INDIAN DRUG MANUFACTURERS' ASSOCIATION

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15 February 2013

The Hon'ble Chairman,
The Committee on Petitions of Rajya Sabha,
Rajya Sabha

Sub.: Presentation by IDMA before the Committee on Petitions of Rajya Sabha on 15th February 2013 in Mumbai in respect of issues raised in the Petition by Shri Rahul Gaur

Respected Sir,

We courteously submit our views on the issues raised in the Petition as above

i) The spread of use of spurious drugs in the Indian Market may be controlled immediately through upgradation of appropriate laws. The recommendations of Dr Mashelkar Committee, i.e., specifically mentioning spurious drugs an offence under IPC and making the offence non-bailable and cognizable and recommending a maximum of death penalty for this offence may be implemented.

At the outset, regarding the extent of menace of 'spurious drugs', this petition *prima facie* is incorrect because WHO has not done any study in 2001 (as mentioned by the petitioner) or later whereby it is proved that 35% of the world's spurious drugs are produced in India (as per Mashelkar Committee report).

With reference to the above subject, we are providing our point-wise comments:

1. It is stated in the petition that 35% of world's Spurious Drugs are produced in India. This statement is grossly incorrect as evident from the following submission:

    1.1 A study conducted in the recent past (2009-10) by Ministry of Health, Govt. of India on spurious drugs in India says "The extent of spurious drugs in retail pharmacy is much below the projections made by

various media, WHO, SEARO and other studies i.e. only 0.046% (11 samples out of 24,136 samples)" *(Photocopy enclosed, Annexure 1).*

If we take this figure of 0.046% of spurious drugs in India vis-à-vis the total sales of medicines in the world as claimed in the petition then even it will be much lower than 0.046%.

1.2 A study of samples of drugs tested all over the country by the state drugs controllers during the years 2001 to 2008 reveals that about 0.3% - 0.4% of around 40,000 samples fall within the category of spurious drugs.

If we take this figure of 0.3% – 0.4% of spurious drugs in India vis-à-vis the total sales of medicines in the world as claimed in the petition then it will be much lower than 0.3% – 0.4%.

1.3 Department-related Parliamentary Standing Committee on Health and Family Welfare Fifty- ninth report on the functioning of the Central Drugs Standard Control Organisation (CDSCO) presented to the Rajya Sabha on 8th May, 2012 (laid on the table of the Lok Sabha on 8th May, 2012) also confirms that the incident of spurious drugs is 0.5%. The relevant paras 15.1 and 15.2 state the following:

Para 15.1: The Committee was apprised that the propaganda on alleged availability of spurious drugs is motivated and manipulated by foreign drug manufacturers with a view to damage the reputation of Indian domestic manufacturers, who have successfully competed with MNCs in both domestic sales and export at much lower prices. The MNCs are deliberately confusing the issue by clubbing and interchanging 'spurious' with 'counterfeit' drugs. The Indian definition of counterfeit refers to the unauthorized use of a registered brand name, even when the product is of acceptable quality. The Western definition is far wider and includes the so-called 'generic' medicines manufactured by anyone other than patent holders without innovator's permission, even when there is no valid patent in India. If the medicines are of high quality and legally produced in India, they are still dubbed as 'counterfeits' by innovators in the West. According to a study by the CDSCO, the prevalence of spurious drugs in India is less than 0.5 per cent as against the allegations by MNCs of 25-30 percent.

Para 15.2: Taking advantage of the confusion created by MNCs over fake and counterfeits, the so-called anti-counterfeit solution providers that sell barcode and other technologies are propagating and lobbying for the use of such expensive, impractical methods by making them

legally compulsory. Use of barcodes will increase the cost of drugs without any benefit to consumers.

Report of the expert committee under the Chairmanship of Dr. R.A. Mashelkar on a comprehensive examination of drug regulatory issues, including the problem of spurious drugs (Ministry of Health and Family Welfare, Government of India) says:

> **Para 8.4.5** WHO had been quoted to have given a figure of 35% of fake drugs produced in the world coming from India. (Reference Patralekha Chatterjee in Lancet 2001, 357 No. 9270; 1776, 2nd June and The Week May 18, 2003). For example, "The Week" published a detailed article titled "Flood of Fake Medicines". It quoted various sources and gave quantitative figures. For example it reported, "According to the WHO, 35% of fake drugs produced in the world come from India, which has a Rs. 4,000 Crore spurious drug market".
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> **Para 8.4.6** Enquiries were made by the office of DCGI with WHO. WHO's response is reproduced in Annexure-10. The WHO representative in India stated that "There is no actual study by WHO, which concludes that 35% of world's spurious drugs are produced in India." I have investigated this matter with our regional office, and they believe that the source is a commentary from 2001 by an Indian journalist in the Lancet.
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> **Para 14** The Committee examined the various reports and statistics presented at various fora and the media by diverse individuals, associations and agencies concerning the extent of menace of spurious drugs. The reported extent ranged widely between 0.5% (based on the cases analyzed by State regulatory authorities reported in this Report) to 35% (ascribed to WHO Studies). However, WHO itself has written in response to a query from the Indian Government that '**There is no actual study by WHO, which concludes that 35% of World's spurious drugs are produced in India'.**

So, this clearly shows that some pre-motivated news have been planted in the press about percentage of spurious drugs in the Indian market with a clear cut motive of defaming the Indian Pharma Industry in the Western world as the export of reasonably priced quality medicines were on the rise and they were becoming threat to even companies in USA.

This malicious propaganda also aimed to to create an environment in India to change the various legislations controlling Indian pharma industry to suit the MNCs to enter the Indian market and to eliminate the competition (over 10,500 pharma

units in the country) so that they can sell their highly priced medicines in India. And, once the market becomes dependent on them, then they could dictate prices as the whole country would be dependent on them, as witnessed in our neighbouring countries.

The following legislations have been introduced /changed in the past decade, to name a few:

- Schedule M (Good Manufacturing Practices and requirement of premises, plant and equipment for pharmaceutical products) (2003)
- Schedule L1 (Good Laboratory Practices) (2010)
- Spurious drugs bill (2008)
- 2D bar code requirements (2011)

All this has resulted in closure of almost 40% of SSI in the country and now to set up a new pharma unit, much more (may be 10 times more) capital investment is needed then what was needed before these legislations.

So, now, if we look back, then we can understand that MNCs were able to achieve their goal to a great extent. On one side, WHO is being blindly 'misquoted' even in the current petition that 35% of world's spurious drugs are produced in India eventhough WHO has clarified to Government of India as per above report that they have not done any such study which proves that 35% of world's spurious drugs are produced in India. So, it seems that the petitioner is being misguided by the motivated press reports starting in Lancet (year 2001) and then continuously being quoted by various press and media. The petitioner has not even bothered to confirm this figure from the Government or the WHO.

2. To control the menace of spurious drugs in Indian market, legislative provisions in related acts / laws have already been introduced as under:

Amendment to Drugs & Cosmetics Act to enhance penalties for manufacture of spurious drugs:

2.1 On 5th December 2008, Drugs & Cosmetics (Amendment) Act 2008 was passed by the Parliament and the provisions came into effect from 10th August 2009. The amendments take into account the suggestions made by Dr. Mashelkar Committee about manufacture and sale of spurious drugs.

2.2 The amended Section 27, provides for enhanced punishment for manufacture of spurious drugs with imprisonment for a term of not less than 5 years, that may extend to life imprisonment with a fine which shall not be less than 10 lakh rupees or 3 times the value of goods confiscated whichever is more.

2.3 Under the amended Section 36AC, the offences related to spurious drugs are made as cognizable and non-bailable.

2.4 Section 36 AB provides for setting up of special courts for trial of offences committed under this Act related to spurious drugs.

2.5 Whistle blower policy Govt. of India, Ministry of Health and Family Welfare has announced the Whistle blower policy to reward the informer of manufacture / distributor of spurious drugs.

It will be noted from above submission that the punishment for manufacture of spurious drugs is comprehensive and adequate. With these amended provisions, a manufacturer of spurious drugs will be subjected to enhanced punishment including life imprisonment and a very stiff penalty. Besides, since the offences are considered as cognizable, the offender will not be released on bail.

3. We take this opportunity to bring to your kind attention the adverse impact of the enhanced punishments on the genuine legitimate licensed manufacture of drugs.

3.1 Spurious drugs are manufactured by criminal elements with a fraudulent intention mostly **without** holding a valid license for manufacture or sale of drugs and they should be subjected to the enhanced penalties specified in the amended Act.

3.2 However, the amended provisions have created a possibility of a genuine manufacturer being harassed by invoking the penal provisions of 36AC whereby prima facie one will be denied bail as explained in the following paras.

3.2.1. It may kindly be considered that the very basis of initiating either departmental action u/r 85 of ‘Rules’ for cancellation or suspension of licence to manufacture for sale of drugs or legal action seeking criminal punishment, is the test report issued by the Government Analyst (G.A.) .

3.2.2. The G.A. issues report in form no. 13, prescribed under 'Rules', vide which the G.A. is required to give his opinion only in respect whether the drug in question is or is not of Standard Quality as defined in the 'Act' and 'Rules'. There is no provision which authorizes the G.A. to report the drug as 'Adulterated' or 'Spurious' or 'Misbranded' and the legislation has left the same open to be interpreted by the Law Enforcing Authorities based on various factors and sub-sections to those sections defining 'Adulterated', Spurious' or 'Misbranded' drugs.

3.2.3. The definition of Spurious drugs in the Drugs and Cosmetics Act is:

A drug shall be deemed to be spurious,—

(a) if it is manufactured under a name which belongs to another drug; or

(b) if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug ; or

(c) if the label or container bears the name of an individual or company purporting to be the manufacturer of the drug , which individual or company is fictitious or does not exist; or

(d) if it has been substituted wholly or in part by another drug or substance; or

(e) if it purports to be the product of a manufacturer of whom it is not truly a product.

3.2.4. We apprehend that due to likely misinterpretation of definition of spurious drugs under Section 17B(d) of the Act the enforcing authority can initiate prosecution by placing the NSQ drugs for failing in Assay (Content of Active Ingredient) under the category of spurious drugs .

It is important to note that the reason for low content could be the drug being exposed to improper storage conditions, error in testing, following of inappropriate analytical test methods etc. (The state of affairs in these Government Laboratories either under control of State Governments or Central Government, has been properly dealt with in the 'Mashelkar Committee Report'.) However, based on these errors, the authorities may end up unwontedly charging a genuine manufacturer for manufacturing spurious drugs.

3.2.5 Same thing applies to situations of an Injectable product that has been declared as not of standard quality (NSQ) for failing in sterility, presence of particulate matter by the GA. Such cases can be termed as adulterated drugs taking recourse to the definition of an adulterated drug under Section 17A(e) of the Act that will lead to the harassment of the honest , bonafide and licensed manufacturers.

3.2.6 In many States, the majority of the cases for NSQ drugs, charges of adulterated or spurious drugs are being framed while filing prosecution. Now, in this new changed bail provisions (36AC) of Drugs and Cosmetics Act if charges of adulteration or spurious drugs are being framed on the bonafide licensed manufacturer then they shall not get the bail.

Please note that in India the criminal acts having very severe penalties have provisions of *mens rea* ([guilty mind]) but the same is not being provided in the Drugs and Cosmetics Act, while on the other side in the new amendment the penalties have been made very severe. So, there are all the chances that many honest and bonafide licensed companies and innocent persons shall be unnecessarily harassed and will have to suffer for no fault and most of manufacturers will withdraw from manufacturing medicines. Now, looking at the risk of undue harassment, manufacturers are not inclined to involve their next generation in this trade.

ii) A system needs to be developed in which doctors prescribe medicines by their generic name, not by their brand name, as is the practice in many developed countries

Before we begin, we need to understand the difference between what is understood as a 'generic product' in India and in the US and other developed countries:

"A 'generic drug' referred to in US and other developed countries is a drug which was under 'product patent' and has become 'generic' after the expiry of the patent. In India, we have had generic drugs being manufactured by many companies with quality brands competing in the market for many years, with prices determined by market forces and hence are very competitive. In fact almost all drugs in the Indian market are generics, barring a few exceptions."

Unlike in other countries, a substantial portion of the Indian formulation market comprises of FDCs which would make it impossible for a doctor to prescribe in generic form.

Quality in healthcare in India is best assured to public through brand names. Any attempt to abolish brand names and to push these generic unbranded products may

not be the right solution and would be counter-productive and not in favor of the patient.

To impose unbranded generics on patients will result in a retail chemist deciding generic of which particular company to be sold instead of the doctors / medical fraternity advising patients to purchase trusted and assured branded generic drugs from a trusted manufacturer with long standing reputation for quality products recognized by its brand names. And, the chemist is going to sell the generic product whereby he gets the maximum margin. So, this will lead to increase in rates of medicines.

India has almost 600,000 chemists who sell 60,000 formulations manufactured by over 10,500 manufacturers. It is an unfortunate fact that retail chemists do not have the required number of qualified Pharmacists whose services are essential in dispensing medicines.

In case of non-availability of a particular medicine and / or in providing an alternative product, if the authority rests with the retail chemist who is not as qualified as a doctor to do so, it would be dangerous for the patient's health and may prove fatal.

India does not have an organized wholesale / retail chain of Chemists who are organized, better equipped and qualified in dispensing medicines as in the West, where it is mandatory for the chemists to be qualified in Pharmacy. There even they have power to suggest changes in prescription and even advice a doctor in the matters relating to medications. These pharmacists are even legally allowed to charge professional fee as percentage of the drugs sold. If this happens in India then our medicines will become more expensive and unaffordable by poor patients.

We have to be very careful in adopting any new system whereby we may kill our advantage of low prices quality drugs because of intense competition among more than 10,500 pharmaceutical companies in the India market. When India became independent, we were importing more than 95% of our medicines. Now, we are exporting medicines worth more than Rs 50,000 crores and our Indian pharmaceutical companies have even become threat to the big pharma companies in the developed countries, because of our low priced quality medicines. So, the strategy of MNCs is to enter the Indian market, to first kill the competition by their sheer size and then to buy out sizeable Indian companies so that there is no one to challenge them. Our drugs are cheapest in the World even if we compare these with Pakistan and the neighboring countries.

From the above, it can be concluded that the Indian system is currently not ready to change over from branded to generics as far as prescriptions are concerned. Any attempt to follow this route would be very fatal in the interest of the patients of our country as well as the health care system in the long run.

iii) Spread of awareness among the consumers so that they are able to buy correct and proper medicines

Awareness among consumers must be spread to ensure that they buy medicines based on prescriptions of doctors. With many brands with similar sounding names in almost all therapeutic categories, the consumer is not medically educated to make the correct choice. Only a qualified medical practitioner can decide the correct and proper medicine for the particular illness. The patient should be educated to visit the doctor again along with medicine and the prescription to confirm that that the right medicine has been purchased.

iv) To put a check on clinical trials more stringently and prevent unethical practices

All clinical trials should be registered and inspection by auditors where the maximum number of patients are enrolled. This will ensure that investigators follow GCP Guidelines completely. Each investigator should also be certified by MCI to conduct clinical trials by taking their written / online exams. This will make compliance more stringent. The Ethics Committee approvals are MUST. Anybody deliberately violating the Schedule Y requirements and GCP etc., should be penalized and barred from conducting clinical trials in future.

v) Uniform pricing of drugs irrespective of the part of the country in which they are sold and the brand name they carry.

All allopathic drugs sold in India have a uniform 'Maximum Retail Price - Inclusive of all taxes' printed on it and no retailer is allowed to sell any drug pack above that price.

In conclusion, we suggest that

1) To build up the confidence of general public in the Indian Pharmaceutical market as well as industry, Government should come forward and create public awareness about the actual extent of spurious drugs as per the surveys done by Govt. of India that it is not more than 0.046% and not 35% as being quoted in the press.

2) The Govt. should pro-actively involve Indian pharma industry including representatives from all sectors – large, medium and SSI - for any policy changes in the regulations.

3) The spurious drugs regulations bill should be further amended to segregate unlicensed criminal elements involved in the trade of spurious drugs and the legitimate licensed manufacturers following the law of the land so that the actual resources and energy of regulatory agencies can be focused on the real criminal elements.

We suggest the following to create a demarcation between the two:

a) Amendment to Penal Section to recognize defense of *mens rea*
Justification:
The Drugs and Cosmetics Act, 1940 casts absolute liability on every person engaged in manufacture, sale and distribution of drugs and cosmetics. The absence of *mens rea* is not considered as defense in trial of offences under the Drugs and Cosmetics Act, 1940. As a result, a *bona fide* mistake committed during the course of routine manufacturing operations and the clandestine / and intentional manufacture of spurious and adulterated drug is placed on the same footing and no distinction is made between the bona fide licensed manufacturer and the unscrupulous elements involved in clandestine activity of manufacture, sale and distribution of spurious and adulterated drugs. It is therefore necessary to amend Section 27 of Act to include mens rea as in most of the cases where penalties like life imprisonment are there.

b) Amendment to Section 36AC
Suggested amendment: After existing proviso following proviso may be added:
"Notwithstanding any other provision, the licensed manufacturer shall be granted bail."

c) Amendment to bring in requirement of prior sanction from the Controlling Authority
Suggested amendment: Insertion of Rule 50B: No prosecution shall be filed in the Court without written consent from the Controlling Authority.

The Drugs and Cosmetics Act has inherent powers to deal with the licensed manufacturers, if there are mistakes committed during the course of routine operations, the administrative actions like suspension or cancellation of licenses can be very effective tools if any company is found violating the provisions of the act or the rules, as after the requirements of new schedule M in the year 2003 (requirement of plant and machinery), setting up of a pharma unit costs crores of rupees.

d) To control the movement of spurious drugs in the market place if any, the provisions of Drugs and Cosmetics Act and the Rules should be strictly implemented. To discourage the purchase of spurious drugs by whole sellers/retailers they should be advised to buy or purchase the drugs on a valid bill and make payment only through a negotiable instrument like cheque /draft / rtgs transfer etc .In case of investigation

by drugs inspectors/authorities if the purchase bill is not available with the whole sellers/retailers of any drug then he should be asked to produce the same to the authorities with in a specified period failing which he should be subjected to heavy penalty or cancellation of licence in the event of non payment .

e) Consumers should be made aware by suitable means to buy medicines only on proper bill/invoice.

f) We suggest that to keep the prices of medicines cheaper in India, the Indian pharmaceutical industry, especially the SSIs should get all the support from the Government of India to face the challenge of big pharma conglomerates of the World.

We would like to appear before the committee to further elaborate on the subject, which is of extreme importance for the survival of the Pharma industry- particularly the small scale industry, so that the confusion prevailing on the subject of spurious drugs can be clarified. The true competition to the MNCs in Indian Pharma market is due to the presence of indigenous manufacturers, and the large number of SSIs Today, medicines in India are cheapest in the world and we should protect the domestic industry at any cost and not get swayed by the false and misleading propaganda of MNCs regarding the prevalence of spurious drugs to the extent projected.

We, the Industry, are the most affected party by circulation of spurious drugs in the market as it kills our reputation, brand, business and we have to face lot of harassment since the criminal elements (duplicators) do not have any address or a face and the label they use are of legitimate licensed manufacturers. So, the legitimate manufacturer has to face the music till the time he proves his innocence.

We are committed to the Government and the people of our country to help curb this menace of spurious drugs in the society and continue providing affordable quality medicines to serve the masses.

Thanking you,

Yours sincerely,

Manish Doshi
President