REPORT OF THE WHO WORKSHOP ON DISSEMINATION OF INFORMATION ON REGULATORY AFFAIRS AND 41ST MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD ON 28TH OCTOBER, 2010 IN THE COMMITTEE ROOM, FDA BHAVAN, KOTLA ROAD, NEW DELHI – 110002.

(List of Participants is at Annexure I)

INAUGURAL DELIBERATIONS

WHO Workshop on Dissemination of information on regulatory affairs and 41st Meeting of the Drugs Consultative Committee was held on 28th October, 2010 in the Committee Room, FDA Bhawan, Kotla Road, New Delhi-110002. Dr. A. K. Panda, Joint Secretary, Ministry of Health and Family Welfare, Dr. S. M. Jharwal, Chairman, National Pharmaceutical Pricing Authority, Dr. Madhur Gupta and Dr. A. Gunasekar from WHO also attended the meeting.

Dr. Surinder Singh, Drugs Controller General (India) and Chairman, Drugs Consultative Committee (DCC), welcomed the members and requested Dr. A. K. Panda, Joint Secretary, Ministry of Health and Family Welfare to address the gathering.

Dr. A. K. Panda in his address stated that India has a place in the global Economy and is a leading player in pharma sector. Pharma Industry has shown excellent growth both in domestic and international fields. The regulatory agencies are required to be geared up to meet the challenges, and their working should be consumer friendly and transparent. The Government of India would be pleased to provide any necessary help to the State Governments for strengthening the State Drugs Control Organizations and capacity building. Computerization and IT enabled services could go long way in making the functioning of the Drugs Control Organizations transparent and public friendly. Drugs Inspectors should be well trained and their visibility in the field will help in improving regulatory control over the drugs moving in the market. Availability of spurious drugs is another scourge and it is essential that cases of spurious drugs are

investigated quickly and stern actions are taken so that it has deterrent effect on the offenders. Reasonable pricing of drugs and their availability to the common man is the other area for the regulatory authorities to ponder.

DCG(I) then informed that the question of computerization of sales of drugs in the country is to be deliberated by the Committee as per directions of the Hon'ble Allahabad High Court. Apart from this a National Portal of the manufacturers of drugs in the country is also being prepared by the CDSCO. He then requested Dr. S. M. Jharwal, Chairman, National Pharmaceutical Pricing Authority to address the members.

Dr. S. M. Jharwal stated that. NPPA is authorised to fix and revise prices of 74 drugs listed under DPCO. These 74 drugs cover around 15,000 formulations manufactured in the country and caters 20% of the domestic requirement. NPPA has also fixed prices of 28 non-schedule formulations under public interest clause of DPCO. State Drugs Control Authorities have a crucial role to play in implementation of Drugs Price Control Order. However feedback from certain Drug Control Authorities in respect of violation of DPCO is not received regularly. This should be looked into. The States should forward the report in a specified format for taking further action. NPPA has conducted review meeting with the Drugs Control Departments of Gujarat, Andhra Pradesh and Jammu & Kashmir during 28th to 30th September, 2010 to streamline the administration of DPCO. Training of State officials on matters relating to DPCO, 1995 can be organised at the State /Regional level.

He emphasised that the manufacturers should not be permitted to retain the brand name while changing the composition of the formulation for circumventing the DPCO and charging much higher price for the product claiming that it does not fall under DPCO. He raised concern about certain new trends like charging of higher price from the patients by the hospitals through the chemist shops located within the premises whereas these drugs are available in the market at cheaper rates, and high variation in prices of Medical Devices classified as drugs viz. Stents, diagnostics kits. These practices should not be permitted. He also stated that certain Drugs Control Organizations grant permission for formulations where price approval is a pre-requisite.

The authorities should satisfy themselves that the applicant has applied for price approval as well.

During interaction certain members sated that fines worth crores of rupees are realized by the NPPA from the firms for violation of DPCO and the State authorities do not get any monetary assistance from NPPA for strengthening their organizations. Dr. Jharwal replied that fines realized goes to the Central treasury of the Government of India and not to the NPPA. However, NPPA would recommend grant of assistance to the States by their Ministry for strengthening regulatory infrastructure in the States. Drug Controller, Gujarat desired that price fixation should be on a more realistic manner so that prices too high or too low are not fixed by NPPA. The procedures for fixation of prices should be reviewed and updated so that it is responsive to the present day needs. It was also pointed out that Jan Aushadhi stores which were required to provide drugs at reasonable rates have large variations in their prices. Members further desired that more number of drugs including drugs for cancer should be included in DPCO for regulating their prices.

In response to a query from the members, Dr. Jharwal stated that designated officers in the States can launch prosecutions for violations of the DPCO. Meetings of NPPA officials with State regulatory authorities could be organised in different zones to exclusively consider the problems in implementation of the DPCO.

Dr. Madhur Gupta of WHO then made a presentation in regard to restricting availability of anti-TB drugs and promoting rational use of second line anti-TB drugs to prevent further emergence of drug resistance in the treatment of Tuberculosis. India accounts for nearly one third of global burden of Tuberculosis. There are five Lakh cases of multidrug resistant Tuberculosis (MDR-TB) and 50,000 cases of extensively drug resistant Tuberculosis (XDR-TB). It is important to check unregulated availability and injudicious use of Second Line drugs. It was emphasised that dispensing of Anti-TB medicines without prescription should be prohibited. A separate Schedule may be introduced under the Drugs and Cosmetics Rules to regulate sale of antibiotics and anti-TB drugs exclusively.

AGENDA NO. 1

FEEDBACK FROM THE STATE DRUGS CONTROLLERS ON CERTAIN AGENDA ITEM CONSIDERED EARLIER BY THE DCC

A. 39TH MEETING OF DCC HELD ON 10TH DECEMBER, 2008.

1. PHASING OUT OF ORAL SINGLE DRUG FORMULATIONS OF ARTEMISININ AND ITS DERIVATIVES FROM THE MARKET ON THE RECOMMENDATIONS OF WHO

Dr. A. Gunasekar, WHO representative (Malaria & Vector borne Diseases), gave presentation on Phasing out of Oral Single Drug formulations of Artemisinin in the country. It was pointed out that resistance to the mono-therapies of anti-malarial drugs is increasing in India and it is necessary to ensure that Oral Single Drugs formulations of artemisinin and its derivatives are withdrawn from the market so that the drugs remain effective in combination formulations with other anti-malarial drugs for the treatment of Malaria. The State Drugs Control Organizations were requested in the 39th meeting of the DCC to phase out the single drug formulations of artemisinin and its derivatives from the market.

The members informed the house that action was taken by them as per recommendations of DCC in the 39th meeting. However if, any specific instance has come to notice then it should be brought to the notice of the concerned authority for an immediate action.

2. CONSIDERATION OF THE PROPOSAL THAT SAME BRAND NAME SHOULD NOT BE PERMITTED TO BE RETAINED WHILE ISSUING OF LICENCES TO MANUFACTURE DRUGS WITH THE CHANGED FORMULATION

The issue was already discussed in detail in the presence of Director NPPA and the members agreed that the manufacturers should not be permitted to retain the same brand name if the composition of the product has been changed especially to circumvent DPCO.

3. CONSITITUTION OF SUB-COMMITTEE TO EXAMINE SUGGESTIONS OF AMENDMENTS TO THE DRUGS AND COSMETICS RULES PLACED BEFORE THE COMMITTEE AND SUGGEST COMPREHENSIVE PROPOSALS FOR AMENDMENT

The chairman brought to the notice of the members that a subcommittee was constituted under the chairmanship of Director Drugs Control, Andhra Pradesh in the 39th meeting to examine suggestions of amendments to the Drugs and Cosmetics Rules placed before the committee. Report of the committee is still awaited. DCC may consider and, if required, reconstitute the committee so that the proposals for amendment to the Drugs and Cosmetics Rules are brought before the committee for its consideration.

The committee after deliberation agreed that the same committee may meet under the chairmanship of Dr. B.R. Jagashetty, Drugs Controller, Karnataka and submit the report.

B. 40TH MEETING OF DCC HELD ON 29TH JUNE, 2009.

CONSIDERATION OF THE GUIDELINES FOR TAKING ACTION ON SAMPLES OF DRUGS DECLARED SPURIOUS OR NOT OF STANDARD QUALITY IN THE LIGHT OF ENHANCED PENALTIES UNDER THE DRUGS AND COSMETICS (AMENDMENT) ACT, 2008.

DCG(I) briefed the members that in order to ensure that enhanced penal provisions are implemented in a uniform and justifiable way, guidelines were prepared in consultation with the Drug manufacturers associations to provide standard operative

procedures for taking action on the drugs samples declared as not of standard quality. The guidelines were forwarded to the States for the purpose of uniform implementation.

The Members informed that by and large they are following the guidelines for taking action on samples of drugs declared spurious or not of standard quality. The members further pointed out that Rules 51 and 52 of the Drugs and Cosmetics Rules provide that duties of Drugs Inspectors are subject to instructions of the controlling authorities.

Members however felt that earlier guidelines prepared in 1993 annexed to the current guidelines have certain ambiguities and need to be updated for present day requirements. The DCC in 1993 had categorised defects as A and B category defects for taking action. This categorisation is required to be re-examined in the context of present day administration of the Drugs and Cosmetics Act and procedures followed by different State Drug Control Organizations.

The DCC after deliberation constituted a committee consisting of following members to review the guidelines in the light of above observations.

1. Drugs Controller, Tamil Nadu
2. Drugs Controller, Goa
3. Drugs Controller, Rajasthan
4. Drugs Controller, Gujarat
5. Drugs Controller, Jammu & Kashmir
6. Drugs Controller, Maharashtra
7. Drugs Controller, Haryana

Dr. D. Roy, DDC(I) North Zone would be the convenor.

The meeting(s) of the Subcommittee will be held at CDSCO HQ, FDA Bhavan, New Delhi and report submitted within two months.

AGENDA NO. 2

PROPOSAL TO CONSIDER UP-GRADATION OF THE QUALIFICATIONS OF GOVERNMENT ANALYSTS UNDER RULE 44 OF THE DRUGS AND COSMETICS RULES

The Qualifications of Government Analysts appointed by State Governments and Central Government are prescribed under Rule 44 of the Drugs and Cosmetics Rules. The Rule prescribes that the Government Analysts under the Act shall be a person who is a graduate in Medicine or Science or Pharmacy or Pharmaceutical Chemistry having five years experience in the testing of drugs.

Shri Gajanan Babar, MP (Lok Sabha) has requested the Union Minister for Health and Family Welfare for Up-gradation of qualification of Government Analysts under the Drugs and Cosmetics rules, 1945. He has stated that the latest edition of the Indian Pharmacopeia has replaced majority of old classical methods with the modern, highly specific and sensitive instrumental methods. This change was inevitable on account of advancements/researches that have taken place in the scientific field. This has therefore, necessitated the up-gradation of quality control laboratories including appointment of quality staff which is competent and conversant with the latest techniques in the theoretical and practical aspects.

The Hon'ble MP has further stated that while Prevention of Food Adulteration Act, 1955 was up-graded to provide minimum Post-graduate or equivalent as essential qualification for public analyst in food testing Laboratories, while rule 44 of the Drugs and Cosmetics rules, 1945 have not been amended since 1977 to have minimum post-graduate qualification to be a government analyst for drugs. The qualifications under the Drugs and Cosmetics Rules should be amended accordingly.

The Prevention of Food adulteration Act, 1954 prescribes the qualifications of Public Analysts as persons holding Master's degree in Chemistry or Biochemistry or Food Technology or Microbiology or Food and Drugs from a University in India. A copy of the relevant extract is at **annexure II**.

It has therefore, been proposed that the qualifications of Government Analysts under the Drugs and Cosmetics Rules may also be amended to have Post-graduate qualification at the entry level while taking care to provide protection to the existing employees.

The fields of specialisation may also be broadened to include subjects like Micro-biology, Biotechnology, Bio-chemistry etc.

DCC may like to deliberate on the proposed amendments and give its recommendations in the matter.

RECOMMENDATIONS

DCG(I) briefed the members that Shri Gajanan Babar, MP (Lok Sabha) had written to the Union Minister of Health and Family Welfare that the qualifications of Government analysts provided under Rule 44 of the Drugs and Cosmetics Rules need to be upgraded to provide minimum Post-Graduate or equivalent as an essential qualification for the Government Analysts to ensure that he is conversant with the latest techniques of testing in both theoretical and practical aspect.

The members agreed to the proposal and further suggested that field of specializations may be revisited to meet the present day testing requirements and include subjects like Microbiology, Biotechnology and Bio-chemistry etc. to make it broadbased. It was further recommended that a protection clause to protect the interests of the Government Analysts which are working on the date of the Notification shall also be inserted.

AGENDA NO. 3

PROPOSAL TO CONSIDER INCORPORATION OF PROVISIONS UNDER THE DRUGS AND COSMETICS RULES FOR RECALL AND DESTRUCTION OF DATE EXPIRED DRUGS BY THE MANFUCTURERS

The Principal Secretary to the Government of Tamil Nadu had written to the Office of DCG (I) for a need to look into the question of cubing the practice of recycling of expired drugs by certain unethical persons and to provide a system of recall of expired drugs and for their safe destruction.

A case of recycling of sale of date expired drugs was unearth by the Drug Control Department of Government of Tamil Nadu. The investigations revealed that one M/s. G.H. Pharma, Arumbakkam was selling Renerve cap. (Vitamin and mineral formulation) of M/s. Strides Arcolab Ltd., and a complaint was filed in Police. It was found that a racket of relabeling and recycling of date expired drugs was indulged in by certain traders in Tamil Nadu. The case was subsequently transferred to CBCID Police of Tamil Nadu for investigations. The police arrested 12 persons and 5 persons surrendered in various Court in Tamil Nadu. Out of the 17 persons arrested, the Police have booked 11 persons under Tamil Nadu Prevention of Dangerous Activity Act also.

The Drugs and Cosmetics Rules do not permit the sale of date expired drugs. The sub Rule (17) of the Rules 65 provides that no drug shall be sold or stocked by the licensee after the dated of expiration of potency recorded on its container, label or wrapper, or in violation of any statement or direction recorded on such container, label or wrapper. It is further provided that such drugs shall be stored separately from the trade stocks and all such drugs shall be kept in packages or cartoons, the top of which shall display prominently, the words ‘not for sale’.

Further Rule 104-A provides prohibition against altering inscriptions on containers, labels or rappers of drug. Alterations are however permitted by the manufacturer with the permission of the licensing authority.

It is however observed that there is no specific provision prescribing the procedure of recall and safe destruction of time expired drugs. In order to curb the practice of relabeling and selling such date expired drugs, it is necessary to incorporate provisions under the rules for recall and safe destruction of such drugs.

DCC may like to deliberate and give its recommendations in the matter.

RECOMMENDATIONS

DCG(I) briefed the members that Secretary (Health) of Tamil Nadu had desired that a system of recall of expired drugs and their safe destruction should be evolved and specified under the Drugs and Cosmetics Rules.

The members agreed that procedure for recall of expired drugs and their safe destruction is required to be incorporated under the Drugs and Cosmetics Rules for uniform implementation in the country.

The Drugs Controller Punjab stated that procedure for destruction or disposal of drugs seized by the Drugs Inspectors has also not been prescribed under the Rules and procedure for the same may also be prescribed. It was further pointed out that the destructions should be in an environment friendly manner to avoid pollution. Destruction process should be well documented so that the regulatory authorities are able to assess the authenticity of destroyed goods.

DCC after deliberation constituted a sub-committee with the following members to examine the matter in detail, in the light of their experience in implementing the provisions of the Drugs and Cosmetics Rules and to suggest the procedures for recall of the drugs and their safe destruction.

1. **Drugs Controller, Punjab**
2. **Drugs Controller, Delhi**

3. **Drugs Controller, Karnataka**
4. **Drugs Controller, Tamil Nadu**
5. **Drugs Controller, Gujarat**

Shri PBN Prasad, DDC(I) HQ, CDSCO will be the convenor.

The terms of reference would include laying down recall procedure which could be implemented by the pharma industry and regulatory authorities, Safe destruction of the stocks recalled and disposal of drugs lying under the custody of Drugs Inspectors on account of seizures of the stocks by them.

AGENDA NO. 4

CONSIDERATION OF THE PROPOSAL TO EXAMINE PROVISION OF LOAN LICENSING SYSTEM UNDER THE DRUGS AND COSMETICS RULES

A system of loan licensing is permitted under the Drugs and Cosmetics Rules for capacity utilization in manufacturing units. Loan licences are granted under rule 69A and 75A to the applicants who do not have their own arrangements for manufacture but intend to avail manufacturing facilities owned by the licencee. The definition of the loan licence as provided under Rule 69 is as under:

> ***Explanation*.-For the purpose of this rule a loan licence means a licence which a licensing authority may issue to an applicant who does not have his own arrangements for manufacture but who intends to avail himself of the manufacturing facilities owned by a licensee in Form 25.**

The Ministry of Health and FW at one stage had observed that under the above definition Loan Licences cannot be granted to applicants having their own manufacturing facilities. However, under the policy to encourage Pharmaceuticals Industry, Loan Licences have been granted to applicants who may have their own manufacturing unit while getting certain drug formulations manufactured from another manufacturer to meet the demand or for any other convenience for marketing the drug products. It is also a fact that while granting the licence it is not considered essential that the loan licencee and the licensor should be located in the same State.

The definition provided under the Rule 69A in its true sense does not permit grant of loan licence to the applicant who has its own arrangement for manufacture. The Ministry of Health has therefore desired that the DCC may examine the definition of the loan licence as to whether it requires any amendment in the light of the policies pursued by the licensing authorities. It may also be ensured that the Loan licensing system should have adequate safeguards to ensure compliance to Good Manufacture Practices and adherence to Schedule M for maintaining quality and there are no loopholes for manufacture of counterfeit drugs.

DCC may kindly deliberate and give its recommendations in the matter.

RECOMMENDATIONS

DCG(I) informed the committee that Ministry of Health and Family Welfare has desired that definition of the term Loan Licence provided under the Rules may be examined by the DCC to ensure that it reflects the policies followed by the State licensing authorities in grant of Loan Licences and suggest whether it require any further amendment. The Ministry of Health has also desired that the DCC should ensure that the system has adequate safeguards to ensure compliance to Good Manufacture Practices and adherence to Schedule M in the case of drugs manufactured under a loan licence, for maintaining quality and there are no loopholes for manufacture of counterfeit drugs.

The DCC after deliberations recommended that the definition of the term Loan Licence under Rule 69A may be amended to read as under:

> ***Explanation*.-For the purpose of this rule a loan licence means a licence which a licensing authority may issue to an applicant who intends to avail the manufacturing facilities owned by a licensee in Form 25.**

Similarly the definition provided under Rule 75A may also be amended to read as under:

> ***Explanation*.-For the purpose of this rule a loan licence means a licence which a licensing authority may issue to an applicant who intends to avail the manufacturing facilities owned by a licensee in Form 28.**

In regard to the maintenance of quality and adherence to Schedule M in the system of Loan Licensing, members were of the view that the quality of the drugs produced and compliance to Schedule M of the facility is taken care of by the manufacturer under whose premises the drugs are being manufactured.

AGENDA NO. 5

CONSIDERATION OF THE PROPOSAL FOR DELETION OF THE REQUIREMENT UNDER SCHEDULE M THAT SHELF LIFE OF FORMULATION PRODUCT SHALL NOT EXCEED THAT OF ACTIVE RAW MATERIAL USED

Schedule M to the Drugs and Cosmetics Rules prescribe Good Manufacturing Practices and requirements of Premises, Plant and Equipment for Pharmaceutical products. The entry number 10.9 under Part I of the Schedule relating to raw material prescribes the following condition in respect of use of raw material for manufacture of formulations:

10.9. Only raw materials which have been released by the Quality Control Department and which are within their shelf-life shall be used. It shall be ensured that shelf-life of formulation product shall not exceed that of active raw materials used.

Indian Drug Manufacturers Association made a request to the Ministry of Health and FW that the above entry may be deleted and the APIs should be permitted to be used until their re-test date or extended re-test date based on the stability of the API.

The matter was considered in a meeting taken by the Hon'ble Union Minister of Health and Family Welfare with the leaders of Indian Pharma industry on 4th September, 2010 at CDSCO, west zone, FDA Bhavan, Mumbai and it was opined that the proposal may not be acceptable as it may bring in variations in shelf-life and it would be difficult to independently asses the re-test data submitted by the different manufacturers. It was however agreed that the matter may however be placed before DCC for its consideration and opinion in the matter.

DCC may kindly deliberate and give its opinion in the matter.

RECOMMENDATIONS

DCG(I) briefed the members that the Indian Drug Manufacturers Association (IDMA) had made a request to the Ministry of Health and Family Welfare that Active Pharmaceutical Ingredients (APIs) should be permitted to be used until their retest date or extended retest date depending upon the stability of the API. For this purpose the association requested for the deletion of entry number 10.9 under part I of the Schedule M relating to raw materials which require that shelf life of formulation product shall not exceed that of the active raw materials used.

DCC after deliberations opined that in the interest of the quality control of drug formulations, it would not be possible to accept the suggestion of IDMA for the deletion of the clause.

AGENDA NO. 6

IMPLEMENTATION OF SCHELDULE L-I ON GOOD LABORATORY PRACTICES AND REQUIREMENT OF PREMISES AND EQUIPMENTS PUBLISHED UNDER NOTIFICATION GSR 780(E) DATED 10TH NOVEMBER, 2008.

The Drugs and Cosmetics Rules were amended to incorporate Schedule L-I on Good Laboratory Practices and Requirement of Premises and Equipments published under notification GSR 780(E) dated 10th November, 2008. A period of two years was granted for the pharma industry to make necessary arrangement to comply with the requirement of Schedule L-I before these are made mandatory. Accordingly the notification mentioned that these Rules will come into force on first day of November, 2010.

The drug testing laboratories are required to comply with the provisions of Schedule L-1 in respect of Good Laboratories Practices in respect of testing, calibration, validation and other technical activities carried out in the laboratories. It further provides for maintenance, calibration and validation of equipments at regular intervals. The

laboratories are required to prescribe standard operative processers and implement them and maintain records. Internal quality system audits are required to put in practice to verify that the operations conduct in the laboratories comply with the requirements of quality system. A copy of the notification is **annexed.**

State Licensing Authorities may ensure that the provisions under Schedule L-I are implemented in the testing laboratories set up by the manufacturers for in house testing and approved testing laboratories.

RECOMMENDATIONS

The committee was informed that the Drugs and Cosmetics Rules were amended vide GSR 780(E) dated 10.11.2008 to incorporate Schedule L-I on Good Laboratory Practices and requirements of premises and equipments for the laboratories. The notification will come into force from 01.11.2010 and the Drug Testing Laboratories setup by the manufacturers or other independent testing laboratories are required to comply with the provision of Schedule L-I. This would help in proper maintenance of the laboratory, records of testing procedures followed, calibration and validation of equipments and other technical activities in accordance with the provisions of the Schedule. A two years time was already provided under the notification for the industry to make necessary arrangements for compliance of the Schedule. State Licensing Authorities may ensure that the provisions of the Schedule L-I are implemented by the laboratories under their jurisdiction. Government laboratories for testing drugs under the State Governments should also ensure compliance to the Schedule.

The Committee agreed that the State Drugs Control Department may through interactions with the drug manufacturers and testing laboratories followed by inspections ensure that the provisions of Schedule L-I are implemented.

AGENDA NO. 7

CONSIDERATION OF THE PROPOSAL TO AMEND RULE 122-E OF THE DRUGS AND COSMETICS RULES FOR DELETION OF THE CLAUSE HAVING REFERENCE TO INDIAN PHARMACOPEIA

Rule 122-E of the Drugs and Cosmetics Rules prescribes definition of the term 'New Drug'. An explanation under the Rule has reference to the Indian Pharmacopeia as under:

"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. "

The Government of India has now established Pharmacopeia Commission as an independent body for the purpose of preparing and publishing Pharmacopeia of India. The question of establishing the safety and efficacy of a drug which has not been used in the county to any significant extent under the condition prescribed, recommended or suggested should therefore be not linked to its inclusion in the Indian Pharmacopeia.

It has therefore been proposed that the following words from the clause (ii) under Rule 122-E may be deleted.

"or its inclusion in the Indian Pharmacopoeia, whichever is earlier"

DCC may kindly deliberate and give its opinion in the matter.

RECOMMENDATIONS

The committee was briefed that the Indian Pharmacopeia is now published by an independent Indian Pharmacopeia Commission (IPC) setup by the Ministry of Health and Family Welfare for the purpose and it has been observed that certain drugs are included in the Indian Pharmacopeia while the mandatory period of four years from the date of first approval has not yet been completed. It was therefore proposed that from the definition of the term 'new drug' under rule 122E may be amended to delete the condition of inclusion of the drug for excluding it to be considered as a new drug.

Dr. G.N. Singh, Secretary cum Scientific Director, IPC stated that Indian Pharmacopeia is a book of standards and the testing procedures when finalized for the drugs permitted to be marketed in the country are included in IP so that standards are available with the testing laboratories for testing samples for these drugs.

Members were however, of the view that if the drug is included in IP, they grant the licence as provided under the rules.

After deliberation it was agreed that IPC will consult DCG(I) in future before inclusion of the drugs under IP and the office of DCG(I) may provide a list of drug on their website which are considered as new drug for the information of the State Licensing Authorities. The list should be updated regularly.

AGENDA NO. 8

PROPOSAL TO CONSIDER THE QUESTION OF REGULATING QUALITY OF SINDOOR/KUMKUM MANUFACTURED IN THE COUNTRY CONTAINING SYNTHETIC MATERIALS AND LEAD SALTS

A complaint was received in the office of DCG(I) regarding the sale of toxic and environmentally unfriendly sindoor/kumkum products at religious shrines as well as retail outlets in the country. The commercially available sindoor contain chemical dyes, synthetic materials and lead salts. Mostly it contains toxic low grade commercial red lead oxide as such or along with other synthetic or natural bulking materials. Sindoor manufactured from industrial dyes and synthetic chemicals can cause serious problems such as rashes, pigmentation, skin cancer and other disorders.

Schedule S of the Drugs and Cosmetics Rules lays down the standard for the list of cosmetics in the finished form which shall conform to the Indian Standard specifications laid down from time to time by the Bureau of Indian Standards. Under entry number 27, kumkum powder (IS :10999) is included under Schedule S. The requirements of pH, heavy metals (as lead) and arsenic have been included in the Standard along with their test methods. The BIS has also published standard for Sindoor under IS 14649:1999. These standard prescribe that lead oxide should not be used in sindoor.

It has been claimed by certain manufacturers that if such products are not marketed as cosmetics and sold for religious purposes only, it is not mandatory to obtain a licences under the Drugs and Cosmetics Act. Matter has been considered by the Hon'ble Madras High Court (K. Bhimraj vs. State of Tamil Nadu: Crl, M.P. 10957 of 1986) and they had opined that sale and distribution of kumkum /sindoor made from dyes, colors and pigments can be permitted only if it is manufactured after obtaining a licence under the Drugs and Cosmetics Act.

As the manufacturing licences for cosmetics are granted by the State Drugs Controller Authorities, DCC may deliberate the matter for developing a National consensus for regulating the quality of sindoor marketed in the country.

RECOMMENDATIONS

DCG(I) briefed the members that a complaint was received in his office that commercially available Sindoor is being manufactured without a licence for manufacture of cosmetics in the country. The Sindoor so manufactured contain chemicals dyes, synthetic materials and lead salts which can cause serious problems like rashes, pigmentation etc to the users. Schedule S to the Drugs and Cosmetics Rules include Kumkum powder (IS: 10999) as a cosmetic which is required to be manufactured under a licence for manufacture of cosmetics. Plea is being taken that Sindoor is manufactured for religious purposes and is therefore not covered under the definition of Cosmetics.

It was brought to the notice of the members that BIS has also published standard for Sindoor under IS:14649:19999. It was therefore proposed to include Sindoor under Schedule S so that it is manufactured under a licence and conform to the standard prescribed by the BIS.

DCC after deliberations agreed to the proposal to amend Schedule S to include Sindoor under it along with the BIS standard to ensure that the product is manufactured under a licence and conforms to the standards.

AGENDA NO. 9

CONSIDERATION OF THE APPLICABILTY OF DRUGS PROHIBITED THROUGH NOTIFICATION UNDER SECTION 26A IN RESPECT OF THE FORMULATION MANUFACTURED FOR ANIMALS USE

The screening of drug formulations marketed in the country and considered harmful or irrational in the context of present technical knowledge is undertaken by the office of DCG(I) in consultation with the experts and the Drugs Technical Advisory Board. The drugs for which harmful effects are reported or if therapeutic justification is found inadequate, and the drug is recommended to be prohibited for manufacture for sale in the country, the recommendation of DTAB are forwarded to the Ministry of Health and FW for prohibiting the drug in the country through a notification issued under section 26A of the Drugs and Cosmetics Act.

It has been observed that harmful effects of the drugs under consideration are normally reported in human subjects. The technical data examined by the expert committees also relates to the use of the drug in the human subjects. The notifications in many cases do not specifically mention that the drugs have been prohibited for human use only.

Questions have been raised as to whether the ban on the drug formulations where specific reference has not been made about ban of the drug for human use, are applicable to the preparations meant for animal use also.

The prohibition of manufacture and sale of these banned products is regulated by the State Drugs Control Authorities. Members may give their opinion and the feedback about implementation of notifications issued under 26A for creating a consensus in the matter.

RECOMMENDATIONS

DCG(I) briefed the members that the Drugs are prohibited by the Central Government under Section 26A for manufacture, sale or distribution in public interest. The notifications issued sometimes specifically mention that the drugs have been prohibited for human use only while in certain cases the notifications prohibits the manufacture, sale and distribution of a drug or drugs without making specific mention that these are prohibited for human use only. The office of DCG(I) has received certain queries as the whether the notifications pertaining to drug formulations banned without any specific reference are made applicable to the preparations meant for animal use also. The members were asked to give their opinion in the matter.

The members were of the view that in the cases of the notifications which do not specifically mention that the drugs covered under it are prohibited for human use only, the manufacture and sale of notified drugs are prohibited for animal use also.

AGEND NO. 10

CONSIDERATION OF THE PROPOSAL TO REGULATE SALE OF ANITBIOTICS MORE STRICTLY IN THE COUNTRY

Antimicrobial resistance is an intrinsic and inevitable aspect of microbial survival that continually challenges human health. The recent debates in the media have called for formulating a national policy for antibiotic use as separate from a policy for hospital infection. Since antibiotic resistance is the result of environmental and behavioral causes, physician prescription practice and laxity in enforcement of laws and regulations on sale of antibiotics etc., a multipronged view has been taken for containing and ensuring zero tolerance to the indiscriminate and irrational use of antibiotics.

Ministry of Health & Family Welfare has therefore constituted a Task Force, under the Chairmanship of DGHS, to assess, review and suggest measures to counter anti-microbial resistance.

Schedule H of the Drugs and Cosmetics Rules, 1945, contains a list of 536 drugs which are required to be dispensed on the prescriptions of a registered medical practitioner only, In order to have a separate regulation to check unauthorized sale of antibiotics, a separate schedule may be introduced under the Drugs and Cosmetics Rules to regulate sale of antibiotics exclusively. Corresponding provisions under the Rules could be framed for their implementation. To enforce the law strictly, Drug Inspectors in the Zonal and Sub-Zonal offices of CDSCO along with the State Drug Inspectors may conduct surprise raids at the chemist shops to ensure that the provision of the Drugs and Cosmetics Rules especially in respect of new Schedule are strictly complied by the licencees.

DCC may kindly deliberate and give its opinion in the matter.

RECOMMENDATIONS

DCG(I) briefed the members that the concern is growing about the reports of increased anti-microbial resistance because of indiscriminate use of third generation antibiotics in the country. Government of India in the Ministry of Health and Family Welfare is in the process of developing an antibiotics policy so that indiscriminate prescription of antibiotics and their easy availability at chemist shops is restricted. Guidelines are being framed for Medical Professionals and Hospitals in respect of prescription of antibiotics by the physicians. The Government has desired that easy availability of antibiotics at chemist shops should be restricted under the Drugs and Cosmetics Rules. Even though antibiotic are covered under Schedule H of the Drugs and Cosmetics Rules and are required to be sold on the prescriptions of a Registered Medical Practitioner only, these drugs are freely available at the chemist shops because of weak administration of the provisions of the Drugs and Cosmetics Rules. It is therefore proposed to have a separate Schedule under which antibiotics could be regulated in a more focused manner and a copy of the prescription on which these drugs are dispensed is retained by the chemist.

The Drugs Controller, Punjab desired that habit forming drugs which are misused in many parts of the country because of their easy availability should also be included under this Schedule. Members further desired that anti-TB drugs should also be included in this Schedule.

The members after deliberations agreed that certain select categories drugs belonging to antibiotics, anti-TB drugs and habit forming drugs should be included in a new Schedule and named as Schedule HX. These drugs should be sold on double prescriptions where one copy of the prescription is retained by the chemist for one year. This will help in auditing the sale of such drugs by the chemists. Further the container of the medicine shall be labelled with the following clause for the purpose of information of the consumer as well as chemist.

"Schedule HX drug – dangerous to take this preparation except in accordance with medical advice
-Not to be sold by retail without the prescription of a Registered Medical Practitioner.

It was further recommended that the use of certain latest antibiotics should be restricted to tertiary care hospitals only and used judiciously where culture and antibiotic sensitivity reports are positive for that specific anti-biotic. These antibiotics should be permitted to be sold to the tertiary care hospitals only and suitable provision may be made under the Rules to make the provision mandatory.

AGEND NO. 11

CONSIDERATION OF THE PROPOSAL TO PROMOTE GENERIC DRUGS IN THE COUNTRY AND ENSURING THEIR QUALITY

Thirty-ninth Report of the Department-Related Parliamentary Standing Committee on Health & Family Welfare has recommended that the use of generics in the public as well as private sectors will reduce the drug costs and increase drug availability. Competitive bulk procurement in generic name will help in procuring drugs at competitive prices.

A branded medicine internationally is referred to as the drug product of the originator under a brand name that was first authorized for marketing worldwide (normally as a patented product). The branded medicines are authorized for marketing on the basis of detailed documentation of its safety, efficacy and quality according to requirements at the time of authorization.

Generic medicines are those which contain same amount of same active ingredient(s) in same dosage form, and are intended to be administered by the same route of administration as that of branded medicine. These medicines are usually intended to be interchangeable with the originator brand product. Generic medicines are manufactured and marketed after the expiry of patent.

It may be stated that earlier the Drugs and Cosmetics Rules, 1945 were amended vide GSR 27(E) dated 17.01.1981 for the purpose of marketing of five drugs in generic name only.

Subsequently on the directions of directions of the Hon'ble High Court the amendment was withdrawn.

It is however important that generic drugs are promoted to reduce the cost of the drugs and increase their availability to the common man.

DCC may kindly deliberate and give its opinion as to how the generic drugs could be promoted while ensuring their quality in the country.

RECOMMENDATIONS

DCG(I) briefed the members that the Parliamentary Standing Committee of the Ministry of Health and Family Welfare, in its 39th report has recommended the use of generics in the public as well as private sector to reduce the drug costs and increased drug availability. Marketing of drugs in generic names will bring equal competition for all manufacturers manufacturing formulation of that drug.

The members agreed that marketing of generic drugs should be promoted in the country while ensuring that they are of comparable standards. Excise duty concessions may further help in reducing the prices of drugs marketed in generic names.

The DCC recommended that members may grant licences for marketing of single drug formulation in generic name only to promote availability of generic drugs at affordable prices in the country.

SUPPLEMENTARY AGENDAS

AGENDA NO. S-1

CONSIDERATION OF THE DIRECTIONS OF THE HON'BLE HIGH COURT OF JUDICATURE AT ALLAHABAD IN THE CASE OF CWP NO. 16212 OF 2008, BRAHMAJI V/S STATE OF U.P. AND OTHERS

A Public interest litigation CWP No. 16212 of 2008, Brahmaji v/s State of U.P and Other is being heard in the High Court of Allahabad. The litigation is concerned with curbing the menace of spurious drugs.

The issue of complete computerization of the trade in drugs was considered by the Hon'ble Court. This would enable the authorities to track the movement of drug formulations starting from the drug manufacturers and ending with the retailers. However for such computerization of the trade in drugs, an effective coordination between the Central Government and various States is essential for linking the network through of the country.

The Hon'ble Court in the hearing on 28th October, 2010 has directed that the proposal for networking of all transactions of medicine from the manufacturer to the dealer may be discussed in the next DCC meeting and proposal submitted to the Court on the next date of hearing i.e. 25th November, 2010. The Court was however apprised that it will need considerable time and effort to bring all stake holders on board with respect to networking of the manufacture, sale and distribution of drugs in the entire country. There are more than 8,000 drug manufacturers and Six Lakh sale and distribution outlets in the country.

DCC may kindly examine the direction of the Hon'ble Court and give its recommendations as to how computerization of sales of drugs in the country can be achieved. The feasibility of the recommendations would then be discussed with the National Informatics Centre (NIC) for examining technical feasibility.

RECOMMENDATIONS

DCG(I) briefed the members that Hon'ble High Court of Allahabad in the case of a PIL (CWP number 16212 of 2008), Brahmaji vs. State of UP, has directed during the course of hearing on 20.10.2010, that proposal of networking of all transactions of medicine from the manufacturer to the retail chemist may be discussed in the next DCC meeting and the action taken report submitted to the Court on the next date of hearing i.e. 25.11.2010.

The committee was informed that there are more than 8,000 drug manufacturers and 1,96,000 distributors and around 3,60,000 sale outlets in the country which would be required to be interlinked for networking of sales as desired by the Hon'ble Court.

Dr. Y.K. Sharma, Shri Kashinath and Shri Vishwjeet Ringe, representatives of NIC, invited to provide inputs for networking of drugs sales in the country, informed the committee that system of networking has to be created to link the manufacturers, distributors, wholesalers and retail chemist in the country and for this cooperation from all stake holders including manufacturers, sellers and regulatory authorities is required. The availability of link pattern at grass root level is required to be studied for its feasibility and effectiveness of the system. It will be a time consuming process. Even though manufacturers of drugs are mainly located in seven or eight States, having 80% of production of drugs in the country, the sale outlets are spread far and wide in the country. Cost factors are also to be taken into consideration while developing the system and its applicability. The drug manufacturers associations are required to be consulted for framing the policy as well as the system for tracking the transactions from the manufacturer to the retail chemist.

The members appreciated the concern shown by the Hon'ble Court and felt that such a networking could provide valuable information not only to the regulatory authorities but also to the public.

The Committee after deliberations decided to setup a sub committee consisting of the following members to have an indepth study to evolve a National strategy for networking of transactions of sale of drugs from manufacturer to the retail chemist, and the stages under which the Court directions could be implemented including feasibility as varied level of internet connectivity is available in the country:-

1. **State Drug Controller of Tamil Nadu**
2. **State Drug Controller of Gujarat**
3. **State Drug Controller of Utter Pradesh**
4. **State Drug Controller of Goa**
5. **State Drug Controller of Arunachal Pradesh**
6. **Representative of NIC**
7. **Shri Malay Mitra, DDC(I) CDSCO, HQ will be the convenor.**

The committee shall also consult representatives of Drug Manufacturers Associations and Chemists Associations and other stakeholders as per directions of the Hon'ble High Court.

AGENDA NO. S-2

CONSIDERATION OF THE REPRESENTAIONS FROM MEDICAL AND SALES REPRESENTATIVES UNIONS REGARDING SALE OF DRUGS BY THE COMPANIES THROUGH UNETHICAL MEANS

Medical and Sales representative Unions of different States have written to the Union Health Minister alleging gross violation of the Drug and Cosmetics Rules by the well known drug companies. It has been stated that management of many companies are marketing their products through hawkers. The black marketing is being done at the month end's sales closing at different distribution points at different parts of the country. The drug companies are resorting to these illegal practices without any check and control by law enforcement authorities.

Members may deliberate and give their suggestions in the matter.

RECOMMEDATION

The members were of the view that the complaints are vague and general in nature. In case the unions have any specific complaints then these may be forwarded to the concerned State Licensing Authority for taking action in the matter.

AGENDA NO. S-3

CONSIDERATION OF THE PROPOSAL TO PROHIBIT THE MANUFACTURE AND SALE OF ROSIGLITAZONE IN THE COUNTRY

Rosiglitazone maleate is an oral anti-diabetic drug which acts primarily by increasing insulin sensitivity. It is indicated in the management of type 2 diabetes mellitus. In India the drug was approved for marketing on July 14, 2000.

Reports appeared in the International press about the increased risk of heart attack with Rosiglitazone. In 2007, Steven E. Nissen and Kathy Wolski had carried out Meta-analysis on the data of 42 trials of Rosiglitazone, its use leading to risk of Myocardial infarction and death (New England Journal of Medicine).

US FDA updated the labeling of Rosiglitazone on several occasions. Its recommendations for labeling changes for Rosiglitazone included a new warning about a potential increase in heart attacks and heart related chest pain in some individuals using Rosiglitazone.

In India, the matter was examined by National Pharmacovigilance Advisory Committee (NPAC) in its meeting held on 16th January, 2008. NPAC recommended to incorporate following “Box warning” in the package insert and other promotional literature of formulations containing Rosiglitazone.

> “Rosiglitazone can cause fluid retention when used alone or in combination with other ant diabetic agents, including **insulin**, which may lead to or aggravate heart failure. Patients should be observed for signs and symptoms of heart failure. Rosiglitazone is not recommended in patients with symptomatic heart failure and is known to increase the risk of Myocardial Infarction”.

Accordingly office of DCG(I) issued letter to all State Drug Controllers in April, 2008 to direct the manufacturers of rosiglitazone to incorporate the above box warning in package insert and other promotional literature of formulations containing rosiglitazone.

European Medicines Agency (EMA) on 23 Sept, 2010, recommended the suspension of the marketing authorizations for the rosiglitazone containing anti-diabetes medicines. These medicines will stop being available in Europe within the next few months. U.S. Food and Drug Administration (USFDA) has also announced on the same day that they will significantly restrict the use of the diabetes drug rosiglitazone to patients with Type 2 diabetes who cannot control their diabetes on other medications.

The matter was considered by an expert committee on 07.10.10 and the committee made the following recommendations.

(1) Suspension of import / manufacture of rosiglitazone and its FDCs in the country with immediate effect.

(2) Prohibition of manufacture and sale of rosiglitazone and its FDCs under Section 26A of Drugs and Cosmetics Act.

Based on the recommendation of the Expert Committee, letters were issued to all State Drug Controllers on 07.10.10 requesting them to suspend all the licenses granted to manufacture for sale and distribution of rosiglitazone and its fixed dose combinations with other drugs with immediate effect.

As it is now evident that use of rosiglitazone is associated with increased risk of cardiovascular events; i.e, Congestive Heart Failure and Myocardial Infarction, it is appropriate to prohibit the manufacture, sale and distribution of the drug in the country at the earliest under section 26A of the Drugs and Cosmetics Act.

DCC may kindly deliberate and give its recommendations in the matter.

RECOMMENDATION

DCG(I) briefed the members that reports were received about the increased risk of heart failures with rosiglitazone. European Medicine Agency on 23rd September, 2010 recommended the suspension of market authorizations for rosiglitazone and the medicine will stop being available within next few months. U.S. Food and Drug Administration (USFDA) also announced on the same day that they will significantly restrict the use of rosiglitazone to patients with Type 2 diabetes who cannot control their diabetes on other medications. The continued use of the drug in India was examined and an expert committee constituted for the purpose on 07.10.10 and the committee recommended suspension of import /manufacture of rosiglitazone and its FDCs in the country with immediate effect and the drug should be prohibited for manufacture and sale under Section 26A of the D&C Act. State Drug Controllers were therefore requested on 07.10.10 itself to suspend all the licences granted to manufacture for sale and distribution of rosiglitazone and its fixed dose combinations with other drugs with immediate effect.

The committee after going through the recommendations of the expert committee and deliberations felt that the use of the drug is associated with increased risk of cardiovascular events. It therefore recommended that import/manufacture and sale of rosiglitazone and its combination should be prohibited for manufacture and sale in the country under the Drugs and Cosmetics Act.

AGENDA NO. S-4

CONSIDERATION OF PROPOSAL TO INCLUDE KETAMINE UNDER SCHEDULE X TO RESTRICT ILLICIT USE OF THE DRUG IN THE COUNTRY

Ketamine hydrochloride is a commonly used anaesthetic available in injectable form. The drug is official in Indian Pharmacopeia and is a Schedule H drug under the Drugs and Cosmetics Rules. The drug is required to be sold by retail on the prescription of a registered Medical Practitioner only. Drug is stated to have abuse potential. It is evaporated to form a powder which is snorted or swallowed by the drug addicts. Ketamine is also smuggled from India to East Asian countries for abuse.

Even though Directorate General of Foreign Trade (DGFT) has put certain restrictions on export of this drug, several consignments that were attempted to be smuggled out have been seized in India by the Directorate General of Revenue Intelligence. It is therefore necessary that domestic control over the sale of drug should be further restricted.

It is therefore proposed to shift the drug to Schedule X from Schedule H under the Drugs and Cosmetics Rules.

DCC may kindly deliberate and give its recommendations in the matter.

RECOMMEDATION

DCG(I) briefed the members that it is proposed to include Ketamine hydrochloride under Schedule X because of its high abused potential. This will ensure that the drug is available at limited outlets having licence to sell Schedule X drugs and proper records of its sale are maintained by the chemists.

DCC agreed to the proposal of shifting of Ketamine hydrochloride from Schedule H to Schedule X under the Drugs and Cosmetics Rules.

AGENDA NO. S-5

CONSIDERATION OF THE PROPOSAL TO PERMIT SALE OF TRIAL BATCHES OF THE NEW DRUGS MANUFACTURED FOR TEST AND ANALYSIS AFTER THEIR APPROVAL FOR MARKETING IN THE COUNTRY

Representations were received from the Pharma industry for permitting the sale of trial batches manufactured under a licence in Form 29 for manufacture of drug for the purpose of examination, test or analysis.

Application for a licence in Form 29 is made by the applicant to the licensing authorities appointed by the State Government for the grant of licence to manufacture a drug for the purpose of examination, test or analysis.

One of the conditions of licence in Form 29 is that the licensee shall use the drugs manufactured under the licence exclusively for purpose of examination, test or analysis, and shall carry on the manufacture and examination, test or analysis at the place specified in the licence.

DCC may kindly deliberate and give its recommendations as to whether sale of trial batches manufactured prior to the approval of the drug could be permitted.

RECOMMEDATION

DCG(I) stated that request has been received for permitting the sale of trial batches manufactured under a licence in Form 29 for manufacture of drugs for test and analysis.

The DCC after deliberations agreed that such permissions could be granted in exceptional cases only, where drugs are required in a pandemic or epidemic

situation duly declared by the Government. The trial batches should have been manufactured for clinical trial on a commercial scale at the premises which are GMP compliant and the manufacturer should have valid a licence to manufacture the drug for sale and distribution under the Drugs and Cosmetics Rules. Further, the batches have been manufactured under the conditions in which the regular batches are to be manufactured.

AGENDA NO. S-6

CONSIDERATION OF THE PROPOSAL TO PREPARE GOOD STORAGE AND DISTRIBUTION PRACTICES FOR PHARMACEUTICALS PRODUCTS

An issue was raised by certain members that there are no National Guidelines in respect of Good Storage and Distribution Practices in the country. The drug products lose their potency during their shelf life because of improper storage and handling during transportation. Drugs are required to be stored under the conditions prescribed on the labels so as to ensure that essential and lifesaving drugs should not lose their potential before they reach the consumer. The prescribed storage conditions are required to be maintained during the period of transportation also.

The DCC agreed that it is important to have uniform guidelines for Good Storage and Distribution Practices for implementation in the country. Adherence to such guidelines will ensure that the quality of the drug is maintained throughout its shelf life.

The Drugs Controller, Karnataka agreed to prepare the draft guidelines for Good Storage and Distribution Practices for the consideration of the DCC in the next meeting.

AGENDA ITEMS FROM THE STATES

The members observed that large number of agenda items had been forwarded by the various State Drug Control Organizations for consideration of the DCC. It would not be possible to have indepth deliberation on these items because of the paucity of time. The members agreed that these agendas may be taken up for consideration in the next meeting of DCC. It was further desired that the meetings of the DCC should be held outside Delhi also so that the State Drugs Control Organizations also get an opportunity to host the meetings. The Drugs Controller Goa offered to provide necessary logistics for conducting the meeting in his State in the first place.

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ANNEXURE I

List of the participants of Drugs Consultative Committee meeting held on 28.10.2010 under the Chairmanship of Dr. Surinder Singh, Drugs Controller General (India)

A. List of participants from State Drugs Control Organisations

S. no.	Name & Designation of the participants
1.	Sh. Satish Gupta, Drugs Controller, Jammu and Kashmir, Jammutavi- 180001 (J&K)
2.	Sh. Shiv Narayan Sahu, Drugs Controller, Bihar Vikas Bhawan, Bailey Road, Patan-800001 (BIHAR)
3.	Dr. S.S. Ghonkrokta, Drugs Controller Delhi, Govt. of National Capital Territory of Delhi, F-17, Karkardooma, Dte. of Health Services Building, (Near Karkardooma Court), Shahadara, Delhi
4.	Sh. P. K. Jaggi, Asstt. Drug controller, Delhi Govt. of National Capital Territory of Delhi, F-17, Karkardooma, Dte. of Health Services Building, (Near Karkardooma Court), Shahadara, Delhi
5.	Sh. H. G. Koshia, Commissioner, FDCA Gujarat, Food and Drugs Control Administration, Ist Floor, Block No.-8, Dr. Jivraj Mehta Bhawan, Gandhi Nagar-382010 (GUJARAT)
6.	Sh. Salim A. Veljee, Drugs Controller, Goa, Dte. of Food & Drugs Administration, Old G.M.C. Building, Panaji, GOA.
7.	Sh. R.M.Sharma, Drugs Controller, Haryana Dte. General of Health Services, Civil Dispensary, Sector 20, Punchkula (HARYANA)
8.	Sh. Navneet Marwaha, Assistant Drugs Controller, Himachal Pradesh Health & F.W. Deptt., SDA Complex, Kasumpati, Shimla-17009 (HIMACHAL PRADESH)
9.	Sh. A. L. Arya, Deputy Drugs Controller, Uttar Pradesh Swasthya Bhawan, Lucknow-6, (UTTAR PRADESH)
10.	Dr. B. R. Jagashetty, Drugs Controller Karnataka, Drugs Control Department, Next to Carlton House, Palace Road, Banglore
11.	Mr. M. Khalid Ahmed Khan, Assistant Drugs Controller, Karnataka, Drugs Control Department, Next to Carlton House, Palace Road, Banglore
12.	Sh. C.S. Satheesh Kumar, Drugs Controller & Licensing Authority, Kerala, Public Health Laboratory Campus, Red Cross Road, Thiruvananthapuram, KERALA

13.	Sh. P. R. Uttarwar, Commissioner, FDA. Maharashtra Food and Drugs Administration, Mumbai, MAHARASHTRA
14.	Sh. K.B. Shende, Technical Officer, FDA. Maharashtra Food and Drugs Administration, Mumbai, MAHARASHTRA
15.	Sh. Devistone Swer, Assistant Drugs Controller Meghalaya Director of Health Services, Meghalaya, Shillong
16.	Sh. Shobhit Koshta, Controlling and Licensing Authority Madhya Pradesh, Food & Drugs Adm. Idgah Hills, Bhopal (MADHYA PRADESH).
17.	Sh. Bhag Singh, Drugs Controller, Punjab Sector 34-A, Chandigharh (PUNJAB)
18.	Sh. A.S.Das, Drugs Controller, Orissa New Nandan Kanan Road, Bhubneshwar (ORISSA)
19.	Sh. D. K. Shringi, Drugs Controller, Rajasthan, Medical and Health Services (FW), Swasthya Bhawan, Tilak Marg, Jaipur, RAJASTHAN
20.	Sh. M. Bhaskaran, Drugs Controller Tamil Nadu, 359, Anna Salai, Tynapet, Chennai.
21.	Sh. Sunil Kumar Choudhay, Licensing Authority, Chandigharh (UT) CHANDIGHARH
22.	Sh. G. Thyemge, Assistant Drugs Controller, Arunachal Pradesh Dte. Of Health Services, Naharlagun-791110 (ARUNACHAL PRADESH)
23.	Sh. Deepak Kumar, Drug Inspector, Uttarakhand Directorate of Medical Health Uttarakhand, Dehradun, UTTARAKHAND
24.	Dr. Sajal Kumar Roychoudhary, Drugs Controller, West Bengal, Directorate of Drugs Control, K.I.T. Building, 5th Floor,P-16, India Exchange Place Extension, Kolkata
25.	Sh. C.N. Sharma, Chief Drugs Inspector, Sikkim, Department of Health and Family Welfare, Gangtok-737101, SIKKIM
26.	Dr. S. Ibomcha Singh, Director of Health Services, Manipur Medical & Health Services, Lamphlept, Imphal-7795004
27.	Sh. Rajkumaran, Drugs Controller, Puducherry 99-A, Mission Street, Puducherry-605011, PUDUCHERRY
28.	Sh. Avijit Roy, Deputy Director, Andaman and Nicobar Islands Port Blair-744104, ANDAMAN AND NICOBAR ISLANDS
29.	S.Babu, Dy. Drugs Controller, Food & Drugs Admn, Raipur, Chhattisgarh

B. Ministry Of Health & Family Welfare

30.	Dr. A. K. Panda, Joint Secretary, Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi

C. Invitees

31.	Dr. S. M. Jharwal, Director National Pharmaceutical Pricing Authority (NPPA), Jai Singh Road, New Delhi.
32.	Dr. Madhur Gupta, WHO, New Delhi
33.	Dr. A. Gunasekar, National Professional Officer WHO Country Office for India, New Delhi
34.	Dr. Y. K. Sharma, DDG, National Informatics Centre (NIC), CGO Complex, Lodi Road, New Delhi-110003
35.	Dr. Kashi Nath, DDG, National Informatics Centre (NIC), CGO Complex, Lodi Road, New Delhi-110003
36.	Sh. V.V. Ringe, National Informatics Centre (NIC), CGO Complex, Lodi Road, New Delhi-110003

D. Drug Testing Laboratories

37.	Dr. P.K. Guha, Director, Central Drugs Laboratory, 3, Kyd Street, Kolkata
38.	Dr. G.N. Singh, Secretary-cum-Scientific Director, Indian Pharmacopeia Commission, Raj Nagar, Sector -23, Ghaziabad 201002 (U.P)
39.	Sh. K.K. Singh, Head Publications, Indian Pharmacopeia Commission, Raj Nagar, Sector -23, Ghaziabad 201002 (U.P)

E. Zonal Offices of CDSCO

40.	Dr. D.Roy, DDC (I), I/c, CDSCO, North Zone, Ghaziabad
41.	Dr. R. Ramakrishna DDC (I) I/c, CDSCO, West Zone, Mumbai
42.	Ms. Rubina Bose, ADC(I), CDSCO, East Zone, Kolkatta
43.	Ms. Shanthy Gunasekaran, DDC(I), I/c, CDSCO, South Zone, Chennai
44.	Sh. A.C.S. Rao, ADC(I),CDSCO, Sub-Zone, Hyderabad
45.	Dr. A. Ramkishan, ADC(I), CDSCO, Sub-Zone, Ahmadabad

F. CDSCO, Hqrs

46.	Sh. A. B. Ramteke, DDC(I), FDA Bhawan, New Delhi
47.	Sh. M. Mitra, DDC (I), CDSCO, FDA Bhawan, New Delhi
48.	Dr. S.Eswara Reddy, ADC (I), CDSCO, FDA Bhawan, New Delhi
49.	Sh. Lalit Kishore, Technical Consultant, CDSCO, FDA Bhawan, New Delhi
50.	Sh. Rishi Kant Singh, Legal Consultant, CDSCO, FDA Bhawan, New Delhi
51.	Sh. A.K.Pradhan, ADC (I), CDSCO, FDA Bhawan, New Delhi
52.	Sh. Arvind Kukrety, ADC (I), CDSCO, FDA Bhawan, New Delhi
53.	Sh. Naresh Sharma, Drugs Inspector, CDSCO, FDA Bhawan, New Delhi
54.	Sh. Sushant Sharma Drugs Inspector, CDSCO, FDA Bhawan, New Delhi
55.	Sh. A. K. Khanna, Technical Officer, CDSCO, FDA Bhawan, New Delhi

56.	Sh. S.N. Basu Technical Officer, CDSCO, FDA Bhawan, New Delhi
57.	Sh. Aseem Sahu, Technical Officer, CDSCO, FDA Bhawan, New Delhi
58.	Sh. Jayant GangaKhedkar, Technical Officer, CDSCO, FDA Bhawan, New Delhi
59.	Sh. Nitin Kalra, Technical Data Associate, CDSCO, FDA Bhawan, New Delhi
60.	Miss Kavnit Kaur, Technical Data Associate, CDSCO, FDA Bhawan, New Delhi
61.	Sh. Varun Arya, Technical Data Associate, CDSCO, FDA Bhawan, New Delhi
62.	Miss Kamna, Technical Data Associate, CDSCO, FDA Bhawan, New Delhi
63.	Sh. Abhinav Shrivasatava, Technical Data Associate, CDSCO, FDA Bhawan, New Delhi
64.	Sh. Kshitiz Saini, Technical Data Associate, CDSCO, FDA Bhawan, New Delhi
65.	Miss Prabhjot Kaur Deol, Technical Data Associate, CDSCO, FDA Bhawan, New Delhi
66.	Sh. Rahul Malhotra, Technical Data Associate, CDSCO, FDA Bhawan, New Delhi
67.	Miss Sakshi Nautiyal, Technical Data Associate, CDSCO, FDA Bhawan, New Delhi

Annexure II

EXTRACTS OF PREVENTION OF FOOD ADULTERATION ACT, 1954

PART-IV PUBLIC ANALYSTS AND OOD INSPECTORS

Qualification of Public Analyst:- A Person shall not be qualified for appointment as a public analyst unless he:-

(1) holds a Master's Degree in Chemistry or Bio-chemistry or Food Technology or Microbiology or Food and Drugs from a University establishment in India by law or is an Associate of the Institution of Chemists (India) by examination in the section of Food Analysis conducted by the Institution of Chemists (India) or has an equivalent qualifications recognised and notified by the Central Government for such purposes and has not less than three years' experience in the analysis of food.

(2) has been declared qualified for appointment as a public analyst by a Board appointed and notified by the Central Government for such purposes;

Provided that a person who is a public analyst on the date of commencement of these Prevention of Food Adulteration (Amendment) Rules 1994, or who has worked as a public analyst for a period of three years before such commencement may hold office as such, subject to the terms and conditions of service applicable to him even though he does not fulfil the qualification laid down in clause (1) and (2)."

Provided further that a person who:-

(i) holds a degree in science with Chemistry or Bio-Chemistry or Food Technology or Food and Drugs from a University established in India by Law or

has an equivalent qualification recognized and notified by the Central Government for such purpose and has not less than five years of experience after graduation in the analysis of food, and

(ii) (a) has been declared qualified for appointment as a Public Analyst by a Board appointed and notified under clause (2) of this rule, prior to commencement to the Prevention of Food Adulteration (Amendment) Rules, 1994, or

(b) shall be declared qualified for appointment as a Public Analyst by a Board appointed and notified under clause (2) of this rule upto the period of 31st March 1999.

shall be eligible for appointment as public analyst, even though he does not fulfil the qualification laid down in clause (1).

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No.X-19013/1/2010 - D
DIRECTORATE GENERAL OF HEALTH SERVICES
CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
(O/o DCG (I))

FDA Bhawan, Kotla Road,
New Delhi.
Dated: the 16 November, 2010

OFFICE MEMORANDUM

Subject: Constitution of a Sub-Committee of the Drugs Consultative Committee to review the guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs and Cosmetics (amendment) act, 2008 and suggest the changes in the light of present day administration of the Drugs and Cosmetics Rules and procedures followed by the States Drugs Control Authorities– reg.

The 41st meeting of Drugs Consultative Committee (DCC), a statutory body under the Drugs and Cosmetics Act, 1940 was held on 28th October, 2010 to discuss the matters arising out of the administration of the Drugs and Cosmetics Act, 1940 and rules made thereunder in the country. During the course of the meeting it was felt that earlier guideline, prepared in 1993 and annexed to the current guideline are required to be re-examined for upgradation. The DCC after deliberations constituted the following sub-committee to review of the guidelines in light of the above observations.

Composition of sub-committee

1.	Drugs Controller, Tamil Nadu	Member
2.	Drugs Controller, Goa	Member
3.	Drugs Controller, Rajasthan	Member
4.	Drugs Controller, Gujarat	Member
5.	Drugs Controller, Jammu & Kashmir	Member
6.	Drugs Controller, Maharashtra	Member
7.	Drugs Controller, Haryana	Member
8.	Dr. D. Roy, DDC(I) North Zone	Convenor

Terms of Reference:

1. The meeting(s) of the Subcommittee will be held at CDSCO HQ, FDA Bhavan, New Delhi.
2. The Committee will give report in two months.

(Dr. Surinder Singh)
Drugs Controller General (India)

To

The Members of Committee

No.X-19013/1/2010 - D
DIRECTORATE GENERAL OF HEALTH SERVICES
CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
(O/o DCG (I))

FDA Bhawan, Kotla Road,
New Delhi.
Dated: the 16 November, 2010

OFFICE MEMORANDUM

Subject: Constitution of a Sub-Committee of the Drugs Consultative Committee to examine and recommend a system of recall of expired drugs and their safe destruction which could be incorporated under the Drugs and Cosmetics Rules– reg.

The 41st meeting of Drugs Consultative Committee (DCC), a statutory body under the Drugs and Cosmetics Act, 1940 was held on 28th October, 2010 to discuss the matters arising out of the administration of the Drugs and Cosmetics Act, 1940 and rules made thereunder in the country. During the course of the meeting it was recommended to constitute a subcommittee for preparing recall procedures of date expired drugs their safe destruction including disposal of drugs lying under the custody of Drug Inspectors on account of seizures. The DCC after deliberations constituted the following sub-committee for the purpose.

Composition of sub-committee

1.	Drugs Controller, Punjab	Member
2.	Drugs Controller, Delhi	Member
3.	Drugs Controller, Karnataka	Member
4.	Drugs Controller, Tamil Nadu	Member
5.	Drugs Controller, Gujarat	Member
6.	Shri PBN Prasad, DDC(I) HQ, CDSCO	Convenor

Terms of Reference:

1. Preparation of recall procedures especially for date expired drugs which could be implemented by the regulatory authorities as well as pharma industry.
2. Procedures for safe destruction in an environmental friendly manner to avoid pollution.
3. Documentation required for proper verification of the destroyed stocks.
4. Procedures for disposal of drugs lying under the custody of Drug Inspectors on account of seizures of the stocks by them.
5. Amendments required to be made for the purpose under the Drugs and Cosmetics Rules.

(Dr. Surinder Singh)
Drugs Controller General (India)

To

The Members of Committee

No.X-19013/1/2010 - D
DIRECTORATE GENERAL OF HEALTH SERVICES
CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
(O/o DCG (I))

FDA Bhawan, Kotla Road,
New Delhi.
Dated: the 01 November, 2010

OFFICE MEMORANDUM

Subject: Constitution of a Sub-Committee of the Drugs Consultative Committee to evolve a National strategy of networking of sale transactions of drugs from manufacturer to the retail chemist– reg.

The 41st meeting of Drugs Consultative Committee (DCC), a statutory body under the Drugs and Cosmetics Act, 1940 was held on 28th October, 2010 to discuss the matters arising out of the administration of the Drugs and Cosmetics Act, 1940 and rules made thereunder in the country. During the course of the meeting the committee considered the directions of the Hon'ble High Court of Allahabad to examine the proposal of networking of all transactions of medicine from the manufacturer to the dealer in consultation with NIC. The DCC after deliberations felt that the matter needs and indepth study with all stakeholders for evolving a National strategy and constituted the following sub-committee to examine and evolve a National strategy for networking of sale transactions of drugs from the manufacturers to the retail chemists in the country.

Composition of sub-committee

1. State Drug Controller of Tamil Nadu	Member
2. State Drug Controller of Gujarat	Member
3. State Drug Controller of Utter Pradesh	Member
4. State Drug Controller of Goa	Member
5. State Drug Controller of Arunachal Pradesh	Member
6. Representative of NIC	Member
7. Shri Malay Mitra, DDC(I) CDSCO, HQ	convenor

Terms of Reference:

1. Study of technical feasibility of networking of sale transactions of drugs from the manufacturers to the retail chemists in the country in consultation with stakeholders like manufacturers and chemists.
2. Evolve a National strategy for implementation of the networking of sales in the country.
3. Estimation of costs of the networking in the whole of the country and methodology for sharing the costs between the stakeholders.
4. Consultation with the State Drugs Control Authorities and Industry in different zones in the country for suggesting a working model.

(Dr. Surinder Singh)
Drugs Controller General (India)

To
The Members of Committee

F.No.15-49-/2010-DC
Directorate of General of Health Services
Central Drugs Standard Control Organization
FDA Bhawan, Kotla Road, New Delhi
(O/o DCG (I)

To,

All State Drug Controllers

Subject:: Action on the recommendations of the Parliamentary Standing Committee of Ministry of Health and Family Welfare for promotion of use of Generic Drugs in the country to reduce the drug cost and increased drug availability–reg.

Sir,

Parliamentary Standing Committee on Health & Family Welfare in its 39th and 45th Report gave recommendations on the "Issues Relating to Availability of Generic, Generic-branded and Branded Medicines, their Formulation and Therapeutic Efficacy and Effectiveness. The committee has given number of suggestions to ensure that only generic drugs are purchased by the Government procurement authorities. This would result in huge savings on drug expenditure and enable rational use of drugs in the country. The salient recommendations of the committee were forwarded to the State Drugs Controllers vide letter No. 15-49/2010-DC, dated 19.11.2010 (**annexure I)**.

The proposal to promote generic drugs in the country and ensuring their quality was considered in the 41st meeting of the Drugs Consultative Committee held on 28th October, 2010 at New Delhi. The committee after deliberations agreed that marketing of generic drugs should be promoted in the country while ensuring that they are of comparable standards. DCC recommended that members may grant licences for marketing of single drug formulation in generic name only to promote availability of generic drugs at affordable prices in the country. Relevant extracts of the agenda and recommendations are placed at **annexure II.**

It is requested that action taken by your State in promoting generic medicines at affordable prices and progress in granting licenses for marketing single drug formulation in generic name only may kindly be forwarded to this office on priority basis by 31st December, 2010 positively.

Yours faithfully,

(Dr. Surinder Singh)
Drugs Controller General (India)

Copy forwarded for information to zonal /sub-zonal office for pursuing with the State Drug Control Authorities to furnish information to this office at the earliest but not later than 31st December, 2010.

Central Drugs Standard Control Organization

Dr. Surinder Singh
DRUGS CONTROLLER GENERAL (INDIA)

Directorate General of Health Services
Tele – 011-23236965
Fax - 011 -23236973
Email: - surindersingh_n@yahoo.co.in
Web: WWW.cdsco.nic.in
FDA Bhawan, Kotla Road, New Delhi –110002.

F.No. X-19013/1/2010-D

Dated: 31st December, 2010

To,

All State Drugs Controllers

Sub: Report of the Workshop on dissemination of Information on Regulatory Affairs, (41st Meeting of the Drugs Consultative Committee) held on 28th October, 2010, at FDA Bhawan, Kotla Road, New Delhi-110002 - reg.

Sir,

41st meeting of the Drugs Consultative Committee and Workshop dissemination of Information on Regulatory Affairs was held on 28th October, 2010, at FDA Bhawan, Kotla Road, New Delhi – 110002.

The Report of the Workshop on dissemination of Information on Regulatory Affairs and 41st meeting of the Drugs Consultative Committee held on 28th October, 2010, containing agenda and minutes of the meeting, duly approved by the Chairman is annexed herewith for your information and taking further necessary action, wherever required, in the matter.

Yours faithfully,

Encl. Copy of the minutes

(Dr. Surinder Singh)
Drugs Controller General (India)

Copy forwarded for information and necessary action to

Zonal offices/Sub-zonal offices

F.No.X-19013/1/2010-D
Directorate of General of Health Services
Central Drugs Standard Control Organization
(O/o DCG (I)

Sub: Report of the Workshop on dissemination of Information on Regulatory Affairs, (41st Meeting of the Drugs Consultative Committee) held on 28th October, 2010 at FDA Bhawan, Kotla Road, New Delhi-110002 - reg.

41st meeting of the Drugs Consultative Committee and Workshop dissemination of Information on Regulatory Affairs was held on 28th October, 2010 at FDA Bhawan, Kotla Road, New Delhi – 110002.

The Report of the Workshop on dissemination of Information on Regulatory Affairs and 41st meeting of the Drugs Consultative Committee is annexed herewith for kind information and record.

(Dr. Surinder Singh)
Drugs Controller General (India)
31.12.2010

US(D)

F.No.X-19013/1/2010-D
Directorate of General of Health Services
Central Drugs Standard Control Organization
(O/o DCG (I)

Sub: Report of the Workshop on dissemination of Information on Regulatory Affairs, (41st Meeting of the Drugs Consultative Committee) held on 28th October, 2010 at FDA Bhawan, Kotla Road, New Delhi-110002 - reg.

41st meeting of the Drugs Consultative Committee and Workshop dissemination of Information on Regulatory Affairs was held on 28th October, 2010 at FDA Bhawan, Kotla Road, New Delhi – 110002.

The Report of the Workshop on dissemination of Information on Regulatory Affairs and 41st meeting of the Drugs Consultative Committee is annexed herewith for kind information and necessary action wherever required.

(Lalit Kishore)
Consultant
11.01.2011

JDC(R)

DDC(MM)

DDC(BR)

ADC(P)

ADC(ER)

ADC(AK)

ADC(SPS)

DI(N)
DI(SS)
TO(GK)
TO(SK)
TO(AS)
TO(H)