The Indian Pharmaceutical Association (IPA)

Platinum Jubilee Year

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MISSION

The Indian Pharmaceutical Association (IPA) is the national professional body of pharmacists engaged in various facets of the profession of pharmacy. The IPA is commited to promote the highest professional and ethical standards of pharmacy, focus the image of pharmacists as competent healthcare professionals, sensitize the community, government and others on vital professional issues and support pharmaceutical education and sciences in all aspects

IPA/110/228

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Sub: Comments on the Draft Drugs and Cosmetics (Amendments) Bill 2015

Dear Sir,

Let me take this opportunity to introduce our organization, the Indian Pharmaceutical Association (IPA), which is a premier professional organization registered as a charitable trust, with an objective to promote the science and art of pharmacy in all aspects and impart suitable education and training to professionals working in the pharmacy profession. Our organization is representing Pharmacists from Research, Industry, Education, Hospital and Community Pharmacy nationally. IPA is celebrating its platinum jubilee this year. As a member of the Drug Technical Advisory Board (DTAB), IPA is actively involved in advising the government on matters of Drug Regulations and drug industry. IPA is actively involved in healthcare activities in collaboration with international organizations like - World Health Organization (WHO), Partnership for Maternal, Neonatal and Child Health (PMNCH) & International Pharmaceutical Federation (FIP).

On behalf of Indian Pharmaceutical Association, we would like to appreciate the efforts being initiated for updating the Drugs and Cosmetics Act under the Bill 2015. The proposed bill has some proposals, which are good for the purpose like – Substitution of the term "Inspector" by "Drug Control Officer". But, some proposals included in the bill may be against the purpose of providing universal health care to the people.

The proposed draft of Drugs & Cosmetics Act (Amendment) Bill, 2015 in its present format contains various conflicting provisions which if not reviewed/corrected, would hinder the growth of the pharmaceutical industry, specially the Small and Medium Scale Pharmaceutical Industry on one hand, and can have far reaching consequences on public health on the other. These provisions are proposed so as to centralize the power in the hands of Union Government vis-à-vis Central Licensing Authority (CLA),

which will undermine the functions of State Licensing Authority, which has a large and capable infrastructure. Empowering only CLA to regulate Medical Device and Clinical Trials throughout the country having miniscule structure in comparison to SLA will seriously hinder proper vigilance leading to significantly poor compliance of regulatory mandates and ultimately hamper the consumer interests. Public health measures in our opinion thus be seriously affected and compromised.

Some of the propositions in the draft Bill also show a marked deviation from the recommendation of Drug related Parliamentary Standing Committee (seventy ninth reports). Detailed comments are given below:

Sl. No.	Section/ Chapter	Proposition in Draft D&C (Amendment) Bill, 2015	Principal Act (D&C Act, 1940)	Comments	Suggestions
1.	Section 3, clause X	"New Drug" definition	In the D&C Rules, New drugs are defined under Rule 122E where it is stated as 'New drugs shall continue for a period of four years form its first approval....."	Not fixing a period is an arbitrary proposition. It may overpower CLA to take whimsical decision and will encourage monopoly of particular manufacturing company, due to which public health could be adversely affected.	It should be in tune with Rule 122E or other specific periods.
2.	Chapter 1A	Under heading Clinical Trial Sec 4A (3)New Drug	No such Provisions	--	Should be reviewed in the above context.
3.	Sec-3, Clause Y	Definition "New Medical Device"	No such Provisions	No duration is prescribed	It should be in the similar line as per Rule122E of D&C Rule.
4.	Chapter1A, Sec-4H&4T	Drugs Control Officer authorized by CLA has been empowered to inspect any institution conducting Clinical Trial.....". Drugs	No such Provisions	It would not be possible to regulate, exercise proper vigil in a vast country by the central Drugs Control Officer having minimum infrastructure.	For effective regulation, State Drugs Control Officer should also be given power in both Sec. 4H and Sec. 4T

		Control Officer authorized by CLA has been empowered to institute prosecution under Sec-4T		Consumer interests will be compromised. This is also a deviation from the recommendations of Prof. Ranjit Roy Chaudhury committee, which was of the opinion to empower State Drugs Control Officers.	
5.	Sec-5A, Clause(1)	Constitution of Medical Devices Technical Advisory Board	No such Board	Experts from all the concerned departments/Institutions are included except from Pharmaceutical Profession	Since this is a broad based body, due to overall competence and professional expertise, one expert with Pharmacy Education nominated by PCI and the other Pharmacist from Drug Control administration should be included in the Board.
6.	Chapter IIA, Sec. 7F(4)	Central Licensing Authority Shall have exclusive power to issue license for manufacture for sale or distribution or marketing of any Medical Device.....	No such Provisions	In large country to regulate medical device by the CLA would not be wise proposition	For effective surveillance and proper implementation of the Act, SLA should also be empowered in such matter
7.	Sec-18, Clause(3)	".....on and from commencement of D&C Amendement	No such provision"	This leads to extreme centralization of power by the CLA	Amendment is unjustified and should be

		Act,14 CLA shall have exclusive power to issue licence..... .....drugs spcecified in Third Schedule....."		and will cause serious hindrance to the pharmaceutical Industry to handle the regulatory issues including taking approval from the centre for no fault of theirs. This will be against the development of Pharmaceutical industry in our country.	dropped.
8.	The Third Schedule	Categories of drugs for which the Central Licensing Authority is empowered to issue license and permission	No such provision	Centralized the power to issue license for the drugs specified in third schedule by the CLA is a marked deviation from the existing system and will cause severe administrative problem and is against subject-matter contained in Article 246(2) of Indian Constitution. SLA having equal competence & knowledge with adequate human resource will remain idle.	This provision should be dropped as it contravenes Article 246(2) of Constitution of India vis-s-vis Concurrent List of Seventh Schedule. This provision has far reaching consequences on the public health as- • It will not be possible with weak infrastructure and inadequate manpower for the CDSCO for proper vigilance leading to delay in action. • The local

					manufacturers have to travel many miles for persuasion or for getting licenses or endorsement of a product from CDSCO. This will be a burden on the SSI manufacturers. Moreover this may lead to contravene Article 246 of the Constitution of India as the subject is under concurrent list. By virtue of this, the proposed Sec. 18 (3) and Third Schedule is beyond the scope of the Constitution of India and therefore illegal and unconstitutional. Sera, vaccine, blood products should remain both in the domain of the CLA and SLA as it was before.
9.	Sec. 33V	Power of Central Government to	No such provision	This provision is a blatant attempt to	This provision for encroachment

		suspend, cancel permission, license or certificate granted by the State Licensing Authority....		usurp the power from State and is against the Constitution of India (article 246) as the subject is under the concurrent list. State is also answerable before State Legislature.	SLA's power should be dropped in the interest of the health of the people.

Hope you will kindly look into the matter seriously in the interest of the health of the people and will help the proposed universal health care. We may also apprise you in person if you give us an opportunity.
Thanking you and with best regards.

Yours faithfully,

Kaushik Desai
Hon. Gen. Secretary