# Forecast 2015

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**'Is Indian pharma under seige?'**

Is Indian pharmaceutical industry under siege? By whom? USTR & Big Pharma? US FDA? NPPA? CDSCO? Other regulatory agencies? NGOs? Indian pharma is facing more challenges than opportunities at current times. As the year 2014 is exiting and a New Year is dawning, the Indian generic pharma industry needs to lay down strategies for the future.

On the international front, the first time in many years, quality related issues dominated over intellectual property disputes, even though there appeared to some relation between the two at the core. The offensive came from both the USTR and Big Pharma on TRIPs compliance issues. The US FDA inspections and warnings to Indian manufacturing sites of leading generic pharma companies were at too frequent intervals during the current year.

On the domestic front, the pharma industry was hard-hit by a plethora of issues. Clinical trials and consequent drug approval processes were severely affected by delays and hold-ups. The fixed dose combination (FDC) approvals and re-approvals including issues related to irrational (?) combinations persisted.

Most disconcerting and disturbing negative moves came from National Pharmaceutical Pricing Authority (NPPA) orders for extending the range of price controls beyond the ambit of the Drugs Price Control Order (DPCO). Government, more specifically the NPPA, appears to be not realising that the affordability is secondary to availability. The severe cuts and spreading of the net of controls, led to leading brands with high quality and reliability being replaced by newly introduced brands of companies who could afford to continue to market

under low overheads. To add fuel to the fire of stress, IP related litigations were on the increase during the year, making deep dents in the budget of Indian companies.

**Pharma under one roof?**

Pharma, biotech, herbal, neutraceutical, vaccines themselves make a wide range. By another classification, Active Pharmaceutical Ingredients (APIs), formulation dosage forms including parenterals, New Drug Delivery Systems (NDDS), Ayush (Ayurveda etc.), medical devices (implants and equipment), packing materials (capsules, glass, pet etc.) need a variety of expertise to oversee which is clearly lacking in single ministry. The pharma industry has to currently deal with a large number of ministries such as

1. Pharmaceutical Dept. of Chemicals Ministry – APIs, pricing, infrastructure
2. Ministry of Health – CDSCO, DGHS, ICMR, Ethics Committee, DCG(I)
3. State FDAs – Manufacturing and product licences, sales and marketing
4. Ministry of Commerce – Pharmexcil (international trade)
5. Ministry of Environment – Bio Diversity Act, Pollution Control, Waste Management & disposal
6. Dept. of Industrial Policy & Promotion (DIPP) – Patents TMs, Designs, Bilateral Trade Negotiations
7. Ministry of HRD – Pharma Education, Copyrights
8. Ministry of Science & Technology – R&D approvals, research project related funding
9. Dept of Ayush – Ayurveda, herbal, neutraceuticals
10. Ministry of Industry – MSME, location approvals
11. Ministry of Finance/Revenue – Customs, Excise (central and state excise), Service Tax
12. Narcotics Control Dept./NDPS (Dangerous Drugs Department)
13. Ministry of Labour – Perennial and ongoing dispute with Medical Representatives (FMRI)
14. Ministry of Transport, Aviation & Shipping
15. Ethical (?) marketing issues – MCI/IMA – Industry -Codes

The list is endless, many more. While all of this cannot be brought under one umbrella, the best possible is to combine health, pharma department and pharma trade both domestic and international, including pharma and health education under one ministry. This can only be

done at the Centre, not at the State level, as the (Indian) Drugs and Cosmetics Act is a concurrent Act.

Significant amendments will be required to Drugs & Cosmetics Act, 1940. It is admitted that such an amendment is long overdue. Lately, the government has come up with strict action against unethical practices in industry-medical profession relationships. It will be interesting to wait and see how and through which agency the government proposes to implement the statutory code and punitive measures, if any for violation thereof.

In conclusion, the entire exercise of bringing all pharma related regulatory and administrative activities under one roof can only succeed, if such a mammoth organisation is headed by a competent authority and is well structured and empowered with human resources, logistics and infrastructure. Very often the solution causes more problems. The phase which Indian pharma industry is currently undergoing is very critical. Quality issues including Good Manufacturing Practice (GMP) need to be utmost priority. Negotiations of Substandard /Spurious /Falsely-labelled/Falsified/Counterfeit FDC (SSFFC) and counterfeit at various global levels including with US and EU need to be handled in the best interest of India. International Conference of Harmonization (ICH) need to be addressed.

On the biotech front, biosimilars need urgent expedited attention. Scaling up fermentation, serums and vaccines, both at research and production levels need urgent attention. Most deliberations lead to one report or another which collects dust in the shelves, thereafter, such a Mashelkar Committee Report and Satwant Reddy Committee Report. Hope the present move will also not land up in the dustbin.