REPORT OF THE WHO WORKSHOP ON DISSEMINATION OF INFORMATION ON REGULATORY AFFAIRS AND 43RD MEETING OF THE DRUGS CONSULTATIVE COMMITTEE HELD ON 14TH NOVEMBER, 2011 IN THE COMMITTEE ROOM, FDA BHAVAN, KOTLA ROAD, NEW DELHI – 110002.

(List of Participants is at Annexure I)

INAUGURAL DELIBERATIONS

Dr. V. G. Somani, Drugs Controller General (India) I/c and Chairman, Drugs Consultative Committee (DCC), welcomed the members and thanked them for sparing their valuable time to attend the meeting and desired that the committee will have fruitful discussions on the various matters placed before the committee for its consideration and recommendations.

The members congratulated Dr. Somani for taking charge as Drugs Controller General (India) and hoped that interaction between the Central and the States Drugs Control Departments will be further strengthened for achieving the goal of effective drug regulatory system in the country.

Dr. Somani briefed the members that only three agenda items from the Central Government were included in the agenda which required urgent attention of all regulatory authorities. Other agenda items are from the different State Drugs Controller Authorities.

The agenda item No. (1) relates to the functioning the Blood Banks to ensure that the incidence like reported transfusion of HIV infected blood at Junagadh in Gujarat is not repeated. The Blood Banks function under the licences granted by the Drug Control authorities and are required to adhere to the conditions of the licence. National AIDS Control Organization (NACO) is the nodal organization of the Central Government for

prevention and control of AIDS in India. Dr. Sandhya Kabra, ADG(BS), NACO will address the members to sensitize them about the critical areas which are required to be taken care of during the inspection of Blood Banks.

The second agenda relates to misleading advertisements which appears in the print media on the drugs. Dr. D. R. Rai, Secretary General, Indian Medical Association will highlight the concerns of IMA and to extend its cooperation in regulating misleading advertisements.

The third agenda is related to the need of having an effective recall system of drugs in the country. Concerns were expressed on many forums about the absence of regarding in effective recall system of drugs which have been declared not of standard quality in the country. The Committee was requested to discuss and evolve guidelines and procedures for effective recall system of drugs declared not of standard quality in the country.

DCG(I) further stated that instances had come to the notice of his office that certain States Licensing Authorities had granted permissions to certain drug formulations especially Fixed Dose Combinations of drugs in the recent past, which fall in the ambit of the definition of new drug under the Drugs and Cosmetics Rules. Such permissions are in violation of the provisions of the Drugs and Cosmetics Rules and are required to be withdrawn. He requested that the State Drug Control Authorities should take extra care while granting the manufacturing permissions to ensure that the formulations of new drugs and Fixed Dose Combinations falling under the definition of 'new drug' are not permitted for manufacture without prior approval of the Drugs Controller General (India). Further in the cases of drugs prohibited by the Central Government under Section 26A of the Drugs and Cosmetics Act, through the notification are withdrawn from the market with immediate effect.

He then requested to Dr. Sandhya Kabra to address the committee.

AGENDA NO. 1

CONSIDERATION OF THE PROPOSAL FOR BETTER COORDINATION BETWEEN THE STATE LICENSING AUTHORITIES AND STATE BLOOD TRANSFUSION COUNCILS FOR PROMOTING SAFE BLOOD TRANSFUSION PRACTICES

Press reports had recently appeared in September, 2011 that Thalassemia patients were transfused with HIV infected blood in Gujarat. It was reported that 23 thalassemic kids from Junagadh district in Gujarat State were tested HIV positive in last one year because of the transfusion of the HIV infected blood. There are about 100 thalassemic patients in the district who regularly visit the civil hospital for blood transfusion. All of them visit the hospital just for the transfusion process, and most of the times they bring the blood with them. The hospital authorities stated that lack of high end HIV screening equipment in the district is making it difficult for the local Blood Banks to screen the donated blood for HIV.

National AIDS Control Organisation (NACO) is the nodal organization of the Central Government for HIV/AIDS Control Programme in India. National Blood Transfusion Council promote voluntary blood donation and ensure safe blood transfusion.

In order to ensure that such incidents are not repeated and the Blood Banks follow safe blood transfusion practices, a better coordination between the State Licensing Authorities and States Blood Transfusion Councils is required.

DCC may deliberate and prepare guidelines for better coordination with States Blood Transfusion Councils for safe blood transfusion practices.

RECOMMENDATIONS

Dr. Sandhya Kabra gave a detailed presentation on the critical areas to be taken care of during the inspections of Blood Banks. In her address she stated that well equipped blood centres with adequate infrastructure and trend manpower is an essential requirement for quality, safety and efficacy of blood and blood products. Government of India had prepared the National Blood Policy to ensure easy accessibility and adequate supply of safe blood & blood

components collected from Voluntary Non-remunerated Regular Blood Donor (VNRRB) donors in well equipped premises, which is free from Transfusion Transmitted Infections (TTI) and are stored and transported under optimum conditions and transfused under supervision of trained personnel for all who need it irrespective of their economic or social status through' comprehensive, efficient & through comprehensive, efficient and a total quality management approach. The policy also provides to make available latest technology for operating the Blood Transfusion Services and ensure its functioning in an updated manner.

It was emphasized that fresh licences to 'Stand Alone Blood Banks' should not be granted. Efforts should be made to encourage voluntary blood donations. The Blood Banks should have written Standard Operative Procedures to be followed for collection, processing, compability testing, storage and distribution of blood as prescribed under the Drugs and Cosmetics Rules. Instances like that of Junagadh only happen when there are deviations in the prescribed procedures by the Blood Banks.

She further suggested that State Blood Transfusion Council (SBTC) should be involved in the inspection of the Blood Banks. Drug Controller Mizoram however, informed that there is no SBTC in his State.

The committee after deliberations and taking into accounts the views expressed by the members recommended that the State Drugs Control Organizations and SBTC should extend cooperation and members of SBTC may be associated in inspections of Blood Banks wherever possible. However, in the cases where SBTCs are not available the State Drugs Control Department may go ahead with the inspections independently. The presentation of Dr. Kabra highlighting the critical areas which should be taken care of during inspections should be kept in mind as guidelines for inspection of Blood Banks and annexed to the minutes. The presentation is at annexure II.

Dr. Kabra assured the house that the NACO would be happy to answer any queries of the State Drugs Control Organizations regarding functioning of the Blood Banks. The State Licensing Authorities are free to approach NACO for any clarification or guidance in respect of monitoring of the functioning of the Blood Banks.

AGENDA NO. 2

CONSIDERATION OF THE PROPOSAL TO DISCUSS THE WAYS AND MEANS TO CURB THE MISLEADING ADVERTISEMENTS OF DRUGS MAKING UNSUBSTANTIATED CLAIMS

Advertisement of drugs and magic remedies are regulated under the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 administered by State Governments. Under the said Act, advertisement of drugs for certain diseases and disorders is prohibited. The Central Government may, however, give permission through a Gazette Notification in public interest to advertise specified drugs or class of drugs, irrespective whether they are prescription drugs covered under Schedule H or X of the Drugs and Cosmetics Rules. The Act, however, does not regulate the advertisements relating to offer for treatment.

Concerns have been expressed at many forums that advertisements on drugs appearing in print as well as electronic media in many cases make unsubstantiated claims taking gullible public for a ride. Only medical practitioners and drugs specialist know the components of various drugs in a formulation and their effects on the human body. Self medication based on the advertisement and without proper medical advice and in quantities not prescribed by doctors can lead to life threatening situations. The number of people developing immunity to antibiotics has been increasing in the recent years because of self medication. The use of superlatives like “tested”, “trusted”, “guaranteed success” etc. without any substantiation are totally misleading and should not be permitted to be used.

WHO has prescribed certain norms for medicinal drug promotion. It stipulates that no unsubstantiated claims about the drug benefits should be

made. Every advertisement should contain details of all the components in the drug. The text should be legible and the advertisement should contains summary of scientific information along with the information about the dosage form, approved therapeutic uses, side effects, precautions and warnings in the use of the drug etc.

The Drugs and Cosmetics Act and Rules made thereunder do not have at present any rule to control the advertisements of drugs in the country. However in case of cosmetics, rule 148-B was inserted making prohibition against false or misleading claims on its label. It provides that no cosmetics may purport or claim to purport or convey any idea which is false or misleading to the intending user.

DCC may kindly consider and suggest the ways and means through which misleading advertisements on drugs could be curbed.

RECOMMENDATIONS

Dr. D. R. Rai, Secretary General of Indian Medical Association gave a presentation on the Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 and stated that advertisements on drugs appear in both print and electronic media making misleading claims taking gullible public for a ride. The Act at present does not cover advertisements in electronic media which is under the control of Ministry of Information and Broadcasting. He however, desired that State Drugs Control Departments, which are authorized under the said Act, should take appropriate action in the cases of apparent misleading advertisements appearing in the print media.

Some of the State Drugs Controllers stated that most of the advertisements relating to false and misleading claims pertain to the drugs belonging to Indian System of Medicines or by the practitioners inviting for a particular treatment without indicating any drug and such advertisements do not fall under the ambit of DMR (OA) Act.

The DCC after deliberations agreed that the State Licensing Authorities should take proactive approach in respect of advertisements originating in their

State and appearing in National or vernacular print media in order to put a check on the rampant publications of misleading advertisements. The committee further recommended that the Central Government may take steps to amend the Drugs and Magic Remedies (Objectionable Advertisements) Act 1954, making penalties most stringent and to include electronic media as well as treatment under its ambit. This would help in taking effective action against the advertisements and fake doctors claiming guaranteed cure in respect of diseases for which no permanent cure is available.

(43rd meeting of DCC held on 14th November, 2011)

AGENDA NO. 3

CONSIDERATION OF THE PROPOSAL TO PREPARE GUIDELINES AND PROCEDURE FOR RECALL OF DRUGS UNDER THE DRUGS AND COSMETICS RULES, FOR EFFECTIVE RECALL OF NOT OF STANDARD QUALITY, ADULTERATED AND SPURIOUS DRUGS BY THE MANUFACTURERS AS WELL AS CHEMISTS

The Schedule M to the Drugs and Cosmetics Rules, 1945 provides for prompt and effective product recall system of defective products by the licensees. The specific provision provided under the heading 'PRODUCT RECALLS' is as under:

27.1 A prompt and effective product recall system of defective products shall be devised for timely information of all concerned stockists, wholesalers, suppliers, upto the retail level within the shortest period. The licensee may make use of both print and electronic media in this regard.

27.2. There shall be an established written procedure in the form of Standard Operating Procedure for effective recall of products distributed by the licensee. Recall operations shall be capable of being initiated promptly so as to effectively reach at the level of each distribution channel.

27.3 The distribution records shall be readily made available to the persons designated for recalls.

27.4 The designated person shall record a final report issued, including reconciliation between the delivered and the recovered quantities of the products.

27.5 The effectiveness of the arrangements for recalls shall be evaluated from time to time.

27.6 The recalled products shall be stored separately in a secured segregated area pending final decision on them.

It is however observed that there is no uniform and time bound procedure followed by the State Licensing Authorities for effective recall of drugs by the manufacturers as well as sale licensees. It does not provide any specific time frames for effective recall in case of grossly substandard, adulterated or spurious drugs.

Concerns have been expressed that in the absence of any guidelines or mechanism to freeze the sale and manufacture of impugned drugs, within the

short period of time, from further availability to the consumers, such drugs are not withdrawn from the market in time. The problem is more acute in the cases of drugs manufactured in one State and found sub-standard in another State.

The DCC may kindly consider for laying down guidelines and procedures to be followed for effective and uniform recall for drugs which may be adopted by the State Licensing Authorities for uniform implementation.

RECOMMENDATIONS

DCG(I) briefed the members that even though Schedule M provides for a prompt and effective product recall system of defective products by the manufacturers, and the manufacturers may use both print and electronic media for this purpose. However, there are no uniform and time bound procedures laid down which should be followed uniformly by the manufacturers as well as regulatory authorities to ensure that there is an effective and time bound recall of the drugs declared as not of standard quality. Drug declared as not of standard quality is not required to be further consumed by the public. For this purpose there should be a time bound system in operation for freezing the sale of the impugned drugs.

Drugs Controller, Rajasthan stated that the issue of recall of drugs becomes more difficult in the cases where the drug is manufactured in another State and the recall has to be ordered by the Drugs Controller of that State. In such cases even the information about the action taken is not received from some of the State Drugs Control authorities.

Commissioner FDA, Maharashtra stated that in his State information regarding substandard drugs is communicated through e-mail to the retailers and manufacturers associations in the State for quick recall. The manufacturers are requested to make electronic withdrawal of such drugs from the market.

Commissioner, FDCA, Gujarat, stated that the similar procedure is being followed in Gujarat also.

The committee after deliberations felt that the issue is a complex one because of interstate withdrawal. It therefore, recommended that a committee may be formed to deliberate on various aspects of withdrawal of such drugs from the market and the difficulties faced by the regulatory authorities in monitoring the withdrawals. The committee may consider evolving a priority recall system in the cases of banned drugs and grossly substandard drugs as well as withdrawal of other categories of drugs declared as not of standard quality. The committee shall consist of the following members.

1. **Shri H. G. Koshia, Commissioner FDA, Gujarat**
2. **Shri Navneet Marvaha, ADC, Himachal Pradesh**
3. **Shri S. A. Veljee, Drugs Controller Goa**
4. **Dr. C. M. Ghosh, Drugs Controller, West Bengal**
5. **Shri P.B.N. Prasad, DDC(I),**

The Committee may examine and prepare a guidance document for having an effective and time bound recall system in the country for various categories of drugs. It may also recommend necessary changes, if any, which are required to be brought in the Drugs and Cosmetics Rules for effective implementation.

RAJASTHAN

AGENDA NO. 4

Providing constitutions of licensed firms and other relevant documentary evidences by Licensing Authorities when required for launching prosecution against offending firms :-

Licensing of manufacturers and dealers is for ensuring manufacture and sale of Quality Drugs. While grant of licences documentary evidences relating to constitutions of firm and name & addresses of technical staffs are taken on records by Licensing Authority for manufacture and sale of Drugs/ Cosmetics. In the event of a any drugs/cosmetic found grossly substandard, adulterated or spurious, decisions are taken to launch prosecution in the Courts and then information regarding constitution of the firms is required. Though, time and again, Drugs Consultative Committee have recommended that constitution and investigation reports should be provided by State Licensing Authorities to each other, but it is not followed.

Under Sec. 175 & 176 of Indian Penal Code, every Public Servant is legally bound to produce or give such information or deliver any document to another Public Servant. If he intentionally omits to do so, he shall be punished with imprisonment up to one month or with fine up to 500 rupees. If the document is to be produced or delivered to the Court, the term of imprisonment is up to six months or fine up to 1000 rupees or both.

> Illustration:- A, being legally bound to produce a document before a District Court, intentionally omits to produce the same, A has committed the offence defined in this section.

As per Sec. 91 and 92 of Criminal Procedure Code 1973 if the documents/information required for legal purpose by a Public Servant is not provided which is necessary for enquiry/investigation or trial before Court, the Court may issue summons to such officer or a written order to the person in whose possetion such document/information is believed to be to produce it in the Court.

Therefore the State Licensing Authorities should avoid such a bitter situation, where he is requested through Court, to make available the documents in Courts on application under Sec. 91 & 92 of Cr. P. C. Therefore the desired information available with them should be made available within one month positively.

RECOMMENDATIONS

Drugs Controller, Rajasthan stated that he wanted to bring it to the notice of the house that the earlier recommendations of DCC regarding the interstate cooperation are not being adhered to by many State Drugs Controllers. In spite of repeated reminders vital information regarding constitution of the manufacturing firms or name and address of the technical staff etc was not provided for launching prosecutions even in cases of grossly substandard drugs. He further mentioned that provisions of section 175 and 176 of India Penal Code as well as section 91 and 92 of Criminal Procedures Code provide powers to the courts to take cognizance of non furnishing of documents before the Hon'ble Court. Invoking of these clauses may result in unpleasant situations.

The DCC after deliberations agreed that there may be some delays in providing the requisite information by the licensing authorities because of certain difficulties. However, State Drugs Controllers should take care that the norms laid down by DCC are followed in letters and sprit and full cooperation is extended in investigations of the cases of not of standard quality of drugs. The investigating officers should however, also play a proactive role and visit the concerned State to collect the necessary documents required for launching of the prosecution. In case of apparent non-cooperation the investigating officers are free to use other instrument of law as pointed out by Drugs Controller, Rajasthan for obtaining the information. However, such situations should be avoided as far as possible.

AGENDA NO. 5

Whether Private Hospitals, Nursing Homes etc. require to take sale licences for keeping the drugs for making them available to the indoor patients:-

Making the drugs available to the consumers by way of sale or distribution are well defined under the sale licences which are issued under the Act & Rules and accordingly by making the drugs available to patients for consideration of their price necessitate to obtain the sale licences by the Private Hospitals, Nursing Homes etc. under the provisions of Drugs & Cosmetics Act, 1940 and Rules there under. The provisions relating to exemptions are contained in the Schedule K of Drugs & Cosmetics Rules, 1945.

Entry No. 5 refers to exemption in respect of drugs to be supplied by the Registered Medical Practitioners to their own patient and Entry No. 5A refers to exemption in respect of drugs to be supplied by a Hospital or Dispensary maintained or supported by Government or local body. No such exemptions provisions exists to Private Hospitals, Nursing Homes etc. which implies that all Private Hospitals, Nursing Homes etc. should necessarily obtain the sale drugs licences for making the drugs available to the patients, where drugs are prescribed by various Registered Medical Practitioners of these institutions. But at the same time when we observe certain conditions of wholesale licences on Form 20B & 21B, it shows that drugs may be sold and supplied to such institutions irrespective of drugs licences.

The corresponding Rule 65(5)(1) clarify that wholesale licensee is required to mention the name & address of the licensee to whom sold in cash or credit memo but in case of sale to an authority purchasing on behalf of the Government, or to hospital, medical, educational or research institution or to a registered medical practitioner for the purpose of supply to his own patients the name and address of the authority, institution or the registered medical practitioner as the case may be should be written; which implies that sale can be made to “hospital, medical, educational or research institution” also. The Rule 65 (9) (b) further support this view as it prescribe the conditions for making supply of Schedule H & Schedule X drugs to Registered Medical Practitioners, Hospitals, Dispensaries and Nursing Homes against the signed order in writing.

Even the definition of “Retail Sale” under Rule 2(f) of Drugs & Cosmetics Rules, 1945 says that “retail sale means a sale [whether to a hospital, or a dispensary, or a medical, educational or research institute or to any other person] other than by way of wholesale dealing”. This on bare reading suggest that sale of drugs

can be done to hospital, or a dispensary, or a medical, educational or research institute.

Thus there is contradiction in Rules relating to sale of drugs to Hospitals, Dispensaries and Nursing Homes vis-à-vis exemption under Schedule K of Drugs & Cosmetics Rules, 1945 and needs to be deliberated.

RECOMMENDATIONS

Drugs Controller, Rajasthan stated that while sale of drugs is permitted to the hospitals by way of wholesale the exemption under Schedule K is limited to a hospitals or dispensary maintained or supported by Government or local body. Under this situation whether Private Hospitals, Nursing Homes etc. are required to take sale licences for keeping the drugs for making them available to the indoor patients.

Drugs Controller, Kerala stated that in a case, Kerala High Court, had given some directions in this regard and these shall be followed by all State for uniformity. He agreed to provide a copy of judgment.

The DCC decided that the matter may be taken up in the next meeting along with the copy of the Court order for making appropriate recommendations in the matter.

AGENDA NO. 6

Mandatory provision be incorporated in Drugs & Cosmetics Rules to test drug samples by govt. Analysts in time frame:-

Testing of drug samples often takes very long time & in some cases the test reports are received even after expiry date. If such sample is declared adulterated/spurious, the manufactures gets the benefit as he is debarred of his right to challenge the test reports. Therefore maximum time limit be prescribed for testing/analysis of drug samples by the Govt. Analysis as in case of

Prevention of Food Adulteration Act, where 40 days are prescribed under Rule 7 to the Public Analyst for analysis of Food samples.

RECOMMENDATIONS

Drugs Controller, Rajasthan desired that a time limit may be prescribed for testing of drug samples by the Government analysts under the Drugs and Cosmetics Rules.

Dr. G. N. Singh, Secretary IPC informed the house that the matter was earlier discussed in the Government analysts conference also but the final decision is still pending.

The Director CDL, stated that the normal guidelines followed by his laboratory are as under.

HPLC testing	**60 days**
Normal Chemical testing	**45 days**
Biological products	**90 days**

The DCC recommended that it may be difficult to prescribed time limits for testing of drug samples under the Drugs and Cosmetics Rules. However, the broad guidelines followed by CDL, Kolkata may be followed as model time lines by the Government Drug Testing Laboratories for testing drug samples.

AGENDA NO. 7

The numbers of loan licences and contract manufacturing that can be permitted to a manufacturer licenced under the provisions of Drugs & Cosmetics Act 1940 & Rules thereunder.

RECOMMENDATIONS

Drugs Controller, Rajasthan desired to know whether any limit could be prescribed for number of loan licences which could be granted to a manufacturer.

The members observed that loan licences are granted for utilization of the excess capacity available with the manufacturers. DCC therefore recommended that it would not be possible to specify a number of loan licences that can be permitted to a manufacturer. The State licensing authorities may, however, assess the capacity of the manufacturer before granting the loan licence.

KARNATAKA

AGENDA NO. 8

Interstate co-operation during investigation-

Whenever officers of this state are visiting other state for investigation, we do not get cooperation from other state. Though requests are made to send the documents pertaining to the constitution of the company, copies of licenses, renewal certificate, copy of the product permission etc, the same is not furnished by the other state drugs control authorities. State Drug Control authorities may be directed to provide necessary cooperation during investigation and to furnish the details called for at the earliest. DCC time and again has informed the State Drugs Control Authorities to have interstate co-operation during investigation. Unfortunately some of the states do not follow these directions.

RECOMMENDATIONS

The matter has already been discussed under agenda no. 4.

AGENDA NO. 9

No reply is received on action taken report against the manufacturers regarding Not of Standard quality reports.

Whenever Drug is declared as Not Of Standard quality, copy of the test report is sent to the concerned State Drugs Control Authority requesting to take necessary action against the manufacturer. In spite of sending several reminders reply is not received. This dept is required to answer to the audit, legislatures regarding action taken against the manufacturer. It becomes quiet embracing to state that no reply is received from the concerned state. Government is contemplating to address letters to the concerned state Chief Secretaries in this regard. In view of this DCC may be direct all the state drugs control authorities to send the reply at the earliest and time limit may be framed in this regard.

RECOMMENDATIONS

Drugs Controller, Karnataka stated that some of the State Drugs Controllers do not forward the action taken reports against manufacturers located in their jurisdictions, whose samples were declared as not of standard quality. This sometimes creates audit problems. DCC may consider if any time limit could be prescribed for providing this information.

The members were of the view that it would be difficult to follow any time lines in such cases as procedural formalities take lot of time and may vary from case to case.

DCC after deliberations and taking into consideration the difficulties and procedural formalities faced by the State Drug Control Authorities recommended that even though it may not be possible to specify a time limit for providing information of the action taken against the manufacturers. The members may, however, provide the status of action being taken in the matter should be communicated to the concerned State Drugs Controllers within six months time.

AGENDA NO. 10

Reference Standards-

Reference standards for all the Pharmacopoeial drugs (IP) and Patent and Proprietory drugs are essential in test or analysis of the Drugs. However these are not available in CDL Kolkatta. In absence of these reference standards analysis cannot be carried out. Hence arrangements may be made to make it available. List of available reference standards available at present may be published and for other reference standards it may be published periodically as and when it is available.

RECOMMENDATIONS

The Drugs Controller, Karnataka raised the issue of non-availability of certain reference standards which are essential for test and analysis of the drugs.

Sh. P.K. Guha, informed the house that CDL, is maintaining 116 Indian Pharmacopeia Reference Standards (IPRS) and 31 Cultural Reference Standard (CRS) and these samples are provided free of cost. However, now the mandate of keeping reference standards is with the Indian Pharmacopeia Commission.

Dr. G.N. Singh, Secretary IPC, informed the members that 230 Reference Standards are available with the IPC and these are available on price. The list of available reference standards is on their website ipc.gov.in. He further stated that IPC will be able to provide testing methods for testing of new drugs and reference standards to the Government Drug Testing Laboratories if a request is made for the purpose. The proposal of providing reference standards to Government laboratories at subsidized rates will however be placed before the Governing Body of IPC for its consideration.

AGENDA NO. 11

Whether Test License in form 29 can be issued as a loan license.

It is learnt that some of the State Licensing authorities are issuing test license on loan licenses. If so under what form the same is issued.

RECOMMENDATIONS

The DCC recommended that it has no objection to the grant of test licences on loan licence. The name of the facility should however, be mentioned in the licence. DCC also agreed that the validity of the test licence in Form 29 may be

increased to two years and appropriate amendment placed before DTAB for its consideration.

AGENDA NO. 12

Training of Analysts from Drugs Testing Laboratory at Labs other than CDL.

This department is contemplating to depute Analysts from the Drugs Testing Laboratory for training at other than CDL. The same may be considered so that Analysis will be exposed in analysis of different categories of products. Further it is requested to provide accommodation facilities in such cases.

RECOMMENDATIONS

DCC recommended that it has no objection that Government analysts from Drug Testing Laboratories are sent for training to laboratories other than CDL which have requisite infrastructure for such testing.

AGENDA NO. 13

Narcotics Dept./Customs Authority has asked for issue of NOC for destruction of Fentanyl Nasal Spray.

One of the Clinical Research Organization intends to destroy remaining quantity of Fentanyl Nasal Spray after they have completed their clinical trials. The said product is a Narcotics Drugs. In this regard Narcotics dept/ Custom authorities have requested this dept issue NOC. Whether NOC can be issued by this dept.

RECOMMENDATIONS

DCC recommended that NOC may be granted for destruction of fentanyl Nasal Spray as requested by the Department of Narcotics.

AGENDA NO. 14

Amendment to Rule 122-F (3)

As per Rule 122-F (3) it has been mentioned as – "Application by licensee to manufacture **additional drugs** listed in the application shall be accompanied by a fees of rupees three hundred for **each drug** listed in the application."

Instead o motioning it as Drug it should be substituted by the words "Blood components" /Blood products.

Necessary amendment may be made in the said Rule.

RECOMMENDATIONS

DCC did not agree to the proposed amendment of rule 122F (3) as the word 'drug' conveys the meaning without any ambiguity.

AGENDA NO. 15

Amendment to Rule 122-P (d)

Maintenance of Reference samples- The Rule does not specify as to how many days the reference sample to be maintained. Hence necessary amendment may be made in the said Rule.

RECOMMENDATIONS

DCC observed that there is a provision under Schedule F, Part XII B under the heading Blood Banks /Blood components, in the note appended to para K, that Blood samples of donors in pilot tube and the blood samples of the recipient shall be preserved for 7 days after issue.

AGENDA NO. 16

Amendment to Part XII B.

1) Part XII B of the Drugs and Cosmetics Rules stipulates the requirements for the collection, storage, processing and distribution of whole human blood, human blood components by blood banks and manufacture of blood products, which *inter alia* prescribes the definition of "Blood Bank", "Donor" etc.

As per Rule **122-F,** application for the grant and/or renewal of licence for the operation of a Blood Bank/processing of human blood for components/manufacture of blood products shall be made to the Licensing Authority appointed under part VII in Form 27-C or Form 27-E, as the case may be, and shall be accompanied by licence fee of rupees six thousand and an inspection fee of rupees one thousand and five hundred for every inspection thereof or for the purpose of renewal of licence.

As per Rule 122G, a licence for the operation of a Blood Bank or for processing whole human blood for components and manufacturer of blood products shall be issued in form 28-C or Form 28-E or Form 26-G or Form 26-I, as the case may be.

Rule 122G(2) was inserted vide Gazette notification no GSR 733(E) dated 21-12-2005 which reads as follows- Application for the grant or renewal of licence for operation of a Blood Bank or processing of human blood for components shall be made by the Blood Bank run by the Govt., Indian Red Cross Society, hospitals, charitable trust or voluntary organization approved by a State/Union Territory Blood Transfusion council only.

Explanation – For the purpose of this sub-rule, "renewal" shall include renewal of any license issued prior to the commencement of the Drugs and Cosmetics (....Amendment) Rule 2005.

Therefore, Rule 122G(2) stipulates that the application for grant or renewal has to be made only by the following categories or applicants-

i) Government,
ii) Indian Red Cross Society,
iii) Hospital,
iv) Charitable trust or voluntary organization
and no one else.

In view of this rule, whether fresh license and /or renewal of the stand alone blood banks or the blood bank owned by a private person or by a blood bank with partnership firm or private limited company can be done.

RECOMMENDATIONS

DCC observed that in view of the fact that the rule was already amended vide GSR 267(E) dated 27.04.2006 and the word 'prior' was change to 'after', the proposed amendment is not required.

TAMIL NADU

AGENDA NO. 17

Sampling procedures for Blood units and Blood components may be evolved since one Blood Bag/ Unit is a batch and hence procedure of dividing the Blood unit into 3 portions and detailed sampling procedures for this may be discussed and evolved.

RECOMMENDATIONS

The members were of the view that the sampling of the blood on the lines of samples of drugs as stipulated in the Act is a complex issue and raises many questions like the procedures for testing such samples, who will be the Government Analysts for testing of such blood samples and the procedures for taking action in such matters. The DCC recommended that the Drugs Controller, Tamil Nadu, if considered essential may take up the matter with the NACO for further clarifications in the matter.

AGENDA NO. 18

As per the existing Drugs and Cosmetics Act and Rules made there under, there are no specific procedure given to recall the expiry drugs by the manufacturer and hence necessary amendment may be made in Schedule 'M', Part I (SI.No.27) under the subject "Product Recall" to include expiry drugs in the category.

RECOMMENDATIONS

Agenda had already been discussed under agenda item number 3.

AGENDA NO. 19

As per Rule 96 of the Drugs and Cosmetics Rule, the manufacturers are giving the brand names, generic name, manufacturing date, expiry date etc. in their labels of blister packs/ strips packs of tablets and capsules (10/15's pack). However in practice as per the prescription of the Doctors the drugs are supplied only in split quantities and not as a full blister pack as supplied by the manufacturers. Due to this the portion supplied to the consumer may not have all the particulars especially brand name, expiry date and batch no. Hence it is suggested that in Rule 96 necessary amendments may be made so that atleast brand/generic name, batch No. and expiry date appears atleast in 3 or 4 places in a blister/strip packing.

RECOMMENDATIONS

DCC after deliberations opined that as large number of essential information is required to be provided on the strip of tablets and capsules, it may not be feasible to make it mandatory to give brand /generic name, batch number and expiry date at 3 or 4 places on the strip packs.

BIHAR

AGENDA NO. 20

Oxytocin inj. for vet. use:

To stop the misuse of oxytocin inj. for vet. use, it is imperative to put the drug under Schedule X under Section 26B of Drugs & Cosmetics Act, 1940, as the case of Tamiflu Tabs/Inj.

RECOMMENDATIONS

The DCC recommend that no useful purpose will be served by putting Oxytocin injection under Schedule X as this would make availability of the drug difficult to the legitimate users. The misuse of the drug by the dairy owners etc. is because of clandestine supply of the drug through illegal channels and its misuse can only be curbed through increased surveillance.

GOA

AGENDA NO. 21

Consideration of the question whether 108 Emergency Response Services is the State under any MOU with State Government on "no point no loss basis" requires to obtain a drug distribution or storage licence for distribution and storage of drugs through their 108 EMR service ambulances :

This State has entered into an MOU with 108 EMR Services, on no profit and no loss basis, wherein ambulance service equipped with all emergency equipment as well as emergency drugs are made available to the general public. Each such EMR 108 ambulance services are provided with some trained para medical staff to provide preliminary emergency medical assistance or treatment until the patient reaches to the nearest hospital. These 108 EMR ambulances are provided with certain basic emergency drugs and which drugs each 108 EMR supplied by their Central stores.

Several of the State Drugs Controllers have issued letters in favour of such agencies that they have no objection to the purchase of medicines from Wholesale licensed dealer without obtaining licence under Drugs and Cosmetics Rules 1945 (copy enclosed). Although this Directorate does not insist on any drugs storage licence on any of 108 EMR ambulance units, but clarification is sought whether the Central stores of these EMR Services, who are buying drugs from various Wholesalers or Manufacturers are required to possess any drug licence under Drugs and Cosmetics Rules 1945 for their Central stores, who in turn then supply emergency medicines to the para medical staff on each 108 EMR ambulances.

RECOMMENDATIONS

Drugs Controller, Goa desired to know whether the Central stores of EMR Services, who are buying drugs from various wholesalers or manufacturers are required to possess any drug licence under Drugs and Cosmetics Rules 1945 for their Central stores, who in turn then supply emergency medicines to the para medical staff on each 108 EMR ambulances.

The DCC after deliberations recommended that in such cases the Central stores should be licenced under the Drugs and Cosmetics Rules.

AGENDA NO. 22

Consideration of the question on storage conditions stipulated for the same APIs in two different monographs have different contradictory storage requirements:

The API of Pancreatin in the I.P. 2006 monographs prescribes storage condition as "Store away from moisture", whereas the B.P. monographs for the same API stipulates that the material is required to be stored at a temperature not exceeding 15^{o} C and the same B.P. monographs stipulates that the Finished Product of Pancreatin tablets is required to be stored at a temperature between $2^{0} - 8^{0}$ C. However the Finished Product is not official in I.P. Hence, clarification is sought on the storage condition to be printed on such drug formulation when the monograph in the I.P. and B.P. stipulate contradictory storage condition for the API.

RECOMMENDATIONS

The DCC recommended that in general, the requirements specified in IP should be followed by the manufactures. However in the specific case the matter may be decided in the light of the IP 2010 and in consultation with Indian Pharmacopeia Commission which prescribe standards for drugs.

AGENDA NO. 23

Consideration of question whether product permitted for export under Neutral Code can be permitted to be labeled only with the name and address of the importer :

Under the Rule 94 of Drugs and Cosmetics Rules 1945, the drug manufacturers manufacturing drug formulation are permitted to export their product under Neutral code and in such circumstances, the manufacturers do not indicate the name and address of the actual manufacturer on the label of the product. However it is seen that the manufacturers are adopting the practice of incorporating the name and address of the importer without the words "manufactured for" or "marketed by" and in the absence of these words, it convey a meaning from the label of such product that the said importer is

the actual manufacturer of the said product, which is a misleading and hence clarification is sought on whether product exported under Neutral code can be permitted to be labeled in the above manner, as per the current practice adopted by the manufacturers/Industry.

RECOMMENDATIONS

Drugs Controller, Goa stated that manufacturers are adopting the practice of incorporating the name and address of the importer without the words "manufactured for" or "marketed by", which is misleading.

The DCC agreed that as the Drugs and Cosmetics Rules, provide exemption for labels on packages or containers of drugs for exports to be adapted to meet the specific requirements of the law of the country to which the drug is to be exported and such labeling is not objected to by the importing country, no further action is required in the matter.

AGENDA NO. 24

Consideration of the question whether claims such as kills or removes bacteria and viruses on cosmetics products should be considered as a drug or cosmetics.

This Directorate has received an application for the manufacture of Grade-3 toilet Soap cosmetic product where the manufacturer has made the claims on the product as under:-

1) 100% better germ protection.
2) Help fight bacteria and virus that cause diseases.
3) World No.1 selling germ protection Soap.

The above claim, to the understanding of this Directorate are tall claims and exaggerating the use of this cosmetics and in the literal sense they are entering the domaine of a medical claims of such products and therefore consider in a such product as cosmetics would be improper.

In the light of the above claim, the Directorate seeks clarification on the matter that cosmetics with such tall claims should be allowed to be manufactured as cosmetics or the manufacturer should be directed to apply as a drug or in the alteration refrain from such claims.

RECOMMENDATIONS

Drugs Controller, Goa stated that certain manufacturers of toilet soaps make tall claims such as it kills or remove bacteria etc and DCC may advice as to whether these should be licenced as drugs.

The DCC recommended that if the claim made is indicative of therapeutic benefits from the cosmetic then it should be licenced as a drug. Further, rule 148 B provides that no cosmetic may purport or claim to purport or convey any idea which is false or misleading to the intending users, the State Licensing Authorities may therefore take appropriate action in respect of false and misleading claims made.

DELHI

AGENDA NO. 25

Under Section 31 of Drugs & Cosmetics Act 1940, presently there is no provision for the confiscation of the machinery / implements etc. which are used by any person for the manufacture, sale or distribution etc. of misbranded, adulterated and spurious cosmetics. This Department has strong feeling that the said provision be amended suitably so as to enable the court to pass suitable orders for confiscation of the machinery / implements etc. used by any person for the manufacture of misbranded , adulterated and spurious cosmetics.

Unless this is done, the accused can always get the benefit and may seek for the return / release of machinery / implements etc. from the court, if seized by the Drugs Inspectors in such cases, which the court may not be able to refuse. Moreover, the Accused may again start indulging in same/similar activity at some other place.

The existing provision is as under :

31. Confiscation.—5[*(1)*] Where any person has been convicted under this Chapter for contravening any such provision of this Chapter or any rule made thereunder as may be specified by rule made in this behalf, the stock of the drug 6[or cosmetic] in respect of which the contravention has been made shall be liable to confiscation 7[and if such contravention is in respect of—

8[(*i*) manufacture of any drug deemed to be misbranded under section 17, adulterated under section 17A or spurious under section 17B; or

(*ii*) 9[manufacture for sale, or for distribution, sale, or stocking or exhibiting or offering for sale,] or distribution of any drug without a valid licence as required under clause (*c*) of section 18;

any implements or machinery used in such manufacture, sale or distribution and any receptacles, packages or coverings in which such drug is contained and the animals, vehicles, vessels or other conveyances used in carrying such drug shall also be liable to confiscation.]

PROPOSED

31. Confiscation.—5[*(1)*] Where any person has been convicted under this Chapter for contravening any such provision of this Chapter or any rule made thereunder as may be specified by rule made in this behalf, the stock of the drug 6[or cosmetic] in respect of which the contravention has been made shall be liable to confiscation 7[and if such contravention is in respect of—

8[(*i*)***(a)*** manufacture of any drug deemed to be misbranded under section 17, adulterated under section 17A or spurious under section 17B; or

(b) manufacture of any cosmetic deemed to be misbranded under section 17 C, adulterated under section 17E or spurious under section 17D; or

(*ii*) 9[manufacture for sale, or for distribution, sale, or stocking or exhibiting or offering for sale,] or distribution of any drug ***[or cosmetic]*** without a valid licence as required under clause (*c*) of section 18;

any implements or machinery used in such manufacture, sale or distribution and any receptacles, packages or coverings in which such drug***[or cosmetic]*** is contained and the animals, vehicles, vessels or other conveyances used in carrying such drug shall also be liable to confiscation.]

RECOMMENDATIONS

Drugs Controller, Delhi stated that section 31 does not have a provision for confiscation of the machinery / implements etc. which are used by any person for the manufacture, sale or distribution etc. of misbranded, adulterated and spurious cosmetics. It was therefore been proposed to amend the said section to include confiscation in respect of adulterated and spurious cosmetics.

DCC agreed to the proposed amendment and recommended that the proposal may be forwarded to the Ministry of Health and Family Welfare for inclusion in the proposed amendment to the Act.

AGENDA NO. 26

Because of the stricter statutory pollution norms and increase in the awareness in the society regarding disposal of Medical Waste, It is suggested that under sub rule (17) of Rule 65 of the Drugs and Cosmetics Rules, 1945 the following lines may be inserted after the words ------*direction recorded on such container, label or wrapper:*

> ***"Drugs which have crossed the date of expiration of potency shall be treated as 'Bio-medical Waste' and shall be disposed of accordingly".***

The existing provision is as under :

> [1][*(17)* No drug shall be sold or stocked by the licensee after the date 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:

PROPOSED

[1][*(17)* No drug shall be sold or stocked by the licensee after the date 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: ***Drugs which have crossed the date of expiration of potency shall be treated as 'Bio-medical Waste' and shall be disposed of accordingly***

RECOMMENDATIONS

Drugs Controller, Delhi stated that date expired drugs should be treated as biomedical waste and disposed of accordingly.

The DCC did not agree to the proposed amendment as most of the drugs are chemicals and cannot be treated as biomedical waste.

AGENDA NO. 27

Under sub-rule 2 of Rule 64 of Drugs & Cosmetics Rules 1945, the conditions required to be satisfied before a licence in different statutory forms, including Form 20G ,is granted have been described . Perhaps the idea of the legislature was that these conditions are required to be satisfied in respect of all those premises where ever a wholesale licence is to be granted :

This Department feels that the said provision be amended suitably ***so as to treat the conditions required to be satisfied before a licence on Form 20G is granted to be at par with the conditions required to be satisfied before a licence on Form 20B and/or 21B or both are granted.*** \

However, ***the prescribed Form 20G*** *(which is a licence to sell, stock or exhibit or offer for sale or distribution by wholesale drugs specified in Schedule X on Form 20G)* ***does not have any column where the name of competent person can be recorded.***

In view of forgoing, it is proposed that

(A) Rule 64 of the Drugs & Cosmetics Rules 1945 be amended accordingly
(B) A new column should be included in Form 20G to record the name of the competent person / registered pharmacist in charge for the whole sale of drug specified in Schedule 'X'.

The existing provision is as under :

[2][Provided further that in respect of an application for the grant of a licence in Form 20-B or Form 21-B or both, the licensing authority shall satisfy himself that the premises in respect of which a wholesale licence is to be granted are:-

(i) of an area of not less than ten square meters; and]

[3][*(ii)* in the charge of a competent person, who—

(*a*) is a Registered Pharmacist, or

(*b*) ----------

(*c*) ----------

PROPOSED

[2][Provided further that in respect of an application for the grant of a licence in Form 20-B or Form 21-B or both, ***and/or Form 20G,*** the licensing authority shall satisfy himself that the premises in respect of which a wholesale licence is to be granted are:-

(i) of an area of not less than ten square meters; and]

[3][*(ii)* in the charge of a competent person, who—

(*a*) is a Registered Pharmacist, or

(*b*) ----------

(*c*) ----------

Formats of existing and the proposed Form 20G are also being Annexed herewith as Annexure 'A' & 'B' respectively.

RECOMMENDATIONS

Drugs Controller, Delhi stated that the Form 20 G does not have any column where the name of competent person can be recorded as is the case in Form 20 B and /or 21 B. It is therefore proposed to amend the Form 20 G accordingly.

The DCC agreed to the proposed amendment and recommended that Form 20 G may be amended accordingly. The Form 20 D which also require similar change should also be amended.

AGENDA NO. 28

Part XV (A) of the Drugs and Cosmetics Rules, 1945 prescribe the conditions for the approval of institutions for carrying out tests on drugs, cosmetics and raw materials used in their manufacture **on behalf of licensees for manufacture for sale of drugs / cosmetics.**

The said approved institution has to issue a report of test or analysis on Form 39 in accordance with Rule 150E (f). The said Form 39 is reproduced hereunder:-

FORM 39

[See rule150E(f)]

Report of test or analysis by approved institution

(1) Name of manufacturer from whom sample received together with his

manufacturing licence number under the Act and under the rules made thereunder.

(2) Reference number and date of the letter from the manufacturer under which the

sample was forwarded.

(3) Date of receipt of the sample.

(4) Name of drug / cosmetics / raw material purporting to be contained in the sample.

(5) Details of raw material/final product in bulk/final product (in finished pack) as*

obtained from the manufacturer:

(a) Original manufacturer's name in the case of raw materials and drugs

repacked.

(b) Batch number.

1[(c) Batch size as represented by sample.]

(d) Date of manufacture, if any.

(e) Date of expiry, if any.

(6) Results of test or analysis with protocols of test or analysis applied.

*In the opinion of the undersigned, the sample referred to above is *of standard*

quality/is not of standard quality as defined in the Act and the rules made thereunder for the reasons given below.

Date..... *Signature of Person-in-charge of testing*

Note:- Final product includes repacked material.

**Delete whichever is not applicable*

As per Para (1) of Form 39, the name of the manufacturer from whom the sample is received together with its manufacturing licence no. under the Act and Rules framed thereunder, is required to be mentioned alongwith other details viz. Batch size etc., which can only be provided by a manufacturer.

In actual practice, almost all the major procurement agencies viz. CGHS, ESI, DHS, MCD etc. as well as all major Govt. Hospitals get the supplies of drugs received by them, routinely tested from these approved testing institutions and the said institutions, in turn, invariably issue test report in Form 39, which is not the mandate of the Drugs and Cosmetics Rules, 1945 .

In view of the above referred divergent situation, it is proposed as under :-

“A new form may be included for the approved testing institutions to report for the samples of drugs / cosmetics to any person [or any recognised consumer association, whether such person is a member of that association or not,] who has forwarded the said sample”.

The proposed form can be included as Form 39A having the following format:-

FORM 39A

[See rule150E(f)]

Report of test or analysis by approved institution

(1) Name and address of person from whom sample received:

(2) Reference number and date of the letter of person under which the

sample was forwarded:

(3) Date of receipt of the sample:

(4) Name of drug / cosmetics / raw material purporting to be contained in the sample

(5) Details of the manufacturer:

(a) Batch number:

(b) Quantity of sample:

(c) Date of manufacture, if any:

(d) Date of expiry, if any:

(6) Results of test or analysis with protocols of test or analysis applied:

In the opinion of the undersigned, the sample referred to above is of standard quality/is not of standard quality as defined in the Act and the rules made thereunder for the reasons given below.

Date..... *Signature of Person-in-charge of testing*

To give effect to the said amendment, there will be a need to amend the existing Rule 150E (f) as under:-

The following words shall be inserted to Rule 150E (f) after the words Form 39 ***"or Form 39A, as the case may be".***

The existing provision is as under :

150E. Conditions of approval –An approval in Form 37 shall be subject to the following general conditions: —

(a)

(b)
(c)
(d)
(e)
(f) The approved institution shall furnish reports of the results of test or analysis in Form 39.

PROPOSED

150E. Conditions of approval –An approval in Form 37 shall be subject to the following general conditions: —

(a)
(b)
(c)
(d)
(e)
(f) The approved institution shall furnish reports of the results of test or analysis in Form 39 ***or Form 39A, as the case may be***.

RECOMMENDATIONS

Drugs Controller, Delhi stated that the institutions approved for carrying out test on Drugs and Cosmetics under rule 150-C also test drugs on behalf of procurement agencies like CGHS, ESI, DHS, MCD etc. and the test reports are issued in Form 39. It was therefore proposed to insert Form 39 A for the issuing report of test and analysis to the said institutions.

The DCC did not agree to the proposed amendment as the institutions, under the rules, are approved for carrying out test on behalf of licensees for manufacture for Drugs and Cosmetics and not on behalf of procurement agencies.

MADHYA PRADESH

AGENDA NO. 29

Amendment of condition No. 3 and condition No. 2 respectively mentioned in drug licence in form No. 20, 21, 20F – under the Drugs and Cosmetics Rules, 1945

Drugs and Cosmetics Rules, 1945 prescribes licence in form 20, 21 and 20F for retail sale of drugs. As per the condition stipulated in above licences, "licensee shall report to the licensing authority any change in the qualified staff within one month of such change.

Since it is only a matter of reporting the change in the qualified staff, the time limit of 30 days provides for such report is considered to be a big period. In the opinion of this Administration it should be reduced to 7 days so that the authority will be able to know such change and will be able to effectively monitor the licensee to ensure that sale is not carried out in the absence of qualified staff.

RECOMMENDATIONS

Drugs Controller, Madhya Pradesh stated that the proposal relates to the limiting of the time period from 30 days to 7 days for the licensees in Form 20, 21 and 20F for retail sale of drugs under the conditions of the licence to ensure that sale is not carried out in the absence of qualified staff.

The DCC agreed to the proposal and recommended that the Forms may be suitably amended for the purpose.

UTTAR PRADESH

AGENDA NO. 30

Amendment of Rule 96 of the Drugs and Cosmetics Rules, to insert a clause that nothing in addition to what is prescribed in clauses 1 to 4 of rule 96 and clauses 1 to 5 of rule 97 shall be printed on the label except whatever is prescribed to be printed on the label under any other provisions of the Drugs and Cosmetics Rules

In the case of a Writ Petition ' Anil Kumar Bajpai Versus of Union of India and others', it has been alleged that brand owners of certain drugs are the Marketing Companies who get their drug products manufactured from licensed drug manufacturers but on the labels of such products the names of such marketing companies are got printed such as to pose themselves as actual manufacturers of products i.e. the prominence is given to the name of the marketing company over the name of actual manufacturer by printing the name of marketing company in bigger and bold fonts than the name of actual manufacturer. Such marketing Companies do not hold any manufacturing licence(s). The above practise is bye passing the legally recognised loan licensing system provided under the Drugs and Cosmetics Rules, 1945 simply to escape mandatory compliance to be made as prescribed under Rules 69A/71B, 75A/76A. In the said Writ Petition it has been alleged that such drugs being manufactured without having loan licence violate the provisions of Rule 96 and are also misbranded under Section 17(b) and spurious under Section 17-B(e) of the Drugs and Cosmetics Act. Furthermore, mentioning the name of marketing company is not prescribed under Rule-96.

Moreover, the said practice is also causing loss of revenue to the government which otherwise could be earned by the State Government through grant of loan licences. For example if a marketing company gets its 2 products manufactured from a licensed manufacturer, then under the present law the concerned manufacturer shall have to deposit a total fees of Rupees six hundred only as prescribed under Rule 69(5) to get the additional items endorsed on the existing licence but if the same marketing company seeks a loan licence on the same manufacturer it will have to deposit a total of

Rupees seven thousand and five hundred (Rupees six thousand plus Rupees one thousand and five hundred as inspection fees).

In the said matter it is proposed that the following clause should be inserted in the Rule-96 of the Drugs and Cosmetics Rules, 1945:-

Nothing in addition to what is prescribed in clauses-1 to 4 of Rule-96 and clauses 1 to 5 of Rule-97 shall be printed on the label except whatever is prescribed to be printed on the label under any other provisions of the Drugs and Cosmetics Rules.

By such amendment in Rules no persons/ firms (marketing companies) shall be able to mention their names on the label to mislead the public as if the products have been manufactured by them.

RECOMMENDATIONS

Drugs Controller, Uttar Pradesh stated that it was proposed to amend rule 96 of the Drugs and Cosmetics Rules so that the label of the drug should not contain anything else except what is prescribed to be printed on the label under the Drugs and Cosmetics Rules.

The DCC after deliberations did not agree to the proposed amendment as any additional information on the label cannot be considered as contravention of the rules. Moreover, the manufacturers may have to include certain other information which are mandatory under other laws like Essential Commodities Act, 1955 etc.

ANNEXURE I

List of the participants of 43rd Drugs Consultative Committee meeting held on 14.11.2011 under the Chairmanship of Dr. V.G. Somani, Drugs Controller General (India)

A. List Of Participants from State Drugs Control Organizations

S. No.	NAME AND ADDRESS OF THE PARTICIPANTS
1	Shri M. Kodanda Ram , Director, D.C.A., Andhra Pradesh, Drugs Control Bhawan, Vengalrao Nagar, Hyderabad – 500 038
2	Shri G. Tayeng, Assistant Drugs Controller, Arunachal Pradesh Directorate of Health Service, Naharlagun, AP-791 111
3	Shri M.C. Deka, Dy. Drugs Controller, Assam, Hengrabari, Guwahati – 781036
4	Shri Sanjay kumar, Joint Secretary, Govt. of Bihar Vikas Bhawan, Department of Health, Patna
5	Shri D. N. Sahu, State Drugs Controller,Department of Health, Vikas Bhawan, Patna, Bihar
6	Shri K. Subramanian, 322, DKS Bhavan Mantralaya, Raipur, 492001
7	Mrs. Madhu Krishna Garg, Drugs Controller, Delhi F-17, Karkardooma, Delhi 110 032.
8	Shri P.K. Jaggi, Drugs Control Department, Delhi F-17, Karkardooma, Delhi 110 032
9	Shri A.K. Nasa, Drugs Control Department, Delhi F-17, Karkardooma, Delhi 110 032
10	Shri Salim A. Veljee, Director, Food and Drug Administration, Goa, Old IPHB Complex, Altinho, Panaji, Goa – 403 001
11	Dr. H. G. Koshia, Commissioner FDCA, Gujarat, Block No. 8, Dr. J. M./ Bhavan, Gandhi Nagar, Gujarat – 382010
12	Shri R.M. Sharma, Drugs Controller, Govt. of Haryana, Govt. Dispensary, Sector – 20, Panchkula, Haryana – 139 109
13	Shri Navneet Marwaha, Drugs Controller, Himachal Pradesh Sai Road Baddi, Disstt. Solan-173205
14	Shri Nazir Ahmed Wani, Dy. Controller, Drug and Food Organisation, J&K Bemina, Srinagar – 190 018
15	Shri S. K. Mukhopadhyay, Director of Drugs Control, Jharkhand RCH Campus, Namkum, Ranchi, Jharkhand
16	Dr. B. R. Jagashetty, Drugs Controller, Karnataka, Palae Road, Bangalore – 560 001, Karnataka
17	Shri R. Bhandary, Additional Drug Controller, Karnataka, Palae Road, Bangalore – 560 001, Karnataka
18	Shri S.B. Jairam, Dy. Drug Controller, Karnataka, Palae Road, Bangalore – 560 001, Karnataka

19	Shri C.S Satheesh Kumar, Drug Controller, Kerla, Red Cross Road, Thiruvananthapuram- 695 035
20	Shri Ashwini Kumar Rai, IAS, Govt. of Madhya Pradesh Idgah Hills, Bhopal (M.P.)- 462 001
21	Shri D.M. Chincholkar, State Licensing Authority, Madhya Pradesh Idgah Hills, Bhopal (M.P.)- 462 001
22	Shri Mahesh zagade, I.A.S. Commissioner, FDA, Maharashtra Bandra Kurla Complex, Bandra (E), Mumbai – 400 051
23	Shri P.R. Uttarwar, Joint Commissioner, FDA, Maharashtra, Opposite RBI, Bandra Kurla Complex, Bandra East, Mumbai –400 051
24	Shri Singhajeet Akoijam, Senior Drug Inspector, Manipur, Directorate of Health Services, Imphal –West.
25	Shri Lal Sawma, Dy. Drugs controller, Dte. Of Health Services, Dinthar Veng, Aizwol, Mizoram – 796 001
26	Shri R. F. Lotha, Addl. Drugs Controller, Nagaland Directorate of Health & Family Welfare, Kohima- 797001.
27	Shri Annada Sankar Das, Drugs Controller, Odisha Dte of Drugs Control,Nandankanan Road, Bhuvneswara – 751 017
28	Shri Ajay Singla, Drug Controller, Punjab, Directorate of Health & Family Welfare, Pariwar Kalyan Bhawan, Sector – 34A, Chandigarh – 22
29	Shri D.K. Shringi, Drug Controller, Rajasthan Swasthaya Bhawan, Tilak Marg, Jaipur – 302 015
30	Dr. I. L. Sharma, Additional Director, Drugs and Cosmetics Cell, Sikkim Department of HC, H.S,& F.W., Convey Ground, Tadong, Gangtok, East, Sikkim - 737 102
31	Shri C.N. Sharma, Chief Drug Inspector, Sikkim Convey Ground, Tadong, Gangtok, East, Sikkim -737 102
32	Shri G. Selvaraj, Director Drugs Control, Tamil Nadu, DMS Campus, Anna Salai, Chennai – 600 006
33	Shri M. Dhup Kumar, Senior Drug Inspector, Tamil Nadu DMS Campus, Anna Salai, Chennai – 600 006
34	Shri O.P. Verma, Additional Food Safety and Drug Admn. Commissioner, Uttar Pradesh 9, Jagat, Narayan Road, Lucknow
35	Shri A. K. Jain, Drug Licensing and Controlling Authority, Uttar Pradesh 9, Jagat, Narayan Road, Lucknow
36	Dr. S.K. Pant, Senior Drug Inspector, Uttar Pradesh 9, Jagat, Narayan Road, Lucknow
37	Dr. S. C. Sharma, Drugs Controller, Uttrakhand, Dte. of Medical Health, Sahashtra Dhara Road, Dehradun
38	Dr. C. M. Ghosh, Director Drugs Control, West Bengal, P-16, KIT Building, India Exchange Place Extension, Kolkatta – 700 073
39	Shri Sunil Chaudhary, Drug Control Officer, Chandigarh GMSH, Sector -16, Chandigarh

B. Invitees

40	Dr. D. R. Ray, Indian Medical Association, IMA House, New Delhi
41	Dr. Anil Bansal, Indian Medical Association, IMA House, New Delhi
42	Dr. V.N. Sharma, Indian Medical Association, IMA House, New Delhi
43	Dr. Sandhya Kabra, ADG, (BS), NACO 9th Floor, 36 Janpath, New Delhi

C. Drug Testing Laboratories

44	Dr. G. N. Singh, Secretary-cum-Scientific Director, Indian Pharmacopeia Commission, Raj Nagar, Sector -23, Ghaziabad 201 002, UP
45	Shri P.K. Guha, Director, Central Drugs Laboratory, 3, Kyd Street, Kolkata
46	Dr. A.R. Singh, Director, Regional Drug Testing Laboratory, Sector 39C, Chandigarh
47	Dr. N. Murugesan, Director, Central Drug Testing Laboratory, 37, Naval Hospital Road, Periamet, Campus G.M.S.D., Chennai – 600 003.

D. Zonal Offices of CDSCO

48	Shri P. B. N. Prasad, DDC(I), CDSCO, South Zone, Chennai
49	Shri A.C.S. Rao, DDC(I), CDSCO, Hyderabad
50	Shri B. Kumar, ADC(I), CDSCO, Sub Zone, Chandigarh
51	Shri D. K. Chauhan, ADC(I), CDSCO, Mumbai
52	Dr. A. Ramkishan, ADC(I), Ahmedabad, CDSCO, Air Cargo Complex, Airport, Ahmedabad-380 003

E. CDSCO Hqrs

53	Dr. K. Bangarurajan, DDC(I), CDSCO, FDA Bhawan, New Delhi
54	Shri A. K. Pradhan, DDC(I), CDSCO, FDA Bhawan, New Delhi
55	Shri Satyapal Shani, DDC(I), CDSCO, FDA Bhawan, New Delhi
56	Shri S. Manivannan, DDC(I), CDSCO, FDA Bhawan, New Delhi
57	Mrs. Shanthy Gunasekaran, DDC(I), CDSCO, FDA Bhawan, New Delhi
58	Shri Lalit Kishore, Consultant, CDSCO, FDA Bhawan, New Delhi

59	Mrs. Swati Srivastava, ADC(I), CDSCO, FDA Bhawan, New Delhi
60	Dr. S. Eswara Reddy, ADC(I), CDSCO, FDA Bhawan, New Delhi
61	Shri Sanjeev Kumar, ADC(I), CDSCO, FDA Bhawan, New Delhi
62	Shri Arvind Kukretty, ADC(I), CDSCO, FDA Bhawan, New Delhi
63	Shri A. Senkthir , ADC(I), CDSCO, FDA Bhawan, New Delhi
64	Shri Dhananjay Sable, Drug Inspector, CDSCO, FDA Bhawan, New Delhi
65	Shri Sidharth Malhotra, Drugs Inspector, CDSCO, FDA Bhawan, New Delhi
66	Shri Gouri Shawkar, Drug Inspector, CDSCO, FDA Bhawan, New Delhi
67	Shri Naresh Sharma, Drugs Inspector, CDSCO, FDA Bhawan, New Delhi
68	Shri Shushant, Drugs Inspector, CDSCO, FDA Bhawan, New Delhi
69	Dr. R.K. Sharma, Technical Officer, CDSCO, FDA Bhawan, New Delhi
70	Shri Aseem Sahu, Technical Officer, CDSCO, FDA Bhawan, New Delhi
71	Shri Sunil Kumar, Technical Officer, CDSCO, FDA Bhawan, New Delhi
72	Shri S. Basu, Technical Officer, CDSCO, FDA Bhawan, New Delhi
73	Shri Gaurav Kumar, Technical Officer, CDSCO, FDA Bhawan, New Delhi
74	Shri Kshitij Saini , TDA, CDSCO, FDA Bhawan, New Delhi
75	Shri Kartik Sahni, TDA, CDSCO, FDA Bhawan, New Delhi
76	Mrs. Prabjyot Kaur, TDA, CDSCO, FDA Bhawan, New Delhi
77	Shri Fayazul Islam, TDA, CDSCO, FDA Bhawan, New Delhi
78	Shri Atul Kumar Thakran, TDA, CDSCO, FDA Bhawan, New Delhi
79	Mrs. Pragya, TDA, CDSCO, FDA Bhawan, New Delhi

Central Drugs Standard Control Organization

DR. V. G. SOMANI
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FDA Bhawan, Kotla Road, New Delhi –110002.

F.No. X-19013/2/2011-D

Dated: 26th December, 2011

To,

All State Drugs Controllers

Sub: Report of the 43rd Meeting of the Drugs Consultative Committee held on 14th November, 2011, at FDA Bhawan, Kotla Road, New Delhi-110002 - reg.

Sir,

43rd meeting of the Drugs Consultative Committee was held on 14th November, 2011, at FDA Bhawan, Kotla Road, New Delhi – 110002.

The Report of the 43rd meeting of the Drugs Consultative Committee held on 14th November, 2011, 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.

Yours faithfully,

Encl. Copy of the minutes

(Dr. V. G. Somani)
Drugs Controller General (India)

Copy forwarded for information and necessary action to
Zonal offices/Sub-zonal offices.