CONFEDERATION OF INDIAN PHARMACEUTICAL INDUSTRY (SSI) (Regd.)

(Registered Office : A-3/314, First Floor, Paschim Vihar, New Delhi-110063)

Mailing Add. : 128, Lok Vihar Appts., Vikaspuri, New Delhi - 18. Fax : 011-28538801, E-mail : sk_aries2001@yahoo.co.in, Website : www.cipi.in
Chairman Office : **BELCO PHARMA** 515, MIE, Bahadurgarh-124507, Haryana E-mail : pkgupta_cipi@yahoo.in

Chairman :	*Co-Chairman :*	*Secretary General :*	*Treasurer :*
P. K. Gupta	**Dr. A.M.D. Nambudiri**	**B. Sethuraman**	**R.K. Jain**
Cell : 09811106606	Cell : 09847030460	Cell : 09444083286	Cell : 09312285623

Constituent Members

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All India Small Drug Mfrs. Association, Mumbai-400014

Gujarat Pharma Small Scale Industries Association, Vadodara - 390002

Haryana Pharmaceutical Mfrs. Association, Ambala City - 134003

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Bahadurgarh Pharmaceuticals Mfrs. Association, Bahadurgarh-124507

Ref. No.: CIPI/2015/612
9th February 2015

Dr. G.N. Singh
Drugs Controller General (India)
FDA Bhawan, New Delhi

Sub: **Meeting with the Associations of Pharma Manufacturers on 21st February, 2015 at FICCI**

Dear Sir,

We whole heartedly welcome and appreciate your move to hold the above meeting for an interaction with the stake holders concerning the regulatory issues. We are definitely moving towards complete transparency, accountability and overall improvement in our day to day dealings and updates through the website of CDSCO. This is a great relief to the manufacturer across the country as they can track their applications through internet by logging to your website. In spite of all this, there are a number manufacturers specially in small and medium segment who are not taking the benefit of this facility. In this regard our humble request is that CDSCO throughout the country through its respective zonal offices may conduct workshops to educate the manufacturers about the availability and the benefits of this facility.

As desired by you, we are pleased to mention our issues and general information.

General Information

There are about 9500 units which are licensed by the State Drugs Controllers of the Country out which about 1500 units are ideal as they are not manufacturing or they are holding the licenses for future planning.

Total Pharmaceutical Formulation Units	:	9500
Non functional Units	:	1500
Large / Multinational Companies	:	800
Medium scale units	:	1000
MSME Units	:	6200

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Issues of small and medium scale units

As shown in the figures above, there are 6200 pharmaceuticals manufacturing units which are MSME segment having their presence across the country, even in remote areas. It is quite possible that in certain cases micro and small units may not have implemented Schedule M as far as infrastructure and certain other provisions of the D&C Act and Rules are concerned. Due to liberal policies of the States and Central Government and price control on drugs under DPCO their infrastructure and functioning have been accepted, as a result, more than 90% of such units have go their licenses renewed.

In the present scenario, where the D & C Act and Rules are reviewed frequently, SME segment is facing numerous problems and the working has adversely affected. The latest being the proposed D & Cosmetics Act (Amendment) Bill, 2015 under which grant of manufacturing of 17 drugs is to be shifted to the office of DCGI requiring the manufacturers to approach CDSCO(HQ) for grant and renewal of their licenses.

Q.1 What is the future of Pharmaceutical MSME sector?

Transparency/ Accountability

All small scale or Medium industries are working under the Drugs and Cosmetics Act and Rules, 1945. It has been noticed, at the time of inspection of our units either by the officers of State Drugs Controller or by CDSCO or both, there is always difference of opinion between State officers, CDSCO officers and manufacturers. There is always an argument that the documents maintained by the company are not to their satisfaction. When the manufacturer tells that all these documents have already been approved by the previous inspection team, the present inspection team insists to maintain the document as per their advice. Accordingly, the manufacturer advices its staff to maintain the documents as per the new instructions and this happen during each and inspection. The net result is that small scale industry's technical staff remains busy on to changing the documents.

Q.2 Whether it is possible that CDSCO to a prepare Model Proforma of all the documents whether it is a SOP, MFR, Qualification of Equipments, validation and documentation for various types of approvals etc and so that a uniformity be

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maintained throughout the country or to prescribe all the documents in detail like Schedule U and V is prescribed in Drugs and Cosmetics Rules?

Issue of Reference Standard

In the current Indian Pharmacopoeia, British Pharmacopoeia and United States Pharmacopoeia, every year almost in all the products some extra parameters are incorporated. The biggest issue which are faced by the small scale industries is the non availability of reference standards and the impurity standards to check the impurity test which is almost in all the products, these impurity standards are available only in developed countries and the price is so high e.g. 20 mg costs minimum 800 U.S. Dollars and this may not be sufficient to check the production of one batch i.e. checking of raw material and finished goods.

Q.3 Sir, how to resolve this issue of reference standard, especially to check impurity test?

Issue of quality drugs viz a viz functioning of State Laboratories

It is noted that 70% Laboratories in the country have no infrastructure, no equipment as desired under current good laboratory practices. The labs do not have any reference standard especially to check limit test for testing of finished goods and raw materials as given in pharmacopoeia. There is no system of purified water, continuous electricity i.e., 24 hours and above all, trained staff for testing, micro expertise and to handle the sophisticated instruments. In view of this, we cannot reach to a conclusion about the quality of a drug tested at state laboratory..

All the test reports issued so far, majority of them have discrepancies in the report itself. One time, Govt. Analyst declares a clear and colorless solution. In the same reports, he mentioned colored solution. It is also surprising that any report issue by State Laboratories, when challenged in Central Drugs Laboratory (CDL), State Laboratory says the product assay is 10% and CDL says, it is 100%. There is vice-versa also, State Laboratory says 90% while CDL says, it is 10% for the same product.

Therefore, it is dangerous to test a drug in the state laboratories where there is no infrastructure, no expert technical staff, no continuous electricity. If in such laboratories, legal samples will be tested either spurious drug will be declared of standard quality or a

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Q.4 Kindly explain what is the view of Ministry of Health or office of CDSCO in case of State laboratories as explained above.

Our suggestion is that the State Testing Laboratories may be asked to adopt the below mentioned procedure:

- Government Analyst, while sending the Test report to the inspector, shall also send complete testing procedure and all the calculation made during the testing of such sample.

- Government Analyst shall not issue the sample report if he/she is not having proper equipments, chemicals, reference standards required for testing generic products and proprietary and patented drugs. If Government Analyst does not have a testing procedure, he/she must ask to the manufacturer of drugs for providing testing procedure before testing the sample.

- Government Analyst shall maintain all the records and remaining sample for a period of 5 year or for six months after the expiry of product.

- Government Analyst shall maintain a log book for all the instruments installed in the laboratory.

- Government Analyst shall maintain microbiological area as given in the Drugs and Cosmetic Act and Rules. Further it must be free from bacteria and fungus, before to test any sample.

- Government Analyst shall maintain high standard of cleaning and sanitation

- Government Analyst shall implement the Schedule M and L1 of Drugs and Cosmetics Rules 1945.

Issue of FDCs

The matter has been discussed several times in the past, but so far no conclusion has come out. Industry is upset and worried about their licensed products which are in the market for a very long period.

Q.5 Sir, you are requested to kindly inform as to how the MOH wants to resolve this issue?

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Issue of WHO-GMP/COPP

For the last 20 years, WHO-GMP plants were approved by SDCs by holding a joint inspection of CDSCO and SDCs. In the 46th meeting of the DTAB as per agenda item no. 5 for issue of COPP, the guideline require the firm to apply to the SDC and one set of document shall be sent to CDSCO Zonal Office . CDSCO will scrutinize all the documents and will give its opinion within 21 days whether to issue the COPP or to furnish further documents as required. Only after the recommendation of CDSCO, the technical committee in the state will scrutinize the documents.

If everything is in order, SLA will issue the COPP and if there is a query, the applicant will be informed. This is a lengthy procedure and not acceptable to the industry. Due to non-availability of COPP in time the Country is losing foreign exchange.

Q.6 Sir, today we are losing foreign exchange for want of one document i.e. COPP.

Issues of Exporters, Industry and Trade about Hardship faced at Ports

1. A number of exporters have informed us that the NOC for export is not granted by the ADC at Airport mainly for FDCs which are licensed by SLAs but not approved by DCGI.

2. Many a times, it is pointed out by ADC airport that the label is incomplete, whereas rule 94 of D & C Act allows such product which have minimum information on label as per rule 94 of Drugs and Cosmetics Rules. At the time of import, sometimes, samples are taken by the ADC and a bond is furnished by the importer to carry the goods but such drugs cannot be used until reports come from laboratory.

3. Sometimes, laboratories take long time for testing the material resulting in delays and cancellation of export orders. Samples are also taken of the drugs which are approved by DCGI and of the drugs which are imported against advance license even on furnishing an undertaking that the imported raw materials will not be used in domestic market.

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Q.7 Sir, as mentioned above, this is a very lengthy procedure, by the time reports come from analytical laboratory either the importer of formulation cancel the order or letter of credit issued by the importer expired.

Seek your advice.

Issue of Drugs Banned by DCGI

It has been noticed that sometimes drugs are banned with immediate effect without giving any opportunity to the industry and trade. This issue may looked in to so that wherever possible the industry may be given time to liquidate the stock in the market.

Draft D&C Act (Amendment Bill), 2015

In the act amendment 2015, definition of drugs has been changed i.e.

1. All substances intended for use as components of a drug thus it means that all the excipients used in the manufacturing of formulations i.e. ointments, oral liquids, tablets, capsules, injectable substances which includes starch, lactose, talcum, essences, propylene glycol and so any other chemicals.

2. Whether such substances mentioned above shall also appear on the label and permission for their use may be taken at the time of approval of additional items from the state drug controller.

3. Definition of manufacturer to be changed.
   The definition of manufacturers has been changed, Now manufacturers means a person who himself or through any other person on his behalf manufacturing drugs, thus it means the companies which get their products manufactured from any other company on third party basis shall also be treated as manufacturers.

Q.8 Kindly clarify it.

CiPi

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Other Issues

i) **DCGI** directed to the manufacturers that paracetamol used with any other analgesic be maintain quantity of paracetamol not more than 325 mg. In few states general letter issued that in such cases fresh permission is not required, manufacturers should reduce automatically. However it is noticed that few states asked for fresh renewal.

ii) In many states it has been allowed that if any drug is approved under brand name the same drug can also be manufactured in generic name. Similarly, if the manufacturers have approval in generic/ proper names, can manufacturer the same drug under brand name, in both the cases permission is not required from the state drug controller. However in many SLAs insist to take permission in both the cases.

iii) If any product approved earlier under BP and USP but now has been incorporate in IP, whether we need a fresh approval of state drug controller or we may start production as per IP, without any fresh permission.

iv) It is also noted that many states are giving permission to manufacturer additional items under BP/USP, but a few states refuges to give permission and the manufacturers are advised that it is a new drug and to approach to the DCGI.

v) What is the status of veterinary drugs for which so far the permission has been given by State Drug Controllers, It is also noted that DCGI from 1961 has not approved any veterinary drugs.

vi) It is noted in the product list of DCGI, Lotopredinol etavonate ophthalmic solutions is approved on 15/3/2002 as a clear solution, but all the preparations available in the market is in suspension form. It is also noted in the list of new drugs approved by DCGI, many products do not have strength and many products do have dosage form i.e capsules or tablets etc.

vii) PET Containers: Kindly advise the Government's stand about the use of PET containers in drug formulations.

For Confederation of Indian Pharmaceutical Industry

P. K. Gupta, Chairman