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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Goa Pharmaceutical Mfrs. Association, Mapusa - 403526

Ref. No.: CIPI/2015/1073
29th November 2015

Hon'ble Shri J. P. Nadda
Union Minister of Health & Family Welfare
Government of India, Delhi

Sub: **Representation on behalf of Confederation of Indian Pharmaceutical Industry (CIPI) (Small Scale) to resolve the various difficulties faced by Small Scale Industry of Pharmaceutical formulations in India.**

Hon'ble Sir,

ABOUT CONFEDERATION OF INDIAN PHARMACEUTICAL INDUSTRY (CIPI)

CIPI is the apex body of the manufacturers of drugs and pharmaceutics in the country representing all Pharmaceutical formulation units. All the major State level associations of the Pharmaceutical manufacturers in this segment are federating members of CIPI representing about 7000 pharmaceutical units and having domestic turnover of Rs. 40,000 crores and exports approximate Rs. 30,000 crores.

Sir, we extend our deepest gratitude for the successful working of Ministry of Health and Family Welfare under your able leadership supported by officials of the Ministry of Health & Family Welfare. We are further pleased to confirm that functioning of Drugs Controller General (India) office at FDA bhavan is doing excellent job with complete transparency and industry finds their job within a stipulated period, any delay or deny is dealt with heavy hands by the DCG(I).

Sir, we are grateful to you for providing us an opportunity for the unresolved issues concerning to the Indian Pharmaceutical Industry. Sir, that will be a great moment when Hon'ble Health Minister with his senior officers shall sit with the pharmaceutical industry to listen to their issues and to decide on the spot, such a moment will be wonderful.

Contd.... 2

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Sir, there is no doubt that medicine manufactured in India by small scale sector is well accepted by all countries except Europe and United States of America. This all because of quality drugs at affordable price.

Sir, this is the only reason that the small scale sector who has forced the developed countries to take a notice of small scale industry in India. The reason is very simple, the medicines were exported from Europe and USA to under-developed countries on a very high price. As a result, the pharmaceutical industries in Europe and USA now have an eye on small scale sector Pharma industry in India.

Sir, for further growth in exports and to manufacture zero defects medicine both for export and domestic market, we have few issues which are needed to be resolved immediately. Such issues are mentioned below:

1. **Issue of 294 Fixed Dose Combinations (FDCs) banned by earlier DCG(I) (Mr. Venkateshwar Loo) in the year 2007, viz. a viz. stay order from Madras High Court:**

   DCG(I) banned 294 FDCs by simply issuing a terse letter addressed to different State Drugs Controller (SDCs) at state levels and this was not all as there were several other drugs formulations under scrutiny to be banned in near future. Many associations including Confederation of Indian Pharmaceutical Industry (CIPI) approached the then DCG(I) and requested him for to lift the ban on 294 drugs. For further discussion, meeting was organized by DCG(I) at Niper, Mohali where all the association, State Drugs Controllers (SDC) of various states and Managing Director, CEO of Large companies were present.

   Pharmaceutical industry invited the kind attention of DCG(I) that banning of 294 FDCs is not justified and is not according to the spirit of Drugs and Cosmetics Act. But the DCG(I) did not agree to lift the ban on 294 FDCs. Industry was not having any other option except to approach the legal system of the country.

Contd...3

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Thus a petition was filed by CIPI at Madras High Court. The hon'ble judge of Madras High passed a stay order on such a ban and that stay order is still in force. However, during this period a committee was formed by the DCG(I) to check the rationality of the FDCs but so far no order has been passed by the office of DCG(I) and the matter is pending in the Madras High Court. We have already said to the members of the committee and DCG(I), if any product is irrational, industry is ready to accept that but the matter shall be decided without any further delay.

May be resolved as under:

This matter is pending for the last nine years, we request kindly suitable directions be passed.

2. Issue of safety and efficacy for all FDCs which were permitted to manufacture by SDCs without the approval of DCG(I):

DCG(I) issued a letter dated 15.01.2013 to all SDCs/ UTs directing them to convey the manufacturing units of their states for approval of safety and efficacy of FDCs which was permitted for sale by SDCs in the country without due approval from office of DCG(I). A lengthy procedure having implication of Finance, when we noticed the procedure and finances involved, we were of the opinion that small scale sector may not be in a position to provide so many documents and finance. The majority of the manufacturers in small scale sector have decided once again to approach the legal system of the country.

Thus, federating member of CIPI filed an application at Punjab and Haryana High Court at Chandigarh and Himachal Pradesh High Court at Shimla and both the High Court stay the contents of letter dated 15.01.2013 and subsequently letters. Both the cases are pending in respective High Courts at preliminary stage.

Our request to the Hon'ble Union Health Minister of India that if any FDC is irrational, that can be banned.

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Sir, it is to be noted that so far by consuming any FDC available in Indian Market or in exporting countries, it is a matter of satisfaction that so far no adverse report (grossly substandard) is received throughout the country.

3. Frequent amendments in the Drugs and Cosmetics Rules (Schedule M, L or other rules):

Sir, as you are aware that in the year 2003, Central Govt. made draft rules for revising the already difficult schedule M.

The revised Schedule M was so stringent that it was not possible to fulfill its different parameters by our small scale units. Being extra land and huge amount of money was involved, we approached the then Health Minister Smt. Sushma Swaraj, very kindly she listened to us and decided to extend the date of its implementation and also accepted the industry demands for deletion of few rules. After that, all the manufacturers throughout the country did best and made possible changes which were approved by the SDCs under the guidelines of new schedule M.

Another draft rules in schedule M have been circulated by Ministry of Health to know the views of the pharmaceutical industry.

Small scale sector who is working in the domestic market have not much resources and further not interested to increase the cost of the production, as many drugs are under Price Control whereas other drugs also need to be sold on reasonable prices.

Sir, we invite your kind attention that there are about 7000 units which are actually working. Out of that 1000 units are of large nature and have approvals from Europe, Pharmaceutical Inspection Co-operation Scheme (PIC/S), USFDA, the present draft rules of Schedule M is already implemented by these companies.

Contd... 5

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Sir, another 1000 units of Medium scale sector have already been certified on the guidelines of WHO GMP. These units are also implementing the revised Schedule M.

Sir, remaining units which are in category of small scale, many units may have implemented revised Schedule-M & many of them in the process of implementing them. The target to achieve **further revised Schedule M** seems to be difficult as many chapters are new for the industry and there is no institute to educate the manufacturers / technical staffs. Many companies in Small Scale Sector do not have extra space to put extra computer or to store documents, new guidelines of schedule M is on the line of WHO GMP and PIC/s.

May be resolved as under:

We request to find a solution which may not hurt the oldest small scale industry of this country who are responsible for the supply of drugs in the remotest area of the country and also help in maintaining the price line of this sector.

4. Frequent amendments in Drugs and Cosmetics Act in respect of increase in punishment

Sir, we draw your kind attention that punishment:

Under Section 27(a) of Drugs and Cosmetics Act: was enhanced to its maximum i.e. life imprisonment along with fine which is not less than 10 Lakh rupees whereas

Under section 27(b): punishment has increased from 3 years to 5 years along with fine which shall not be less than One Lac rupees.

Under sub-section 27(c): punishment is increased to 7 years and may extend to life with a fine which shall not be less than Three Lac rupees.

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Addition of New Section 36(AC): offences under this section shall be cognizable.

Sir, another draft rules published by Ministry of Health and Family Welfare on 31.12.2014. In the said amendment bill, in

Section 13 (a) : increased the punishment from maximum 3 years to minimum 10 years.
Section 27(d) : for small offences heavy penalty has been imposed i.e. 2 Lakh rupees.

Section 27(e) : this is another section incorporated after the 27(d) and heavy penalty of Rs. 5 Lakh has been imposed for small offences.

Section 28: penalty enhanced from 1 year to 3 years and fine from Rupees 20 thousand to 3 lakh.

Section 28A: penalty enhanced from 1 year to 3 year and fine from Rupees 20 thousand to 3 lakh.

Section 28B: Penalty has enhanced from "May extend to 3 years" to "shall not be less than 3 years" and fine from Rupees 5000 to 5 Lakh.

Sir, as mentioned above Drugs and Cosmetics Act was amended in 2008, in the said amendments, punishment was increased many fold along with fine, now once again Ministry of Health has published draft rules for the amendments in the Drugs and Cosmetics Act, 1940. This bill is presently pending in the Parliament.

The best straw on the camel's back is the passing of a hill. Recent amendment in Drugs and Cosmetics Act recommending the offence nonbailable, stringent punishment and heavy penalties and powers given to the police for registration of cases, but they have not provided any safe guards for genuine manufacturers. The implication of this draconian law are just horrifying when seen in the context of technical flaws:

Contd...7

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Technical Flaws

- Inadequate infrastructure in testing laboratories.
- Lack of Technical Expertise.
- Drug sample passing in all tests yet declared to be of sub standard quality.
- Error in calculation.
- Wrong testing method adopted by Testing Laboratories.
- Difference of opinion in state laboratories and Central Drugs Laboratory (CDL).
- Lack of control on labs by State or Central Government.
- Storage condition at retail shops.

5. Adulterated/Spurious drugs viz. a viz. Working of Government testing laboratories in the country:

We invite your attention to the enclosed test report of the Drugs Laboratory, Kandaghat (HP) concerning the sample of Ceftriaxone-1000 Injection tested by them. The following discrepancies may be noted:

i) Ceftriaxone 1000 Injection in IP, there are more than 9 to 10 tests are prescribed, whereas the Govt. Analyst performed two tests i.e.

- Assay
- Particulate Matter

Further we are surprised to note that the Govt. Analyst has passed the product in Assay and has failed it on account particulate matter.

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Regarding Assay, the Govt. Analyst has declared that the powder is 1.065 g and if we calculate in respect to conversion factor than the filled quantity of the power, shall be 1.2 g approximately therefore as per this, product failed in Assay and have not performed the other tests. This proves that the Govt. Analyst does not know the testing method.

ii) The same discrepancy has been found in the other report also. In this case the filled power must be 1.3 g where as the analyst found the same as 1.02 g.

I have numerous reports in my possession, where a state laboratory declares content of the active drug in a formulation to be 10%, the same sample when tested at a central laboratory is declared to be 100% in quantity, the same is true otherwise also, where the state laboratory declares a sample to be of 90% quantity, the central laboratory finds it 10%. It is beyond our imagination, how a medicine tested on certain prescribed scientific principles, can have two completely opposite results. You will appreciate that this is not opinion of a judge which may differ from one presiding officer to another. A drug sample is tested on the prescribed protocols which are uniform through out, hence the outcome of the result can vary except for negligence and other deviation.

I have a report with me, where in Betamethasone cream manufactured as per British Pharmacopoeia, was supplied to a govt. hospital. Its sample was drawn by the drugs inspector & sent for analysis to CDL, Kolkatta.

On receipt of the analytical report by the manufacturer, he was shocked to find that report had declared the sample to contain NIL medicine. On scrutiny of the said report by the manufacturer, he was surprised & amused that the CDL, Kolkatta, Which had failed the sample, had applied a wrong testing method which was not to be found in the British Pharmacopoeia.

Contd... 9

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Actually, the CDL analyst, by negligence had applied a method of testing given in Indian Pharmacopoeia, in Indian Pharmacopoeia actually there is no method of testing betamethasone cream, but however, there is a method to test betamethasone ointment. On comparison of both the methods of IP & BP, it was found that both were entirely different.

Subsequently, the opinion was sought from The Registrar, British Pharmacopoeia, UK, who opined that it is not possible to test Betamethasone cream with the method of betamethasone ointment as contained in IP. On reference of all these opinions including the one from UK to CDL, Kolkatta, they still persisted with their opinion that they had adopted the correct procedure. Since as per Act, CDL is the final authority, no other laboratory can officially test this. Thus a product which was 100% genuine was declared spurious.

May be resolve as under:

The industry is of a very strong opinion that equal responsibility be placed, whether on a drug manufacturer or an analyst, who so ever be at fault, the manufacturer for making fake drugs & the analyst for making wrong declaration & thus landing an innocent manufacturer in jail.

We believe that let a milk sample be declared, Milk only and not as water. Once the testing laboratories realize that their faulty declaration can be held against them also, they would be doubly cautious before declaring the outcome of a drug sample. It may be of interest for you to know that nearly many drug samples, declared spurious are because of laboratory negligence. This would automatically bring down the incidence of spurious drugs.

May be resolved as under:

A committee under the supervision of DCG(I) comprising of Senior officers of DCG(I) office and if possible two Government analysts from any state and director, CDL, Calcutta be constituted for finding the working of Government Analyst throughout the country.

Contd...10

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Infrastructure, equipment, reference standards, chemicals and procedures of testing.

6. Issue of Huge Variations while inspecting the units

Huge variations in methodology of working even in the same state. It is observed that each inspecting authority in the same state tends to disagree or disallow the works, procedures & infrastructure, once permitted by the previous officer.

May be resolved as under:

It is requested that necessary advice or message be conveyed to all the licensing authorities, that once an infrastructure is approved at the time of grant of licence & similarly once the documents are approved during yearly inspection, no query be raised in this respect subsequently, barring those circumstances, where arbitrary changes have been made by the licensee or any provisions in the act so demand due to any amendment.

7. Inspections done by state officers and joint inspection by state and CDSCO officers:

The Drugs and Cosmetics Act prescribes inspections of the units should be once in a year. However, authorities sometime inspect the plant 2-3 times in a year. The companies which have been licensed under revised schedule M also be asked at the time of inspection changing in the infrastructure, plant and machinery.

May be resolved as under:

It is our request that units may kindly be inspect once in a year. However in the case of a complaint the inspecting authorities may inspect any firm, in such cases the inspection be confined to the specific complaint, inspecting authorities may not object infrastructure, building, plant and machinery. However, working defects can be advised and the firm be guided by inspecting staff in such cases.

Contd...11

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8. Issue of Indian Pharmacopoeia (I.P.), British Pharmacopoeia (B.P.) and United States Pharmacopoeia (U.S.P.):

Sir, I.P., B.P. and U.S.P. drugs are being manufactured for the last more than 30 years. Suddenly State Drugs Controllers of various states have stopped to give the permission to manufacture I.P., B.P. and U.S.P. products in many of the states. However, few states are giving permission to manufacture under the same Pharmacopoeia. Therefore there is no uniform policy adopted by the states.

May be resolved as under:

Directions may kindly be issued to ask all the states or State Drugs Controller (SDCs) to give approval for I.P., B.P. and U.S.P. products.

9. Issue of Brand Name/Trade Name to be permitted to manufacture under Generic name without obtaining separate permission:

Sir, Government of India, Ministry of Health and Family Welfare has instructed to State Drugs Controllers (SDCs) that any product be approved under Generic name/Proper name only. Therefore present approvals given by present State Drugs Controllers is only under generic name. However, many SDCs refusing to approve the products under generic name which are approved before such instructions and many states like Punjab, Madhya Pradesh allowed to the manufacturers to manufacture the earlier approved brand name drugs in Generic name.

May be resolved as under:

Sir, now it is a policy of Ministry of Health, not to approve any brand name therefore already approved brand name may be allowed to manufacture in generic names.

Contd...12

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A, B, C may be resolved as under:

Appropriate guidelines may be issued to the state and central medicine procurement agencies for uniform policy in respect of turnover, COPP and usual strength as per I.P.

11. Products permitted by a state, other states' Drugs Controller refuse to approve the same product:

It is noted that some states give approval to manufacture FDC whereas other states are not giving permission of the same formulation. However, the same formulation is being used throughout the country.

May be resolved as under:

Maintain uniformity among the states.

12. Renewal of manufacturing Licenses:

It is noted that manufacturing licenses are not renewed by State authorities in time. In many cases they took years to renew the licenses. It is also noted that at the time of renewal many products cancelled without any reason.

May be resolved as under:

Manufacturing Licenses may kindly be renewed within a fixed time and none of the products already approved be cancelled except the banned items under Section 26A of Drugs and Cosmetics Act.

13. Failure of Sample:

In the case of failure of sample on minor defects and state authorities want to take administration action i.e. suspension of license for a particular period.

May be resolved as under:

In such cases, as mentioned above, if the defects are not harmful to any patients, state authorities may take any administration action but by giving at least 30 days time to the manufacture so that manufacturers can plan his schedule.

Contd...14

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10. Issue of Government supply for Pharmaceutical formulation in various states:

Sir, it is noted that procuring agencies of state Governments at the time of tender floating put many undesirable conditions such as:

a. **Certificate of Pharmaceutical Product(COPP):**
The Supreme Court of India has already passed an order that COPP is not required for tender business. Moreover, DCG(I) has already given in writing that COPP can not be issued for domestic purpose. It is only for export purposes. Even then many states are asking for COPP product wise.

b. **Turnover class:**
Major states and other agencies responsible for procuring of Pharmaceutical formulation at the time of tenders put mandatory class of turnover. Some states say 40 crores others say 50 crores. To fulfill such turnover class is not possible for Small Scale Sector hence they are deprived of supplying Hospital supplies and such class is benefited for Multinational companies.

c. **Issue of strength viz. a viz. usual strength given in I.P.:**
Sir, only usual strength which are given in I.P. are approved by State Drugs Controllers (SDCs) whereas apart from the usual strength, other strengths which are not in I.P. are available in the country and such approval is given by major states but few states do not agree on the issue of strength. Even, state procuring agencies if ask for a product with strength which is not in the I.P. may not be approved in some states and can be approved in other states.

Contd...13

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It is to be noted spurious or adulterated drugs are not more than 0.34% in year 2008 and now it is 0.1%.

14. Pharmaceutical formulation Exports are backbone of the Industry and country:

Sir, it has been proved without any doubt that Indian medicines are best and export on affordable price for the developed countries, developing countries and under-developed countries supplied by Indian Large companies, Multinational companies, MSME sector companies. The share of the small scale sector is about 30-35% of the total exports which is presently 1 Lakh crore and growing at the rate of 20% p.a.

The supply of export consignments by the MSME sector is due to cheaper skilled workers, skilled technical staff and hardwork done by MSME sector. This is not the end of business, it can be further many fold. If the central Government and state government made simplifying procedure, model proforma of all the certificates be prepared and implemented throughout the country. All the State Drugs Controller shall provide the certificates as per approved proforma and within a stipulated period. We have noted many a times we failed in participating in the international tenders and time bound supplies. This is all due to non-availability of various certificates which are:

1. Certificate of Pharmaceutical Product (COPP)
2. Free Sale Certificate (FSC)
3. WHO-GMP site
4. Non-conviction Certificate
5. Renewed Manufacturing License
6. Capacity Certificate
7. Performance Certificate
8. Validity Certificate and few more.

It is also noted that when we do not get the certificate in time many Governments and distributors becomes restless and ultimately they cancel the order.

Contd... 15

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It is also noted that sometimes pharmacopoeial approvals are also not given on the issue of the strength of products which is not according to Indian Pharmacopoeia whereas British Pharmacopoeia and United States Pharmacopoeia never given any strength.

May be resolved as under:

COPP and other certificates as mentioned above be issued for minimum 5 years instead of 2 years and such certificates and approvals shall be granted within the stipulated period. This period for to issue certificate may kindly be fixed at Central level and then be circulated to all State Drugs Controllers.

15. Issue of Approval of Veterinary drugs:

It is noted that DCG(I) from 1961 has not approved any veterinary drugs, on the other side, State Drugs Controllers are also refusing to give approval for veterinary drugs.

May be resolved as such:

A clear policy may kindly be prepared and distributed to all the State Drugs Controllers in India.

Other Issues:

1. To ensure continuity in the availability of APIs, Form 41 may be renewed at least 3 months before the date of expiry. Similarly Form-10 may be renewed at least 2 months before the date of expiry. If Indian Agents are also the importers of the drugs to be registered under Form-41, they may be allowed to file Form-8 along with Form-40 and Form-10 granted along with Form-41 on registration of the drug.

2. No fresh POA attested by the Indian Embassy may be required at the time of renewal of RC in Form-41. Only an undertaking duly notarized from the manufacturers confirming that the POA executed earlier in favour of the Indian Agent is valid, may be sufficient.

Contd... 16

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

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

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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

All India Small Scale Pharmaceutical Mfrs. Association, New Delhi-110054

All India Small Drug Mfrs. Association, Mumbai-400014

Gujarat Pharma Small Scale Industries Association, Vadodara - 390002

Haryana Pharmaceutical Mfrs. Association, Ambala City - 134003

Himachal Drug Mfrs. Association, Baddi -173205

J&K Small Scale Drug Mfrs. Association, Jammu - 180010

Kerala Pharmaceuticals Mfrs. Association, Kerala - 679322

Organisation of Pharmaceutical Mfrs., Hyderabad - 500038 (A.P.)

Ludhiana Drug Mfrs. Association, Ludhiana - 141001

Rajasthan Pharmaceutical Mfrs. Association, Jaipur - 302006

The Pharmaceutical Mfrs. Association of Tamilnadu, Chennai - 600015

Pharmaceutical Mfrs. Association (Kanpur), Kanpur, U.P.

West Bengal Small Scale Pharmaceutical Mfrs. Association, Kolkata - 700033

Baghat Pharmaceutical Mfrs. Association, Solan - 173212

BBN Industries Association, Baddi - 173205

Federation of Pharma Entrepreneurs, Gurgaon - 122015

Association of Pharmaceutical Mfrs., Haridwar - 249403

Devbhoomi Association of Pharmaceutical Mfrs., Dehradun - 248002

Karnataka Drugs & Pharmaceutical Mfrs. Association, Bangalore - 560001

Sirmour Pharma Mfrs. Association, Paonta Sahib - 173025

Ambala Pharmaceutical Mfrs. Association, Ambala City - 134003

Gurgaon Pharmaceuticals Mfrs. Association, Gurgaon - 122001

Bahadurgarh Pharmaceuticals Mfrs. Association, Bahadurgarh-124507

Goa Pharmaceutical Mfrs. Association, Mapusa - 403526

3. Once an application is accepted for any kind of approval as per check list, there shall be no query letter from CDSCO as to non submission of any document as specified in the check list. After technical scrutiny of the documents submitted by the applicant, in the case of any deficiency, a single deficiency letter may be issued by CDSCO. It shall be ensured that multiple deficiency letters are not issued once a deficiency letter has been appropriately replied.

4. All the applications relating to different types of approvals may be processed on first-cum-first served basis as per diary number allotted at the time of submission and there shall be no discretion left to pick and choose files for processing ignoring this principle.

We further endorse all the issues provided by Indian Drugs Manufacture Association (IDMA). All these points may also be discussed along with our agenda.

Hon'ble Sir,

MSME industry of Pharma is gazing at us and dependent on the outcome of our representation. Members have very high expectations and we are of the opinion that once the mentioned issues are resolved, the industry will be protected under natural justice shall be highly MSME industry would run and grow smoothly and would produce zero defect products.

Regards

For Confederation of Indian Pharmaceutical Industry

P. K. Gupta
Chairman