The candidate having obtained Master of Pharmacy in the year 1968 was engaged in Industrial Pharmacy in Small Scale Sector at Indore since then till the year 2004, when he preferred VRS from his own Industry.

Having worked in different capacities in the Industry from Junior Manufacturing Chemist to Director of a company, the candidate came across 'N' number of Regulatory and other complications which an industrialist, more particularly is Small Scale Sector, is forced face.

The candidate during last over 4 decades observed that Drug Regulatory in the Country, more or less, plays negative role. The Drugs and Cosmetics Act 1940 (herein after referred as ‘The Act’) and Drugs & Cosmetics Rules 1945 (herein after referred as the ‘Rules’) framed there under is Federal Law whereas responsibility of its enforcement rests on Provincial Governments. Of late licensing a few of categories like Large volume Parental (LVP), Import Export, Clinical Trials, Blood Products, New Drugs etc. has been entrusted on Central Drug Standard Control Organization (CDSCO) a Central Govt. Regulatory body, office of DCGI, with headquarter in New Delhi and Zonal offices in Calcutta (East), Ghaziabad (North), Mumbai (West) and Chennai (South).

The candidate has been actively involved in Industrial Associations from ‘Local’ to ‘National’ level bodies and has deeply felt that the “Regulatory” in the country is totally mismanaged, is in the hands of in-competent persons, political leaders are not willing to understand the subject the authorities are playing in the hands of multinational companies’ (MNC’s). The testing laboratories, both at Central and State levels, on whose reports action of regulatory is solely based, have proved to be ‘Bad Tools’ in the control of Central and State Governments respectively as has been concluded in reports of various committees appointed by Central and State Governments (Justice Lentin Commission in Maharashtra) right from health Committee 1975 to Mashelkar Committee in 2003. Union Health Ministers have ‘outspoken’ tall talks on different occasions as appeared in Indian media viz.

i. Mr. Shatrughan Sinha – manufacturers and traders of spurious drugs should be hanged on ‘Sooli’.

ii. Mrs. Shushma Swaraj – manufacturers of spurious drugs are responsible for mass murder and must be hanged.
iii. Dr. Ramdoss in the year 2005- The National Drug Authority, at par with USFDA shall take shape within two years.

iv. Mr. Gulab Nabi Azad – Indian Drug regulatory shall be up graded at par with USFDA.

With mainly following objects, the candidate took up the Herculean task in the year 2006, probably for the first time in the Country, to overview 'Drug Laws' of various countries, both Developed and Developing, on various aspects divided in Ten Chapters. The Enforcement of the these laws are more important then simply its framing, making it more & more stringent or providing more teeth to the penal provisions, can not be considered as proper enforcement and ultimately it leads to its gross misuse and industry / trade is ruined.

(i) Study the Drug Laws being enforced in Developed and Developing Countries.

(ii) Enforcement processes of these laws in those Countries.

(iii) Basic theme of Enforcement i.e. whether 'punitive' or 'corrective'

(iv) Quality and Quantity of Expert Staff engaged in Enforcement of Drug laws in those Countries.

(v) Infrastructure available with FDA authorities in those Countries

(vi) Role of World Health Organization (WHO)

(vii) Application of Information Technology (IT)

(viii) Data available on internet.

(ix) All these and other aspects to be compared with Indian Drug Laws and its Enforcement

(x) Critical views of the candidate with suggestions with expectations that Enforcement of Drug Laws in India may improve in the time to come.

The candidate has visited nearly one hundred sites on internet and decided to study a few of them. It is also observed that information available on USFDA site is wonderful and probably it is considered to be the 'Model' FDA in the Globe. As on today the India Drug Laws are under revolutionary changes for the last about over 10 years the
licensing to manufacture for certain category of drugs and pharmaceuticals have been assigned to CDSCO, the scope of 'New Drug'. Banning of irrational, harmful and therapeutically less active Drugs etc. have been introduced/widened.

The Government of India is also in process to create National Drug Authority (NDA) desiring (?) it to be at par with USFDA and before that squeezing of powers of State FDA on various Counts, is in pipeline.

Captains of Pharma ships sailing in the great Indian ocean have been shouting from roof tops that the Indian Pharma Industry is the most over regulated on planet Earth.

The candidate 'hopes' that his efforts may open eyes of those who are not actually sleeping.

Jagmohan Rai Agarwal