773

SPECIAL MESSENGER

X.11035/32/2012-DFQC
Government of India
Ministry of Health & Family Welfare

Nirman Bhavan, New Delhi
Dated the 28th December, 2012

OFFICE MEMORANDUM

Subject: 59th Report of Department-Related Parliamentary Standing Committee on Health and Family Welfare on the functioning of the Central Drugs Standard Control Organisation (CDSCO)-Regarding.

The undersigned is directed to refer to Rajya Sabha Secretariat's O.M. No. R.S.10/2(vi)/2011-Com (H&FW), dated 9th May, 2012 and letter dated 11th December, 2012 received from Shri Brajesh Pathak, Chairman, Department related Parliamentary Standing Committee on Health & Family Welfare and to enclose herewith a revised Action Taken Note in English on the observations/recommendations contained in the aforesaid Report for kind perusal of the Department related Parliamentary Standing Committee on Health & Family Welfare.

2. This issues with the approval of Secretary (Health & Family Welfare), Ministry of Health & Family Welfare.

3. Hindi version will follow.

(Sudhir Kumar)
Under Secretary to the Government of India
Telefax: 23062292

Rajya Sabha Secretariat
(Kind Attn.: Ms. Arpana Mendiratta)
Joint Director
Parliament House Annexe
New Delhi

28/12/12

Copy to:1.Hindi Section, Ministry of Health & Family Welfare with the request to provide hindi version immediately to this Section.
2. Parliament Section.

FINAL ACTION TAKEN REPORT ON THE OBSERVATIONS / RECOMMENDATIONS CONTAINED IN THE 59TH REPORT OF THE DEPARTMENT RELATED PARLIAMENTARY STANDING COMMITTEE ON HEALTH & FAMILY WELFARE ON THE FUNCTIONING OF THE CENTRAL DRUGS STANDARD CONTROL ORGANISATION (CDSCO)

PRELIMINARY SUBMISSIONS:

1. The Ministry of Health & Family Welfare in general agrees with the observations of the Hon'ble Committee. It regrets the delay in submission of this final Action Taken Report.

2. The Government had constituted a three member expert committee comprising Dr. V.M. Katoch, Secretary (Department of Health Research) and Director General, ICMR, Dr. P.N. Tandon, President, National Brain Research Centre, Department of Biotechnology, Manesar and Dr. S.S. Aggarwal, former Director, Sanjay Gandhi Post-graduate Institute of Medical Sciences, Lucknow under the following terms of reference and give its report:

I. To examine the validity of the scientific and statutory basis adopted for approval of new drugs without clinical trials as pointed out in the Report for further appropriate action in the matter.

II. To outline appropriate measures to bring about systemic improvements in the processing and grant of statutory approvals.

III. To suggest steps to institutionalize improvements in other procedural aspects of the functioning of CDSCO.

3. The three member expert Committee which was required to submit its report within a period of two months took longer as it had to undertake comprehensive consultations with a large number of medical experts all over the country. The Committee submitted its report to the Government on 22.11.2012. A copy of the full report is being submitted to the Rajya Sabha Secretariat separately. The gist of its recommendations are as under:

"(I) Is there scientific validity of the statutory provision for allowing approval of drugs (already approved in countries abroad) without clinical trial in India?

The overwhelming response of the selected medical professional community to this question was "conditional Yes". The committee agrees with the same. However, this provision shall be applied only in highly selected cases and in a transparent and accountable manner. The committee recommends:

i) A select group should be constituted of knowledgeable medical professionals to:
   a. lay down the principles of determining the circumstances where such provision may apply, and
   b. lay down the procedure that should be adopted while applying this provision

   The Committee has also given a list of names that can be considered for constituting this group.

ii) A group of medical professionals and legal experts shall be constituted to *revise* the existing Rule 122A (2), Rule 122B (3) (1) and sub-clause (3) of Clause 1 of Schedule Y on the basis of guidelines and procedures evolved by the group constituted vide recommendation No. (i) above to provide for approval/licensing of drugs (already approved abroad from recognized countries) in India without clinical trial in India under exceptional circumstances *only*.

iii) The CDSCO shall take appropriate steps to implement the revised statutory provisions and the guidelines and the procedures laid down by the expert group constituted under recommendation No. (i) above. For this purpose the CDSCO shall issue appropriate guidance to the Industry and the NDACs should lay down SOPs for implementation of the provision of providing approval/licensing of drugs in India without clinical trial in India. All future approvals/licensing of drugs without clinical trial in India should be regularly monitored.

iv) All the 38 approvals granted under existing provisions, as identified by the Parliamentary Standing Committee (and CDSCO), *and also others, if any*, shall be re-reviewed by the respective newly constituted New Drug Advisory Committees as per revised provisions and the SOPs laid down by them. It would be prudent to take any action on already approved/licensed drugs, such as withdrawal of the approval etc., only after such a re-review. The NDACs may ask additional desired information from the manufacturers as deemed necessary. This should be carried out in a time bound fashion.

v) The Committee endorses the recommendations of the Parliamentary Standing Committee to be extra careful in approving the FDCs. The CDSCO should constitute a Committee of experts to lay down the *principles and procedures* to be adopted for approval of FDCs. The committee shall also review the *existing statutory provisions* for the approval of FDCs by the CDSCO and State Drug Authorities and recommend appropriate changes, if necessary. It should be a thorough and systematic exercise carried out with due diligence.

vi) In India, to by-pass the price regulatory requirement, the use of FDCs is rampant. Once the rationale, principles and procedures for approval/licensing of new FDCs are laid down, all the existing FDCs may be re-reviewed in the interest of public health at large.

(II) Measures to bring about systemic improvements in the processing and grant of statutory approvals
(III) Steps to institutionalize improvements in other procedural aspects of the functioning of CDSCO.

In respect of (II) and (III) above, the Committee feels that a consultant /consultancy needs to be commissioned to review the structure of CDSCO based on the recommendations of the Mashelkar Committee.

4. **Steps taken to strengthen the drug regulatory system of the country**: A number of steps have been taken to strengthen the CDSCO during the last four years. While the CDSCO had a total strength of 111 posts in 2008 with 32 posts of Drug Inspectors, its strength has increased to 310 sanctioned posts with 169 posts of Drug Inspectors. Efforts are being made to further create additional posts in view of the increasing requirements of the organization and also to fill up vacant posts. The organization which had only 12 Drug Inspectors in position in 2008 has presently 65 Drug Inspectors and selection of 90 more has recently been completed. Further, as against in 2008 when there was no Deputy Drugs Controller, now there are 14 Deputy Drugs Controllers.

In view of the constraints of staff due to delay in regular appointments, the Government has resorted to appointment of 234 persons in various categories, including 113 technically qualified personnel on contract basis so as to assist the organization in coping with the work load at the Head Quarters as well as Zonal Offices. Strengthening of zonal offices of CDSCO has also been done. During this period, two sub-zonal offices (Ahmedabad and Hyderabad) have been upgraded to zonal offices and three new sub-zones (Chandigarh, Bangalore and Jammu) have been set up. Now there are 6 Zones and 3 Sub-Zones of CDSCO in different parts of the country. The Ministry has already identified places for creation of three more Zones / Sub-Zones at Goa, Indore and Guwahati.

The Ministry has ambitious plans for capacity building for drug testing in the country during the 12th Plan. This includes upgradation of existing labs, setting up of new labs, setting up of Mini labs at ports of entry, commissioning of Mobile Labs, special labs for medical devices and cosmetics, etc.

On skill development front, the CDSCO has been vigorously engaged in imparting comprehensive training to the staff of CDSCO at various levels. A separate training division has already been constituted and operationalized in CDSCO.

For attending to the area of Pharmacovigilance, which is already being done through the Pharmacovigilance Programme of India the Ministry aims at involving all medical colleges in the country in the programme.

The status of working of States' Drugs regulatory mechanism has been an area of concern as the enforcement of Drugs & Cosmetics Act is mainly done by them. The Ministry has given special attention to this deficient area. Considering the importance of making good quality drugs available to the public at large, in the 12th Plan it is proposed to strengthen the drug regulatory mechanism in the State/UTs through a specific scheme. This envisages augmentation of both the physical infrastructure and human resources. A new budget line has been opened and an initial token provision of Rs. 2 crore has been made in 2012-13 budget.

5. **Measures taken to streamline the process of new drug approval:** In order to streamline the process of drug approvals, 12 New Drug Advisory Committees (NDAC) and 6 Medical Device Advisory Committees (MDAC) consisting of eminent medical experts from across the country have been constituted to advise the Drugs Controller General (India) in matters related to regulatory approval of new drugs, clinical trials and new medical devices. Two more Committees of Experts also advise the DCG(I) in matters related to regulatory approval of clinical trials for Investigational New Drugs (IND) and special biological products. Expert committee would be constituted to define polices, guidelines and lay down Standard Operating Procedures (SOPs) for approval of new drugs. The situation is still evolving and will be a continuous process.

6. **WHO National Regulatory Authority (NRA) Assessment (December, 2012):** A WHO-led team conducted a comprehensive review of the functioning of the National Regulatory Authority of India (CDSCO) and its affiliated institutions (including drugs testing laboratories) by its international experts drawn from eight different countries (USA, France, Sweden, Switzerland, China, Indonesia, Thailand and Iran) to assess whether CDSCO meets WHO published indicators for a functional vaccine regulatory system. WHO has established stiff benchmarks that define international expectations for a functional vaccine regulatory system. The regulatory functions of CDSCO and its affiliated institutions were assessed for compliance against the WHO indicators. In addition to the general framework for the system, the following regulatory functions were evaluated: marketing authorization and licensing; post-marketing surveillance including adverse events following immunization (AEFI); lot release by the national regulatory authority; laboratory access; regulatory inspections of manufacturing sites and distribution channels; and authorization and monitoring of clinical trials. WHO prequalification, which is a guarantee that a specific vaccine meets international standards of quality, safety and efficacy, is a prerequisite for manufacturers to supply to countries through United Nations procuring agencies. The WHO assessment concluded that the vaccine manufacturers in India continue to remain eligible to apply for Prequalification of specific products. The WHO assessment also concluded that the National Regulatory Authority of India, i.e., CDSCO continues to be functional (copy of the communication received from World Health Organisation (WHO) in this regard is enclosed at Appendix).

ACTION ...EN REPORT

PARA No.	RECOMMENDATIONS	ACTION TAKEN NOTE / COMMENTS
Para 2.2	The Committee is of the firm opinion that most of the ills besetting the system of drugs regulation in India are mainly due to the skewed priorities and perceptions of CDSCO. For decades together it has been according primacy to the propagation and facilitation of the drugs industry, due to which, unfortunately, the interest of the biggest stakeholder i.e. the consumer has never been ensured. Taking strong exception to this continued neglect of the poor and hapless patient, the Committee recommends that the Mission Statement of CDSCO be formulated forthwith to convey in very unambiguous terms that the organization is solely meant for public health.	2.2: The functions of CDSCO emanate from the provisions of the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945. The preamble of the Drugs and Cosmetics Act, 1940 is to regulate the import, manufacture, distribution and sale of drugs and cosmetics. The quality control is exercised through the system of licensing and inspections as provided under the Act and Rules. In the spirit of the recommendations of the Hon'ble Committee a Mission Statement of CDSCO has been formulated as under: "To safeguard and enhance the public health by assuring the safety, efficacy and quality of drugs, cosmetics and medical devices."
Para 2.19	The Committee notes with serious concern that CDSCO is substantially under-staffed. Of the 327 sanctioned posts, only 124 are occupied. At this rate, what would be the fate of 1,045 additional posts that have been proposed is a moot point. If the manpower requirement of the CDSCO does not correspond with their volume of work, naturally, such shortage of staff strains the ability of the CDSCO to discharge its assigned functions efficiently. This shortcoming needs to be addressed quickly. Consideration can also be given to employ medically qualified persons as Consultants/Advisers (on the pattern of Planning Commission) at suitable rank.	2.19: The Government agrees with the observations of the Hon'ble Committee. Staff constraint has always been the key factor in the functioning of the organization. The Ministry has been making continuous efforts at improvement in the situation. Though it has been attempted to take care of the constraint of medically qualified personnel through NDACs in some respects, the Ministry has already decided to consider engagement of highly qualified medical professionals in various therapeutic fields to assist the CDSCO in its core functioning.
Para 2.20	The Committee also gathers that the average time taken for the completion of recruitment process is approximately 12 to 15 months. The Committee, therefore, recommends that to overcome the staff shortage, the Ministry should engage professionally qualified persons on short-term contract or on deputation basis until the vacancies are filled up. Due to the very sensitive nature of regulatory work, great care will need to be taken to ensure that	2.20: The Government agrees with the observations of the Hon'ble Committee. Delays in recruitment process do, however, take place as there are very time consuming procedures adopted by the recruiting agencies (UPSC and SSC) mandated by various Government

	persons employed for short periods did not and will not have Conflict of Interest for a specified period.	instructions. These delays at times are beyond the control of the Ministry and despite the Ministry's efforts at expediting these recruitments, the situation has not improved. The Ministry would continue its efforts to expedite the recruitment process. However, to bridge the gap between the demands of the functioning of the organization and the availability of manpower, the Ministry has resorted to engagement of personnel on contract basis.
Para 2.21	At the same time, the optimal utilization of the current staff in the best interest of public is the responsibility of those who run the CDSCO. In a resource constrained country like India, it is extremely difficult to meet the demands, however, genuine, of all the State entities in full. Hence, prioritization is the key. For example, work relating to an application for Marketing Approval of a New Drug that will be used by millions and thus have an impact on the well being of public at large in India for years to come, is far more important and urgent than giving permission to a foreign company to conduct clinical trials on an untested new patented, monopoly drug.	2.21: The Government agrees with the observations of the Hon'ble Committee and has noted them for due compliance. The DCG(I) has been adequately sensitized in this regard. However, the requisite policies and Standard Operating Procedures (SOPs) for prioritization in this regard would also be prepared.
Para 2.22	The Committee also observes that the strengthening of drugs regulatory mechanisms cannot be achieved by manpower augmentation alone. A host of issues involving capacity-building of CDSCO like upgradation of existing offices, setting up of new offices, creation of new central drugs testing laboratories and equipping them with the state-of-the-art technology to enable them to carry out sophisticated analysis of drugs, upgradation of the existing 6 Central Drugs Testing Laboratories, skill development of the regulatory officials, implementation of an effective result-oriented pharmacovigilance programme drawing on global experience, increased transparency in decision-making of CDSCO etc. will have to be addressed before the desired objectives are realized.	2.22: The Government agrees with the observations of the Hon'ble Committee and has noted them for due compliance.
Para 2.23	In the absence of any reasons for unwillingness on the part of medically qualified persons to join CDSCO, the Committee is of the opinion that emoluments and perquisites may not be the main or only reason. It is noticed that minimum prescribed academic qualifications for the post of DCGI is barely B.Pharm. On the other hand for Deputy Drugs Controller (DDC), the prescribed minimum qualification is post-graduation for medically qualified persons. The stumbling block is the requirement that DCGI should have experience in the "manufacture or testing of drugs or enforcement of the provisions of the Drugs and Cosmetic Act for a minimum period of five years." This requirement virtually excludes even	2.23, 3.6, 3.7 & 3.8: The Government has duly taken care of the observations of the Hon'ble Committee. The Drugs & Cosmetics Rules provide the qualification for the post of licensing and controlling authority as "Graduate in Pharmacy or Pharmaceutical Chemistry or in Medicine with specialization in Clinical Pharmacology of Microbiology". These rules were made long before. As per these existing rules, the DCG(I) being the

	highly qualified medical doctors from occupying the post of DCGI. Moreover the rule stipulates that doctors with post-graduation should be either in pharmacology or microbiology only, thus excluding post-graduates, even doctorates (like DM) in a clinical subject. Besides, highly qualified medical doctors may be reluctant to work under and report to a higher officer with lesser qualifications in a technology driven regulatory authority set-up. Unless these concerns are addressed, it would be difficult to get the desperately required medically qualified professionals on the rolls of CDSCO.	licensing and controlling authority in CDSCO must have these minimum qualifications. The post of DCG(I) is equivalent to Joint Secretary and hence the qualification for the post is required to be of sufficiently higher level to maintain its high level position. Therefore, additional higher qualifications were considered for this post. Accordingly, the present notified RRs for the post of DCG(I) contain the basic qualification prescribed in the Drugs & Cosmetics Rules and additional higher qualifications as under: "Essential: (i) Graduate degree in Pharmacy or Pharmaceutical Chemistry or in Medicine with specialization in Clinical Pharmacology or Microbiology from a recognized University established in India by law; (ii) Postgraduate degree in Pharmacy/ Pharmaceutical Chemistry/ Biochemistry/ Chemistry/ Microbiology/ Pharmacology from a recognized University or equivalent; and (iii) 15 years' experience in manufacture or testing of drugs in a concern of repute or enforcement of the provisions of the Drugs and Cosmetics Act, 1940 and Rules. Desirable: (i) Two years' experience in dealing with problems connected with drugs standardization and control and import and export of Drugs, and/or administration of the Drugs and Cosmetics Act and Rules (ii) Ph.D in Pharmaceutical Sciences" However, the qualifications and the notified Recruitment Rules for the post of DCG(I) are sub-judice in the Madras High Court on the directions of the Hon'ble Supreme Court. However, the Ministry would set up an expert committee as also recommended
Para 3.6	The Committee fails to understand as to how a graduate in pharmacy or pharmaceutical chemistry (B.Pharm) is being equated with a medical graduate with MD in Pharmacology or Microbiology. Apart from the obvious anomaly, with rapid progress in pharmaceutical and biopharmaceutical fields, there is urgent need to revise the qualifications and experience as minimum eligibility criteria for appointment as DCGI. The Committee is of the view that it is not very rational to give powers to a graduate in pharmacy, who does not have any clinical or research experience to decide the kinds of drugs that can be prescribed by super specialists in clinical medicine such as those holding DM and PhD qualifications and vast experience in the practice of medicine and even research.	
Para 3.7	On a larger plane, the Committee is disillusioned with the qualifications provided in the age old Rules for the head of a crucial authority like CDSCO. The extant Indian system is nowhere in so far as sheer competence and professional qualifications are concerned when compared with countries like USA and UK. There is, therefore, an urgent need to review the qualifications, procedure of selection and appointment, tenure, emoluments, allowances and powers, both administrative and financial of the DCGI. While doing so, the Government may not only rely on the Mashelkar Committee Report which recommended augmented financial powers to DCGI but also take cue from similar mechanisms functioning in some of the developed countries like USA, UK, Canada, etc in order to ensure that only the best professional occupies this onerous responsibility. The Committee should be kept informed of the steps taken to address this issue.	
Para 3.8	In the considered opinion of the Committee, there can never be a more opportune time than now, to usher in these changes recommended by it. The post of DCGI is vacant as of now, with an official holding temporary charge. They, therefore, desire that the government should take immediate measures in terms of their instant recommendations to ensure that CDSCO is headed by an eminent and professionally qualified person.	

		by the three member expert committee to review and lay down the qualifications / experience, job description, powers and responsibilities etc. for the post of DCG(I) in consultation with the Ministry of Law as the matter is sub-judice. Additionally, this committee would also review these issues relating to other senior level posts in the organization.
Para 4.5	From an analysis of the above facts, the Committee concludes that shortcomings witnessed in respect of coordination with and between the States as also in implementation of applicable legislations in the States are primarily an offshoot of inadequacies in manpower and infrastructure in the States. Strengthening the regulatory mechanism in the States will remain a far cry unless these infirmities are taken care of.	4.5 & 4.6: The Ministry agrees with the observations of the Hon'ble Committee and envisages strengthening of the States' drug regulatory system during the 12th Five Year Plan through a suitable scheme.
Para 4.6	Given the lack of adequate resources in the States it would be unrealistic to expect them to improve the infrastructure and increase manpower without Central Assistance for strengthening drug control system. The Committee, therefore, recommends that the Ministry of Health and Family Welfare should work out a fully centrally sponsored scheme for the purpose so that the State Drug Regulatory Authorities do not continue to suffer from lack of infrastructure and manpower anymore. The Committee desires to be kept apprised of the initiatives taken by the Ministry in this regard.	
Para 4.7	It is a matter of grave concern that there are serious shortcomings in Centre- State coordination in the implementation of Drugs & Cosmetics Act and Rules. This, the Committee notes, is despite the Ministry's own admission that Section 33P of the Drugs and Cosmetics Act contains a provision that enables the Central Government to give such directions to any State Government as may appear to it to be necessary for implementation of any of the provisions of the Drugs and Cosmetics Act and Rules made thereunder. The Committee understands that these provisions are meant to be used sparingly. However, there have been several situations which warrant intervention through Rule 33 P. Therefore the committee hopes that in future the Ministry would not be found wanting in considering the option of using Section 33P to ensure that provisions of central drug acts are implemented uniformly in all states.	4.7: The Ministry agrees with the observations of the Hon'ble Committee. The issue of cancellation of licenses by the State Licensing Authorities for manufacture of drug formulations failing under the purview of the new drugs especially in respect of fixed dose combinations in the light of the observations made by the Parliamentary Standing Committee was discussed in the Drugs Consultative Committee in the meeting held on 20th July, 2012. It has been reiterated in the meeting that such license for new drugs for unapproved FDCs must not be granted by any State Licensing Authorities. The State drug licensing authorities had also been issuing licenses of drug

		formulations along with the brand names which were not as per the provisions of the Drugs & Cosmetics Rules. The Ministry has used the provisions under section 33P of the Act in the past. In order to take care of these aforesaid issues, the Ministry has again issued statutory directions under section 33P to the State Governments on 1.10.2012 on the following issues: 1. Not to grant licenses for manufacture for sale or for distribution or for export of new drugs, except in accordance with the procedure laid down under the said rules i.e. without prior approval of the Drugs Controller General (India). 2. To grant / renew licenses to manufacture for sale or for distribution of drugs in proper / generic names only. Copies of the two letters dated 1.10.2012 of the Ministry containing the said directions are enclosed at **Annexures - I & II**.
Para 4.8	As regards lack of databank and accurate information, the Committee would like to observe that given the information technology resources currently available, developing an effective system of coordination amongst State Drug Authorities for providing quality and accurate data could have been accomplished long back had the Ministry taken any initiative towards encouraging the States to establish a system of harmonized and inter-connected databanks. Evidently, no serious efforts seem to have been made in this regard. The Committee, however, expects that the Ministry would, at least now, play a more pro-active role in encouraging the States to employ modern information technology in the implementation of tasks assigned to them. At the same time a centralized databank (e.g. licenses issued, cancelled, list of sub-standard drugs, prosecutions etc.) may be created to which all the State Drug Authorities should be linked.	4.8: The Ministry agrees with the observations of the Hon'ble Committee. The following steps have so far been taken by the CDSCO in this regard: (i) The data regarding about 85000 brands of drug formulations approved by the various state licensing authorities as obtained from the State Food & Drug Control Administration (FDCA), Gujarat has been uploaded on the web-site of CDSCO. (ii) Information on various approvals / licenses granted by the CDSCO are uploaded on its web-site from time-to-time. (iii) Recommendations of the NDACs in matters related to approval of new drugs

		and clinical trials are being uploaded on the CDSCO web-site from time-to-time. (iv) A file tracking system and posting of queries / approvals etc on the website of CDSCO on daily basis have been introduced. The Government would take further necessary action on priority basis on creation of the required infrastructure in this direction. During the 12th Plan, the Ministry envisages to put a proper e-Governance system in place which will include inter-linking of all offices of Zonal/Sub-Zonal/Port offices/Laboratories of CDSCO and offices of State Drugs Controllers for fast communication and effective monitoring of quality of Drugs. The proposed system will include IT enabled services, National Registry, Video Conferencing facilities, archiving of all files etc. The WHO assessors during the assessment of the National Regulatory Authority (NRA) in December, 2012 have also recommended to have e-governance in the functioning of CDSCO.
Para 5.11	The Committee agrees that the capacity-building of the Central Drugs Testing Laboratories is the need of the hour. In this era of newer innovations coming up at rapid pace, equipping the Drug Testing Laboratories with the high-end sophisticated equipments is very essential. However, the Committee is aware that monitoring the quality of drugs is primarily the responsibility of the State Drugs Authorities, supplemented by CDSCO, which play a major role in collection of samples and testing them. Without manpower augmentation and upgradation of State Drugs Testing Laboratories, the objective of ensuring availability of quality drugs to the public cannot be realized. The Committee, therefore, recommends strengthening of both Central and State Drug Testing Laboratories.	5.11: The Ministry agrees with the observations of the Committee. The Ministry would take up the matter with the Department of Expenditure about the necessity of augmenting the resources of the central labs and consider creation of more posts. The strengthening of the States' drugs regulatory systems, including the upgradation of the State Labs would also be facilitated during the 12th Plan period.
Para 6.2	The Committee agrees with the above suggestion and recommends that the Ministry of Health and Family Welfare should take initiative towards addressing the shortcomings forthwith in coordination with the Ministry of Civil Aviation at all seaports/airports handling import and exports of pharmaceutical products. The Committee will like to be informed of steps taken to address this problem.	6.2: The Ministry would take up the issue with the concerned authorities in the Ministry of Civil Aviation and Ministry of Shipping for necessary action.

Para 7.13	The Committee is of the view that due to untraceable files on three drugs, it is not possible to determine if all conditions of approval (indications, dosage, safety precautions) are being followed or not. Moreover the product monographs cannot be updated in the light of recent developments and regulatory changes overseas. Therefore all the missing files should be re-constructed, reviewed and monographs updated at the earliest.	7.13: The concerned files have since been reconstituted, though the complete details are still not available. The issues relating to continued marketing of these drugs and updating of their product monographs in the light of recent knowledge and regulatory changes overseas will be referred to the NDAC for examination and review.
Para 7.14	On scrutiny of 39 drugs on which information was available, the Committee found the following shortcomings: • In the case of 11 drugs (28%) Phase III clinical trials mandated by Rules were not conducted. These drugs are i, Everolimus (Novartis), ii. Colistimethate (Cipla), iii. Exemestane (Pharmacia), iv. Buclizine (UCB), v. Pemetrexid (Eli Lilly), vi. Aliskiren (Novartis), vii. Pentosan (West Coast), viii. Ambrisentan (GlaxoSmithKline), ix. Ademetionine (Akums), x. Pirfenidone (Cipla), and xi. FDC of Pregabalin, Methylcobolamine, Alpha Lipoic Acid, Pyridoxine & Folic Acid (Theon); • In the case of 2 drugs (Dronedarone of Sanofi and Aliskiran of Novartis), clinical trials were conducted on just 21 and 46 patients respectively as against the statutory requirement of at least 100 patients; • In one case (Irsogladine of Macleods), trials were conducted at just two hospitals as against legal requirement of 3-4 sites; • In the case of 4 drugs (10%) (Everolimus of Novartis; Buclizine of UCB; Pemetexid of Eli Lilly and FDC of Pregabalin with other agents), not only mandatory Phase III clinical trials were not conducted but even the opinion of experts was not sought. The decision to approve these drugs was taken solely by the non-medical staff of CDSCO on their own. • Of the cases scrutinized, there were 13 drugs (35%) which did not have permission for sale in any of the major developed countries (United States, Canada, Britain, European Union nations and Australia). None of these drugs have any special or specific relevance to the medical needs of India. These drugs are: i. Buclizine for appetite stimulation (UCB); ii. Nimesulide injection (Panacea); iii. Doxofylline (Mars) iv. FDC of Nimesulide with Levocetirizine (Panacea); v. FDC of Pregabalin with other agents (Theon); vi. FDC of Tolperisone with Paracetamol (Themis); vii. FDC of Etodolac with Paracetamol (FDC); viii. FDC of Aceclofenac with Thiocolchicoside (Ravenbhel); ix. FDC of Ofloxacin with Ornidazole (Venus), x. FDC of Aceclofenac with Drotaverine (Themis); xi. FDC of Glucosamine with Ibuprofen (Centaur); xii. FDC of Diclofenac with Serratiopeptidase (Emcure) and xiii. FDC of Gemifloxacin with Ambroxol (Hetero).	7.14 & 7.15: The Ministry agrees with the observations of the Committee regarding review of the approvals to ensure safety of patients, fair play, transparency and accountability. The issues relating to continued marketing of these drugs and updating of their product monographs in the light of recent knowledge and regulatory changes overseas will, however, be referred to the NDACs for examination and review. The Ministry agrees with putting the recommendations of the experts on the web-site. The DCG(I) has been adequately sensitized in this regard. The Ministry will also take further measures to bring transparency and accountability in approvals.

	• In the case of 25 drugs (64%), opinion of medically qualified experts was not obtained before approval. • In those cases (14 out of 39 drugs), where expert opinion was sought, the number of experts consulted was generally 3 to 4, though in isolated cases the number was more. In a country where some 700,000 doctors of modern medicine are in practice such a miniscule number of opinions are hardly adequate to get diverse views and come to a well considered rational decision apart from the possibility of manipulation by interested parties. As against this, to review just the dose of popular pain-killer paracetamol, the United States Food and Drug Administration (USFDA) constituted a panel of 37 experts drawn from all over the country. After extensive debate 20 members sought ban on the combination of paracetamol with narcotics (17 opposed), 24 members sought reduction of dose from 500mg to 325mg (13 opposed) and 26 members advised to make high dose (1000mg) formulation a prescription only medicine (11 opposed). The voting pattern shows independent application of mind by each member. The opinions and decisions are in public domain (website of USFDA) so that anyone is free to scrutinize, offer comments and give suggestions. In India, every discussion and document is confidential away from public scrutiny. This matter needs to be reviewed to ensure safety of patients, fair play, transparency and accountability.	
Para 7.15	Unless there is some legal hitch, the Committee is of the view that there is no justification in withholding opinions of experts on matters that affect the safety of patients from public. Consideration should be given to upload all opinions on CDSCO website.	
Para 7.16	According to information provided by the Ministry, a total of 31 new drugs were approved in the period January 2008 to October 2010 without conducting clinical trials on Indian patients. The figure is understated because two drugs (ademetionine and FDC of pregabalin with other ingredients) were somehow not included in the list. Thus there is no scientific evidence to show that these 33 drugs are really effective and safe in Indian patients.	7.16: The Ministry has noted the observations of the Committee. Accordingly, the 33 drugs will be referred to the NDACs for examination and review. The Ministry will also constitute an expert committee to define policies and lay down SOPs for approval of new drugs.
Para 7.27	It is obvious that DCGI clears sites of pre-approval trials without application of mind to ensure that major ethnic groups are enrolled in trials to have any meaningful data. Thus such trials do not produce any useful data and merely serve to complete the formality of documentation.	7.27, 7.28 & 7.29: The Ministry has noted the observations of the Committee. While examining the applications for clinical trials by CDSCO, the proposals are examined in consultation with NDACs. The NDACs at the time of approving the trial sites will be advised to take note of the recommendations of the Parliamentary Standing Committee. The DCG(I) has been adequately sensitized in this regard.
Para 7.28	The Committee recommends that while approving Phase III clinical trials, the DCGI should ensure that subject to availability of facilities, such trials are spread across the country so as to cover patients from major ethnic backgrounds and ensure a truly representative sample. Besides, trials should be conducted in well equipped medical colleges and large hospitals with round the clock	

	emergency services to handle unexpected serious side effects and with expertise in research and not in private clinics given the presence of well equipped medical colleges and hospitals in most parts of the country in present times.	The Ministry will also constitute an expert committee to define policies, lay down guidelines and SOPs for approval of clinical trials and new drugs. This committee would also examine the issues relating to the minimum number of subjects, number of sites, their distribution, etc in clinical trials for the purpose of approval of new drugs in the country.
Para 7.29	The Committee is of the view that taking into account the size of our population and the enormous diversity of ethnic groups there is an urgent need to increase the minimum number of subjects that ought to be included in Phase III pre-approval clinical trials to determine safety and efficacy of New Drugs before marketing permission is granted. In most western countries the required numbers run into thousands. However since the major objective in India is to determine the applicability or otherwise of the data generated overseas to Indian population, the requirement should be re-assessed and revised as per principles of medical statistics so that major ethnic groups are covered. A corresponding increase in the number of sites so as to ensure a truly representative sample spread should also be laid down in black and white. Furthermore, it should be ensured that sites selected for clinical trials are able to enroll diverse ethnic groups. For domestically discovered drugs, the number of subjects should be revised as well. This can be easily achieved by changes in the Good Clinical Practice (GCP) guidelines.	
Para 7.31	A review of the opinions submitted by the experts on various drugs shows that an overwhelming majority are recommendations based on personal perception without giving any hard scientific evidence or data. Such opinions are of extremely limited value and merely a formality. Still worse, there is adequate documentary evidence to come to the conclusion that many opinions were actually written by the invisible hands of drug manufacturers and experts merely obliged by putting their signatures..... Is the Committee mistaken in coming to the conclusion that all these letters were collected by interested party from New Delhi, Mumbai, Chandigarh and Secunderabad and handed over to office of the DCGI on the same day? If so, it is obvious that the interested party was in the loop in the entire process of consultation with experts. (Annexure 6).....It is inconceivable that a letter dated 17-6-2005 from New Delhi will be delivered to the office of DCGI also in New Delhi after more than two months. The conclusion, as in aforementioned cases, is obvious. (Annexure 8)	7.31, 7.32, 7.33 & 7.34: The Ministry has noted the observations of the Committee. The applications for new drugs including FDCs are now examined by the NDACs and decisions on their approval are taken based on the recommendations of these committees. The issues relating to the Fixed Dose Combination of aceclofenac with drotaverine would be referred to the NDAC for examination and review. As mentioned earlier, the Ministry had constituted a three member expert committee. The expert committee submitted its report to the Ministry on 22.11.2012. The committee has recommended instituting an enquiry into the matter.
Para 7.32	If the above cases are not enough to prove the apparent nexus that exists between drug manufacturers and many experts whose opinion matters so much in the decision making process at the CDSCO, nothing can be more outrageous than clinical trial approval given to the Fixed Dose Combination of aceclofenac with drotaverine which is not permitted in any developed country of North America, Europe or Australasia. In this case, vide his letter number 12-298/06-DC dated 12- 2-2007, an official of CDSCO	As recommended by the Hon'ble

	advised the manufacturer, Themis Medicare Ltd. not only to select experts but get their opinions and deliver them to the office of DCGI! No wonder that many experts gave letters of recommendation in identical language apparently drafted by the interested drug manufacturer.	Committee, the DCG(I) will constitute an enquiry committee to investigate into the matter.
Para 7.33	In the above case, the Ministry should direct DCGI to conduct an enquiry and take appropriate action against the official(s) who gave authority to the interested party to select and obtain expert opinion and finally approved the drug.	
Para 7.34	Such expert opinions in identical language and/or submitted on the same day raise one question: Are the experts really selected by the staff of CDSCO as mentioned in written submission by the Ministry? If so how can they, situated thousands of miles away from each other, draft identically worded letters of recommendation? Is it not reasonable to conclude the names of experts to be consulted are actually suggested by the relevant drug manufacturers? It has been admitted that CDSCO does not have a data bank on experts, that there are no guidelines on how experts should be identified and approached for opinion.	
Para 7.35	The Committee is of the view that many actions by experts listed above are clearly unethical and may be in violation of the Code of Ethics of the Medical Council of India applicable to doctors. Hence the matter should be referred to MCI for necessary follow up and action. In addition, in the case of government employed doctors, the matter must also be taken up with medical colleges/hospital authorities for suitable action.	7.35: The Ministry has noted the observations of the Committee. As mentioned earlier, the Ministry had constituted a three member expert committee. The expert committee submitted its report to the Ministry on 22.11.2012. The committee has recommended instituting an enquiry into the matter. The committee has also recommended laying down a code of conduct for the members participating in these bodies as also Ethics Committees. An expert committee would be constituted to define policies and SOPs for identification of experts and their participation in these bodies. However, as recommended by the Hon'ble Committee, the Ministry would also refer the issue to the Medical Council of India for necessary action. For Government employed doctors, the matter will be brought to the notice of the concerned medical colleges / hospital authorities for appropriate action.

Para 7.36	There is sufficient evidence on record to conclude that there is collusive nexus between drug manufacturers, some functionaries of CDSCO and some medical experts.	7.36, 7.37 & 7.38: The Ministry has noted the observations of the Committee. Now, the applications for new drugs including FDCs are examined by the NDACs and decisions on their approval are taken based on the recommendations of these committees. All members of the NDACs are required to sign a declaration of conflict of interest before being involved with NDACs. The Ministry will also constitute an expert committee to define policies, lay down guidelines and SOPs for approval of clinical trials and new drugs. The policies and SOPs for identification of experts would also be formulated. The recommendations of the NDACs are being put on the web-site for ensuring transparency and accountability. The DCG(I) has been adequately sensitized in this regard.
Para 7.37	On a more fundamental issue the Committee has come to the conclusion that when it comes to approving new drugs, too much is left to the absolute discretion of the CDSCO officials. There are no well laid down guidelines for determining whether consultation with experts is required. Thus the decision to seek or not to seek expert opinion on new drugs lies exclusively with the nonmedical functionaries of CDSCO leaving the doors wide open to the risk of irrational and incorrect decisions with potential to harm public health apart from the possibility of abuse of arbitrary discretionary powers.	
Para 7.38	The Committee, therefore, strongly recommends that there should be nondiscretionary, well laid down, written guidelines on the selection process of outside experts with emphasis on expertise including published research, in the specific therapeutic area or drug or class of drugs. Currently, the experts are arbitrarily chosen mainly based on their hierarchical position which does not necessarily correspond to the area or level of expertise. All experts must be made to file the Conflict of Interest declaration outlining all past and present pecuniary relationships with entities that may benefit from the recommendations given by such experts. The consulted experts should be requested to give hard evidence in support of their recommendations.	
Para 7.41	The Committee is of the view that responsibility needs to be fixed for unlawfully approving Buclizine, a drug of hardly any consequence to public health in India, more so since it is being administered to babies/children. At the same time the approval granted should be reviewed in the light of latest scientific evidence, regulatory status in developed countries, particularly in Belgium, the country of its origin.	7.41: The issues relating to the drug Buclizine would be referred to the NDAC for examination and review. As mentioned earlier, the Ministry had constituted a three member expert committee. The expert committee submitted its report to the Ministry on 22.11.2012. The committee has recommended instituting an enquiry into the matter. As recommended, the DCG(I) will constitute an enquiry committee to investigate into the issue.
Para 7.42	Letrozole discovered by Novartis, is an anti-cancer drug for use only in postmenopausal women and is contraindicated (not permitted) to be used in women of reproductive age. If it is to be used for any	7.42 & 7.43: As mentioned earlier, the Ministry had constituted a three member expert committee. The expert committee

	other indication except breast cancer, then the drug is categorized as a New Drug under Indian laws. On 10-04-2007, DCGI approved the use of letrozole for improving female fertility. The Drugs and Cosmetic Rules require that while approving a drug for use in females of reproductive age, animal studies are to be done in this specific group. No such studies were done in India. The innovator also did not conduct such studies abroad because there was no plan to use letrozole in women of reproductive age. Under Indian rules, Phase II studies should have been conducted before Phase III since such studies were not conducted anywhere. Permission to conduct Phase III studies was given without prior Phase II studies. Phase III clinical trial was conducted on just 55 women by three doctors in private practice while the minimum requirement as per mandatory Good Clinical Practice (GCP) rules is at least 100. After approval, the sponsor, Sun Pharmaceuticals did not submit periodic PSURs due every six months as required by law. No action was taken against the Company in such a sensitive case since India is the only country where the drug is permitted to be used for female infertility. Post-marketing data is crucial and critical in detecting adverse effects both in women and babies born to them if they use letrozole before the onset of pregnancy. Clearly there was a serious lapse on the part of CDSCO. In the wake of media outcry, in a diversionary move, the DCGI instead of investigating the allegations of regulatory lapse and taking corrective measures referred the matter to clinical experts, DTAB etc. on the restricted issue of safety and efficacy. DCGI is expected to take action against those CDSCO functionaries who colluded with private interests and got the drug approved in violation of laws. The drug has since been banned by the Ministry for use in female infertility.	submitted its report to the Ministry on 22.11.2012. The committee has recommended instituting an enquiry into the matter. As recommended, the DCG(I) will constitute an enquiry committee to investigate into the issue.
Para 7.43	The Committee takes special note of this case of gross violation of the laws of the land by the CDSCO. First, in approving the drug for use in case of female infertility and thereafter, in exhibiting overt resistance in taking timely corrective steps despite very strong reasons favouring immediate suspension of use of letrozole for the said indication. Belatedly, the drug has been banned for use in female infertility.	
Para 7.45	The Committee is of the opinion that there must be some very good reasons for Danish Medicine Agency (Denmark) not to approve a domestically developed drug where an anti-depressant drug would perhaps be in greater demand as compared to India. Curiously, Deanxit is allowed to be produced and exported but not allowed to be used in Denmark.	7.45, 7.46 & 7.47: The Ministry has noted the observations of the Committee. Now, the applications for new drugs including FDCs are examined by the NDACs and decisions on their approval are taken based on the recommendations of these committees. The drug FDC of Flupenthixol and Melitracen, of which the Deanxit is also a
Para 7.46	The Committee feels that the DCGI should have gone into the reasons for not marketing the drug in major developed countries such as United States, Britain, Ireland, Canada, Japan, Australia just to mention a few. United States alone accounts for half of the	

	global drug market. It is strange that the manufacturer is concentrating on tiny markets in unregulated or poorly regulated developing countries like Aruba, Bangladesh, Cyprus, Jordan, Kenya, Myanmar, Pakistan, and Trinidad instead of countries with far more patients and profits. Many of these developing countries are handicapped due to lack of competent drug regulatory authorities. Instead of examining and reversing regulatory lapses, DCGI has referred the matter to an Expert Committee to look at the isolated and restricted issue of "safety and efficacy" instead of unlawful approval in the first place.	brand, is already under examination in consultation with an expert committee. The expert committee recommended for conducting Phase IV Clinical trial after getting the protocol approved. The protocol for the trial submitted by the firm is under examination by that expert committee. The drug was approved in the country in 1998 and since then it is in the market. It is also marketed in other countries. Since the Hon'ble Committee has raised concern over the manner of approval of the drug and has recommended that the same needs to be revisited, it has been decided that the manufacturer of the drug shall be instructed to establish the safety and efficacy of the FDC within 6 months, failing which the drug would be considered for being prohibited for manufacture and marketing in the country.
Para 7.47	The Committee recommends that in view of the unlawful approval granted to Deanxit, the matter should be re-visited and re-examined keeping in mind the regulatory status in well developed countries like Denmark, the country of origin; the United States, Britain, Canada, European Union and Japan etc. It is important to keep in mind that in Europe, there are two types of marketing approvals: Community-wide (cleared by European Medicine Agency) and individual regulators of member nations. EMEA is known to clear drugs after great deal of scrutiny while the competence and expertise of drug regulatory authorities of individual nations is not uniform and varies greatly from country to country.	
Para 7.49	The Committee recommends an enquiry into the said letter. The responsibility should be fixed and appropriate action taken against the guilty. The Committee should be kept informed on this case.	7.49: As mentioned earlier, the Ministry had constituted a three member expert committee. The expert committee submitted its report to the Ministry on 22.11.2012. The committee has recommended instituting an enquiry into the matter. As recommended, the DCG(I) will constitute an enquiry committee to investigate into the issue. The Hon'ble Standing Committee would be kept informed on this issue.
Para 7.51	The Committee takes special notice of this case of persistent insolence on the part of CDSCO and hopes that never again shall the DCGI approve drugs in violation of laws, that too for use in neonates and young children.	7.51 & 7.52: The Ministry has noted the observations of the Committee and action will be taken as mentioned in previous recommendations.
Para 7.52	The Committee expresses its deep concern, extreme displeasure and disappointment at the state of affairs as outlined above. The Ministry should ensure that the staff at CDSCO does not indulge in	As mentioned earlier, the Ministry had constituted a three member expert committee. The expert committee

	irregularities in approval process of new drugs that can potentially have adverse effect on the lives of people. It is difficult to believe that these irregularities on the part of CDSCO were merely due to oversight or unintentional. Hence all the cases listed above and cases similar to these should be investigated and responsibility fixed and action taken against erring officials whether currently in service or retired.	submitted its report to the Ministry on 22.11.2012. The committee has recommended instituting an enquiry into the matter. The enquiry committee would be constituted by the DCG(I) to investigate into the matters. As regard similar other cases, as and when they are brought to the notice, appropriate action will be taken.
Para 8.4	The Committee has noted that there are a very large number of alternative analgesics, antipyretics in the Indian market. With so many countries banning Analgin, not to mention unlawful over-promotion by manufacturers, the CDSCO should be directed to re-examine the rationality of continued marketing of Analgin.	8.4: The issue of rationality and continued marketing of Analgin in the country was examined by DTAB in its 61st meeting held on 24th July 2012. The board after deliberations recommended that the continued marketing of the drug may be examined by expert committee in the context of present day knowledge while the manufacturers of Analgin may be directed to market the product giving the full indications approved earlier by DTAB as under: "Severe pain or pain due to tumor and also for bringing down the temperature in refractory cases when other antipyretics fail to do so." The board further recommended that the use of all analgesics with special reference to Analgin should be placed under focused Pharmacovigilance under Pharmacovigilance Programme of India (PvPI). The safety data so collected should be properly analyzed to take further suitable action on use of such drugs. Based on recommendations of the board, the DCG(I) has issued letters to all State Drug Controllers on 13.09.2012 requesting them to direct the manufacturers of analgin formulations to market the drug mentioning the above indications in the package insert / promotional literature of Analgin formulation.

		Further, as per the recommendations, all analgesic with special reference to analgin have been placed under focused PvPI. The continued marketing of analgin will also be referred to NDAC for examination. The DCG(I) has been adequately sensitized in this regard.
Para 8.5	It is to be kept in mind that a drug becomes a candidate for withdrawal not only due to serious side effects but also when safer, more efficacious drugs are launched. Unfortunately, no attention is being paid to this issue. This principle should apply to all cases and all drugs need to be evaluated periodically.	8.5: As mentioned earlier, the Ministry had constituted a three member expert committee. The expert committee submitted its report to the Ministry on 22.11.2012. The committee is also of the view that there should be an adequate system for withdrawal of drugs – with appropriate guidelines & SOPs, so that unsafe drugs are weeded out in a timely fashion. It would be pertinent to mention that most newer drugs are generally found to be more expensive, while the previous drugs may be less expensive and relatively affordable. Thus, this would require examination on case-to-case basis. The matter would be referred to an expert committee to formulate guidelines, policies and procedures in this regard.
Para 8.7	The documents submitted by the Ministry show that even in large developed countries with well developed drug regulation such as US the adverse reactions are not detected by spontaneous reports from doctors in practice. All major side effects were detected in large scale controlled, focused Post-Marketing Phase IV trials involving thousands of patients such as SCOUT on anti-obesity drug sibutramine (now banned) and the RECORD trial on rosiglitazone (now banned). Therefore to expect that any spontaneous reports from medical profession, either in private practice or even institutions (medical colleges, large hospitals) will pick up hitherto unknown side effects in India is not realistic. There is hardly any alternative but to take immediate cognizance of serious adverse drug reactions reported from countries with well developed and efficient regulatory systems. The health and lives of patients in India cannot be put to risk in the hope of detecting ADRs within the country.	8.7 & 8.8: It has since been decided that whenever a drug is banned due to adverse drug reactions in countries with well developed and efficient regulatory system viz. USA, UK, EU, Australia, Japan and Canada, the manufacture, import and marketing of such drugs would be immediately put under suspension till the safety of the drug is examined and established in the country. The DCG(I) has been adequately sensitized in this regard.

Para 8.8	The Committee feels that since the chances of picking up unknown serious adverse effects of drugs being marketed in the country are remote, therefore CDSCO should keep a close watch on regulatory developments that take place in countries with well developed regulatory systems in the West and take appropriate action in the best interest of the patients.	
Para 8.10	In most cases, most of these experts whether appointed by CDSCO or DTAB are from Delhi. The following facts reveal this pattern: • Rimonabant was referred to a committee of six experts, all from Delhi. • Levonorgestrel: Four out of five from Delhi. • Letrozole: Four out of five from Delhi. • Sibutramine: All five from Delhi. • Rosiglitazone: All five from Delhi. A review of membership shows that one expert sat on 5 of the 6 committees. One wonders whether expertise on drugs is confined to Delhi.	8.10: As regards one expert, namely Dr. Y.K. Gupta who attended five of the six committees, it may be mentioned that Dr. Y.K. Gupta is Professor & Head, Department of Pharmacology, AIIMS, New Delhi. Dr. Gupta has wide experience and expertise in the relevant field. Being based in delhi and considering his standing, he was invited for attending most of those meetings. However, henceforth, such committees will be constituted with experts from across the country in light of the observation of the Hon'ble Committee. The DCG(I) has been adequately sensitized in this regard.
Para 8.11	The Committee strongly recommends that with some 330 teaching medical colleges in the country, there are adequate number of knowledgeable medical experts with experience who can be requested to give their opinion on the safety and efficacy of drugs. The need is to make such consultations very broad based so as to get diverse opinion. The opinions, once received, can be put in public domain inviting comments. Once the experts know that their opinions will be scrutinized by others, including peers, they would be extra cautious and give credible evidence in support of their recommendation.	8.11: The Ministry agrees with the observations of the Committee. Efforts would be made to make such consultations as broad-based as possible. The opinions of the experts would also be put on the web-site. The DCG(I) has been adequately sensitized in this regard.
Para 9.2	Unfortunately some State Drug Authorities have issued manufacturing licenses for a very large number of FDCs without prior clearance from CDSCO. This is in violation of rules though till May 2002, there was some ambiguity on powers of the State Drug Authorities in this respect. However the end result is that many FDCs in the market have not been tested for efficacy and safety. This can put patients at risk.	9.2, 9.3, 9.4, 9.5, 9.6 & 9.7: The issue of cancellation of licenses by the State Licensing Authorities for manufacture of drug formulations falling under purview of the new drugs especially in respect of fixed dose combinations in the light of the observations made by the Parliamentary Standing Committee was discussed in the Drugs Consultative Committee in the meeting held on 20th July, 2012. It has been reiterated in the meeting that such
Para 9.3	To remove such unauthorized FDCs from the market, the Central Government can either issue directions under Section 33P to states to withdraw the licences of FDCs granted without prior DCGI	

	approval or the Central Government can itself ban such FDCs under Section 26A.	license for new drugs for unapproved FDCs must not be granted by any State Licensing Authorities.
Para 9.4	The Committee was informed that DCGI has been requesting State Drug Authorities not to issue manufacturing licences to new FDCs and suspend licences of unauthorized FDCs issued in the past. However in exercise of powers under Section 33P specific directions have not been issued. The Ministry failed to provide any coherent reason for lack of action under this Rule. The Ministry informed the Committee that even if Section 33P was invoked, there was no provision to take action against States if directions were not carried out. If considered necessary, the Ministry may examine the possibility of amending the law to ensure that directions under Section 33P are implemented.	Earlier, in 2007, direction was issued to the State Drug Controllers to withdraw the 294 FDCs which were licensed without approval of DCG(I). However, the manufacturers Association got stay order from the Madras High Court. The matter is still sub-judice. The Ministry has, however, again issued statutory direction under section 33P to the State Governments on 1.10.2012 to refrain from granting new drugs licensing including FDCs without approval of DCG (I). In the light of the observations of the Hon'ble Committee: (i) Action in respect of the aforesaid 294 FDCs will be taken after the outcome of the court case in Madras High Court; (ii) In respect of other FDCs licensed by the State Licensing Authorities before 1.10.2012, i.e. the date of issue of direction under section 33P, without the permission of DCG(I), it has now been decided that the DCG(I) will ask all the State Drugs Controllers to ask the concerned manufacturers to prove the safety and efficacy of such FDCs before the CDSCO within a period of 18 months failing which such FDCs will be considered for being prohibited for manufacture and marketing in the country. As regards the new FDC, if any, licensed by the States Licensing Authorities after 1.10.2012 without approval of DCG(I), the same will be considered for being prohibited from manufacturing and marketing in the country.
Para 9.5	It is also possible to ban FDCs, not authorized by CDSCO by invoking Section 26A which empowers the Central Government to ban any drug to protect public health. The Committee was informed that the Government has not evoked Section 26A either so far. No explanation was offered for not using powers under Section 26A.	
Para 9.6	The Committee was informed that the issue regarding grant of Manufacturing Licenses for unapproved FDCs by some State Drug Authorities were first deliberated in 49th DTAB meeting held on 17 February, 2000 i.e. 11 years ago. It is a matter of great concern that even after a lapse of a decade, no serious action has been taken.	
Para 9.7	The Committee is of the view that those unauthorized FDCs that pose risk to patients and communities such as a combination of two antibacterial need to be withdrawn immediately due to danger of developing resistance that affects the entire population.	
Para 9.8	The Committee is of the view that Section 26A is adequate to deal with the problem of irrational and/or FDCs not cleared by CDSCO. There is a need to make the process of approving and banning FDCs more transparent and fair. In general, if an FDC is not approved	9.8: The Ministry agrees with the observations of the Committee. Requirements for approval of FDCs are

	anywhere in the world, it may not be cleared for use in India unless there is a specific disease or disorder prevalent in India, or a very specific reason backed by scientific evidence and irrefutable data applicable specifically to India that justifies the approval of a particular FDC. The Committee strongly recommends that a clear, transparent policy may be framed for approving FDCs based on scientific principles.	specified in Appendix VI of schedule Y. At present, all proposals of new fixed dose combinations are examined in consultation with the NDACs. Decision to approve any FDCs in the country is taken based on the recommendations of these committees. Further, the Ministry of Health and Family Welfare has recently issued statutory direction under section 33P to the State Governments on 1.10.2012 to refrain from granting new drugs licensing including FDCs without approval of DCG (I). The CDSCO would constitute a Committee of experts to lay down policies, guidelines and procedures to be adopted for approval of FDCs. The DCG(I) has been adequately sensitized in this regard.
Para 10.2	The Committee feels that though the Ministry is forming NDACs, which are given very important powers, there is no transparent procedure for the selection of experts of such Committees. The Committee also recommends that institutions from which experts are chosen should be from different parts of the country.	10.2: The 12 New Drug Advisory Committees so far constituted consist of medical specialists from Government medical colleges and reputed institutes across the country as under: • AIIMS, New Delhi • PGIMER, Chandigarh • JIPMER Pondicherry • LHMC & RML Hospital, New Delhi • VMMC &Safdarjung Hospital, New Delhi • Tata Memorial Hospital, Mumbai • CMC, Vellore • MAMC with GB Pant & LNJP Hospital, New Delhi • UCMS (University College of Medical Sciences) with GTB Hospital, New Delhi • Seth GS Medical College & KEM Hospital, Mumbai • Regional Cancer Centre, Trivandrum • SMS Medical College, Jaipur • Medical College, Kolkata • KGMU, Lucknow • IPGME&R and SSKM Hospital, Kolkata • Madras Medical College, Chennai • Institute of Medical Sciences, Banaras Hindu University, Varanasi • Gawahati Medical College and Hospital,

		Gawahati • Govt. Medical College, Jammu • Nizam's Institute of Medical Sciences, Hyderabad The Committees would be more broad-based. The criteria for selection of experts will be decided by a committee of experts and willing experts from Government, other institutions of high repute and excellence will be invited for preparing a panel of experts to advise CDSCO in various technical matters. The DCG(I) has been adequately sensitized in this regard.
Para 11.2	The Committee strongly recommends that all such cases should be thoroughly reviewed in close coordination with State Drug Authorities. Specific procedures may be framed for approval of brand names. The procedure adopted by the Registrar of Newspapers to avoid duplication may be worth emulating. As a beginning, a data bank of all branded pharmaceutical products along with their ingredients should be uploaded on the CDSCO website and regularly updated.	11.2: The Ministry of Health and Family Welfare has recently issued statutory direction under section 33P to the State Governments on 01.10.2012 for Issuance of manufacturing license of drugs in generic names only. The Ministry will take initiative to set up data bank with networking with all state drug controllers. The DCG(I) has also been adequately sensitized in this regard. The CDSCO has already uploaded in its web-site about 85000 brands of drug formulations as obtained from the State Food & Drug Control Administration (FDCA), Gujarat. The State Governments have been advised to initiate immediate action to have data base of all drugs licensed by them, manufacturers, etc.
Para 12.2	In order to scrutinize the compliance of this rule, the Ministry was asked to furnish PSURs in respect of 42 randomly selected new drugs. Since files in respect of three drugs were reportedly missing, PSURs should have been supplied for the balance 39 drugs. The Committee is, however, constrained to note that PSURs in respect of only 8 drugs were submitted by the Ministry. The Committee was informed that 14 drugs though approved were not being marketed	12.2 & 12.3: Out of 42 new drugs, the files in respect of 3 drugs were missing. Out of the remaining 39 drugs, the requisite documents have already been furnished to the Rajya Sabha Secretariat in respect of 23 drugs. The other 16 drugs were reportedly not launched in the market.

	or were launched lately and hence PSURs would be expected later. There was no explanation for not submitting PSURs in respect of rest of 17 drugs.	The FDC of glucosamine with ibuprofen was approved in favour of M/s Centaur Pharma Ltd on 21.10.2009. As per the letter of the firm dated 22.2.2011, the firm informed that they propose to launch this FDC In the year 2012 (first quarter) and would comply with the requirement of submitting the PSUR. In other case, Moxonidine drug was approved in favour of M/s Solvay Pharma (I) Ltd. On 27.2.2007. The firm vide their letter dated 21.2.2011 informed the office of DCG(I) that they had not launched the product for marketing in the country. It has been decided that the DCG(I) will issue general directions addressed to all the State Licensing Authorities and the manufacturers stating that in case an applicant / manufacturer fails to launch their product for marketing in the country within a period of six months from obtaining the permission / license from CDSCO, the permission / license will be treated as cancelled. Further to ensure that the PSURs are submitted by the companies as per the regulatory requirement, the system is being streamlined and a new cell in CDSCO under the overall charge of a Deputy Drugs Controller has been set up.
Para 12.3	Out of 14 drugs that were reported to be either not yet launched or lately launched, the Committee discovered that, at least, two products (FDC of glucosamine with ibuprofen; and moxonidine) were indeed in the market for some time and concerned manufacturers should have submitted PSURs. But the Committee has not been given any explanation for non-submission of PSURs for these two drugs.	
Para 12.4	The Committee observed that even, in those cases where the PSURs were submitted, the frequency and/or format was not as per rules. In the case of two drugs of MNCs (dronedarone of Sanofi Aventis and pemetrexid of Eli Lilly), the PSURs were neither India specific nor in the approved format as required by law. Some companies submitted PSURs for the products being marketed in the country but very few PSURs were India-specific.	12.4, 12.5 & 12.6: The applicants who have been granted approval of new drugs, have been instructed vide letter dated 13.9.2012 to submit India specific PSUR in the format as specified in the rules. The non-compliance of this provision would attract suspension/ cancellation of the marketing approval.
Para 12.5	The Committee is of the firm view that there is a poor follow-up of side effects in Indian patients both by doctors and manufacturers. The objective of PSURs is to collect information about adverse effects on patients in India which would help to determine ethnic	

	differences, if any and result in dosage adjustment, revision of precautions and warnings, if necessary. The Committee takes strong exception to such rampant violation of the mandatory requirements.	
Para 12.6	The Committee strongly recommends that the Ministry should direct CDSCO to send a stern warning to all manufacturers of new drugs to comply with mandatory rules on PSURs or face suspension of Marketing Approval. PSURs should be submitted in CDSCO-approved format which would help track adverse effects discovered in Indian ethnic groups.	
Para 13.3	The Committee feels that the conventional system of locating side effects through spontaneous reporting by doctors to either drug companies or drug regulators has been found to be unsatisfactory. The most effective system is by controlled post-marketing Phase IV studies on a very large number of patients. In the past decade, all the major adverse effects that led to banning of drugs were identified in large scale Phase IV trials. The Ministry may wish to consider the possibility of using this format in the country.	13.3: The Ministry has noted the observations of the Committee. At present, proposals for approval of new drugs are examined in consultation with NDACs. At the time of approval of new drugs, the applicants are instructed to conduct appropriate Phase IV clinical trial as per the recommendation of the committees wherever considered necessary by the committee. This is in addition to the mandatory requirements of submitting PSURs six monthly for initial 2 years and annually for another 2 years. As mentioned earlier, the Ministry had constituted a three member expert committee. The expert committee submitted its report to the Ministry on 22.11.2012. The committee has felt the need for an adequate system for withdrawal of drugs - with appropriate guidelines & SOPs and the need for carrying out Phase IV studies to be made mandatory for special situations. The issue raised by the Hon'ble Committee will, however, be addressed by an expert committee while defining the policies, guidelines, procedures etc. for approval of new drugs.
Para 14.3	The Committee feels that unless information on marketed drugs is continuously updated, there is risk of irrational or inappropriate use of medicines putting patients at risk. The Committee, therefore, recommends that immediate steps need to be taken to address this issue. The CDSCO should be directed to continuously update	14.3: The Indian Pharmacopeia Commission has published the National Formulary of India (NFI) 2011, the book of reference for the use of clinicians, pharmacists and nurses containing

	monographs based on information from regulatory authorities the world over.	detailed information about medicines, their dosage, contraindications, etc. The NFI has been put on the official website of CDSCO so that relevant information reaches the user easily. A cell has been created in CDSCO to update the information for appropriate and rational use of the marketed drugs.
Para 15.4	A drug can be categorized 'Not of Standard Quality' for a variety of both major and minor technical reasons such as not stating the name of the pharmacopoeia correctly, problem with quality of bonding agent, colouring agent, dissolution time, etc. However, there are other more serious cases, where the active ingredient is significantly less in quantity that can harm patients. Therefore, this problem needs to be addressed with all the seriousness that it deserves both by more rigorous checks in procuring bulk drugs (particularly from developing countries with not so stringent quality checks and export controls) and by in-house quality control by manufacturers or solving the problem in transportation and/or storage at distribution/retail levels.	15.4 & 15.5: The Ministry has noted the observations of the Committee. Recently, guidelines have been issued on good distribution practices for ensuring the quality of biological products during all aspects of distribution process. Further, to check the GMP facilities of foreign manufacturing sites, overseas inspections of such sites have started. Six bulk drug manufacturing units in China were inspected in May 2011. Registration Certificate and Import License of one unit so inspected, was cancelled. Further, in March 2012, four manufacturing units in China were inspected. In one case, Registration certificate was cancelled. In another case the inspection of the manufacturing facility showed some non-compliance with the requirements of Schedule M of Drugs and Cosmetics Rules. The firm was issued show cause notice. In reply to the notice, the firm submitted satisfactory compliance report along with documentary evidences. As the firm initially did not comply with the regulatory requirements, the Registration Certificate and Import License of the firm was suspended for 15 days to ensure that the firm will be cautious in future. CDSCO has also formulated guidelines on recall and rapid alert system for drugs including biologicals and vaccines. The same has been uploaded on its web-site.
Para 15.5	By the time a sample is tested, a large number of packs get sold out with undeterminable injury to patients. There is no effective method of recalling unsold stocks lying in the distribution network. This cannot be allowed to go on.	

		CDSCO has started the drug alert system in respect of drugs found to be of not-of-standard quality, spurious, adulterated etc by central drug testing laboratories.
Para 15.6	The Committee feels that there should be severe punishment for manufacturing and for allowing sub-standard drugs to enter the distribution chain. Products with severe deficiencies should be penalized the same way as producers of spurious drugs by amending rules. There is also a case to incorporate penal provisions for manufacturing misbranded and adulterated drugs.	15.6: Dealing in spurious drugs has an element of intent whereas the same in respect of sub-standard drugs may be for a variety of reasons and may not be intentional. However, as per the Drugs and Cosmetics Act, 1940, punishment for selling any not-of-standard quality drug which may cause death or grievous hurt is same as that applicable for spurious or adulterated drugs causing death or grievous hurt which is imprisonment for a term which shall not be less than 10 years but which may extend to imprisonment for life and with fine which shall not be less than ten lac rupees or three times the value of the drug confiscated whichever is more. The penal provision for manufacture and sale of misbranded drugs is covered under section 27(d) of the Act.
Para 15.7	It is known that retail chemists also stock and sell items other than drugs including chocolates, cold drinks etc. During summer these items are stored in the refrigerator while due to paucity of space temperature-sensitive medicines may be lying outside. When samples are picked up, tested and found to be sub-standard, the State Drug Authorities blame and prosecute manufacturers. Therefore the Committee recommends that specifically in the case of temperature sensitive products such as insulins, due consideration should be given to the reference samples of the same batch preserved by the manufacturers.	15.7: The Ministry has noted the observations of the Committee. The State Drugs Controllers have already been directed to take necessary action.
Para 15.9	The Committee is extremely anxious on both counts: such hugely costly imported drugs losing their potency before use and the possibility of fakes entering the chain. It is strange that multinational drug companies that have well staffed marketing offices in India, instead of importing drugs from their overseas affiliates and selling them are using traders to handle this activity. Apart from risk to patients, there is leakage of revenue to income tax. While the promotional expenses on imported formulations are being paid by the Indian branch of MNCs thus reducing income tax	15.9: The Ministry has noted the observations of the Committee. Ministry has referred the matter to Department of Revenue to look into the issues raised by the Hon'ble Committee and give its advice.

	liability, there is no corresponding income since traders are paying directly to overseas offices of MNCs. The Committee would like the Ministry to ensure that in cases where MNCs have offices in India, traders are not permitted to import formulations of such companies. The Committee would like to be kept informed of the steps taken on this issue.	
Para 15.11	The Committee recommends that once a batch of a drug is found to be substandard and reported to CDSCO, it should issue a press release forthwith and even insert paid advertisements in the newspapers apart from uploading the information on the CDSCO website. Retail chemists should be advised to stop selling unsold stocks and return the same to local Drugs Inspectors as per rules. The Committee understands that at least two State Drug Authorities, that of Maharashtra and Kerala, have taken the initiative to upload information on spurious and sub-standard drugs on their websites on a monthly basis. These are welcome measures worth emulating by other states and the Centre.	15.11: CDSCO has started the drug alert system in respect of drugs found to be of not-of-standard quality, spurious, adulterated etc by central drug testing laboratories. The Ministry will, however, consider the feasibility of placing advertisements of such cases regularly in the newspapers.
Para 16.2	The Committee would like the Ministry to take appropriate action against the companies that have advertised the above Schedule H drugs in the lay press. The provisions in the Drugs and Magic Remedies Act are not stringent enough with the result that manufacturers violate them at will. It also recommends that apart from giving sharper teeth to the Drugs and Magic Remedies Act, a provision should also be incorporated in the Drugs and Cosmetics Rules to ban such practices and penalize offenders. The Committee would like to be informed of the action taken to implement these recommendations.	16.2: The Ministry has noted the observations of the Committee. The proposed amendment to prohibit advertisement of Schedule H drugs has been deliberated and approved in Drugs Consultative Committee (DCC) on 20.7.12 as well as in DTAB on 24.7.12. The matter is under process.
Para 17.3	The Committee is of the firm opinion that accurate information on drugs for patients is absolutely essential to prevent inappropriate use more particularly in children, elderly, during pregnancy and lactation. The Committee recommends that the matter may be looked into to ensure that consumers have the required information to use medicines safely. Given the widespread internet connectivity, it is advisable to devise a system where patients can get unbiased information on drugs at the click of the mouse in any language.	17.3: The Ministry has noted the observations of the Committee. The Indian Pharmacopeia Commission has published the National Formulary of India (NFI) 2011, the book of reference for the use of clinicians, pharmacists and nurses containing detailed information about medicines, their dosage, contraindications, etc.. The NFI has been put on the official website of CDSCO so that relevant information reaches the user easily.
Para 18.2	Due to the sensitive nature of clinical trials in which foreign companies are involved in a big way and a wide spectrum of ethical issues and legal angles, different aspects of Clinical trials need a thorough and in-depth review. This Committee has, accordingly, taken it up as a subject for detailed examination separately under the heading 'Clinical Trials of Drugs'.	18.2: No comments

Annexure - I

745

23

अति-तत्काल / स्पीड पोस्ट द्वारा
MOST IMMEDIATE / BY SPEED POST

सं.एक्स.11011/1/2011-डीएफक्यूसी/1
No.X.11011/1/2011-DFQC
भारत सरकार / Government of India
स्वास्थ्य व परिवार कल्याण मंत्रालय / Ministry of Health & Family Welfare
स्वास्थ्य व परिवार कल्याण विभाग / Department of Health & Family Welfare

निर्माण भवन, नई दिल्ली
Nirman Bhavan, New Delhi
दिनांक 1 अक्टूबर, 2012
dated the 1st October, 2012

To

Principal /Health Secretaries of
All States/ Union Territories

Subject: Direction under section 33(P) of Drugs and Cosmetic Act, 1940 of cancellation of licences to manufacture drug formulations falling under the purview of 'New Drugs' including Fixed Dose Combinations (FDCs) as defined under Rule 122 (E) of the Drugs and Cosmetics Rules, 1945 – regarding.

Sir,

The Regulatory control over the manufacture and sale of drugs is exercised by the State Licensing Authorities appointed by the State Governments under the provisions of the Drugs and Cosmetics Act, 1940. Rule 122E of the Drugs and Cosmetics Rules, 1945 made thereunder provides the definition of the term 'New Drugs'. The drugs falling under this category require prior approval from the Licensing Authority defined under Rule 21(B) i.e. the Drugs Controller General (India) [DCG (I)] before the grant of a licence for manufacture by the State Licensing Authority. As per Rule 122E, new drug shall mean and include-

(a) A drug, as defined in the Act including bulk drug substance which has not been used in the country to any significant extent under the conditions prescribed, recommended or suggested in the labelling thereof and has not been recognized as effective and safe by the licensing authority mentioned under rule 21 for the proposed claims:

Provided that the limited use, if any, has been with the permission of the licensing authority.

(b) A drug already approved by the Licensing Authority mentioned in Rule 21 for certain claims, which is now proposed to be marketed with modified or new claims, namely, indications, dosage, dosage form (including sustained release dosage form) and route of administration.

(c) A fixed dose combination of two or more drugs, individually approved earlier for certain claims, which are now proposed to be combined for the first time in a fixed ratio, or if the ratio of ingredients in an already marketed combination is proposed to be changed, with certain claims, viz. indications, dosage, dosage from (including sustained release dosage from) and route of administration.

Explanation - For the purpose of this rule-

(i) all vaccines and recombinant DNA (r-DNA) derived drugs shall be new drugs unless certified otherwise by the Licensing Authority under Rule 21;

(ii) a new drug shall continue to be considered as new drug for a period of four years from the date of its first approval or its inclusion in the Indian Pharmacopoeia, whichever is earlier.

2. Instances were brought to the notice of the Central Government from time to time that the licensing authorities of many States and Union Territories have been granting licenses for manufacture of new drugs including Fixed Dose Combinations (FDCs) falling in the category of new drug defined under Rule 122E of Drugs & Cosmetic Rules without the prior approval of the Licensing Authority defined under Rule 21 (b) in violation of the said provision of the Drugs and Cosmetics Rules. The Parliamentary Standing Committee on Health & Family Welfare has taken strong objection to this practice in its 59th Report on the Functioning of Central Drugs Standard Control Organisation (CDSCO). In the light of the observations made by the Parliamentary Standing Committee, the issue of cancellation of licences by the State Licensing Authorities for manufacture of drug formulations falling under purview of the new drugs especially in respect of Fixed Dose Combinations was accordingly discussed in the Drugs Consultative Committee in the meeting held on 20th July, 2012. It was reiterated in the meeting that such licence for new drugs for unapproved FDCs must not be granted by any State Licensing Authorities.

3. In view of above, in pursuance of the provisions contained in Section 33 (P) of the Drugs and Cosmetics Act, 1940, as amended from time to time, the Central Government hereby directs all States / Union Territory Governments to instruct their respective drug licensing authorities to abide by the provisions prescribed under the Drugs and Cosmetics Rules for the grant of manufacturing licenses for the drugs falling under the definition of the term 'new drug' and not to grant licenses for manufacture for sale or for distribution or for export of such new drugs, except in accordance with the procedure laid down under the said rules i.e. without prior approval of the Drugs Controller General (India).

Yours faithfully

(संजय प्रसाद)
(Sanjay Prasad)
/ निदेशक / Director
टेलीफैक्स/Telefax: 23062352

Copy to: Drugs Controller General (India), FDA Bhavan, Kotla Road, New Delhi.

Annexure-II (25) 743

अति-तत्काल / स्पीड पोस्ट द्वारा
MOST IMMEDIATE / BY SPEED POST

सं.एक्स.11011/1/2011-डीएफक्यूसी/
No.X.11011/1/2011-DFQC
भारत सरकार / Government of India
स्वास्थ्य व परिवार कल्याण मंत्रालय / Ministry of Health & Family Welfare
स्वास्थ्य व परिवार कल्याण विभाग / Department of Health & Family Welfare

निर्माण भवन, नई दिल्ली
Nirman Bhavan, New Delhi
दिनांक 1 अक्टूबर, 2012
dated the 1 October, 2012

To

Principal / Health Secretaries of
all States/Union Territories

Subject: Directions under section 33 (P) of Drugs and Cosmetics Act 1940 for grant / renewal of manufacturing licenses of drug formulations in proper/generic name only – reg.

Sir,

The Regulatory Control over the manufacture and sale of drugs is exercised by the State Licensing Authorities appointed by the State Governments under the provisions of the Drugs and Cosmetics Act, 1940. It has been observed that at the time of the grant of the license for manufacture of a drug formulation, the trade name as submitted by the manufacturer is also endorsed by the licensing authority alongwith proper name of the product thereby giving legitimacy to market the drug under the brand or the trade name. Under the provisions of the Drugs & Cosmetics Rules, 1945, applications in various forms for grant/ renewal of a license to manufacture for sale or distribution of various categories of drugs as well as various forms for grant / renewal of such licenses require the name of the drug to be specified. Such forms for application as well as grant / renewal of the licenses do not require mentioning of any Trade Name / Brand Name.

2. In view of the above, the grant of drugs manufacturing licenses under a trade or brand name is not in accordance to the spirit of the legislation. Therefore, manufacturing license for the drug formulation should be granted in proper / generic name only. In case of drug formulation containing multiple ingredients, the licence should be granted under the name of categories of product viz. "Multivitamin Tablets/Capsule/Syrup", "antioxidants, multivitamins & multi minerals tablets/ capsule/syrup' etc. However, the composition of such product shall mention the name of active ingredients as well as its strength. The

(24)

issue was also discussed in the Drugs Consultative Committee in the meeting held on 20th July, 2012.

3. In view of the above, in pursuance of the provisions contained in Section 33 (P) of the Drugs and Cosmetics Act, 1940, as amended from time to time, the Central Government hereby directs all States / Union Territory Governments to instruct their respective drug licensing authorities to grant / renew licenses to manufacture for sale or for distribution of drugs in proper / generic names only.

Yours faithfully

(संजय प्रसाद)
(Sanjay Prasad)
निदेशक / Director
टेलीफैक्स/Telefax: 23062352

Copy to: Drugs Controller General (India), FDA Bhavan, Kotla Road, New Delhi.

APPENDIX

World Health Organization
Office of the WHO Representative to India

531-37, A-WING, NIRMAN BHAWAN, MAULANA AZAD ROAD, NEW DELHI-110 011, INDIA , E-MAIL:WRINDIA@SEARO.WHO.INT, WEBSITE: WWW.WHOINDIA.ORG
TEL: 91-11-47594800, 23061905, 23061993, 23061922 FAX: 91-11-23062450, 23061505

Reference: WR/D.7

Mr Ghulam Nabi Azad
Hon'ble Minister of Health and Family Welfare
Government of India
Nirman Bhawan, Room 149,
New Delhi 110011

21 December 2012

Your Excellency,

Subject: WHO Assessment of National Vaccine Regulatory Authority (NRA) and relevant Institutions, 10-14 December 2012

I would like to wholeheartedly congratulate the Ministry of Health & Family Welfare, Government of India, for the recent success in the WHO NRA Assessment of Indian Vaccine Regulatory Authority and relevant institutions, from 10-14 December 2012. I am delighted to know that the Indian Regulatory Authority has been declared as functional against the stringent WHO NRA assessment indicators. This assessment ensures that the regulatory oversight of NRA for vaccines continues to meet international standards.

This is indeed a great achievement and I would like to congratulate the efforts of Central Drugs Standard Control Organization, Central Drugs Laboratory, Kasauli, Immunization Division, Ministry of Health & Family Welfare, and other relevant institutions engaged in the regulation, control and testing of vaccines in India.

The recent success is the culmination of intensive effort by the CDSCO, in collaboration with WHO, to implement the roadmap (institutional development plan) to strengthen capacity for regulation of vaccines. As for all NRA assessments, sustainability of the gains made in regulatory capacity is critical. For this purpose, the team which has just completed the assessment in India has drawn up a detailed institutional development plan for the period 2013-2015, with scaled up and continued technical support from WHO for strengthening the drug regulatory system in India.

I am sure that the outcome of the NRA Assessment of 2012 shall go a long way in strengthening the National Regulatory System in India and will reaffirm WHO's Country Cooperation Strategy's (CCS) strategic priority of supporting an improved role of the Government of India in global health with particular focus on strengthening the pharmaceutical sector, including drug regulatory capacity. I especially thank you for your oversight and support to the entire process.

Please accept, Excellency, the assurance of my highest consideration.

Yours sincerely,

Dr Nata Menabde
WHO Representative to India