

DRUG REGULATION IN INDIA: SWOT ANALYSIS

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REVIEW ARTICLE

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ABSTRACT

Drug regulation plays pivotal role in any country because the purpose of drug regulation is to promote and to protect public health by ensuring the safety, efficacy and quality of drugs. Drug regulation should cover all products for which medicinal claims are made and all aspects of drugs like manufacturing, import, export, distribution, dispensing, promotion, sell and supply. But unfortunately drug regulation does not meet these requirements in India as legislation omits or exempts certain areas of pharmaceutical activity from the scope of control in India. Although there are so many deficiencies, lacunae and hurdles in Indian drug regulation, there is a wider scope for drug regulation in India because government is taking positive steps to reform it. One can say India is a vast ocean of opportunities. Hence it is tried to analyse the drug regulation of India using the framework of SWOT (Strengths, Weaknesses, Opportunities, Threats). SWOT analysis aids to find out possible ways to overcome the weaknesses and threats, and to utilize the strengths and opportunities properly

Keywords: Drug regulation, SWOT Analysis, Strengths, Weaknesses, Opportunities, Threats.

INTRODUCTION

“Drug Regulation” is the control of drug use by international agreement and/or by regulatory authorities such as the US Food and Drug Administration (FDA), the European Medicines Agency (EMA) and the Japanese Pharmaceutical and Medical Devices Agency (PMDA). This includes regulations concerned with the development, approval, manufacturing and marketing of drugs. (1)

Overview of Indian Drug Regulation

- Drugs regulatory system in India

Drugs and Health is in concurrent list of Indian Constitution. It is governed by both Centre and State Governments under the Drugs & Cosmetics Act, 1940. India's Drugs and Cosmetics Act governs the registration, import, manufacture, testing and sale of drugs and cosmetics. (2)

- Main Bodies

Central Drugs Standard Control Organization (CDSCO)

Ministry of Health and Family Welfare (MHFW)

Indian Council of Medical Research (ICMR)

Indian Pharmaceutical Association (IPA)

Drugs Technical Advisory Board (DTAB)

Central Drugs Testing Laboratory (CDTL)

Indian Pharmacopoeia Commission (IPC)

National Pharmaceutical Pricing Authority (NPPA)

India also follows world level standards like World Health Organization (WHO), US Food and Drug Administration (USFDA), European Union (EU), etc. Pharmaceutical companies found difficult to follow all standards at a time as there may be some changes in regulatory requirements in global scenario than India. It is impossible to follow all standards at a time and get global permission to sell drug.

Objective

The overall objective of a National Regulatory Authority (NRA) is to ensure that medicinal products are of acceptable quality, safety and efficacy, are manufactured and distributed in ways which ensure their quality until they reach the patient or consumer, and their commercial promotion is accurate. (3) In this study it is tried to find out what types of strengths and

opportunities the Drug Regulatory bodies have and weaknesses and threats they face in India.

SWOT ANALYSIS

SWOT analysis of any drug regulatory body investigates the important factors that are possibly affecting the regulated industry and influencing the companies operating in this sector. The purpose of this study is to analyse the drug regulation of India using the framework of SWOT. This paper enlightens the SWOT analysis of Drug Regulation in India and aids to find out possible ways to overcome the weaknesses and threats; to utilize the strengths and opportunities properly. Through this study one can find out the effect of various factors of strength, weakness, opportunity and threat aspect on Drug regulation and its related problems and prospects for the future.

SWOT analysis of Indian Drug Regulation

Strengths

1. The present domestic regulatory environment though in need of further improvement has been conducive to the growth of an emerging pharmaceutical industry. (4)
2. Global competitiveness enhanced by recent amendment to Schedule M (GMP) of Drugs and Cosmetics Act and Schedule Y (new drug discovery).
3. Increasing usage of pro competitive provisions such as Section 3D of the Indian Patent Act to fight against ever greening strategies employed to promote monopoly by big players. (5)
4. Revamped regulatory regime. (6)
5. Centre allots Rs. 1750cr to CDSCO to strengthen drug regulatory system across the country. The funds will be strategically used to help the centre and state drug regulatory departments in their capacity building measures. (7)
6. Compliance with International regulatory and GCP standards. (8)
7. Move to establish an integrated regulatory system through the constitution of a National

Drug Authority so that quality regulation and price control is performed by the same agency.

8. Establishment of pharmacovigilance centres at national, zonal and regional levels to monitor adverse drug reactions.
9. Move to bring nearly 374 bulk drugs under price control and regulate trade margins.
10. Capability strengthening to monitor clinical trials, including the setting up of the Clinical Trials Registry of India (CTRI). (6)
11. First compulsory licence granted by the Indian Patent office and its implication for the Pharmaceutical industry.
12. New CDSCO regulations concerning Biosimilars and ethics committees.
13. New CDSCO guidelines on compensating for injuries and deaths during Clinical trials. (9)
14. The country has significant ability to circumvent API Patents. India has filed a number of non-infringing process patents. The country has a recent success track record in circumventing formulation patents. Proven Legal skills to evaluate IP and commercial strategies are available at least in select top companies. (4)
15. Increasing liberalization of government policies. (10)
16. India has skilled scientists/ technicians/ management personnel at affordable cost leading to low cost of innovation/ manufacturing/capex costs/ expenditure to run cGMP compliance facilities and high quality documentation and process understanding.
17. India is regarded as having an edge over China in terms of qualified, English-speaking manpower and fair protection of intellectual property rights supported by well-developed judicial system. (Appendix IV gives more information on IPR status in India). (4)
18. Cost efficiency (up to 60%) in comparison to USA/ Europe. (6)
19. Governmental initiatives to boost Small and Medium Pharmaceutical Enterprises such as Credit Linked Capital Subsidy (CLCS), Pharma Technological Up gradation Assistance (PTUA), setting up of SEZs, tax holidays etc. (5)

20. The healthy domestic market with rising per capita expenditure is another significant strength enabling achievement of economies of scale. (4)

Weaknesses

1. The country has at times shown inadequate regulatory framework or compliance and enforcement regime, reflected in occurrences such a production of spurious or low quality drugs.

2. The national drug regulatory system though evolved substantially, has been in the need of strengthening its manpower and systems requirements. (4)

3. Lack of experience to exploit efficiently the new patent regime.

4. Lack of experience in International Trade.

5. Low level of strategic planning for future and also for technology forecasting. (10)

6. Lack of data protection.

7. Very competitive environment. (11)

8. Capacity constraints for CCI to scan pharmaceutical mergers and takeovers.

9. Non tariff barriers imposed globally.

10. High market barriers for SMEs with limited financial and technical capacity constraints to enter the larger market due to lack of technical knowhow and inability to comply with GMP.

11. Product patent regime does not favour the generic industry as much as process patent regime did.

12. Linking regulatory issues with IPR issues.

13. Inability to use TRIPS flexibilities.

14. Absent guidelines on regulation of Biosimilars. (5)

15. Inadequate regulatory standards. (12)

16. Lack of adequate mechanisms to safeguard illiterate and vulnerable patients, prevent informed consent violations and ensure proper functioning of institutional ethics committees. (6)

17. Coordination between multiple agencies.

18. Ethics Committee: Frequency of meetings, Guidelines for approval, Letter of Approval, Ethics Approval Time.

19. Investigator Site: Lack of data bases, Difference in global and local disease focus, Institutional policies on agreements, Knowledge of regulations. (8)

20. Dual licensing mechanism acts as a deterrent to uniform implementation of regulatory procedures.

21. Lack of transparency in licensing procedures.

22. Inadequate regulatory expertise and testing facilities to implement uniform standards.

23. Need for greater clarity on patentability of pharmaceutical substances and conditions under which firms can apply for compulsory licences to prevent legal battles between local firms, MNCs and civil rights groups.

24. Need for greater coordination, accountability and transparency in functioning among different ministries concerned with drug regulation. (6)

25. Stringent pricing regulations affecting the profitability of Pharma companies. The National Pharmaceutical Pricing Authority sets prices of different drugs, which leads to lowers profitability for the companies. (13,14)

26. Presence of more unorganised players versus the organised ones, resulting in an increasingly competitive environment, characterised by stiff price competition. (13)

27. Information asymmetry and inelastic demand to changes in price makes collusion conducive and profitable. (5)

28. Regulatory Approval Time (8)

Country	Approvals Time (Weeks)
• US	4-6
• Western Europe	8-12
• Eastern Europe	10
• Estonia	08-10
• Russia	10
• India	12-16
• Hong Kong	12
• Taiwan	12

29. Lack of resources to compete with MNCs for New Drug Discovery Research and to commercialize molecules on a worldwide basis. (12)

30. Indian pharma sector has been marred by lack of product patent, which prevents global

pharma companies to introduce new drugs in the country and discourages innovation and drug discovery. (14)

31. Rapidly increasing costs of skilled manpower such as scientists/ regulatory compliance personnel/ pharmaceutical lawyers/ international business development personnel is pushing up the cost of innovation. Ability to evaluate contracts/alliances etc. is available only in top companies. Significant lacuna in this area exists and companies are falling into traps created by the competitors. Institutionalisation of learning in the following areas is restricted:

i) Regulatory affairs knowledge for different countries and continents

ii) Process and product patents procedures knowledge for different countries and continents. (4)

32. While India has developed into a pharmaceuticals powerhouse, its regulator has struggled to keep up with the growth of its pharmaceutical industry.

33. In 2012, a report commissioned by an Indian parliamentary committee found CDSCO struggled with staffing shortages, infrastructure issues and its responsibilities to ensure public safety.

34. In 2013, the Ministry of Health attempted to create a "Central Drugs Authority" that would oversee drug manufacturing. However, the proposal was rejected in parliament for being overly bureaucratic. (15)

35. Several drugs have been allowed to be marketed in the country without mandatory clinical trials, while over a dozen which are banned in most developed markets are being sold in India. (16)

Opportunities

1. The migration into a product patent based regime is likely to transform industry fortunes in the long term. The new patent product regime will bring with it new innovative drugs. This will increase the profitability of MNC pharma companies and will force domestic pharma companies to focus more on R&D.

2. Being the lowest cost producer combined with FDA approved plants; Indian companies

can become a global outsourcing hub for pharmaceutical products. (14)

3. TRIPS Flexibilities.

4. Rising opportunities for Contract Research and Manufacturing Services (CRAMS) especially beneficial for SMEs with limited options to grow in a product patent regime.

5. Growing bio-similar industry in light of a large chunk of biotech pharmaceuticals going off patent by 2015. (5)

6. Significant investment from MNCs. (13)

7. Growing incomes.

8. Growing attention for health.

9. Saturation point of market is far away.

10. Globalization.

11. Easier international trading.

12. New markets are opening. (10)

13. Significant export potential. (12)

14. US\$40 billion worth of drugs in the U.S.A and US\$25 billion worth of drugs in Europe are expected to go off patent soon. Assocham estimates that Indian manufacturers may capture 30 percent of that market. This translates to an opportunity of US\$19.5bn which is significant considering the country's current exports of approx. US\$7.25bn. However the figures need to be appropriately deflated since Indian opportunity will lie in generics equivalent of branded or patented drugs, which would be cheaper.

15. Compulsory licensing provisions negotiated in the Doha Round, allows for countries to import cheaper generic versions of patented drugs in the interests of public health. Thailand and South Africa have already started such initiatives from which Indian firms have benefited.

16. Due to the cost advantage in contract manufacturing and Research MNCs (Multi-National Companies) find it compelling to shift their production bases to countries offering such cost advantage. Typical of the industry which requires approval of manufacturing facilities by various drug regulatory agencies of the world involving a very high cost, once such business finds base in India it would continue with it for at least one and half to two decades.

17. Licensing deals with MNCs for NCEs (New Chemical Entities) and NDDS (New Drug Delivery Systems) offer new opportunities for Indian manufacturers.

18. Marketing alliances for MNC products in domestic and international market is another emerging opportunity.

19. Contract manufacturing arrangements with MNCs is estimated at 10% of patented markets estimated at US\$450bn which is approx. US\$45bn.

20. India has a very high potential for developing as a centre for international clinical trials due to its rich diversity. (4)

21. Cheap, diverse clinical trials. (11)

22. Relaxation of duties on import of clinical trial samples.

23. Removal of phase lag and permission to conduct Phase I trials concurrently in India along with rest of the world. (6)

24. Global recognition of Indian clinical research. (8)

25. There is a possibility of greater returns from an Indian entry into mature and more remunerative markets like Brazil, Japan, CIS, Russia, etc.

26. Unleashing of a plethora of preferential trading arrangements, both bilateral and regional, offers opportunities for India to negotiate preferential access to partner markets for Indian pharmaceuticals in the long term and in a sustainable manner. (4)

27. Niche player in global pharmaceutical R and D. (12)

Threats

1. Product patent regime poses serious challenge to domestic industry unless it invests in research and development.

2. R and D efforts of Indian pharmaceutical companies are hampered by lack of enabling regulatory requirement.

3. Drug Price Control Order puts unrealistic ceilings on product prices and profitability. (4)

4. Government expanding the umbrella of the Drugs Price Control Order (DPCO).

5. Other low-cost countries such as China and Israel affecting outsourcing demand for Indian pharmaceutical products. (13)

6. High cost of sales and marketing.

7. High Cost of discovering new products and fewer discoveries. (10)

8. Export effort is hampered by procedural hurdles in India as well as non-tariff barriers imposed abroad. For example:

i. Indian manufacturers are prevented from bidding for government contracts as US permits bidders only from countries that are signatories to WTO Agreement on Government Procurement.

ii. Indian manufacturers have to submit separate state level applications for marketing drugs in the United States as there is no nation-wide system of application even where FDA approval has been received.

9. Lowering of tariff protection has increased competition in domestic markets resulting in erosion of profitability.

10. Specific non-tariff and para-tariff barriers being increasingly adopted by other countries such as long transaction time taken for registration of drugs, insistence on completing long process for registration when the drug may actually have gone through the most rigorous process of registration such as the USFDA; insistence on allowing imports of only those drugs which are registered in some developed countries, etc.

11. Mergers and acquisitions by foreign companies particularly multinational corporations of a few Indian generic leaders may completely change the direction of India's pharmaceutical movement neutralising its thrust on generics and cost competitiveness.

12. Increased competition due to newer Chinese and East European manufacturers. (E.g. there has been massive state level investment by China in the biotechnology sector - though at present India still has the edge due to IP laws.)

13. TA's entered into by the United States of America with third countries (e.g. the Morocco-U.S.A FTA) may be harmful to Indian pharmaceutical exports because of provisions for increases in patent terms, etc. (4)

14. Entry of foreign players (well equipped technology-based products) into the Indian market.

15. Stricter registration procedures.

16. Switching over from process patent to product patent. (10)

17. Government regulations changing.

18. Counterfeiting threat. (11)

19. There are certain concerns over the patent regime regarding its current structure. It might be possible that the new government may change certain provisions of the Patent Act formulated by the preceding government.

20. The short-term threat for the pharma industry is the uncertainty regarding the implementation of VAT. Though this is likely to have a negative impact in the short-term, the implications over the long-term are positive for the industry.

21. Global pressure for data exclusivity, TRIPS plus provision that hampers generic competition. (5)

22. Need for a strong centralized regulatory regime to effectively monitor GCP guidelines. (6)

23. Commercialization of clinical research.

24. Competition from other developing countries. (8)

CONCLUSION

Our country is in the phase of transition from Developing country to Developed country, concomitantly strengthening the Drug Regulation system of the country. Though Indian Drug Regulation need to be reformed due to lacunae, deficiencies and hurdles in regulation system; it has a wide scope for growth and Pharmaceutical industry has a bright future here. While reforming and restructuring the Indian drug regulatory system, regulators should keep in mind the threats in the said field and should take decision to combat them. Changes done in Drug Regulation of India should be properly implemented to take our nation at peak. It is the time where Indian regulatory system needs to be strengthened and should bring in more regulatory reforms in the

drug control administration in line with International standards. (17)

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CONFLICTS OF INTEREST

Author declares that there are no conflict of interest in this work.

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