



DIRTY GAMES OF SPURIOUS BUSINESS

PHARMA LEADERS EXPOSE!!!

Imagine administering a paracetamol tablet to a near and dear one who is down with fever only to find that the medicine is having no effect. This scenario sounds scary, but it could be actually be happening to a lot of people as it has been recently revealed that about 20 per cent drugs sold in India are fake. As per ASSOCHAM's estimation, the market for spurious drugs in India is growing by 25 per cent each year.

Current estimates of fake drugs put the prevalence between 0.5% and 30% of all the Rs34,000 crore-worth drugs sold in India

In fact the latest figures released by the Organization for Economic Cooperation and Development's state that almost 75 per cent of fake drugs exported the world over accrue from India. The emerging picture of the spurious drugs market in India has put the drug controller general's office on alert, which is now planning to undertake the world's biggest ever study to determine the size of this deadly domain. The study of Indian spurious medicine market is scheduled to kick off soon. It will be headed by drug controller general of India, Surinder Singh and should continue for about six months. In a one of its Kind shocker, various Drugs made in China

with "Made in India" labels have been impounded in Africa (Nigeria and other places) as well as in some ports in India. Thus, leading up to an international racket of the worst kind. If these drugs had been used with terrible effects, the Blame would have been posted on India, effectively listing it as Rouge in the Pharmaceutical World. China has now officially for the first time admitted that some of its companies were involved in this dastardly deed, surprising indeed when everything is so tightly controlled. It's well known that nothing can be done on this scale and magnitude without official blessings. So where does this lead us to? Similar incidents such as melamine in the milk powder and other

stuff as well as the lead contamination in the paint used in toys to the dumping of various electronic items including mobile hand sets without IME numbers or multiple hand sets with the same IME numbers everything is Passé. It brings one to the simple conclusion that the Chinese State cannot and will not accept the Indian Nations rise as a Global Power and will rather try their best to discredit us as International forums as well as restrain us at the Regional levels. We are already seeing them continuing with the Border incidents....and as an aggressive push other than the Rail to Tibet as well as the Aksai chin road...they have embarked on their string of pearls whereby they have



bases and port access in our neighborhood vis a vis ports being built in Myanmar, Sri Lanka, Maldives, and others. With a strong Naval Presence and Participation by Pakistan, India faces a real threat of encirclement, by Land, Water and Non Friendly neighboring Nations. How many "Made In India" Labels with produce of China has reached undiscovered is still unknown. India has always been perceived as a Paper Tiger – a Tiger that will only roar but lacks the Bite. its high time that we understand that there are times for peace, but it cannot be without war on all fronts, whether the Economic Front, in Cyber Space, in International Forums or in the High seas and on Our Borders.

India's drugs quality regulator is readying a survey to map the prevalence of counterfeit drugs in the country with a smaller sample size but with a wider range of product categories compared with an earlier proposal for such a study. The survey, in its new form, will pick up 31,000 samples of 62 top-selling medicines across nine therapeutic categories and will cover products of 29 manufacturers. The samples will cut across medicines administered for cardiovascular ailments, pain, infections, tuberculosis and even steroids, putting a diversified basket of drugs under the scanner. This is in marked contrast to the way the study was originally fashioned under M. Venkateswarlu, the previous drug controller general of India, or DCGI, who retired on 30 January. That plan was to cover 50,000 samples each of five-six large volume brands, making for a sample size of up to 300,000 medicines. The aim then was to restrict the number of brands but cast the net deep. The premise of the new survey, redesigned by the office of the current DCGI, Surinder Singh, is to cover the drug market as widely as possible. The first-of-its-kind survey is expected to throw up a robust official estimate of the prevalence of spurious and fake drugs in the country. Current estimates put the prevalence between 0.5% and 30% of all the Rs34,000 crore-worth drugs sold in India. Countries in Europe and Africa have complained of Indian exports of counterfeit drugs into their markets. "We have developed the study design with the help of Indian Statistical Institute (in Hyderabad) to ensure the results from

the current sample size are statistically significant. Once we have the data, we will know where we stand," said DCGI Singh, who expects a realistic estimate to emerge from the survey. The survey would not only give clarity on the true extent of menace in the country but also help India face up to international criticism "from a position of strength", said Singh. A senior official in the DCGI's office, who preferred anonymity, said the survey would also help identify "geographical pockets" where the problem of fake drugs is rampant. "We will collect two strips of each drug. One will be retained with us and the other sent to the drug makers. The companies will have to give in writing if the sample is original, made by them or not. If not, we will call it counterfeit," said the official, explaining the methodology of the proposed survey. The other strip with the drug authorities could then be used for laboratory testing to check the quality of the drug. The survey would be launched as soon as the financial grant of Rs50 lakh is sanctioned. Amendments to the Drugs and Cosmetics Act, 1940, are being finalized by the Union ministry of health and family welfare, as part of legislation that will levy hefty fines and punishment up to life imprisonment for offenders caught in the fake drugs trade. An expert warned that while spreading out was a vital survey component, the sampling should cover rural areas, pockets of which are notorious for such activities and include medicine godowns as well. "The surveyors should definitely take as many samples as possible from the dealers (and) localities that have been identified as being notorious over the years. The pharmacies in rural areas and resettlement colonies are another important link," said P.N. Bhargava at the drug anti-counterfeiting cell of Indian Pharmaceutical Alliance, an industry lobby. "In fact, large-scale godowns should also be in the survey as a lot of counterfeit drugs find their way into the system and are transacted in at that point." A study funded by the World Health Organization and carried out by global policy think tank International Pharmaceutical Federation found 3.1% of the more than 10,000 samples of 56 top-selling brands that it picked up to be counterfeit.

Ministry of Health & family Welfare

Reward Scheme for whistleblowers in the fight against the menace of spurious or fake drugs, cosmetics and medical devices.

Public Health is one of the major objectives of Government of India. Drugs / Medicines are the most essential component to fight various diseases prevalent in the country. It is, however, important that the drugs so available are not only of standard quality but are safe, potent and efficacious also. Drugs is in the concurrent list of Constitution of India. Regulatory control over the quality of drugs in the county is exercised by both the Central and State Governments through the provisions of the Drugs & Cosmetics Act, 1940 and the Drugs & Cosmetics Rules, 1945 made thereunder. The manufacture and sale of drugs is looked after by the State Drugs Control Authorities appointed by the State Governments while imports, market authorisation and new drugs are the responsibility of the Central Government. The Central Drugs Standards Control Organisation (CDSCO) with the Drugs Controller General (India) [DCG(I)] as its head is the Central regulatory body for enforcing the quality standards of drugs, cosmetics and medical devices in the Central Government.

2. International ranking of the country in pharmaceutical sector has improved enormously with the sector growing at 12-14% per annum. The country now accounts for about 8% of global production and 2% of the world pharmaceutical market. The country meets 95% of its domestic demands through indigenous production covering almost all therapeutic categories and imports only a few high technology products. The size of Indian pharma industry is about Rs.85000 crores, with about 40% i.e. Rs. 35000 crores worth of pharma products being exported. It is among top 20 countries if the world exporting pharma products. Vaccines and bio-pharma products are exported to about 151 countries. Further in the segment of Active Pharmaceutical Ingredients (APIs), India ranks third in the world providing over 400 APIs.

3. The country's hold on international pharmaceutical market, especially the status enjoyed by it in providing high quality drugs on cheapest prices invited some unhealthy competition from various quarters. Internationally, the



vested interests are supplying spurious medicines manufactured by them but with 'Made in India' label. Allegations of marketing and circulation of spurious or fake drugs within the country also are raised from time to time by the media, consumer associations, NGOs as well as in legislative forums. The volume of the pharmaceutical market and stakes involved in it makes it easy for the people to fall prey to the lures of money and indulge in various malpractices. The manufacture and sale of spurious drugs is a clandestine activity generally indulged in by anti-social elements and carried out by unlicensed manufacturers which exploit the confidence enjoyed by certain fast selling drugs by making their imitations.

4. The Drugs & Cosmetics Act, 1940 and Drugs & Cosmetics Rules, 1945 contain comprehensive penal provisions which act as sufficient deterrent for those intending to indulge in the malpractices relating to drugs/medicines. Since the Drugs & Cosmetics Act, 1940 is a Central enactment, the core concept of implementation of deterrent measures with respect to countering the menace of spurious drugs is better coordinated between states as well as the centre. Despite these deterrent provisions of law, availability of spurious drugs in market is a fact which cannot be denied altogether. The Drugs Controller General (India) has been in continuous touch with the state drug control authorities, the revenue intelligence authorities, the custom authorities and all port officials for keeping a close watch on such clandestine activities to check the menace of spurious drugs.

5. The CDSCO is conducting an all India survey to assess the extent of availability of spurious drugs in the country by drawing samples from different regions and different strata in the country on the basis of statistical principles provided by the Indian Statistical Institute, Hyderabad. The samples are being analysed and action would be taken as per the provisions of the law. This would help in identifying the geographical areas where spurious drugs are available so that a focussed monitoring is done by the concerned authorities in these areas for eliminating the menace of spurious drugs. Assistance has also been provided under the World Bank assisted Capacity

Building Project to upgrade testing facilities and to establish new drug testing laboratories so as to enhance the capacity of laboratories to test large number of samples. Under the project, 23 States' and 6 Central Drug laboratories have been strengthened through renovations, extensions and equipments. Further, Schedule M of the Drugs and Cosmetics Rules, 1945 pertaining to Good Manufacturing Practices makes it mandatory, at par with the international standards, for the manufacturers of drugs to comply with the requirements for the Schedule for quality control of the drugs manufactured by them. Detailed guidelines have been issued to the State Governments to undertake focussed surveillance over possible movement of spurious drugs. Specific training programmes have been conducted for regulatory officials of State Governments on logistics of intelligence work, prosecutions, etc with the assistance of FDA, Maharashtra. The pharmaceutical industry and the trade have been motivated to fight the menace of spurious drugs as a share responsibility.

6. The Drugs & Cosmetics Act, 1940 has recently been amended by the Drugs & Cosmetics (Amendment) Act, 2008 for providing more stringent penalties to those involved in the trade of spurious drugs. Representations were received from various stakeholders on difficulties in the implementation of these amended provisions and the concerned expressed at their misuse. A committee under the Drugs Controller General (India) was, therefore, set up to look into the matter to frame suitable guidelines for the purpose. As per the recommendation of the committee, guidelines were framed and thereafter the provisions of the amended Act have been enforced w.e.f. the 10th August, 2009.

7. Since spurious or fake drugs is a sensitive issue affecting the health of the citizens as well as the prestige of the country's pharmaceutical trade interests, there is a sense of urgency in taking on the menace on priority basis. There is no dearth of good intentioned people who may wish to work for the country's interests as the whistle blowers in eradicating the menace. People's participation is imperative in this regard and would be a highly

effective step in augmenting the efforts of taking on the elements engaged in such illicit trade of spurious drugs. With this aim in view, a scheme has been devised by the Central Government for giving monetary rewards to the whistleblowers who can take risk of providing the information about the perpetrators of such crime. Such scheme is already operational in other enforcement departments of Government which pays good dividend also in terms of voluminous catches / seizures. The Reward scheme provides for giving handsome rewards to the informers who provide specific information to the designated authorities leading to the seizures of spurious, adulterated, misbranded and not of standard quality drugs, cosmetics and medical devices. This reward scheme will be applicable to both the informers as well as the officers of the CDSCO. In the fight against the menace of spurious or fake drugs, cost of such social participation will be minimal given the proportion of damage inflicted by the perpetrators of the crime on the health of the society and the economic progress of the country.

8. The salient features of the aforesaid reward scheme are as follows:-

(i) The reward scheme shall be applicable for whistleblowers in the area of drugs, cosmetics and medical devices.

(ii) Reward is to be given to the whistleblowers i.e. the informers / officials only when there is a confirmation of the seizure of spurious, adulterated and misbranded drugs, cosmetics and medical devices by the designated officers of the CDSCO.

(iii) The reward of maximum of upto 20% of the total cost of consignments seized will be payable to the informer / officials which should not in any case exceed Rs 25 Lakh in each case.

(iv) In respect of an officer of the Government / CDSCO, the reward should not in any case exceed Rs 5 Lakh for one case and a maximum of Rs 30 Lakh in his / her entire service.

(v) With a view to ensure that the informers are not made to wait till the final disposal of the matter, 25% of the amount will be given at the time of filing of the charge sheet in the court of Law.



(vi) Further, with a view to ensure that the informers do not turn hostile during the trial of the case and continue to assist the court in deciding the matter in favour of the Government, 25% of the amount will be given to them at the time of disposal of the case in favour of the Government in the first court of law.

(vii) The remaining 50% amount will be paid only when the case has been finally disposed of in favour of the Government and no appeal with respect to the matter is pending in any other Court of Law in the country.

(viii) The eligibility of the informer and the quantum of cash rewards would be decided by a Committee, which will consist of officials from different departments / offices. The Committee will consist of the following persons:

(a) Director General Health Services Chairman (ex-officio)

(b) Director / Deputy Secretary (Drugs), Ministry of Health & Family Welfare Member (ex-officio)

© Chief Controller of Accounts or Director, Internal Finance Division, Ministry of Health & Family Welfare Member (ex-officio)

(d) A Representative of the respective zonal / sub-zonal office of CDSCO nominated by DCG(I) Member

(e) Drugs Controller of the concerned State / Union Territory Member

(f) A Representative of social groups / NGOs nominated by the Ministry of Health & Family Welfare Member

(g) A legal representative nominated by the Ministry of Health & Family Welfare in consultation with the Ministry of Law & Justice Member

(h) A representative of the Customs Department in case of international movement of spurious drugs only Member

(I) DCG(I) or his nominee Member Secretary

(ix) The eligibility of Government servants for the rewards shall be decided by the Committee depending upon the final outcome of the case only.

(x) The Government will engage senior advocates who have sufficient experience of the cases relating to Drugs as its counsel in the cases.

(xi) To ensure speedy trials of the cases,



these cases will be filed before the Designated / Special Courts set up for the purposes of drugs related issues as per the provisions of the Drugs and Cosmetics (Amendment) Act, 2008.

(xii) Special instructions are to be given to the Drug testing laboratories to send their reports at the earliest, within the minimum time possible, so that the matter is disposed of expeditiously.

(xiii) Drug Controller General (India) along with other officials will be the nodal authority who will inter alia oversee the functioning of the Reward Scheme as proposed herein above.

(xiv) The zonal and sub-zonal officers of the CDSCO will act as the nodal officer to whom the whistle blower / informer can provide the information about the manufacture / movement of spurious / adulterated drugs.

(xv) The identity of the whistle blower / informer will be kept secret and will be known only to the concerned zonal and sub-zonal officers of the CDSCO, the DCG(I) and the Director General Health Services. It will be the responsibility of the concerned officials to keep the details of the whistle blower / informer secret.

(xvi) The identity of the whistle blower / informer will not be disclosed to the committee.

(xvii) On receipt of the information from the whistle blower / informer, the concerned officers will organize immediate and systematic investigation in co-ordination with the State Drugs Control Administration to unearth the spurious drugs racket.

(xviii) As the Licenses are granted by the State Drugs Control Authorities, they will take suitable action like prosecution etc depending upon the evidences available in the case.

(xix) The details of the investigations will then be forwarded by the concerned zonal / sub-zonal officer to the DCG(I) for the consideration of the committee to decide about the merit of the case for reward and the quantum of reward to be given to the whistle blower / informer.

(xx) The details of the nodal authority and the zonal / sub-zonal officers of the CDSCO for the purposes of this reward scheme, to whom the concerned information may be given by the whistle blower / informer, are as follows:

| Name | Addresses and phone number, mobile number, fax number |
|---|---|
| Dr. Surinder Singh, Drugs Controller General (India), | Central Drugs Standard Control Organization, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India, FDA Bhavan, ITO, Kotla Road, New Delhi -110002; Phone: +91-11-23236965 / 23236975; Fax: +91-11-23236973E-mail address: dci@nb.nic.in |



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| <p>Dr. D. Roy, Deputy Drugs Controller (India)</p> | <p>(For the states Haryana, Himachal Pradesh, Jammu & Kashmir, Punjab, Rajasthan, Uttaranchal, Uttar Pradesh, N.C.T. of Delhi & Union Territory of Chandigarh)</p> <p>Central Drugs Standard Control Organization (North Zone), CGO Building - I, Kamla Nehru Nagar, Hapur Chungi, Ghaziabad- 201002 (U.P.) Phone: +91-120-2719483 / 2750013 / 2701927; Mobile Number: +919811203186 Fax: 0120-2701927 E-mail address: cdsconz@gmail.com</p> |
| <p>Dr. R. Ramakrishna, Deputy Drugs Controller (India)</p> | <p>(For the states Chattisgarh, Goa, Daman & Diu, Madhya Pradesh, Maharashtra, Dadar & Nagar Haveli and Lakshadweep)</p> <p>Central Drugs Standard Control Organization (West Zone), 4th Floor, FDA Bhavan, GMSD Compound, Bellasis Road, Mumbai Central, Mumbai-400008 (Maharashtra) Phone: +91-22-23002279 / 23002215; Mobile Number: +919820256032 Fax: 91-22-23002271 E-mail address: cdscowz@gmail.com</p> |
| <p>Dr. A. Ramakishan</p> | <p>(For the state Gujarat)</p> <p>Central Drugs Standard Control Organization (Sub-Zonal Office), Air Cargo Complex, Old Terminal Building, Airport, Ahmedabad-380016 (Gujarat) Phone: +91-79-22865244; Mobile Number: +919723398877 Fax: 079-22865244 E-mail address: cdsosbz@gmail.com</p> |
| <p>Shri ACS Rao</p> | <p>(For the state Andhra Pradesh)</p> <p>Central Drugs Standard Control Organization (Sub-Zonal Office), Unit No.18, Second Floor, Cargo Satellite Building, RGI Airport Shamshabad, Hyderabad (Andhra Pradesh) Phone: +91-40-24008270 / 24008236; Mobile Number: +919440115452 / +919618727439 Fax: 040-24008270 E-mail address: adchyderabad@gmail.com</p> |
| <p>Smt Shanty Gunashekharan</p> | <p>(For the states Karnataka, Kerala, Pondicherry and Tamil Nadu)</p> <p>Central Drugs Standard Control Organization (South Zone), 2nd Floor, Shastri Bhavan, Annexe 26, Haddows Road, Chennai - 600006 (Tamil Nadu) Phone: +91-44-28278186 / 25610402 / 25610906; Mobile Number: +919841181929 Fax: 044-28213079 E-mail address: ddcisz@tn.nic.in</p> |
| <p>Shri Souman Mukhopadhyay</p> | <p>(For the states Andaman and Nicobar Island, Arunachal Pradesh, Assam, Bihar, Jharkhand, Manipur, Meghalaya, Mizoram, Nagaland, Orissa, Sikkim, Tripura & West Bengal)</p> <p>Central Drugs Standard Control Organization (East Zone), CGO Buildings, Nizam Palace West, 2nd Floor, 234/4, Lower Circular Road, Kolkata - 700020 (West Bengal) Phone: +91-33-22470513; Mobile Number: +919432104906 Fax: 033-22813806 E-mail address: cdscoez@gmail.com</p> |

Any clarification / information in respect of the scheme may be had from the undersigned:

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