Ref No 7B/7752 13 May 2009

Shri V.N.Garg, I.A.S
Executive Director
Udyog Bandhu
12-C Mall Avenue, Lucknow

Kind Attention: Shri V.K.Seth

Subject: Agenda points for Drug & Pharmaceutical Industries Working Group Meeting

Dear Sir,

We are submitting IIA comments and proposals related to Drug & Pharmaceutical Industries in U.P for discussion in the working Group meeting as under:

Drug Industries in U.P- An Introduction

The Health of Drug Industries has never been good in the State right from the day it's roots got fixed in U.P. The Drug Industries and Drug Control Department both utterly failed in keeping a pace with the technological growth which had been simultaneously taking place in States like Maharastra, Gujrat, Delhi, Andhra Pradesh and Karnataka. The Industry had engaged itself in making conventional formulation in already established dosage forms which could make industry run but not grow. The industry lacked in fore sightedness and indeed dependence on R & D was nil.

However during past two decades there has been some growth in number of industries and we had nearly 425 units operating in the state. But then Govt of India through Drugs & Cosmetic Act & Rules made "Good Manufacturing Practice (GMP)" mandatory since July 2006 for all units. This up gradation required heavy investment which was beyond the bearing capacity of most of SSI units. No financial assistance was provided to Small Scale units by the State Govt as was extended to industry in Gujarat. The results were disastrous for SSI because they could not bear the financial burden and more than 300 units had to face closure. Only 113 units were able to get licences with GMP provisions.

Now the Drug Control Organisation has got a face lift and "Food & Drug Commissionerate" has been formed. Both the FDA and the industry has to work in tandem for ultimate growth from this point.

Under the changed scenario the working group has to look into genuine problems of the Industries and make workable suggestions to allow the industry to grow positively.

With the above background we submit the following recommendations alongwith justifications for consideration in the working group meeting:

1. Financial Assistance to SSI Sector

All existing units are now GMP compliant units and forthcoming challenge is in form of GLP (Goods Laboratories Practices). Until now the Drug Act provide a unit

to get its products tested from outside facility where use of sophisticated analytical instruments is involved in testing of formulations.

Under GLP Provisions, one would require to have its won independent testing facility. In instruments alone initial investment would be around Rs. 10-15 lacs. Further Rs 2-3 lacs investment would be required for infrastructural up gradation in the laboratory .

Suggestions :

(1) Investment required for establishing GLP provisions may be provided as a loan by the Banks with a 2 years moratorium at an interest which should be 2% less than PLR.
(2) Govt. may also extend some grant to the SSI units for implementation of GLP.
(3) Centralized testing facility may be allowed in a cluster form so that 5 -10 units can jointly use the facility.
(4) R & D in SSI Sector may be mobilised though cluster net work as Lucknow has CSIR institutes like CDRI, CIMAP, NBRI, ITRC etc and its fruits could be shared by U.P State SSI Pharma units.

2. Simplified licensing

Licensing procedures are very cumbersome in our state and takes about a year time to get a licence cleared.

Suggestions:-

(1) Standard site plans should be available for different section like Tablets, Injectables, Liquids and Capsules etc with the Drug controller Office and all DIC's. It will help in reducing post inspections shortcomings in various forms.
(2) Like Uttrakhand provisional Licence may be released once application is moved for grant of Licence and production may only be permitted after completion certificate by the inspection authorities is issued.
(3) Approval of additional items in already approved category should be completed in max 2-7 days.

3. Reference Standards

Reference standards for Drugs Analysis are proving to be a very costly affair and some methodology has to be designed so that same are available to units at reasonable and affordable prices.

For example rate of levoflzxioivion is approximately Rs. 3000 per Kg. Its reference standards from USA cost Rs. 11850/- per 350 mg which is equivalent to Rs. 33857142/- per kg.

Suggestion:

We have state owned Govt. Analyst Lab which has most of these reference standards. Govt. Analyst Lab U.P may be made Nodal Office to provide

reference standards at no profit & no loss basis with minimum quality required in carrying out a test.

4. Functioning of FDA

Since all existing licenses are GMP Complaint unit, FDA should not carry out checking / inspections of licensed unit with police party accompanying inspecting authorities. This, indeed demoralize the person who is running a licensed manufacturing. The problem worsens when incident get media attention and situation get so messed up that ultimately the prestige of the entrepeneur is put on all sorts of bouts. His integrity in the society with police around him is labelled as spurious drug manufacturer instead of being recognised as licensed manufacturer.

Suggestions

(1) Periodical inspections by Drug Authorities are mandatory in Drug Act and may be carried out at any time by Inspector of Drugs/Asstt. Drug Controller.
(2) The Police should not accompany any such inspections team in any licensed unit.
(3) The role if police should remain limited to search and locate where illegal manufacturing/unlicensed manufacturing is taking place.
(4) The inspecting authorities should be helpful and should function in making suggestions for improvement in the industry and their inspections should not end up with show cause notices.
(5) For proper Growth of this sector, the Government may constitute State Drug Consultative Committee where scientist from CDRI, Director from Medical Directorate or KGMC and member representative from industry are nominated under the chairmanship of FDA Commissioner U.P. This committee may help government in making policies for promotion and growth of the industry.

5. Govt Purchase Policy

The Policy is not encouraging the SSI Sector in any way and its due share is going out of State as no preferential treatment is available to State Drug Industry.

Suggestions

1. The Drug Control Department has complete information as to what formulations are manufactured and in what quantities by its licenses in the State.
2. The Govt. may float special tender for the State units only for items manufactured in U.P.
3. The Govt. has reserved several items to be purchased from UPDPL and tenders are not floated for these items. The policy may hold goods for revival of UPDPL but Govt must also ensure share of SSI Sector. UPDPL is not manufacturing sophisticated or complex formulations but they are making most of generic items which are manufactured in SSI Sector also. Their reservations may be cut down to 50% and 50% be opened to SSI Sector. This process would save lot of money of the State exchanger as UPDPL is charging exorbitant rates for items reserved for them.
4. Two years manufacturing experience clause for items being quoted should be done away with, because a new unit otherwise is selling his products to the

public through Chemists & Druggists. End user is the same Public, so why this 2 year binding.

5. There is still another condition in Tender-itemwise GMP Certificate for the item one has to quote. This criterion is not justified. If one has a GMP certificate for his unit why one has to seek yet again itemwise GMP Certificate. In States like A.P, Karnataka, Bihar, Punjab, Haryana etc. if license is duly renewed under GMP norms no further item wise GMP Certificate required.

6. Decentralisation of Drug Control Department Lucknow

Presently for each and every work at Drug Control Department Lucknow, SSI Pharma Manufacturers are required to visit Lucknow Office from all over U.P even for the petty work like issuance of various Certificates, approval for additional items etc. In this process lot of time and energy is wasted. In most of the matter two - three visits are minimum for getting certificates or approval. There are – 30 Departments with which SSI Units are dealing and SSI Entrepreneur is all in one Manager.

Suggestions

For the smooth working and growth of SSI units in U.P it is proposed that for following petty Day to Day work the powers of Drug Control Department be decentralized to Asst. Drugs Controller/SID Posted at Mandals.

(1) Non Conviction Certificates.
(2) Manufacturing & Marketing experience Certificates.
(3) Production Capacity Certificates.
(4) Validity of Licences.
(5) Approval of additional Items.

7. Working of The Directorate of Ayurvedic/Unani Services Lko.

At present Director Ayurved & Unani is looking after every work related to Manufacturer of Ayurvedic Medicines. Due to overload of work and his busy schedule every work weather it is approval of additional items/renewal of Licence/renewal of GMP Certificates is delayed normally for 4-5 months and in some cases it takes more than one year.

Approval of additional items/renewal of licence or GMP Certificates are technical matters which are performed and by technical persons. Here also decentralisation of the work is essentially required to speed up the process.

Thanking you,

Yours truly,

D.S. Verma
Executive Director

Ref No. 7B/7754 13 May 09

Shri V.N. Garg, I.A.S
Executive Director
Udyog Bandhu, Govt. of Uttar Pradesh
Lucknow

Kind Attention: Shri V.K. Seth

Subject: Supplementary agenda for Drug and Pharmaceutical Industry Working Group Meeting

Dear Sir,

We refer to our letter No 7B/7752 Dated: 13th May 2009 regarding IIA comments and proposals for discussion in the Working Group Meeting of Drugs and Pharmaceutical Industry. We submit the following additional comments and proposals for your kind consideration and inclusion in the agenda :-

General Comments

- Turn over clause of Rs.20 crores in the ESI, CGHS tenders, has taken away participation opportunity for SSI sector units of the State. This clause is against the purchase and price preference policy of the Govt also. Hence should be removed in all future purchases.
- In our earlier proposal, We have not taken into account the adverse impact of Tax Free Zones created by the Central Govt. in neighbouring State of Uttrakhand. Industries in U.P has been suffering because of such disparities. As such, suitable measures are to be incorporated in the Policy of the State Govt. to neutralise the effect.

FDA Organisational Structure

The very formation of FDA has to be in accordance with the provisions laid down in the Drugs & Cosmetic Act & Rules, and the Drug Controller should remain Head of the Department and should report all matters of the department to the FDA Commissioner. In the present set-up The State Drug Controller has been made Joint Commissioner and above him two Additional Commissioners have been placed , one a senior PCS officer and one Senior IPS Officer, a system which can never allow independent working of the Drug Controller who otherwise should remain subordinate only to the Commissioner. .This is going to cause little or no free hand to the Drug Controller in day to day working of the department. These senior officer will always effect working as they will direct the Drug Controller as what he has to do and not vice-versa.

Suggestion

- Let there be one Food & Drug Commissioner cum Secretary Health.
- One Additional Commissioner Drugs – The Drug Controller
- Two Joint Commissioners one Junior level PCS as JC(Administration) and PPS as JC(Vigilance) – No Additional Commissioners.
- Commissionary - wise Assistant Commissioner who shall also be the independent DLA.

Govt. Purchase Policy

All purchases are made in the Government through CMSD by Rate Contract or the Quantity Contract, but there is no encouragement to the SSI sector units. The entire purchase policy has to be revamped so that SSI sector gets its due share in the Govt. Business.

Additional Suggestions

- The CMSD should float special tenders for the State units and 25% purchases be reserved for them.
- The items appearing in Q.C. and those manufactured in U.P. should be brought out from list of Q.C. and put in R.C. (Q.C. should only be permitted for those items which are not manufactured in U.P.)
- The ceiling limit of turnover clause for firms from outside of U.P. should be raised to 20 crores as even in a small State like Uttrakhand this limit is 15 crores and in our State it is just 2 crores for them.

Thanking you,

Yours truly,

D. S. Verma
Executive Director