Drugs and Cosmetics (Amendment) Act, 2015
A Bill further to amend the Drugs and Cosmetics Act, 1940

To Be Introduced in Budget Session of Parliament in 2015

PROPOSED CHANGES/ALTERATIONS (MEDICAL-RELATED) BY CONFEDERATION OF INDIAN PHARMACEUTICAL INDUSTRY

Serial No.	Page No. & Details	Clauses as per Guidelines	Changes Suggested	Reasons
1	Page No. 4 Section 3 **Definitions** (j) "drug" includes..	"drug" includes- (i) all medicines for internal or external use of human beings or …… (ii) such substances, other than food, intended to affect structure…… (iii) all substances intended for use as components of a drug including	The following changes may please be done: (i) "all substances" may kindly be replaced with "Active Pharmaceutical Ingredients" (ii) "such substances" be replaced with "such Active Pharmaceutical Ingredients" (iii) "all substances" may be replaced with "all Active Pharmaceutical Ingredients"	Reason to replace "such substance" and "all substances" as mentioned in part (i), "all substances intended to be used...." is very much confusing because there is no definition/ specified list of "all substances". In part (iii) the words " all substances intended for use as components of a drug....." are used, on the other hand the component of a drug is mostly chemicals, preservatives, essence, colourants, etc. and these substances can not be called drugs.
2	Page No. 4 Section 3 **Definitions**	Kindly insert a new subpoint (q) after subpoint (p)	(q) "Indian abbreviated new drug" means a combination of drugs which are individually already approved or are existing licensed medicines;	The inclusion of Abbreviated New Drug is very much required as the combinations (as described) can not be considered as new drug.

Serial No.	Page No. & Details	Clauses as per Guidelines	Changes Suggested	Reasons
3	Page No. 5 Section 3 **Definitions**	(r) "investigational new medical device" means a new device which is an object of a clinical investigation or research or development involving one or more human participants to determine the safety and the effectiveness of a device;	(r) "investigational new medical device" means a new device which is ~~an object of a clinical investigation or research or development involving one or more human participants~~ under investigation in a clinical trial to determine the safety and the effectiveness of a device;	The definitions of "investigational new medical device" and "investigational new drug" should be same.
4	Page No. 5 Section 3 **Definitions** (u) "manufacturer" means	"manufacturer" means a person who himself or through any other person on his behalf manufactures drug, cosmetic or medical device;	In new addition of definition of "Manufacturer", "or through any other person on his behalf manufactures" may be deleted.	If any person manufactures Drugs or Cosmetics from any person, he cannot be called manufacturer, because all the activities of manufacturing is done by the person who actually manufactured the drugs. Therefore, simply somebody has manufactured the drugs from any other person, legally, he can not be called manufacturer as he do not have any license for manufacturing of Drugs and cosmetics.

Serial No.	Page No. & Details	Clauses as per Guidelines	Changes Suggested	Reasons
5	Page No. 5 Section 3 **Definitions** (w)	(w) "new cosmetic" means any cosmetic containing ingredients which have not been established as safe for use in cosmetics;	This clause should not be substituted as such	There is no reference list that includes cosmetics which are not safe to be used.
6	Page No. 5 Section 3 **Definitions** (x)	(x) "new drug" (i) a drug, including bulk drug substance, which has not been used in the country to any significant extent under the specified conditions, recommended or suggested in the labelling thereof and has not been recognised as effective and safe by the Central Licensing Authority for the expected claims and its limited use, if any;	(i) a drug, including bulk drug substance, which has not been used in the country ~~to any signifiant extent under the specified conditions, recommended or suggested in the labelling thereof and has not been recognised as effective and safe by the Central Licensing Authority for the expected claims and its limited use, if any;~~	When a new drug is being defined as the one not yet used in the country the need to specify approval by CLA and recognition of safety and efficacy as parameterss is out of context.
7	Page No. 6 Section 3 (x) **Definitions**	(x) "new drug" (ii) a drug approved by the Central Licensing Authority for certain claims, which is proposed to be marketed with modified or new claims, namely, indication, route of administration, dosage and dosage form, including sustained release and novel drug delivery systems;	(ii) a drug approved by the Central Licensing Authority for certain claims, which is proposed to be marketed with modified or new claims, namely, indication, route of administration, dosage and dosage form, including <u>modified</u> ~~sustained~~ release and novel drug delivery systems;	Only sustained release can not be incorporated, the terms controlled and delayed are also related to the delivery systems, therefore, in its place, the term modified can be used.

Serial No.	Page No. & Details	Clauses as per Guidelines	Changes Suggested	Reasons
8	Page No. 6 Section 3 (x) **Definitions**	(x) "new drug" (iii) a fixed dose combination of two or more drugs, individually approved earlier for certain claims, which are proposed to be combined for the first time in a fixed ratio, or if the ratio of ingredients in a marketed combination is proposed to be changed , with certain claims, namely, indications, route of administration , dosage, dosage form, including sustained release and novel drug delivery systems;	(iii) a fixed dose combination of two or more drugs, individually approved earlier for certain claims, which are proposed to be combined for the first time in a fixed ratio, or if the ratio of ingredients in a marketed combination is proposed to be changed , with certain claims, namely, indications, route of administration , dosage, dosage form, including <u>modified</u> ~~sustained~~ release and novel drug delivery systems;	Only sustained release can not be incorporated, the terms controlled and delayed are also related to the delivery systems, therefore, in its place, the term modified can be used.
9	Page No. 7 CHAPTER 1(A) CLINICAL TRIALS Section 4A (3)	(3) New drug shall continue to be a new drug for the purpose of this Act for such period …..	It is already prescribed that new drug remains new drug for a period of 4 year from the date of its approval. Kindly delete 4 years and mention 2 years.	It is under general practice of Doctors that when any new drug comes into market, they start to prescribe the new drug, if the new drug remains new drug for 4 years then the manufacturer will be very few and the prices of such new drugs will be very high, therefore the availability of new drugs on reasonable prices from a period of 4 years to 2 years may kindly be done.

Serial No.	Page No. & Details	Clauses as per Guidelines	Changes Suggested	Reasons
10	Page No. 12 CHAPTER 1 A Section 4 T	(1) No prosecution under this Chapter……	(b), (c) , (d) kindly be deleted.	Reason to delete the (b), (c) , (d) is that it will create a lot of confusion if the prosecution is done by Gazetted Officer, the person aggrieved, any recognized consumer association, the manufacturer will remain in the Court if this b,c,d is amended.
11	Page No. 14 CHAPTER II Section 5 Sub-section-2(viii)	(viii) two persons to be nominated by the Central Government from the Pharmaceutical Industry	For "two persons to be nominated by the Central Government from the Pharmaceutical Industry", our request is to increase the members from 2 to 4 from Pharmaceutical Industry.	The pharmaceutical industry has grown in all the sectors, small scale, MSME, large industry and Multinational companies. The turnover of the total pharmaceutical industry is more than 1 lakh 40 thousand crore including exports. There is frequent changes in the Drug and Cosmetics acts and rules as well as international laws, therefore to understand the current situation of the pharmaceutical industry, at least 4 members are required (1) 1 member from the Small scale industry. (2) 1 member from Medium industry (3) 1 member from Multinational Company or as per the direction of Central Government. (4) 1 member from Large Industry.

Serial No.	Page No. & Details	Clauses as per Guidelines	Changes Suggested	Reasons
12	Page No. 14 CHAPTER II Section 5 Sub-section-2(xi)	(xi) One expert to be nominated by the Central Council of…..	3 more experts to be nominated from the Indian Pharmaceutical Association	Earlier, in the Country, there was only one association and now there are 5 association having there members throughout the country and working with Ministry of Health
13	Page No. 15 CHAPTER II Section 5 Sub-section-5	The Board may constitute sub-committes…….	The Board may appoint two members from CIPI whenever there is a constitution of sub-committees.	--
14	Page No. 19 Section 7F	CLA shall have exclusive power to issue a licence of any medical device.	It is suggested that previous system of issuing license be continued i.e. from the State Licensing Authority of respective states	India is a very large country and have so many states. Pharmaceutical manufacturer are located in every part of the country and remote areas also. Manufacturer may not approach to the Central Licensing Authority, Delhi or CDSCO headquarters. There is also a very big problem of language, many manufacturer are in such state where the language is not Hindi or English, may not be able to clarify the question asked by the Central Licensing Authority

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15	Page No. 22 Section 7 J (d)	Whoever, himself or by any other person on his behalf, import…… (d) other than a device referred to in clause (a) or clause (b) or clause (c)…..	Not less than 50 thousand and not more than 1 lakh	Small scale industry can not afford such huge fine.
16	Page No. 25 Section 9B	(f)- "If it does not contain active ingredient"	The said clause (f) should not be inserted.	This clause has already been covered under the same section (d)

Serial No.	Page No. & Details	Clauses as per Guidelines	Changes Suggested	Reasons
17	Page No. 27 Section 13 (a)	Whoever, himself or by any other person on his behalf, imports,- (a) any drug deemed to be adultrated under Section 9A or spurious under Section 9B shall be punishable with imprisonment for a term not less than 10 years and fine not less than 10 lacs	Existing punishment & further amended punishment are not under the purview of law as drug being manufactured in country other than India.	In case of imports of drugs it is advisable whenever any consignment of API or finished formulation or any drug imports to this country, sample may be drawn of each batch and sent to a government lab or any approved laboratory. If the samples are passed then there is no question of supply of spurious or adulterated drugs. If sample fails in any respect manufacturer of the drug that is a foreigner be conveyed and directed to him for sending his representative to India. Sample may again be collected in presence of representative of manufacturer and such samples may be tested in front of the representative of the manufacturer and if the sample is passing then the consignment be allowed to importer or if the sample is not passing then manufacturers be ordered to pay the whole amount to the importer and allow the manufacturer to rebook the consignment. It will be a crime if the importer on failing of sample prosecute under Section 9 A and 9 B

Serial No.	Page No. & Details	Clauses as per Guidelines	Changes Suggested	Reasons
18	Page No. 29 Section 17B	In section 17B of the principal act, after clause e, the following shall be inserted, namely:- "(f) if it does not contain active ingredient"	The said clause (f) should not be inserted as proposed.	Section 9(b) of the principal act deals with spurious drugs and it is already well covered. If the proposed is inserted it will cause confusion at the time of testing.
19	Page No. 31 Section 18 Para 2	(2) The license for the manufacture for sale or distribution or marketting of any new drug shall be issued by the Central Licensing Authority in such manner as may be prescribed.	This clause should be omitted from Section 18 and be included as separate Section as under:- (2) The approval for the manufacture for sale or distribution or marketing of any new drug shall be issued by the Central Licensing Authority in such manner as may be prescribed.	Under the existing law, DCGI is authorized to grant approval to manufacture new drug and manufacturing license is granted by the State Licensing Authority. If Section 18(2) is included as proposed practically more than 70% manufacturers in the country will be required to obtain license from the Central Licensing Authority. Such manufacturers will also be required to obtain manufacturing license from the State Licensing Authority as such manufacturer will also be manufacturing drugs not covered by the definition of new drug.

Serial No.	Page No. & Details	Clauses as per Guidelines	Changes Suggested	Reasons
20	Page no. 31 Section 18 Para 3	(3) Notwithstanding anything contained in sub section (1), on and from the commencement of the Drugs and Cosmetics (Amendment) Act, 2014, the Central Licensing Authority shall have exclusive power to issue a license in respect of manufacturer for sale or for distribution or for marketing of drugs specified in the Third Schedule in such manner as may be prescribed.	It is requested that this clause may not be inserted.	This clause if inserted in the proposed para , there will be no existence of small scale pharma manufacturers on the map of India. The country is so large and saperated by various states and it will be very difficult for the manufacturers, who are having their units much far away fom Delhi or CDSCO offices. Further it is noted that if this proposal is accepted, then more than 80% of drugs available in the market will have to be licensed by the CDSCO and the officers of the State Drug Control Office will remain idle. Rest reason is covered in Annexure 2
21	Page no. 33 Section 23	The Drugs Control Officer or any other officer duly authorised by the Central Government, State Government, the Drugs Controller General India or State Drugs Controller by whatever name called, as the case may be, shall take sample of drug, cosmetic and notified category of medical device for test, analysis and examination under Chapter IIA, Chapter III nad Chapter IV in such manner as may be precsribed."	It is suggested that only drug control officers may collect the samples. There is no need for any other officer to do the same.	Collection of sample is a legal procedure and can only be taken by the person with complete experience. Moreover, there is no need for any other officer as there are sufficient number of drug control officers in the country.

Serial No.	Page No. & Details	Clauses as per Guidelines	Changes Suggested	Reasons
22	Page 34 Section 27 (d)	(d) any drug deemed to be misbranded under Section 17, shall be liable for penalty which may extend to two lakh rupees to be imposed by the Central Licensing Authority or State Licensing Authority, as the case may be, in such manner as may be prescribed.	(i) It is requested that the following may be replaced; any drug deemed to be misbranded under section 17 or not of standard quality as mentioned in the government analyst's report. (ii)which may be extend to one lakh rupees Provided that the Central Licensing Authority or State Licensing Authority may, for any adequate and special reasons, to be recorded in the judgement, impose a penalty which may extend to two lakh rupess.	"Not of standard quality" word is used by all professionals and the report issued by the government analyst throughout the country mentions drug "Not of Standard Quality".
23	Page 34 Section 27 (e)	(e) any drug other than a drug referred to in clause (a), or clause (b), or clause (c), or clause (d), in contravention of the any other provision of this chapter or any other rule made under the Act, shall be liable for penalty which may extend to five lakh rupees to be imposed by the Central Licensing Authority or State Licesing Authority, as the case may be, in such manner as may be prescribed".	It is suggested that the following be replaced that is from Rs. 5 Lac to rupees fifty thousand. Provided that the Court may, for any adequate and special reasons, to be recorded in the judgement, impose a penalty of rupees fifty thousand.	In small sector, mostly technocrats are running their units and also work as technical experts And their business is limited. Such heavy fines of Rs. 5 Lac is not possible to be paid.

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24	Page No. 35 Section 28	In section 28 of the Principal Act, for the words "may extend to one year or with fine which shall not be less than twenty thousand rupees or with both", the words "shall not be less than three years and shall also be liable to fine which shall not be less than three lakh rupees" shall be substituted.	The ammendments in the Section 28 of this Act is not feasible. It is suggested that Section 28 of the Principal act may remain as previous. Provided that the Court may, for any adequate and special reasons, to be recorded in the judgement, impose a sentence of imprisonment for a term which may extend to one year or with a fine which shall not be less than twenty thousand rupees or with both.	The penalty suggested in this section is very harsh in respect of the nature of offence. Moreover, there is no scope for appeal. Such type of disclosure is to be done by Small chemists and druggist where the total value of the shop may not be of three lakh value.
25	Page No. 35 Section 28A	In section 28A of the principal Act, for the words "may extend to one year or with fine which shall not be less than twenty thousand rupees or with both", the words "may extend to three years or fine which may extend to rupees three lakh or both" shall be substituted	The ammendment in Section 28A is not required. It is suggested that Section 28Aof the principal act may be as pevious. Provided that the Court may, for any adequate and special reasons, to be recorded in the judgement, impose a sentence of imprisonment which may extend to one year or with fine which shall not be less than twenty thousand rupees or with both.	This ammendment is not suitable to the small scale industry, therefore, kindly do not ammend this section. The penalty suggested in this section is very harsh in respect of the nature of offence. Moreover, there is no scope for appeal. Such type of disclosure is to be done by Small chemists and druggist where the total value of the shop may not be of three lakh value.

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26	Page No. 35 Section 28B	In section 28 B of the principal Act, for the words "may extend to three years and shall also be liable to fine which may extend to five thousand rupees", the words "shall not be less than three years and shall also be liable to fine which shall not be less than five lakh rupees" shall be substituted.	It is suggested that the Section should be substituted as:- the words "shall may extend upto 2 years and shall also be liable to fine which may extend upto fifty thousand rupees. Provided that the Court may, for any adequate and special reasons, to be recorded in the judgement, impose a sentence of imprisonment for a term which may extend upto 2 years and a penalty which may extend upto fifty thousand rupees.	It is noticed that such type of notification issued by the ministry of health is not known to all the manufacturer immediately. Sometimes it takes months to know the changes in Law. Therefore, our suggesstion may kindly be accepted.
27	Page No. 36 Section 30 Sub section (1A)	(ii) in subsection (1A), for the words "may extend to two years, or with fine which may extend to two thousand rupees", the words "shall not be less than three years and shall also be liable to fine which shall not be less than ten lakh rupees" shall be substituted;	The section may not be amended.	Punishment is so harsh and is not reasonable. If the technocrats will remain behind the bars then the pharma industry will be vanished.

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28	Page No. 36 Section 30 Sub section (2)	(iii) in subsection (2), for the words "may extend to two years , or with fine which shall not be less than ten thousand rupees or with both", the words "shall not be less than two years and shall also be liable to fine which shall not be less than one lakh rupees" shall be substituted.	The section may not be amended.	Punishment is so harsh and is not reasonable. If the technocrats will remain behind the bars then the pharma industry will be vanished.
29	Page No. 36 Section 30	(iv) after sub-section (2), the following sub-section shall be inserted, namely:- (3) Whoever having been convicted of an offence under section 28A or section 28B is again convicted of an offence under that section shall be punishable with imprisonment for a term which shall not be less than three years but which may extend to five years and shall also be liable to fine which shall not be less than five lakh rupees"	This sub-section may be omitted	Punishment is so harsh and is not reasonable. If the technocrats will remain behind the bars then the pharma industry will be vanished.

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30	Page No. 37 Section 31	In section 31 of the principal Act, in sub section (1), in clause (ii), for the words, brackets, letters and figure "clause (c) of section 18", the words and figures "section 18", shall be substituted.	There is no need to ammend this section.	There is every possibility that on few labels, there can be mis-printing.
31	Page No. 39 Section 33V	33V (1) The Central Government may suspend or cancel any permission, license or certificate issued by the Central Licensing Authority or a State Licensing Authority, in public interest and for reasons to be recorded in writing, by notification. (2) Where the Central Government is satisfied that the permission, licence or certificate specified under sub-section (1) is not in accordance with the provisions of this Act and the rules made there under, that Government may, by notification, suspend or cancel such permission, licence or certificate".	Proposed Section 33V may be omitted.	The Central Licensing Authority and State Licensing Authority are quasi-judicial authorities and are expected to function within the frame work of the Drugs and Cosmetics Act, 1940 and Rule, 1945. It is not desirable to vest powers to suspend or cancel license or permission granted by the quasi-judicial authority in the Central Government. The proposal to give powers to the Central Government to suspend or cancel license granted by the State Licencing Authority appointed by the State Government amounts to encroachment of the powers of the State Government.

Serial No.	Page No. & Details	Clauses as per Guidelines	Changes Suggested	Reasons
32	Page No. 40- Section 34 AAA	34AAA- Whoever himself or by any other person on his behalf imports, maufactures, stocks, sells, or distributes, or intends to do so, any drug or cosmetic or notified category of medical device and submits misleading or wrong information or refuses to provide correct information in that regard as required by the Licensing Authority under this Act shall be punishable with imprisonment for a term which shall not be less than two years and shall also be liable to fine which shall not be less than one lakh rupees.	This is extremely harsh punishment as compared to nature of offence. Instead of providing minimum punishment the powers should be given to the Central Licensing Authority as the case may be to impose fine. 34AAA- Whoever himself or by any other person on his behalf imports, maufactures, stocks, sells, or distributes, or intends to do so, any drug or cosmetic or notified category of medical device and submits misleading or wrong information or refuses to provide correct information in that regard as required by the Licensing Authority under this Act shall be liable for penalty which may extend to two lakh rupees to be imposed by the Central Licensing Authority, as the case may be.".	This provision is open to misinterpretation by the officers. It has been noticed that voluminous information is asked and that too within two days within four days etc. Failure to comply such directions will expose the manufacturers and dealers to minimum imprisonment. Whether the information is correct or is misleading is subjective and is open to interpretation against the manufacturer or dealer.