the drug information available to the public [5]. As the pharmaceutical industries throughout the world are moving towards becoming more and more competitive, regulatory agencies or bodies are also being established and stricken in various countries across the globe.

Regulatory agencies provide all strategic, tactical, and operational direction and support for working within regulations to develop and deliver safe and effective healthcare products to society [5, 6]. Every country has its regulatory authority responsible for enforcing the rules, regulations, and issue guidelines for drug development, licensing, registration, manufacturing, marketing and labeling of pharmaceutical products [6, 7]. The various regulatory agencies around the world are listed [7] in **Table 1**.

TABLE 1: VARIOUS REGULATORY AGENCIES THROUGHOUT THE GLOBE

Country	Name of regulatory authority
India	Central drug standard control organization (CDSCO)
UK	Medicines and healthcare product regulatory agency (MHRA)
USA	Food & Drug Administration (FDA)
Australia	Therapeutic goods administration (TGA)
Canada	Health Canada
Europe	European medicine agency
Denmark	Danish medicine agency
Costa Rica	Ministry of health
New Zealand	MEDSAFE - Medicines and Medical Devices Safety Authority
Sweden	Medical Products Agency (MPA)
Netherland	Medicines Evaluation Board
Ireland	Irish Medicines Board
Italy	Italian Pharmaceutical Agency
Nigeria	National Agency for Food and Drug Administration and Control (NAFDAC)
Singapore	Centre for Pharmaceutical Administration Health Sciences Authority
Hong Kong	Department of Health: Pharmaceutical Services
Paraguay	Ministry of Health
Thailand	Ministry of public health
China	State Food and Drug Administration
Germany	Federal Institute for Drugs and Medical Devices
Malaysia	National Pharmaceutical Control Bureau, Ministry of Health
Pakistan	Drugs Control Organization, Ministry of Health
South Africa	Medicines Control Council
Sri lanka	Ministry of Health
Switzerland	Swiss medic, Swiss Agency for Therapeutic Products
Uganda	Uganda National Council for Science and Technology (UNCST)
Brazil	Agencia National de Vigiloncia Sanitaria (ANVISA)
Japan	Ministry of Health, Labour & Welfare (MHLW)

International Organizations: The international regulatory organizations play an essential role in all aspects of pharmaceutical regulations related to drug product registration, manufacturing, distribution, price control, marketing, research and development, and intellectual protection [7, 8].

The various international organizations are including:

- World health organization (WHO).
- Pan American health organization (PAHO).
- International council for harmonization of technical requirements for pharmaceuticals for human use (ICH).
- World intellectual property organization (WIPO).

Various Challenges of Regulatory Authorities:

a. Pricing of Patented Drugs: It is a great challenge for the regulatory authority to improve access of such medicine to the common man's reach; the Government of India should have a tough gaining plan for these products, at a proper price, for supply through government hospitals and dispensaries. It will provide a good facility to patients [8, 9].

2. Spurious Medicine: Fake versions of high-value and high-volume brands of the pharmaceutical companies in India are adversely affecting their business performance, posing another major challenge, more than that it gives a negative impact to the end consumer and a huge health hazard [8-10].

3. Talent Pool: In India, the request for these services has exceeded supply. There is a vast loss in 'Healthcare Manpower' of the country, right from Pharmacists and persons related to the medical field [8-10].

4. Public and Government Pressure to make Drug Prices More Affordable: Indian pharmaceutical Industry is facing pressure from both government and the public society to make generic medicines more affordable for a large section of the population of the country. Pharmaceutical companies, including the government ones, see scope for further reduction of prices for essential medicines in India [8, 9].

5. Inadequate Health Insurance Schemes: As compared to other countries like South Africa, Sri Lanka and Brazil, the health insurance coverage is relatively low in India. In contrast, the current health insurance schemes cover only hospitalization expenses [9]. However, it should also cover domiciliary or in-patient treatment costs and loss of income. The nature and variety of the Indian pharmaceutical market, healthcare objectives, and legal system carriage unique challenges for the pharmaceuticals sector in India. The variety of the challenges are very complex; hence, the Indian pharmaceutical sector has to face these challenges with more courage to develop as one of the leading players in the world pharmaceutical market and to achieve progress in health care [8, 9]. The constant increase in the size of the Indian pharmaceutical market due to a change in lifestyle and high demand for quality health care, making this sector one of the talented contributors to the Indian economy.

The regulatory policies need be improved, especially in the area of patent and price control, to boost the growth and create an impression as the destination for the new generation pharmaceutical market. We know that firms that are able to market patented products earn high margins on them, which enables such companies to invest back more resources into research and development as well as come up with more useful discoveries [8, 9].

Hence, to conclude, the key measures to overcome the basic challenges in the Indian Pharmaceutical industry would be to educate the general mass of people about the Industry, having strict regulations, so that doctors write prescriptions through molecule/salt name only and not by brand names, as we see in the West. This will ensure that high-quality generic medicines at the most affordable price reach the hand of patients. Lastly, to ensure that enough opportunity reaches our internal talent pool for their growth in the country and serve the nation [9-10]. There are some other challenges which we need to concern about includes:

- To promote public health and to protect from harmful and dubious drugs
- To establish proper legalization of all products with a medicinal claim and all

relevant pharmaceutical activities, whether carried out by the public or the private sector.

- To increase worldwide regulatory growth & to ensure the safety of people.

Regulation of Indian Pharmaceutical Sectors: The main control of pharmaceutical regulation is divided between two ministries in the Government of India such as [11-16]:

- The Ministry of Health and Family Welfare.
- The Ministry of Chemicals & Fertilizers (MoC & F) comprises bodies such as the National Pharmaceutical Pricing Authority (NPPA), Department of Fertilizers, Departments of Chemicals & Petrochemicals, *etc.*

However, other ministries also have some vital roles in the drug regulation process. Those ministries include:

- Ministry of Environment and Forests.
- Ministry of Commerce and Industry.
- Ministry of Science and Technology.

In India, the manufacturing of drugs, quality, and marketing of any drugs is regulated in accordance with the Drugs and Cosmetics Act of 1940 and Rules 1945. In accordance with the Act of 1940, there exists a system of dual regulatory control *i.e.*, control at both Central and State government levels [11-13].

Regulatory Bodies under the Ministry of Health & Family Welfare, Government of India:

a. The Central Drug Standards and Control Organization (CDSCO): The CDSCO prescribes standards and measures for ensuring the safety, efficacy, and quality of drugs, cosmetics, diagnostics, and devices in the country. CDSCO has a big role in the country which also regulates the market authorization of new medicines or Investigational new drugs (IND) and controls the clinical trials protocols to approve the new drug in the market. In India, the Central Drugs Standard Control Organization (CDSCO) is the main regulatory body currently regulating the import, sale and manufacture of medical devices which have been notified as drugs with the help of Section 3(b) (IV) of the D&C Act [14]. The CDSCO lays down standards of drug products, cosmetics, diagnostics and devices, and issues licenses to the drug manufacturers and importers. It also lays down regulatory measures, amendments to acts and rules and regulates market authorization of new drugs, clinical research in India and standards of imported drugs, *etc.* The main headquarter of CDSCO in India is located in New Delhi, which is also the capital of India.

The head post of this organization is called the Drug controller of India or DCGI, who has the extreme power to control, regulate and take any measures related to pharmaceutical products and medical devices throughout the country. The DCGI is advised by the Drug Technical Advisory Board (DTAB) and the Drug Consultative Committee (DCC). Licensing and classification of medical devices are handled by the Central Licensing Approval Authority (CLAA). The CLAA is also responsible for setting and applying safety Standards, appointing notified bodies to supervise conformity assessment, conducting post-marketing surveillance, and issuing warnings and recalls for adverse events. The CDSCO establishes safety, efficacy, and quality standards for pharmaceuticals and medical devices [14].

CDSCO is also responsible for publishing and revised the Indian Pharmacopeia (I.P). For all the drugs and device applications, the CDSCO appoints notified bodies to perform conformity assessment procedures, including testing, in order to ensure compliance with their standards.

The CDSCO is also divided into several are a offices which generally dopre-licensing and post-licensing inspections, post-marketing surveillance, and recalls of the drug product, if necessary. In addition to its regulatory functions, the CDSCO also offers technical guidance, training to the regulatory officials and analysts, and monitors adverse events after the drug product approval for the marketing. The CDSCO is also working with the World Health Organization (WHO) to promote the Good Manufacturing Practice (GMP) and international regulatory harmony throughout the country [14].

a. Indian Council of Medical Research (ICMR): The Indian Council of Medical Research (ICMR) is one of the oldest and largest medical research organization throughout the world. The ICMR coordinate and promote the formulation research in biomedical sectors and also funded by Department of Health Research, Ministry of Health and Family Welfare, Government of India. This council's research priorities are associated with national health-related issues such as communicable diseases, fertility control, mental and child health, control of nutritional disorders, and many more. The main aim of this council is to promote the research and health services to control the major and minor health-related problems in the country [15].

These efforts are undertaken with a view to reduce the total burden of disease and to promote the health and well-being of the population. Extramural research is promoted by ICMR by establishing Centers for Advanced Research in different research areas around existing expertise and infrastructure in selected departments of Medical Colleges, Universities, and other non-ICMR Research Institutes. The ICMR also funds task force studies that emphasize a time-bound, goal-oriented approach with clearly defined targets, specific time frames, standardized and uniform methodologies, and often a multi-centric structure. Open-ended research is conducted on the basis of applications for grants-in-aid received from scientists in non-ICMR Research Institutes, Medical Colleges, and Universities located in different parts of the country. Collaborative research projects with other institutes such as the between Institute of Pathology, Delhi, and NCRM are also undertaken [16]. Major functions are to formulate, co-ordinate & promote biomedical research and ethical principles. The clinical trial registry of India (CTRI) is hosted at ICMR. With a huge population & and easy access to a wide variety of treatments of native diseases, India forms a hotbed for clinical trials for both national & international researchers [15, 16].

b. Indian Pharmacopoeia Commission (IPC): The Indian Pharmacopoeia Commission (IPC) is an autonomous body under the Ministry of Health and Family Welfare, responsible for the manufacturing, selling of any pharmaceutical products throughout the country.

The set of technical standards is published under the title Indian Pharmacopoeia (IP), modeled over and historically follows from the British Pharmacopoeia (BP). Since 1st December 2010, the standard that is in effect is the Indian Pharmacopoeia 2010 (IP 2010). I.P., the abbreviation of 'Indian Pharmacopoeia' is familiar to the consumers in the Indian sub-continent as a mandatory drug name suffix. Drugs manufactured in India have to be labelled with the mandatory non-proprietary drug name with the suffix I.P [17].

c. National Institute of Biological Standards and Controls (NIBSC): The National Institute of Biological Standards and Controls plays a pivotal role in the quality of biological products at the national and international levels. The NIBSC ensures the quality of biological products by developing the standards and reference materials for test, control product testing, and applied research during any pandemic situation. NIBSC also ensures quality biological drugs, *i.e.,* vaccines & bio-therapeutics, including therapeutic monoclonal antibodies used by patients suffering from cancer & autoimmune diseases. It undertakes research to develop and validate standards for quality control of biological [18].

Regulatory Bodies under Ministry of Chemicals and Fertilizers, Government of India:

Department of Pharmaceuticals (DOP): DOP examines pharmaceutical issues within the larger context of public health while the main focus is on the industrial policies related to pharmaceutical production and selling [19].

The National Pharmaceutical Pricing Authority (NPPA): The National Pharmaceutical Pricing Authority (NPPA) is a government regulatory agency that controls the prices of pharmaceutical drugs in India. NPPA governs price control by DPCO order and also responsible for fixing the prices of bulk & formulations of drugs within the NLEM. It fixes or revises the prices of decontrolled bulk drugs & formulations at judicious intervals, periodically updates the list under price control through inclusion & exclusion of drugs in accordance with established guidelines; maintains data on production, export & import & market share of the pharmaceutical sector in addition to

imparting inputs to parliament in drug pricing issues [20].

Regulatory Bodies under Ministry of Environment & Forest:

Genetic Engineering Approval Committee (GEAC): The GEA committee generally maintains on the collection, usage & imports of micro-organisms a swell as production of genetically engineered micro-organismsorcell culture.

The main function of this committee is to approve or reject various activities in the cases of large-scale field trials, deregulation and commercialization of micro-organisms and approve permission of GEAC constituted under the MoEF is required in addition to the DBT approval process [21]. Precisely, approval of the GEAC is required from the environmental angle on:

- Import, export, transport, manufacture, process, selling of any microorganisms or genetically engineered substances or cells, including foodstuffs and additives that contain products derived by gene therapy.
- Discharge genetically engineered/classified organisms/cells from laboratories, hospitals, and related areas into the environment.
- Large-scale use of genetically engineered organisms/classified microorganisms in industrial production and applications. Production can only be commenced after obtaining such approval.
- Deliberate release of genetically engineered organisms [21].

Review Committee on Genetic Manipulation (RCGM): RCGM is generally responsible for providing permission for clinical trials & r-DNA strains in the country.

The function of this committee is to frame the regulations for the institutions involved in rDNA research activities and review the on-going researches involving hazardous microorganisms.

This committee also provides legal advice to the customs authority on the import of microorganisms and genetically manipulated products in the country [22].

Regulatory Bodies under Ministry of Commerce & Industry, Government of India:

RE Patent Office in India: The Indian Patent Act, 1970 was amended through the Patents Amendment Act, 2005. A patent claim relating to a pharmaceutical product may relate to an active ingredient independently of or jointly with formulations, salts, pro-drugs, isomers, *etc.*, or cover any of these subject matters separately. It may also solely cover a manufacturing process or include both a process and a product [23].

Pharmaceutical Export Promotion Council of India (Pharmexcil): Pharmexcil is the authorized agency for promoting pharmaceutical export from India. There are few trade associations in the industry representing different groups of producers, the Organization of Pharmaceutical Producers of India (OPPI) representing big Indian Pharma with a high R&D base, Confederation of Indian Pharma Industry (CIPA) – the apex body of small-scale manufacturers of drugs and Pharma in India; Bulk Drug Manufacturers Association (BDMA); and Indian Drug Manufacturing Association (IDMA) [24].

Regulatory Bodies under Ministry of Science and Technology:

National Accreditation Board for Testing & Calibration of Laboratories (NABL): NABL has an agreement with ILAC (International Laboratory Accreditation Conference) and APLAC (Asia Pacific Laboratory Accreditation Cooperation). These are especially valuable for International recognition and mutual acceptance of test results. It assesses laboratories in India for quality and consistency in the results. NABL follows ISO 15189:2007, which is a specific ISO followed worldwide for medical laboratories [25].

Department of Science and Industrial Research (DSIR): DSIR generally carrying out various activities relating to indigenous technology promotion, development, utilization & transfer. It promotes R&D by the industries, supports small & medium industries to develop globally competitive technologies & commercialization of lab-scale R&D [25].

Council of Scientific & Industrial Research: CSIR is an autonomous body under the Ministry of Science & Technology, Government of India.

CSIR covers the entire spectrum of scientific and industrial research of national and international importance in addition to pharmaceutical researches [25].

Bhaba Atomic Research Centre: BARC promotes isotope application in medicine & monitors usage of radioactive materials [25].

Present Regulatory Issues in Indian Pharmaceutical Industries:

- As reported in a survey by economic times, the Pharmaceutical sector is one of the most dynamic sectors in the country, but its compliance structure is more complex since the process for drug approval entails the coordination of different departments [26-28].
- Issues related to industrial policy include the regulation of patents, drug exports, and government support to the industry. With the introduction of the Patents Act, pharmaceutical companies were allowed to patent their process of manufacturing drugs.

  The pharmaceutical industries with a large pool of highly qualified technical human resources have in-process chemistry, which leads to reverse-engineered formulation introduced in the Indian market at a lower price than the regulated market. With WTO norms, India is forced to recognize product patents instead of process patents [26-28].
- Big Pharma companies are now setting up R&D labs to find new molecules. Licensing andqualitycontrolissuesduetorapidongoingc hangesatgloballevelrelatedtoGMP, GCP & GLP [25-28].
- In India, a dual licensing mechanism involving central as well as state Govt. often interferes in the uniform implementation of regulatory procedures. Indian Pharmaceutical industries need to comply with the US Food and Drug Administration, the UK Medicines and Healthcare Products Regulatory Agency, and Indian drug regulators. While exported drugs were of a higher quality (FDA/EMEA/TGA), to meet the required standards in the country of export, in the case of the domestic market, adherence to local quality standards fixed by the regulatory body was sufficient. The issue of the definition of counterfeit drugs is relevant in the context of different drug quality standards prevailing in the Indian market [29].
- Issues related to market authorization, *e.g.*, The Indian Patent Office granted US pharma giant Pfizer patent authorization for Prevenar 13, (Pneumonia vaccine) in 2017, which gives the company exclusive rights to distribute the vaccine within India until 2026 and blocks Indian manufacturers from making a generic version of the life-saving vaccine for export [28, 29].

Drug Pricing Issues:

- Developing and launching a new drug in the market involves enormous costs, and the success or failure is highly dependent on innovation which is critical for the industry. The National Pharmaceuticals Pricing Authority (NPPA) would extend price caps through DPCO to certain new medicines that come into the market, as well as so-called ‘scheduled drugs’ whose prices are already regulated.

  While essential medicines are subject to absolute price controls in the form of ceiling prices, the non-essential or non-scheduled medicines are subject to a managed price increase or a ceiling on price changes [30].

  To make drugs affordable to all, the Govt. of India is promoting the generics & ensuring that prices of life-saving drugs are in the range of affordability to everyone. According to Pharma Industries, this will kill competition and hurt drug makers. An element of cost in the drug industry is the unethical gratification of doctors to induce them to prescribe a particular drug. Issues like delays in clinical trial approvals, uncertainties over the FDI policy, the new pharmaceutical pricing policy, a uniform

code for sales and marketing practices, and compulsory licensing [30].

- Tax authorities use the Central Board of Direct Taxes (CBDT) circular based on MCI guidelines to decide on permissible sales and marketing expenses. Because of differing standards between the DOP and MCI guidelines, there is an increased need for clarity both from the point of view of the industry as well as the tax authorities [30].

Recent Regulatory Issues From US FDA: Three top pharma majors based out of Hyderabad, Dr. Reddy's Laboratories, Aurobindo Pharma, and Divis Laboratories, have been facing one issue after another in the plant inspections/approvals from the US regulator. For Dr. Reddy's, which has a turnover of over ₹14,000 core with a lion's share of it coming from the US market, the USFDA has been a constant source of trouble from 2015 when it received warning letters for three of its plants, including two API units and one cancer products facility.

Even after a recentre-inspection by the US regulator, Dr. Reddy's still faces 'significant observations' on its Duvvada plant. A fresh addition to the list of units with observations is the Bachupally unit, which had 11 observations from the USFDA after its inspection. For Aurobindo pharma, too, the sailing has been tough. Its unit III at Bachupally, which makes oral formulations attracted six observations on procedural aspects. This was followed by another seven observations on its Unit IV (for injectable & ophthalmic products). Both are Form 483 type of observations [31, 32].

Lupin has also been issued some observations on its facilities in Goa and Aurangabad by the US watchdog recently. The US FDA issues a form 483 to drug companies if it spots any condition that in their judgment may constitute violations of the US Food Drug and Cosmetic Act and related Acts during inspections. As on 23rd Feb 2018, USFDA inspection in Sun Pharma Halol plant also received a form 483 [31-34].

FDA FORM 483: Inspectional Observation: It is a form used by the FDA to document & communicate concerns discovered during inspections. It is constituted a list of observation that made by the FDA representatives during inspection facility.

The FDA encourages the resolution of issues through informal mechanisms prior to the issuance of form 483. A recipient of form 483 should respond to the FDA, addressing each item, indicating agreement & either providing a timeline for correction or requesting clarification of what the FDA requires. The response must be submitted within 15 business days regardless of the number of observations. A good response can help a company or organization to avoid receiving of a warning letter from FDA regarding the withholding product approval or plant shutdown [31, 33, 34].

Prosecution of an Indian Drug Maker: Dinesh Thakur is the man behind the prosecution of the Indian drugmaker Ranbaxy Laboratories. The pharmaceutical company was fined US$500 million for malpractice in2013, while he was awarded US $48 million. According to him, "The existing fragmented drug regulatory structure in India needs to be dissolved & a new framework, consistent with globally accepted industry standards needs to be implemented" [35, 36].

Recent Regulatory Initiatives: An integrated regulatory system through the constitution of a National Drug Authority is established so that the same agency performs quality regulation and price control. Establishment of pharmaco-vigilance centers at national, zonal, and regional levels to monitor adverse drug reactions. Move to bring nearly 374 bulk drugs under price control and regulate trade margins capability strengthening to monitor clinical trials, including the setting up of the Clinical Trials Registry of India (CTRI) [37].

Future Avenue or Prospective: India has the world's largest healthcare program for its half of a billion citizens, as per the union budget 2018. The brand-new scheme "Namocare" is covering nearly 40% of the health policy of Indian citizens.

Though, the government has promised to bring some major changes in the DPCO area and probably come out with a new pharma policy to implement "Namocare" across the country and successfully the mission PHARMA2020. The new pharma policy will unify & synergize its various

components such as DPCO, manufacturing, R & D, financing, quality control, drug control, price control & medical devices.

Though, the pharmacists of India are committed to the cause of placing patients first & will continue to advocate the need for better regulations in the Indian pharmaceutical industry [38, 39].

CONCLUSION: The discovery of a new drug molecule or the conversion of a new drug molecule into an appropriate dosage form is very challenging, time-consuming, and cost-effective. Although, the pharmaceutical industries involved in such kind of business are always looking to protect their products in national and international markets by various intellectual property rights. It is always suggestable that the investors feel secure to invest their money into that sector for its better growth. However, it is also necessary to ensure that there are some safeguards so that a few companies do not take over the market in the name of intellectual property rights.

The small-scale pharmaceutical units have problems with WHO-GMP compliance, whereas large-scale firms willingly comply with increasing competitiveness in the global arena. A large number of domestic industries are seeking international regulatory approvals from agencies like USFDA, MHRA in order to export their products in those markets.

There is a need for greater coordination, accountability & transparency in functioning among different ministries concerned with drug regulation. For obvious reasons, industry players have been maintaining that there is nothing 'abnormal' and Indian companies have always been focusing on quality. The impact of these developments on a company's business has been diversified and also involves the cost of remediation.

This current flashpoint is really a manifestation of larger battles over intellectual property, trade and human rights," said Matthew Rimmer, a professor of intellectual property and innovation at the Queensland University of Technology. Thus, the maintaining of proper rules and regulations for the development of a country economy and countrymen is always suggestible and accountable.

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