

# **Ministry of Health & family Welfare**

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## **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 10<sup>th</sup> 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 ( <i>ex-officio</i> )
(b)	Director / Deputy Secretary (Drugs), Ministry of Health & Family Welfare	Member ( <i>ex-officio</i> )
(c)	Chief Controller of Accounts or Director, Internal Finance Division, Ministry of Health & Family Welfare	Member ( <i>ex-officio</i> )
(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 and Designation	Addresses And phone number, mobile number, fax number and e-mail address
<b>Dr. G. N. Singh,</b> 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: +91-11-23236973 E-mail address: dci@nic.in
<b>Mr. A. K. Pradhan,</b> Deputy Drugs Controller (India)  (For the states Haryana, Himachal Pradesh, Jammu & Kashmir, Punjab, Rajasthan, Uttarakhand, Uttar Pradesh, N.C.T. of Delhi & Union Territory of Chandigarh)	Central Drugs Standard Control Organization (North Zone), CGO Building - I, Kamla Nehru Nagar, Hapur Chungi, Ghaziabad- 201002 (U.P.)  Phone: +91-120-2719483 / 2750013 Fax: 0120-2701927 E-mail address:cdsconz@gmail.com

<p><b>Dr. K. Bangarurajan,</b> Deputy Drugs Controller (India)</p> <p>(For the states Chattisgarh, Goa, Daman &amp; Diu, Madhya Pradesh, Maharashtra, Dadar &amp; Nagar Haveli and Lakshadweep)</p>	<p>Central Drugs Standard Control Organization (West Zone), 4<sup>th</sup> Floor, Zonal FDA Bhavan, GMSD Compound, Bellasis Road, Mumbai Central, Mumbai-400008, (Maharashtra)</p> <p>Phone: +91-22-23002279 / 23002215; Fax: 91-22-23002271 E-mail address:cdscowz@gmail.com</p>
<p><b>Dr. S. E. Reddy,</b> Deputy Drugs Controller(India)</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)</p> <p>Phone: +91-79-22865244; Fax:079-22865244 E-mail address:cdscosbz@gmail.com</p>
<p><b>Sh. P.B. N. Prasad,</b> Deputy Drugs Controller (India)</p> <p>(For the state Andhra Pradesh)</p>	<p>Central Drugs Standard Control Organization, Beside AP T.B Demonstration and Training Centre, S.R. Nagar, Hyderabad, (Andhra Pradesh)</p> <p>Phone: +91-40-23811481 Fax:040-23811483 E-mail address:ddchyderabad@gmail.com</p>
<p><b>Dr. S. Manivannan,</b> Deputy Drugs Controller (India)</p> <p>(For the states Karnataka, Kerala, Pondicherry and Tamil Nadu)</p>	<p>Central Drugs Standard Control Organization (South Zone), 2<sup>nd</sup> Floor, Shastri Bhavan, Annexe 26, Haddows Road, Chennai – 600006, (Tamil Nadu)</p> <p>Phone No. +91-44- 28278186 / 25610402 / 25610906; Fax: 044-28213079 E-mail:-ddcsz@tn.nic.in</p>

<p><b>Sh. S. P. Shani,</b> Deputy Drugs Controller(India)</p> <p>(For the states Andaman and Nicobar Island, Arunachal Pradesh, Assam, Bihar, Jharkhand, Manipur, Meghalaya, Mizoram, Nagaland, Orissa, Sikkim, Tripura &amp; West Bengal)</p>	<p>Central Drugs Standard Control Organization (East Zone), CGO Buildings, Nizam Palace West, 2<sup>nd</sup> Floor, 234/4, Lower Circular Road, Kolkata – 700020 (West Bengal)</p> <p>Phone: +91-33-22470513; Fax: 033-22813806 E-mail address:cdscoez@gmail.com</p>
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9. Any clarification / information in respect of the scheme may be had from the undersigned:

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