F. No. X-19013/1/2018-DC

Dated 20 APR 2018

To

All State/UT Drug Controllers

Sub: Report of the 53rd Meeting of the Drugs Consultative Committee held on 9th April, 2018 at New Delhi -110002- reg.

Sir,

53rd meeting of the Drugs Consultative Committee was held on 9th April, 2018 at New Delhi – 110002.

The Report of the 53rd meeting of the Drugs Consultative Committee held on 9th April, 2018 is annexed herewith for your information and taking further necessary action, wherever required as per recommendations decided therein.

Yours faithfully,

(Dr. S. Eswara Reddy)
Drugs Controller General (India)

Encl. Copy of the minutes

Copy forwarded for information to:-

1. Zonal / Sub-zonal/Port Offices of CDSCO
2. Directors of CDL/CDTL/RDTL of CDSCO
3. PPS to Secretary (Health)
4. PPS to DGHS
5. PPS to JS(R)
6. Director, Narcotics Control Bureau, New Delhi
Inaugural Deliberations

Dr. S. Eswara Reddy, Drugs Controller General (India), Chairman, Drugs Consultative Committee, welcomed the participants and thanked them for sparing time for deliberations on the matters placed before the committee. The members congratulated Dr. S. Eswara Reddy for occupying the august chair.

DCG (I) in his address stated that the DCC being a statutory body, consisting of all the Drug Regulatory Authorities of the country, is required to be more proactive in discussing the agenda of national importance relating to drug regulatory matters. States should actively send their agenda well in advance for consideration in the meeting for having fruitful discussions. Both Centre and State regulatory systems should work closely for effective and uniform implementation of the provisions of the Act and Rules.

DCG (I) mentioned that to have fruitful deliberation and decision on various drug regulatory matters, it is important for all State Drugs Controllers to be present in all DCC meetings. In case of their preoccupation, they may intimate well in advance about their inability to attend the meeting so that same can be recorded in the minutes.

DCG (I) stated that as drug regulators, quality of our works only reflects the image thereby the Regulatory Authorities will be respected, recognized and it will also help in building trust in the public. DCG (I) also mentioned that some State Licencing Authorities are issuing drug licences for New Drugs, which are not permitted by DCG (I). Some companies are also manufacturing the New Drugs without having any licence. In this regard, all State Licencing Authorities are requested to have surprise joint inspections so that unlicensed activities can be stopped. The Central Govt. under Capacity Building Program is allocating funds to the States/UTs for upgradation of the drug regulatory system in the country. The States should provide the details of the usage of grants allocated to the states for capacity building for further assessment of requirements.

He further mentioned that the DCC is constituting sub-committees for issues which require in-depth deliberations. These committees should submit
their reports within 3 to 6 months or as stipulated in the order, so that the issues are deliberated by the committee in the next meeting.

He also desired that India should become member of the PIC/S which is a non-binding, informal co-operative arrangement between Regulatory Authorities in the field of Good Manufacturing Practice (GMP) of medicinal products for human or veterinary use for having global footprints.

He stated that it may be desirable if the retest date in place of expiry date for bulk drugs is mentioned on the label of the API produced by the manufacturer for his own captive consumption provided manufacturer proves scientifically the same.

Ms. Preeti Sudan, Secretary, Ministry of Health and Family Welfare spared time from her busy schedule to address the meeting. In her address, she highlighted the importance and responsibilities of regulators to ensure quality of drugs manufactured/ marketed in the country. She stated that the Centre and State regulators should work closely and efficiently to ensure that drugs are manufactured / marketed in the country in strict compliance with the regulatory provisions including Good Manufacturing Practices.

She also mentioned that Central Government has taken various measures for strengthening the drug regulatory system both at the central and state levels. Certain provisions have been amended in the Rules with overall objective of ensuring quality of the drugs. Effective implementation of the regulatory provisions will ensure the quality of the drugs. To redefine our dedication to the objective of providing quality drugs to the patients, there should be regular interaction of DCG (I) with the State Drugs Controllers. The power should be used in discerning manner, so as to earn respect in the society. She mentioned that regulators should build their image by translating the regulatory provisions/ policy into practice.

She drew the attention of the committee to the recent notification by the MoHFW dated 16th March, 2018 specifying various measures to ensure proper TB diagnosis and its management in patients to reduce TB transmission and further to address the problem of emergence and spread of Drug Resistant TB cases. In the efforts to eradicate TB in the country it is very important that these measures are implemented and the sale of anti-TB drugs is monitored properly by the State Licensing Authorities to avoid their improper use.
She also desired that the committee may consider the ways and means for promotion of quality generic medicines in the country. If required, consideration may be given for incorporating necessary provisions under the Drugs & Cosmetics Rules. She mentioned that as part of strengthening of regulatory system, central government has already disbursed Rs 80 crores to various States. Further, for the year 2018-19 Rs. 206 crores has been sanctioned by the government.

She also highlighted the importance of having online processing of applications and comprehensive database of the manufacturing sites, licensed products along with their details of dosage strength etc. for effective regulation as well as implementation of various health schemes. After taking stock of situation from the members she stated that the Central Govt. has created modules under “SUGAM” portal for having data of manufacturing sites and products. Some states expressed their difficulties in integrating the states software with central “SUGAM” portal.

She mentioned that those states who are yet to establish the online processing and database should use the software platform used by State of Gujarat which has been prepared by NIC. She mentioned that NIC shall examine the Gujarat software, which may be modified, if required for online submission and review of applications for grant of sale and manufacturing licences and comprehensive database. This software may be used PAN India, for uniform implementation.

DCG (I) then briefed the Secretary that the Indian Drugs/ Pharmaceuticals Association Forum consisting of various drug industry associations has been constituted for regular interaction with various Drug Associations.

Mr. Praveen Deshpande, Deputy Director (OPS) of Narcotic Control Bureau, also addressed the meeting and elaborated the NCB views over abuse of pharmaceutical preparations in the country. He also opined that the control on illegal trafficking can be achieved by stringent vigilance at wholesale level through intelligence cells created in the States rather than at API level.
1. AGENDA

CONSIDERATION FOR APPROVAL OF REPORT OF 52ND DCC MEETING HELD ON 17.09.2017 AND ACTION TAKEN IN THE MATTERS ARISING OUT OF THE MEETING

The Action Taken Report of the 52nd meeting of the DCC was considered and accepted with certain suggestions in the agendas specified below:

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<th>Sr. No.</th>
<th>Ag. No.</th>
<th>SUBJECT</th>
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<tr>
<td>1.</td>
<td>5</td>
<td>Review of prophylactic doses mentioned under Schedule ‘V’ of Drugs And Cosmetics Rules vis-à-vis the doses prescribed under FSS Act</td>
<td>Matter was referred by DTAB to Indian Council of Medical Research (ICMR) for their comments for amendment of Schedule V and Schedule K. DCC recommended that Shri. Aseem Sahu DDC(I), CDSCO, North-zone (Ghaziabad), for follow up in the matter with the Director General, Indian Council of Medical Research (ICMR).</td>
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<td>2.</td>
<td>6</td>
<td>Consideration of suggestions of industry association in various issues</td>
<td>e) DCC recommended that as per conditions of the licence, the facility can be used only for the manufacture of drugs and not for different types. The conditions of licence that non-drugs should not be manufactured in the licenced premises shall be strictly implemented. f) DCG (I) informed that Shri. A.K. Pradhan, DDC(I), CDSCO (HQ) and Shri. R. Chandrashekhar, DDC (I), CDSCO, Goa are assigned for making the common format. The DCC further suggested having common format in dual language including English as one of the language.</td>
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<td>3.</td>
<td>13</td>
<td>Consideration of the proposal regarding the format for approval of</td>
<td>Shri. Arvind Kukrety, DDC (I), CDSCO, Ahmedabad zone was assigned to look after the common format for approval of drugs to be annexed with various manufacturing</td>
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<td>Sr. No.</td>
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<td>drugs to be annexed with various drugs manufacturing licenses &amp; standardization of WHO-GMP, COPP formats</td>
<td>licences, WHO-GMP certificates, COPP Format etc.</td>
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**AGENDA NO. 2**

**UPDATION OF INFORMATION ABOUT LICENSED MANUFACTURING UNITS AND MEDICAL PRODUCTS BY SELF DECLARATION ON WEBSITE THROUGH SOFTWARE FOR DATA MANAGEMENT**

Members desired that standard common software should be developed for both State and Central regulatory systems to integrate the data available with the States on various software platforms with the NIC software to avoid the unnecessary duplication.

DCC deliberated the matter and agreed in principle to the proposal to upload information about licensed manufacturing units and product details with self declaration on the online portal “SUGAM” (www.cdscoonline.gov.in) by the manufacturers. This information would be required to be verified by the State Licensing Authorities.

It was further recommended that the Drugs and Cosmetics Rules, 1945 may be suitably amended to make mandatory submission of data with respect to licensed manufacturing units and medical products by self declaration by the manufacturers.
AGENDA NO. 3

CONSIDERATION OF THE PROPOSAL FOR IMPLEMENTATION OF THE PROVISIONS INTRODUCED UNDER THE RULES VIDE G.S.R 1337(E) DATED 27.10.2017 REGARDING PERPETUITY OF LICENCE AND INSPECTIONS TO ENSURE COMPLIANCE
(AGENDA FROM THE STATES OF ODISHA AND GOA ALSO)

For mandatory joint inspection of manufacturing units, a base document with guidelines elaborating scope, objective, procedure etc. were forwarded to the members. The DCC deliberated the matter and requested that members should give their comments/ suggestions on the base document within 10 days for consideration.

The members were also informed that certain consequential amendments in the rules in respect of duration of licence and loan licence in Forms 28, 28B & 28D and Forms 28A & 28DA respectively are being considered. The proposal for the same has already been forwarded to the Ministry of Health and Family Welfare.

In respect of the issue raised about the inspection fees, it was clarified that under the amended rules, the inspection fees is required to be charged for every inspection.

In regard to the applications for drug licence submitted before the date of Gazette Notification i.e. 27.10.2017, the committee recommended that such applications should be processed as per the pre-amended rules.

AGENDA NO. 4

CONSIDERATION OF THE PROPOSAL FOR GRANT OF PERMISSION FOR MANUFACTURE OF UNAPPROVED OR APPROVED NEW DRUGS OR BANNED DRUGS FOR EXPORT PURPOSE BY THE STATE LICENSING AUTHORITIES
(AGENDA FROM THE STATE OF PUNJAB ALSO)

DCC deliberated the matter and recommended that for manufacture of unapproved and approved new drugs and banned drugs for export, the
permission may be granted by the State Licensing Authorities based on the export order, facility licence etc. NOC from CDSCO should not be required.

The committee was informed that the proposal and detailed scheme for grant of such permissions ensuring that the drugs so manufactured are not diverted for sale in the Indian market is already under consideration of the Ministry of Health and Family Welfare. The scheme will be forwarded to the State Drugs Control Authorities after due approval.

AGENDA NO. 5

IMPLEMENTATION OF MEDICAL DEVICES RULES, 2017 PUBLISHED VIDE G.S.R. 78(E) DATED 31.01.2017 AND EFFECTIVE FROM 01.01.2018
(AGENDA FROM THE STATE OF ODISHA ALSO)

- Deliberation on usage of CDSCO online software developed by CDAC:

Centre for Development of Advanced Computing (CDAC) made a detailed presentation & live demonstration on usage of CDSCO online software for application for licences through online portal (cdscomdonline.gov.in). CDSCO has already organized training for the effective implementation of the said rules. More numbers of trainings are scheduled to be held in near future.

The State Licensing Authorities were informed to use the login ID and password for designated Nodal Officer (NO), designated Reviewing Officer (RO) and Licensing Authority (LA) already shared with them to process the applications pertaining to manufacturing of Class A and Class B Medical Devices.

As on date two Notified Bodies have been registered with CDSCO (Intertek and TUV) which are available on CDSCO website. The manufacturers applications received shall be forwarded to the Notified Body by mail with a copy to applicant by the State Drugs Controller / Licensing Authority for audit. The audit report may be sent by the Notified Body to the State Licensing Authority by e-mail. After receipt of report and scrutiny of the application the Licensing Authority shall grant the License.
All process flows were demonstrated to most of the State Licensing Authorities and they are familiar with such online system. The State Licensing Authorities were informed that they are given Log-in IDs for three levels, one is Receipt level (called Nodal Officer), other is Reviewing level (called Reviewing Officer) and third one is Licensing Authority level (called LA). State Licensing Authority can assign these Nodal Officer (NO), Reviewing Officer (RO) functions to anybody in their organization. However, it was suggested that RO functions may be assigned to Inspectors and Nodal Officers (NO) can be assigned to Assistant Drug Controller Level / or similar level officers as per availability of post in particular State Licencing Authority structure. It is also possible to assign RO and NO level by same person (if so required). After logging in each officer with his / her respective Log-in IDs, the application can be opened by clicking against the each point of checklist / item provided on screen. Then it need to be read, reviewed and comments on it need to typed in box provided for comments.

1. File will be first received in inbox (dashboard) by Nodal Officers. On receipt of file, it needs to be moved / processed by Nodal Officer to Reviewing Officer for review and Reviewing Officer shall review it and give it to Nodal Officer or Licensing Authority as per procedure of State Licencing Authority.

2. Finally the file shall be forwarded to Licencing Authority by Nodal Officer or Reviewing Officer.

3. The Licensing Authority shall raise query, (if file is deficient) or grant the license online. Both the options (query / grant of licence) are provided in the online system.

4. Once the query is raised by Licensing Authority, it will automatically go to applicant’s inbox after clicking on “raise query”. If licensing authority approves licenses for grant, a license copy will be automatically generated online, which shall be verified and signed digitally by Licencing Authority and uploaded on the system.
5. As mentioned earlier, licencing Authority shall ensure that the application is sent to notified bodies for audit by mail and get the report of inspection.

6. The schematic flowchart of procedure for disposal of medical device applications/ queries is placed below:

SCHEMATIC FLOWCHART OF PROCEDURE FOR DISPOSAL OF MEDICAL DEVICE APPLICATIONS/ QUERIES

- Deliberation on implementation of Medical Devices Rules, 2017:

  DCC deliberated the implementation of Medical Devices Rules (MDR), 2017 and agreed that no audit of manufacturing site shall be
necessary prior to grant of license to manufacture Class A medical devices. Required audit of manufacturing site will be carried out by notified body within 120 days. For Class B medical devices, audit of manufacturing site will be carried out by notified body within 90 days and submit their report to State Licensing Authorities within 30 days of the completion of audit of manufacturing site of Class B. For this purpose, two notified bodies have been registered with CDSCO named as TUV Rhineland Pvt. Ltd. and Intertek Pvt Ltd. List of the same is available at CDSCO website.

It was also agreed to the proposal to designate Medical Device Officer (MDO), Medical Device Testing Officers (MDTO) & Medical Devices Testing Laboratories (MDTL) by Central Government. Similarly, the State Licensing Authorities were requested to designate MDOs, MDTOs & MDTLs in their respective States. Further, CDSCO has already requested State Licensing Authorities to get their laboratories notified as MDTL if they have NABL accreditation.

Further, it was also informed that the provisions for MDTLs are being incorporated in the SUGAM Portal with respect to testing of medical devices. It was insisted to have standard specifications for medical devices to be tested in Central and Private MDTLs.
AGENDA NO. 6

UPGRADATION OF SCHEDULE M AND STABILITY STUDIES TO CONTEMPORARY STANDARDS UNDER THE DRUGS & COSMETICS RULES, 1945

Schedule M

The members were informed that Schedule M relating to Good Manufacturing Practices is being upgraded to make it at par with the standards specified under WHO-GMP Guidelines. The Chairman sensitized the members to appraise the drug manufactures under their jurisdiction regarding the upgradation of Sch. M, for which draft rules is going to be published shortly by Central Govt. for comments from the public.

Stability Studies

DCC deliberated the matter and agreed that the manufacturers are required to ensure stability of all drugs manufactured by them throughout their shelf life so that patients get quality, effective and safe medicines.

It was also decided that for the conduct of stability studies in the case of grant of licence for additional product, a checklist/ Guidance documents/FAQs shall be prepared by Smt. Rubina Bose, Deputy Drugs Controller (India). This Guidance document will then be forwarded to the States for their consideration for the purpose of conduct of stability studies for additional product licence to be issued by the State Licensing Authority.

Final rules under G.S.R 360(E) has since been published on 10.04.2018 replacing the words ‘patent or proprietary medicines’ with the word ‘drugs’ making it mandatory that for all drugs, the applicant shall have to submit stability data etc. as per the provision before grant of product licence by the respective State Licensing Authority.
AGENDA NO. 7

CONSIDERATION OF THE COMPLIANCE TO THE BIOAVAILABILITY AND BIO-EQUIVALENCE STUDIES FOR BCS CLASS II & IV ORAL DOSAGE FORMS AS PER NOTIFICATION G.S.R. 327 (E) DATED 03.04.2017

(AGENDA FROM THE STATE OF GOA ALSO)

DCC deliberated the requirement of bioavailability and bio-equivalence studies of Oral Dosage Forms for BCS Class II & IV drugs. It was also informed that the proposal for amendment replacing ‘Oral Dosage Forms’ by ‘Oral Solid Dosage Forms’ has already been forwarded to the Ministry for consideration.

The members agreed to the guidelines and clarifications issued by CDSCO vide letter dated 13.10.2017 on the subject. A list of products which have been permitted by DCG(I) and considered as reference product for BA/BE studies, will be prepared in a months’ time and then shared with the State Drugs Controllers for their guidance.

Shri. Arup Chatterjee, Assistant Drugs Controller (India) was requested to prepare a Checklist/ Guidance documents/ FAQs in respect of BA/BE studies in coordination with Dr. Bikash Medhi, Professor, Department of Pharmacology, PGIMER, Chandigarh.

It was further suggested that a meeting with all State Drugs Controllers may be convened separately on implementation of bioavailability and bio-equivalence studies of oral dosage forms for BCS Class II & Class IV drugs.
AGENDA NO. 8

CONSIDERATION OF STRENGTHENING OF INTELLIGENCE ACTIVITIES AND SETTING UP OF CENTRAL DRUGS INTELLIGENCE CELL

The committee was informed that CDSCO recently has set up an intelligence cell under the supervision of JDC(I) with following modalities and functions.

1. For planning and executing the intelligence activities independently and / or in coordination with states and other regulatory bodies like police, customs, DRI, NCB etc.
2. To coordinate with State Licensing Authorities and also to support Zonal / Sub-Zonal / Port offices while carrying out raids relating to offences under the Act.
3. Collecting, collating the information on the suspected intelligence activities carried out in contravention to the provision of Drugs and Cosmetics Act and Rules.
4. Collecting, collating information on drugs/cosmetics imported or exported in contravention of the Act.
5. Investigation of the quality complaints received from oversees regulatory agency.
6. To make such enquiries and inspection necessary to carry out the functions assigned to the intelligence cell.

The intelligence cell recently has conducted raids at Uttarakhand and Daman & Diu and number of FDCs which were not approved by DCG(I) were found to be manufactured under the licence granted by the State Licensing Authorities of Uttarakhand and Daman & Diu. Large number of unapproved new drugs was seized and action has been initiated against the manufacturers.

In this regard, DCG(I) desired that the State Licensing Authorities should conduct similar raids in their states for detecting the marketing of New Drugs on the basis of the licence granted by the State Licensing Authorities without due approval of DCG(I).

As regards intelligence cell, DCC deliberated the matter and recommended that the State Drugs Controllers should constitute Intelligence cell in their States for such investigations which may be further integrated with the Central Intelligence Unit. State Drugs Controller, Maharashtra suggested to conduct interstate raids by all states on lines of states of Maharashtra and Gujarat for better enforcement of the Drugs and Cosmetics Act and Rules thereunder.
AGENDA NO. 9

CONSIDERATION OF MEASURES TO TACKLE MISUSE OF OXYTOCIN UNDER PROVISIONS OF DRUGS & COSMETICS ACT, 1940 AND RULES, 1945

DCC was informed about the recommendations of 78th DTAB held on 12.02.2018 for prohibition of import of Oxytocin under Section 10A, regulation of supply of Oxytocin formulations for human use only to registered hospitals and clinics in public and private sector under Section 26A, adopting barcoding system for track and traceability of oxytocin formulations, and restriction of manufacture of oxytocin formulations only to Public Sector Units to avoid its misuse. DCC agreed with the recommendations of the DTAB.

It was also recommended that Indian Pharmacopoeia Commission (IPC) may be requested to revisit the storage conditions of Oxytocin as prescribed in IP vis a vis Schedule P of the Drugs and Cosmetics Rules, 1945.

AGENDA NO. 10

CONSIDERATION OF REGULATORY MECHANISM FOR STRENGTHENING OF INNOVATION AND EASE OF DOING BUSINESS

The committee was informed that CDSCO has created a ‘single window’ under the charge of a Public Relation Officer for disposal of grievances of stakeholders and to provide information to the innovators regarding regulatory requirements for commercialization of their products and also to provide clarifications pertaining to the compliance to the Drugs and Cosmetics Act, 1940 and Rules made thereunder. This would not only ensure cooperation of the manufacturers in maintaining the standards of drugs manufactured and also focus on the initiatives of the Govt. of India on ‘Invest in India/Make in India’.

DCC recommended that the State Drugs Controllers and CDSCO Zonal and Sub-zonal heads should set up such system in their organizations, headed by a senior officer to guide, assist and handhold investors in various phases of manufacture of drugs in the country. Such systems will also provide guidance to innovators who want to give shape to their innovations and facilitate ease of doing business.
AGENDA No. 11

CONSIDERATION OF THE ISSUE OF ABUSE AND TRAFFICKING OF PHARMACEUTICALS

Deputy Director (Operations), Narcotics Control Bureau, Delhi addressed the members and raised serious concern about the issue of abuse and trafficking of Pharmaceutical preparations in the country especially Codeine based cough syrups and Tramadol.

Deputy Director (Operations), NCB, requested all the State Licensing Authorities to re-consider proposal of reduction in batch size for manufacturing such drugs to control the diversion towards its abuse and misuse. He informed that if such products are manufactured with small batches, it will be easier to track the origin of the manufacturer. He also insisted to verify the existence of sale premises before a licence is granted by the states and to conduct surprise raids in this regard. He also informed that, the proposal of considering inclusion of Tramadol under NDPS is under active consideration and notification in this regard will be issued shortly.

DCC deliberated and agreed for considering Tramadol under NDPS, so that the drug should be under restrictions of production as API and controls on import into and export out of India. This will ensure the availability of the drug to the person who need it for pain management and also restrict its illicit movement.

AGENDA No. 12

CONSIDERATION OF THE IMPLEMENTATION OF THE SUGAM PORTAL THROUGH THE ACTIVE PARTICIPATION BY THE STATE DRUGS CONTROL ORGANISATIONS TO ENSURE ITS OPTIMUM UTILISATION

DCC deliberated the matter and recommended that all State Licensing Authorities should ensure effective implementation of the ‘SUGAM’ Portal in all the states.

Members were requested to take initiative in their states for creating awareness among the drug manufacturers under their jurisdiction for updating the database in respect of drug licences issued and licensed drug manufacturing facilities.
AGENDA NO. 13

CONSIDERATION OF MONITORING OF SALE OF ANTI–TB DRUGS BY THE STATE DRUGS CONTROL ORGANISATIONS

DCC deliberated the matter and recommended that all State Licensing Authorities are required to monitor the sale of anti-TB Drugs in their jurisdiction to ensure that these drugs are not used in an improper manner resulting in development of Drug Resistance.

AGENDA NO. 14

ISSUES REGARDING TESTING OF DRUGS BY GOVT. ANALYSTS WITHIN 60 DAYS SPECIFIED IN THE DRUGS AND COSMETICS RULES (AGENDA FROM LABORATORIES/ CENTRAL DRUGS TESTING LABORATORIES (CDTL))

The matter of 60 days time limit for analysis and reporting of drugs samples by Govt. Analysts was deliberated. DCC, however, did not agree to extend the said time limit beyond 60 days. It was agreed that in case of specifications, method of analysis, placebo etc. are not readily available either with the laboratory or IPC, the Govt. analyst should ask for the same at the earliest from the Drugs Inspector/ officer. The stipulated time limit of 60 days will start from the date of receipt of said information. Zonal/ Sub-zonal heads and State Drugs Controllers should instruct the Drugs Inspectors to collect reference standard, method of analysis, placebo from the manufacturers or their authorized vendors at the time of collecting samples itself. The same may be sent to the concerned Govt. analysts, so that he/ she can expedite the process of analysis and reporting, well within the schedule time limit of 60 days.

AGENDA NO. 15

PROPOSALS FROM STATES

A. STATE OF PUNJAB

MANUFACTURE OF MEDICATED SOAPS

DCC deliberated the matter and considered that the medicated soaps should be regulated under the category of ‘drugs’ as per section 3 (b) of the Drugs and Cosmetics Act. However, consideration should be given whether such products falls under ‘New drug’ and require permission from DCG(I).
B. STATE OF GOA

1. NEED TO MONITOR GOOD DISTRIBUTION PRACTICES BY THE MANUFACTURERS

DCC deliberated the matter and placed the draft Guidelines on Good Distribution Practices before the committee which is enclosed as ANNEXURE-A. Members were requested to offer their inputs/ comments on the guidelines within 4 weeks.

2. PRODUCT PERMISSION ON THE BASIS OF FORM 46 AFTER COMPLETION OF FOUR YEARS OF MANUFACTURING OF THE PRODUCT/ GRANT OF NEW DRUG PERMISSION BY DCG(I)

As provided under the Drugs and Cosmetics Rules, 1945, product licence for manufacture of a drug could be granted without permission from DCG (I) after completion of the period of four years of approval of the drug as ‘New drug’ by DCG (I).

3. OUTSOURCING FOR STORAGE OF RECORDS

DCC agreed that the manufacturing records should be stored in the manufacturing premises only for the prescribed period as per the Schedule M of the Drugs and Cosmetics Rules, 1945.

ADDITIONAL AGENDA NO. S1

CONSIDERATION OF THE PROPOSAL TO AMEND SCHEDULE M UNDER DRUGS & COSMETICS RULES, 1945 TO BRING THE PHARMACOVIGILANCE PROGRAM OF INDIA (PvPI) UNDER STATUTORY REQUIREMENT

Due to non-availability of representative from IPC, the agenda was deferred.

ADDITIONAL AGENDA NO. S2

CONSIDERATION OF PROPOSAL TO ADDRESS THE ISSUE OF VERIFICATION OF GLOBAL ENTRY PROGRAMME (GEP) APPLICANT - BY U.S. CUSTOMS AND BORDER PROTECTION (U.S. CBP) DEPARTMENT

DCC deliberated the proposal and agreed.
ADDITIONAL AGENDA NO. S3

AN UPDATE ON THE RECOMMENDATIONS OF 51st DCC FOR DISPOSAL OF EXPIRED DRUGS UNDER THE DRUGS & COSMETICS RULES, 1945

SUBMITTED BY SUB-COMMITTEE

The Chairman requested the members of the DCC to go through the draft Guidelines for disposal of expired drugs placed as part of 53rd DCC meeting and requested them to forward comments /suggestions in this regard for the purpose of finalizing the draft for consideration of the DTAB.

ADDITIONAL AGENDA NO. S4

CONSIDERATION OF THE PROPOSAL FOR REVISION OF THE FEES FOR THE TEST OR ANALYSIS BY AMENDING SCHEDULE B AND SCHEDULE B-1 OF DRUGS AND COSMETICS RULES

DCC deliberated the matter and in principle agreed to the proposed hike in fees for test or analysis by amending Schedule B and Schedule B-1 of Drugs and Cosmetics Rules, 1945. Further, the committee recommended constituting a sub-committee under the Chairmanship of Dr. N Murugesan, Director, CDTL, Chennai with the following members:

1. Dr. N. Murugesan, Director, CDTL, Chennai, TN (Chairman)
2. Smt. Ritu Sahay, Director (Drugs), Jharkhand (Member)
3. Ms. Vaishali Patel, Jt. Commissioner (Testing), Baroda (Member)
4. Dr. Arun Bharadwaj, Director, CDL, Kasauli (Member)
5. Shri P.B.N. Prasad, DDC(I), CDSCO, West zone, Mumbai (Convener)

The sub-committee should submit their report within 3 months from the date of its constitution.
ADDITIONAL AGENDA NO. S5

CONSIDERATION OF PROPOSAL TO INCLUDE THE ADVERTISEMENTS FOR TREATMENT OF THE AILMENTS MENTIONED IN SCHEDULE J UNDER DRUGS & COSMETICS RULES AND IN DRUGS AND MAGIC REMEDIES (OBJECTIONABLE ADVERTISEMENTS) ACT, 1954 & RULES 1955

DCC deliberated the matter and recommended to constitute a sub-committee for considering proposal to amend Schedule J of the Drugs & Cosmetics Rules, 1945 to include restriction/prohibition of advertisements for treatment of such ailments which are included in Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and Rules, 1955.

1. Shri. H. Mahapatra, Drugs controller, Odisha (Chairman)
2. Smt. N.K. Ahooja, State Drugs Controller, Haryana (Member)
3. Shri. Shobhit, Deputy Drugs Controller, FDA, M.P. (Member)
4. Dr. N Goswami, State Drugs Controller, Tripura (Member)
5. Representative from AYUSH (Member)
6. Dr. S.P. Shani, DDC(I), CDSCO, (HQ) (Convener)

The sub-committee should consider inclusion of provisions like Schedule J of Drugs and Cosmetics Rules, 1945 in AYUSH as well. Also, the sub-committee should examine the definition of ‘drug’ prescribed in the Drugs & Cosmetics Act, 1940 with that prescribed in the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and recommend measures to avoid confusion. The sub-committee should submit their report within 3 months from the date of its constitution.

During the deliberations it was also decided that one Drugs Inspector from CDSCO, one Drugs Inspector from State of Gujarat and one Drugs Inspector from state of Maharashtra will be exclusively delegated the responsibilities for looking after the advertisements of the drugs by all means (electronic, paper, social network etc.). In this regard, official order may be issued from CDSCO. Financial assistance should be provided by the Central Govt.
Further it was suggested to create an official email ID for prompt communications amongst the officials working in this regard and for public comments/ suggestions/ complaints. Also a timeline based approach may be designed to report such advertisements and launching of prosecution, in case of violation, should be fast-tracked.

**ADDITIONAL AGENDA NO. S6**

**CONSIDERATION OF PROPOSAL TO MANDATE THE USAGE OF ENGLISH LANGUAGE IN MANUFACTURING LICENCE FOR SALE OR FOR DISTRIBUTION OF DRUGS**

Committee was informed that in some states the manufacturing/ sale licences are being issued only in local language which is sometimes not understandable by other State Licensing Authorities.

DCC deliberated the matter and agreed to mandate the usage of English/ Hindi language in addition to the local languages, in the licence issued for manufacture of drugs for sale and distribution.

The meeting ended with the vote of thanks to the Chair.

**NOTE: ANNEXURE-B: List of Participants**

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GUIDELINES ON GOOD DISTRIBUTION PRACTICES FOR PHARMACEUTICAL PRODUCTS

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Central Drugs Standard Control Organization  
Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India  
FDA Bhawan, ITO, Kotla Road, New Delhi -110002.
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1.0 PREAMBLE

Distribution is an essential activity in the integrated supply-chain management of pharmaceutical products. Various individuals and entities are generally responsible for the handling, storage and distribution of such products. So it's very important to have adequate controls over the entire chain of distribution. To maintain the original quality of pharmaceutical products, every party involved in the distribution chain has to comply with the applicable requirement. Each activity in the distribution of pharmaceutical products shall be carried out according to the principles of Good Distribution Practices (GDP) as applicable. The nature of the risks involved is likely to be similar to that for risks encountered in the manufacturing environment, e.g. mix-ups, adulteration, contamination, cross-contamination, spurious. Further, the involvement of unauthorized entities in the distribution and sale of pharmaceutical products is a particular concern. Only a joint approach of all parties involved in the supply chain can be successful in the fight against spurious/sub-standard pharmaceutical products. Therefore, all parties in supply chain shall take an active part in collaborative activities to protect the pharmaceutical supply chain against the penetration of spurious/substandard pharmaceutical products.

2.0 OBJECTIVE

The objective of these guidelines is to ensure the quality and identity of pharmaceutical products during all aspects of the distribution process. These aspects include, but are not limited to procurement, purchasing, storage, distribution, transportation, documentation and record-keeping practices.

3.0 SCOPE

These guidelines are intended to be applicable to all persons and outlets involved in any aspect of the storage and distribution of pharmaceutical products from the premises of the manufacturer of the product to the person dispensing or providing pharmaceutical products directly to a patient or his or her agent. This includes all parties involved in trade and distribution of pharmaceutical, including the manufacturers of bulk, finished products, wholesalers, as well as others such as suppliers, distributors, Government institutions, international procurement organization, donor agencies and certifying bodies, logistics providers, traders, transport companies and forwarding agents and their employees as well as health workers. It also covers biological products in general. However, for specific purpose, guidelines on Good Distribution Practices for Biological Products as published in CDSCO website shall be referred.

4.0 GENERAL PRINCIPLES

4.1 According to Drugs & Cosmetics Act 1940 and Drugs & Cosmetic Rules 1945, Rules 64 and 65 specify the conditions to be fulfilled to sell, stock, exhibit or offer for sale or distribute the drugs.

4.2 It shall be the responsibility of all parties involved in the distribution of pharmaceutical products to ensure that the quality of pharmaceutical products and the integrity of the distribution chain are maintained throughout the
distribution process from the site of the manufacturer to the entity responsible for dispensing or providing the product to the patient or his or her agent.

4.3 The principles of GDP shall be applicable both to pharmaceutical products moving forward in the distribution chain from the manufacturer to the entity responsible for dispensing or providing pharmaceutical products to the patient and to products which are moving backwards in the chain, for, as a result of the return or recall thereof and shall be applicable for donated pharmaceutical products.

4.4 There shall be collaboration between all parties including government, custom agencies, law enforcement agencies, regulatory authorities, manufacturers, distributors and entities responsible for the supply of pharmaceutical products to patients to ensure the quality and safety of pharmaceutical products and prevent the exposure of patients to spurious pharmaceutical products.

4.5 An agreement shall be in place with all the individual agencies involved in the storage, transportation and distribution.

5.0 REGULATION OF THE DISTRIBUTION OF PHARMACEUTICAL PRODUCTS

5.1 The activities of persons or entities involved in the distribution of products shall be regulated by applicable National legislation.

5.2 The distributor or the organization to which the distributor belongs shall be an entity that is appropriately authorized by applicable legislation to perform the function(s) that it intends to perform and the distributor or the organization to which it belongs shall be held accountable for the activities that it performs related to the distribution of products.

5.3 Only authorized persons or entities who hold the appropriate license shall be entitled to import or export pharmaceutical products.

5.4 Distributors or their agents shall obtain their supplies of pharmaceutical products from persons or entities authorized to sell or supply such products to a distributor and shall supply pharmaceutical products only to persons or entities which are themselves authorized to acquire such products either in terms of an authorization to act as a distributor or to sell or supply products directly to a patient or to his or her agent.

5.5 If the activity of a distributor or his or her agent is subcontracted to another entity, the person or entity to which the activity is subcontracted shall be appropriately authorized to perform the subcontracted activity and shall uphold the same standards as the distributor.

6.0 ORGANIZATION AND MANAGEMENT

6.1 An adequate organizational structure for each entity in the chain of distribution shall be defined with the aid of an organizational chart. The
responsibility, authority and interrelationships of all personnel shall be clearly indicated. An organogram/organizational chart shall be in place.

6.2 There shall be clearly defined duties and responsibilities for individuals and shall be recorded as written job descriptions. At every level of the supply chain, employees shall be fully informed and trained in their duties and responsibilities.

6.3 There shall be designated person appointed within the organization, who has defined authority and responsibility for ensuring that a quality system is implemented and maintained.

6.4 Managerial and technical personnel shall have the authority and resources needed to carry out their duties and to set up and maintain a quality system, as well as to identify and correct deviations from the established quality system.

6.5 It shall be ensured that the responsibilities placed on any one individual shall not be so extensive as to present any risk to product quality.

6.6 There shall be arrangements in place to ensure that management and personnel are not subject to commercial, political, financial and other pressures or conflict of interest that may have an adverse effect on the quality of service provided or on the integrity of pharmaceutical products.

6.7 Safety procedures relating to all relevant aspects including the safety of personnel and property, environmental protection and product integrity, shall be in place.

7.0 PERSONNEL

7.1 All personnel involved in distribution activities shall be trained and qualified in the requirements of GDP, as applicable. Training shall be based on written standard operating procedures (SOPs). Personnel shall receive initial and continuing training relevant to their tasks, and be assessed as applicable, in accordance with a written training programme. In addition, training of the personnel shall include the topic of product handling, safety and security, as well as aspects of product identification, the detection of spurious pharmaceutical product and the avoidance of spurious pharmaceutical product entering the supply chain. A record of all training, which includes details of subjects covered and participants trained, shall be kept.

7.2 Key personnel involved in the distribution of pharmaceutical products shall have the ability and experience for ensuring that the pharmaceutical products are properly stored and distributed as per the requirement of the product.

7.3 There shall be an adequate number of competent personnel involved in all stages of the distribution of pharmaceutical products in order to ensure that the quality of the product is maintained.

7.4 Personnel involved in the distribution of pharmaceutical products shall wear garments and adopt other personnel protection measures suitable for the
activities that they perform. Protective garments as necessary shall be provided to the personnel dealing with hazardous pharmaceutical products, including products containing materials that are highly active, toxic, infectious or sensitizing materials.

7.5 Procedures for personnel hygiene relevant to the activities to be carried out shall be laid down and observed. Such procedures shall cover health, hygiene and clothing of personnel.

7.6 Procedures and conditions of employment for employees, including contract and temporary staff and other personnel having access to pharmaceutical products shall be designed and administered to assist in minimizing the possibility of such products coming into the possession of unauthorized persons or entities.

8.0 QUALITY SYSTEM

8.1 All pharmaceutical product distributors shall establish and maintain Quality System. There shall be documented quality policy describing the overall intentions and requirements of distributors regarding quality, authorized by the management.

8.2 There shall be an appropriate organizational structure with defined responsibilities of the personnel recorded as job descriptions.

8.3 A responsible person shall be appointed by the management for each distribution site, who shall have defined authority and responsibility for ensuring that a quality system is implemented and maintained.

8.4 Senior management shall ensure that all parts of quality system are adequately resourced with competent personnel and suitable and sufficient premises, equipment’s and facilities.

8.5 There shall be written and approved procedure for all the activities.

8.6 Deviations from established procedures shall be documented and investigated.

8.7 Appropriate corrective and preventive action (CAPA) shall be taken to correct deviations and prevent them.

8.8 Procedures for procurement and release shall be in place to ensure that appropriate pharmaceutical products are sourced only from approved suppliers and distributed by approved entities.

8.9 Inspection, auditing and certification of compliance with a quality system (such as the applicable International Standardization Organization (ISO) series, or national or international guidelines) by external bodies are recommended.
8.10 Procedures shall be in place to ensure safe, transparent and secure distribution system which includes product traceability throughout the supply chain.

8.11 There shall be procedures in place to ensure document traceability of products received and distributed, to facilitate product recall.

8.12 All parties involved in the supply chain shall be identifiable depending on type of product and in accordance with National Legislation.

8.13 Measures shall be in place to ensure that pharmaceutical products have documentation that can be used to permit traceability of the products throughout distribution channels from the manufacturer/imported to the entity responsible for selling or supplying the product to the patient or his or her agent. Records including expiry dates and batch numbers shall be part of a secure distribution documentation enabling traceability.

9.0 PREMISES, WAREHOUSING AND STORAGE

9.1 Storage areas shall be maintained or designed to ensure Good storage practices (GSP).

9.2 Storage areas shall be suitably secured, structurally sound and of sufficient capacity to allow for the safe storage and handling.

9.3 Storage areas shall be provided with adequate lighting to enable all operations to be carried out accurately and safely.

9.4 Precautions shall be taken to prevent unauthorized persons from entering storage areas.

9.5 Segregated areas shall be designated for storage of the pharmaceutical products in quarantine and for storage of released, rejected, returned or recalled products as well as those suspected to be spurious.

9.6 Storage areas shall be designed or adapted to ensure appropriate and good storage conditions and shall be clean and dry and maintained within acceptable temperature limits. Pharmaceutical products shall be stored off the floor and suitably spaced to permit cleaning and inspection. Pallets shall be kept in a good state of cleanliness and condition.

9.7 Premises and storage areas shall be cleaned regularly.

9.8 There shall also be a written programme for pest control and the pest control agents used shall be safe and there shall be no risk of contamination of pharmaceutical products. There shall be appropriate procedures for the clean-up of any spillage to ensure complete removal of any risk of contamination.

9.9 If sampling is performed in the storage area, it shall be conducted in such a way as to prevent contamination or cross-contamination. Adequate cleaning procedures shall be in place for the sampling areas.
9.10 Receiving and dispatch bays shall protect pharmaceutical products from the weather. Receiving areas shall be designed and equipped to allow incoming containers of pharmaceutical products to be cleaned, if necessary, before storage.

9.11 Handling and storage of pharmaceutical products shall in such a manner as to prevent contamination, mix-ups and cross-contamination.

9.12 There shall be a system in place to ensure that the pharmaceutical products due to expire first are sold and/or distributed first (first expiry/ first out (FEFO)). Exceptions shall be permitted as appropriate, provided that adequate controls are in place to prevent the distribution of expired products.

9.13 Arrangement shall be made for withdrawing broken or damaged items from unusable stock and storing separately.

9.14 There shall be appropriately identified areas with adequate segregation for storage of quarantined, rejected, expired, recalled or returned products to prevent unintentional or unauthorized use of such products.

9.15 Dedicated area(s) with appropriate additional safety and security measures shall be provided for storage of radioactive materials, narcotics and other hazardous, sensitive and/or dangerous pharmaceutical products, as well as products presenting special risks of abuse, fire or explosion (e.g combustible or flammable liquids and solids and pressurized gases).

10.0 TEMPERATURE, ENVIRONMENT AND STOCK CONTROL

10.1 Storage and handling conditions shall comply with applicable National l regulations.

10.2 Storage conditions for pharmaceutical products shall be in compliance with the recommendations of the manufacturer. This is key to ensure quality of all pharmaceutical products.

10.3 Facilities shall be available for the storage of all pharmaceutical products under appropriate conditions (e.g environmentally controlled when necessary).

10.4 Records shall be maintained of storage conditions if they are critical for the maintenance of the characteristics of the pharmaceutical products. Records of temperature monitoring data shall be available for review. There shall be defined intervals for checking temperature. The equipment used for monitoring shall be checked at suitable predetermined intervals and the results of such checks shall be recorded and retained. All monitoring records shall be kept for at least the shelf-life of the stored product plus one year.

10.5 Storage areas shall be temperature mapped under representative conditions. Temperature mapping shall show uniformity of the temperature across the storage facility. It is recommended that temperature monitors be located in areas that are most likely to show fluctuations.
10.6 Equipment used for monitoring of storage conditions shall also be calibrated at defined intervals.

10.7 Stock discrepancies shall be investigated in accordance with a specified procedure to check that there have been no inadvertent mix ups, incorrect issues and receipts, thefts and/or misappropriations of pharmaceutical products. Documentation relating to the investigation shall be kept for a predetermined period.

11.0 TRANSPORTATION

11.1 Pharmaceutical products shall be transported in accordance with the storage conditions indicated on the packaging information and on the label.

11.2 The individuals responsible for the transportation of pharmaceutical products shall be informed about all relevant conditions for storage and transportation. These requirements shall be adhered throughout transportation and at any intermediate storage stages.

11.3 Pharmaceutical products shall be stored and transported in accordance with procedures such that:

11.3.1 The identity of the product is not lost.

11.3.2 The product does not contaminate and is not contaminated by other products.

11.3.3 Adequate precautions are taken against spillage, breakage, misappropriation and theft. Spillage during transport shall be handled as per type of vaccine (e.g. live, killed, etc.) according to the standard operating procedures of the manufacturer.

11.3.4 Appropriate environmental conditions are maintained, e.g. using cold chain for thermo labile products.

11.4 A written agreement between the manufacturer, Government Institution, agent and Transport Company shall be in place.

11.5 Appropriate transport methods shall be employed which may include transport by air, road, sea, rail or a combination of the above. Regardless of the chosen mode, it shall be demonstrated that the products have not been subjected to conditions during transportation that may compromise their quality. A risk based approach be utilized when planning transportation routes.

11.6 The required storage conditions for pharmaceutical products shall be maintained during transportation within the defined limits as described on the packaging information.

11.7 Where special conditions are required during transportation that are different from or limit the given environmental conditions (e.g. temperature and humidity), these shall be provided by the manufacturer on the labels, shall be monitored and recorded.
11.8 If a deviation has occurred during transportation, this shall be reported to the distributor and recipient of the affected pharmaceutical products. Written procedures shall be in place to investigate and deal with any failure to comply with storage requirements, e.g. temperature deviations.

11.9 In cases where the recipient notices the deviation, it shall be reported to the distributor. Where necessary, the manufacturer of the pharmaceutical product shall be contacted for information about appropriate steps to be taken.

11.10 Pharmaceutical products containing hazardous substances, such as toxic, radioactive material and other dangerous pharmaceutical products presenting special risks of abuse, fire or explosion (e.g. combustible or flammable liquids, solids and pressurized gases), shall be stored in safe, dedicated and secure areas and transported in safe, suitably designed, secured containers and vehicles and the requirements of applicable National legislation shall be met.

11.11 Products containing narcotics and other dependence-producing substances shall be transported in safe and secure containers and vehicles and be stored in safe and secure areas and applicable international agreements and National legislation shall be complied with. Spillage shall be cleaned up as soon as possible to prevent possible contamination, cross-contamination and hazards and written procedures shall be in place for handling of such situation.

11.12 Adequate segregation shall be provided for the storage and distribution during transit of rejected, expired, recalled or returned pharmaceutical products. The products shall be appropriately identified, securely packaged, clearly labelled and be accompanied by appropriate supporting documentation.

11.13 The interiors of vehicles and containers shall remain clean and dry while pharmaceutical products are in transit.

11.14 Properly designed packaging materials and shipment containers shall be provided to prevent damage of pharmaceutical products during transport.

11.15 Drivers of vehicles shall identify themselves and present appropriate documentation to demonstrate that they are authorized to transport the load.

11.16 Damage to containers and any other event or problem that occurs during transit shall be recorded and reported to the relevant department, entity or authority, and investigated.

11.17 Pharmaceutical products in transit shall be accompanied by the appropriate documentation.

11.18 It is the responsibility of the distributor to ensure that vehicles and equipment used to distribute, store or handle pharmaceutical products are suitable for their use and appropriately equipped to prevent exposure of the
products to conditions that shall affect their quality and packaging integrity, and to prevent contamination of any kind.

11.19 There shall be procedures in place for the operation and maintenance of all vehicles and equipment involved in the distribution process, including cleaning and safety precautions.

11.20 Vehicles, containers and equipment shall be kept clean and dry and free from accumulated waste. Organizations in charge of distribution shall ensure that vehicles used are cleaned regularly.

11.21 Particular attention shall be paid to the fact that cleaning agents shall not adversely affect the product quality.

11.22 Vehicles, containers and equipment shall be kept free from rodents, vermin, birds and other pests. There shall be written programs and records for such pest control.

11.23 Equipment used for temperature and humidity monitoring (Data Logger) during transport within vehicles and/or containers, shall be maintained and calibrated at regular intervals at least once a year or earlier depending upon the criticality of the product.

11.24 All monitoring records shall be kept for a minimum of the shelf-life of the product distributed plus one year or as required by National legislation.

11.25 Records of monitoring data shall be made available for inspection by the Regulatory Authority.

11.26 Equipment chosen and used for the cleaning of vehicles shall not constitute a source of contamination and cleaning agents shall be approved by management. It is essential to pay special attention to the design, use, cleaning and maintenance of all equipment used for the handling of pharmaceutical products which are not in a protective shipping carton or case.

11.27 Dedicated vehicles and equipment shall be used, where possible, when handling pharmaceutical products. Procedures shall be in place to ensure that the quality of the pharmaceutical product shall not be compromised where non-dedicated vehicles and equipment shall be used.

Appropriate documents shall accompany pharmaceutical products in transit.

11.29 Vehicles and containers selected shall be of sufficient capacity to allow orderly storage of the various categories of pharmaceutical products during transportation.

11.30 Where possible, mechanisms shall be available to allow for the segregation during transit of rejected, recalled and returned pharmaceutical products, as well as those suspected of being spurious. Such products shall
be securely packaged, clearly labeled and be accompanied by appropriate supporting documentation.

11.3 Adequate measures shall be taken to ensure that no unauthorized persons enter and tamper the vehicles and/or equipment, so as to prevent the theft or misappropriation thereof.

12.0 SHIPMENT CONTAINERS AND LABELING

12.1 Pharmaceutical products shall be transported in shipment containers that have no adverse effect on the quality of the products, and that offer adequate protection from external influences, including contamination.

12.2 Selection of a container and packaging shall be based on the storage and transportation requirements of the pharmaceutical products; namely the space required for the amount of products; the anticipated external temperature extreme; the estimated maximum time for transportation including transit storage at customs and the validation status of the packaging and shipment containers.

12.3 Labels on the containers shall bear sufficient information on handling and storage requirements and precautions to ensure that the products are properly handled and secured at all times.

The containers shall enable identification of the contents of the containers and the source.

12.4 Special care shall be taken when using dry ice in shipment containers. It shall be ensured in addition to safety issues, that Pharmaceutical products do not come in direct contact with dry ice which may have an adverse effect on the quality of the product.

12.5 Written procedures shall be available for the handling of damaged and/or broken shipment containers. Particular attention shall be paid to those containing potentially toxic and hazardous products.

12.6 The need for any special transport and/or storage conditions shall be stated on the shipment container label. If a pharmaceutical product is intended for transfer to areas outside the control of the manufacturer's products management system, the name and address of the manufacturer, special transport conditions and any special legal requirements including safety symbols shall also be included on the container label.

13.0 DISPATCH AND RECEIPT

13.1 Selling or distribution of pharmaceutical products shall be done to persons or entities that are authorized to acquire such products in accordance with the applicable national, state and international legislation. It is required to obtain written proof of such authority prior to the distribution of products to such persons or entities.

13.2 The supplier shall ensure that the person or entity, e.g. the contract acceptor for transportation of the pharmaceutical products, is aware of the
pharmaceutical products to be distributed and complies with the appropriate storage and transport conditions prior to the dispatch of pharmaceutical products.

13.3 Only after the receipt of a valid delivery order or material replenishment plan, the dispatch and transportation of pharmaceutical products shall be undertaken, which shall be documented.

13.4 Written procedures for the dispatch of pharmaceutical products shall be established. Such procedures shall take into account the nature of the product as well as any special precautions to be observed. Pharmaceutical products under quarantine shall require release for dispatch by the person responsible for quality.

13.5 Records for the dispatch of pharmaceutical products shall include at least the following information:
- Date of dispatch;
- Complete business name and address (no acronyms), type of entity responsible for the transportation, telephone number and names of contact persons;
- Complete business name, address (no acronyms), and status of the addressee (e.g. retail pharmacy, hospital or community clinic);
- A description of the products including, e.g. name, dosage form and strength (if applicable);
- Quantity of the products, i.e. number of containers and quantity per container (if applicable);
- Applicable transport and storage conditions;
- A unique number to allow identification of the delivery order; and Assigned batch number and expiry date (where not possible at dispatch, this information shall at least be kept at receipt to facilitate traceability).

13.6 It shall be ensured that records of dispatch contain enough information to enable traceability of the pharmaceutical product. Such records shall facilitate the recall of a batch of a product, if necessary, as well as the investigation of spurious or potentially spurious pharmaceutical products; the assigned batch number and expiry date of pharmaceutical products shall be recorded at the point of receipt to facilitate traceability.

13.7 It shall be ensured that the volume of pharmaceutical products ordered does not exceed the capacity of storage facilities at the destination.

13.8 There shall be no supply or receipt of pharmaceutical products after their expiry date, or so close to the expiry date that this date is likely to be reached before the products are used by the consumer.
13.9 Incoming shipments shall be examined to verify the integrity of the container/closure system, to ensure that tamper-evident packaging features are intact, and that labeling appears intact.

13.10 Batch number and expiry date of pharmaceutical products shall be recorded at the point of receipt to facilitate traceability.

13.11 Methods of transportation, including vehicles to be used, shall be selected with care, and local conditions shall be considered, including the climate and any seasonal variations experienced. Delivery of products requiring controlled temperatures shall be in accordance with the applicable storage and transport conditions.

13.12 Delivery schedules shall be established and routes planned considering the local needs and condition and shall be realistic and systematic. When planning the schedules and routes of delivery, security risks shall also be taken into account.

13.13 To save time when unloading, to prevent physical damage and reduce security risks, vehicles and containers shall be loaded carefully and systematically, where applicable on a first-out/last-in basis. Extra care shall be taken during loading and unloading of cartons to avoid damage.

14.0 DOCUMENTATION

14.1 Documentation comprises all written procedures, instructions, contracts, records and data, in paper or in electronic form.

14.2 Written instructions and records which document all activities relating to the distribution of pharmaceutical products, including all applicable receipts and issues (invoices) shall be available.

14.3 Distributors shall keep records of all pharmaceutical products received. Records shall contain at least the following information:

- Date;
- Name of the pharmaceutical product, batch no, manufacturer’s name.
- Quantity received, or supplied; and
- Name and address of the supplier.

14.4 Procedures shall be established and maintained for the preparation, review, approval, use of and control of changes to all documents relating to the distribution process.

14.5 The contents of documents shall be clear and unambiguous. In particular, instructions and procedures relating to activity that may have an impact on quality of pharmaceutical products shall be designed, completed, reviewed and distributed with care.
14.6 Documentation shall be approved, signed and dated by appropriate authorized persons, as required. It shall not be hand-written; although, where documents require the entry of data, sufficient space shall be provided for such entries.

14.7 Any alteration made in the documentation shall be signed and dated; the alteration shall permit the reading of the original information. Where appropriate, the reason for the alteration shall be recorded.

14.8 Documents shall be retained for a period of 1 year after expiry of the product.

14.9 The distributor shall establish and maintain procedures for the identification, collection, indexing, retrieval, storage, maintenance, disposal of and access to all applicable documentation.

14.10 Documents shall be reviewed regularly and kept up to date.

14.11 Records shall be kept either in the form of purchase/sales invoices, delivery slips, or on computer or in any other form, for any transaction in pharmaceutical products received or supplied.

14.12 Records shall be made at the time each operation is taken and in such a way that all significant activities or events are traceable.

14.13 If electronic copies/data are stored then validation of computers and database management system shall be in place.

14.14 Mechanisms shall exist to allow for transfer of information, including quality or regulatory information, between a manufacturer and a customer, as well as the transfer of information to the relevant regulatory authority as required.

14.15 Records relating to storage of pharmaceutical products shall be kept and be readily available. Pharmacopoeial requirements and current National regulations concerning labels and containers shall be respected at all times.

14.16 Procedures shall be in place for temperature mapping, security services to prevent theft or tampering with goods at the storage facilities, destruction of unsaleable or unusable stocks and on retention of the records.

14.17 All records shall be readily retrievable, and be stored and retained using facilities that are safeguarded against unauthorized modification, damage, deterioration and/or loss of documentation.

14.18 Backup shall be maintained to prevent any accidental data loss where the records are generated and kept in electronic form.
15.0 COMPLAINTS

15.1 Written procedure shall be in place for the handling of complaints. A distinction shall be made between complaints about a pharmaceutical product or its packaging and those relating to distribution. In the case of a complaint about the quality of a product or its packaging, the original manufacturer and/or marketing authorization holder shall be informed as soon as possible.

15.2 There shall be written procedure for reviewing carefully all complaints and other information concerning potentially defective and potentially spurious pharmaceutical products describing the action to be taken, including the need to consider a recall where appropriate.

15.3 Any complaint concerning a material defect shall be recorded and thoroughly investigated to identify the origin or reason for the complaint.

15.4 A risk based consideration shall be given to whether other batches of the pharmaceutical product shall also be checked if a defect relating to a pharmaceutical product is discovered or suspected.

15.5 Appropriate follow-up action shall be taken after investigation and evaluation of the complaint where necessary. A system shall be in place to ensure that the complaint, the response received from the original product manufacturer, or the results of the investigation of the complaint, are shared with all the relevant parties.

15.6 There shall be documentation of product quality problems or suspected cases of spurious products and sharing of the information with the appropriate national and/or state regulatory authorities.

16.0 RECALLS AND RETURNS

16.1 There shall be a written procedure for the management of recalls of defective pharmaceutical products with a designated person responsible for recalls.

16.2 The system of recall shall comply with the guidance issued by National Regulatory Authority.

16.3 In the event of recall the original manufacturer and/or marketing authorization holder shall be informed. Consultation with the original manufacturer and/or marketing authorization holder shall take place, where possible, before the recall is instituted in case recall is instituted by an entity other than the original manufacturer.

16.4 National or State Regulatory Authority shall be shared with information on recall.

16.5 Recall operations shall be capable of being initiated promptly and at any time.
16.6 The distributor shall follow the instructions of a recall message, which shall be approved, if required, by the competent authorities.

16.7 Any recall operation shall be recorded at the time it is carried out and records shall be made available to the competent authorities.

16.8 The distribution records shall be readily available to the person(s) responsible for the recall, and shall contain sufficient information on distributors and directly supplied customers (with addresses, phone and/or fax numbers inside and outside working hours, batches and quantities delivered).

16.9 Recalled pharmaceutical products shall be identified and stored separately in a secure area while awaiting a decision on their disposition.

16.10 Recalled pharmaceutical products shall be segregated during transit and clearly labeled as recalled products. Where segregation in transit is not possible, such goods shall be securely packaged, clearly labeled and be accompanied by appropriate documentation.

16.11 The particular storage conditions applicable to a pharmaceutical product which is subject to recall shall be maintained during storage and transit until such time as a decision has been made regarding the fate of the product in question.

16.12 All customers and competent authorities of all countries to which a given pharmaceutical product may have been distributed shall be informed promptly of any intention to recall the product because it is, suspected to be defective.

16.13 All records shall be readily available to the designated person(s) responsible for recalls containing sufficient information on pharmaceutical products supplied to customers (including exported products).

16.14 The progress of the recall process shall be recorded and a final report shall be issued, including reconciliation between the delivered and recovered quantities of the pharmaceutical products.

16.15 When necessary emergency recall procedures shall be implemented as per guideline on Recall and Rapid Alert System for Drugs (Including Biological and Vaccines) as given on CDSCO website (www.cdsco.nic.in).

16.16 Rejected pharmaceutical products and those returned to a distributor shall be appropriately identified and handled in accordance with a procedure which involves at least: the physical segregation of such pharmaceutical products in quarantine in a dedicated area; or other equivalent (e.g. electronic) segregation.

16.17 Destruction of pharmaceutical products shall be done in accordance with international, national and local requirements regarding disposal of such products, and with due consideration to protection of the environment.
16.18 Records of all returned, rejected and/or destroyed pharmaceutical products shall be kept for a predetermined period.

17.0 SPURIOUS PHARMACEUTICAL PRODUCTS

17.1 Spurious pharmaceutical products if found in the distribution chain shall be completely segregated from other pharmaceutical products, clearly labeled as not for sale and national regulatory authorities and manufacturer of the original product shall be informed immediately.

17.2 The sale and distribution of a suspected spurious pharmaceutical product shall be suspended and the national regulatory authority shall be notified without delay.

17.3 A formal decision shall be taken on its disposal, ensuring that it does not re-enter the market upon confirmation of the pharmaceutical product being spurious and the decision shall be recorded.

18.0 IMPORTATION

18.1 Consignments of pharmaceutical products shall be stored under suitable conditions for as short a time as possible, at the port of entry.

18.2 Importers shall take all reasonable steps to ensure that pharmaceutical products are not mishandled or exposed to adverse storage conditions at wharves or airports.

18.3 Procedures shall be in place for quality assessment of imported pharmaceutical products as per applicable National legislation.

18.4 Customs, enforcement agencies and regulatory agencies responsible for supervision of pharmaceutical products shall establish means for cooperation and information exchange in order to prevent importation of spurious pharmaceutical products.

19.0 CONTRACT ACTIVITIES

19.1 Only parties appropriately authorized to distribute a pharmaceutical product shall be delegated to perform any activity relating to distribution of such product and in accordance with the terms of a written consent.

19.2 The responsibilities of each party including observance of the principles of GDP and relevant warranty clauses shall be defined in the contract. It shall also include responsibilities of the contractor for measures to avoid the entry of spurious pharmaceutical products into the distribution chain, such as by suitable training programme.

19.3 The requirements in these guidelines shall be complied with by all contract acceptors.
19.4 Under certain conditions and subject to the written approval of the contract giver, subcontracting may be permissible, provided that the subcontractors shall be authorized for the function.

19.5 There shall be periodic audit of contract acceptors.

20.0 SELF-INSPECTION

20.1 Self-inspections shall be included in the quality system. These shall be conducted to monitor implementation and compliance with the principles of GDP and, if necessary, to trigger corrective and preventive measures.

20.2 A designated, competent person shall conduct self-inspection in an independent and detailed way.

20.3 There shall be records of self-inspection results which shall contain all observations made during the inspection and if required proposal for corrective measures. There shall be an effective follow-up programme and evaluation of inspection report and corrective action taken by the management.
ANNEXURE-B

List of the participants of 53rd Drugs Consultative Committee meeting held on 9th April, 2018 at New Delhi under the Chairmanship of Dr. S. Eswara Reddy, Drugs Controller General (India)

A. STATE/UTs DRUGS CONTROL ORGANIZATIONS

<table>
<thead>
<tr>
<th>S. NO.</th>
<th>STATE</th>
<th>NAME</th>
<th>DESIGNATION</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Andhra Pradesh</td>
<td>Dr. Ravi Shankar</td>
<td>DG, DCA</td>
</tr>
<tr>
<td>2</td>
<td>Arunachal Pradesh</td>
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<tr>
<td>3</td>
<td>Assam</td>
<td>Sri A. K Nath</td>
<td>Joint Drugs Controller (HQ)</td>
</tr>
<tr>
<td>4</td>
<td>Bihar</td>
<td>Shri. Ravindra Kumar Singh</td>
<td>State Drugs Controller</td>
</tr>
<tr>
<td>5</td>
<td>Chhattisgarh</td>
<td>Shri. Hemant Shrivastava</td>
<td>A.D.C, F.D.A C.G.</td>
</tr>
<tr>
<td>6</td>
<td>Goa</td>
<td>Smt. Jyoti Sardesai</td>
<td>Director, FDA, Goa</td>
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<tr>
<td>7</td>
<td>Gujarat</td>
<td>Dr. H.G. Koshia</td>
<td>Commissioner, FDCA</td>
</tr>
<tr>
<td>8</td>
<td>Haryana</td>
<td>Shri. N.K Ahooja,</td>
<td>State Drugs Controller</td>
</tr>
<tr>
<td>9</td>
<td>Himachal Pradesh</td>
<td>Shri. Navneet Marwaha</td>
<td>Drugs Controller</td>
</tr>
<tr>
<td>10</td>
<td>Jammu and Kashmir</td>
<td>Shri. Nazir Ahmad Khan</td>
<td>State Drugs Controller</td>
</tr>
<tr>
<td>11</td>
<td>Jharkhand</td>
<td>Smt. Ritu Sahay</td>
<td>Director (Drugs)</td>
</tr>
<tr>
<td>12</td>
<td>Karnataka</td>
<td>Shri. Amaresh Tumbagi</td>
<td>Deputy Drugs Controller (HQ)</td>
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<tr>
<td>13</td>
<td>Kerala</td>
<td>Shri. Ravi S. Menon</td>
<td>Drugs Controller</td>
</tr>
<tr>
<td>14</td>
<td>Madhya Pradesh</td>
<td>Shri. Shobhit</td>
<td>Dy. DC, FDA</td>
</tr>
<tr>
<td>15</td>
<td>Maharashtra</td>
<td>Shri. O. S. Sadhwani</td>
<td>Jt. Commissioner (HQ), FDA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Shri. A.T. Nikhade</td>
<td>Jt. Commissioner (HQ), FDA</td>
</tr>
<tr>
<td>16</td>
<td>Manipur</td>
<td>Shri. Akoijam Singhajeet Singh</td>
<td>State Drugs Controller</td>
</tr>
<tr>
<td>17</td>
<td>Meghalaya</td>
<td>Shri. Devistone Swer</td>
<td>Asst. Drugs Controller</td>
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<tr>
<td>18</td>
<td>Mizoram</td>
<td>Shri Lal Sawma</td>
<td>Joint Director, FDA</td>
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<td>20</td>
<td>Odisha</td>
<td>Shri H. Mahapatra</td>
<td>Drugs Controller</td>
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<td>21</td>
<td>Punjab</td>
<td>Shri. Pradeep Kumar</td>
<td>Jt. Commissioner, FDA</td>
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<tr>
<td>22</td>
<td>Rajasthan</td>
<td>Shri. Raja Ram Sharma</td>
<td>Drugs Controller</td>
</tr>
<tr>
<td>23</td>
<td>Sikkim</td>
<td>Dr. T.K. Rai</td>
<td>Joint Drugs Controller</td>
</tr>
<tr>
<td>24</td>
<td>Tamil Nadu</td>
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<tr>
<td>S. No.</td>
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<td>25.</td>
<td>Telangana</td>
<td>Dr. B. Venkateswarlu</td>
<td>Deputy Director</td>
</tr>
<tr>
<td>26.</td>
<td>Tripura</td>
<td>Dr. N. Goswami</td>
<td>State Drugs Controller</td>
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<tr>
<td>27.</td>
<td>Uttar Pradesh</td>
<td>Shri. A.K. Jain</td>
<td>Drug Licensing &amp; Controlling Authority</td>
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<tr>
<td>28.</td>
<td>Uttarakhand</td>
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<td>29.</td>
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<td>30.</td>
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<td>31.</td>
<td>Chandigarh</td>
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<td>32.</td>
<td>Dadar and Nagar Haveli</td>
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<td>33.</td>
<td>Daman and Diu</td>
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<tr>
<td>34.</td>
<td>Delhi</td>
<td>Shri. Atul Kumar Nasa</td>
<td>HOD &amp; Controlling Authority</td>
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<td>35.</td>
<td>Lakshadweep</td>
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<td>36.</td>
<td>Pondicherry</td>
<td>Shri. V. Karthikeyan</td>
<td>Licensing Authority, Dept. of Drugs Control</td>
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B. INVITEES

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<thead>
<tr>
<th>S. No.</th>
<th>NAME</th>
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<tbody>
<tr>
<td>1.</td>
<td>Ms. Preeti Sudan</td>
<td>Secretary, Ministry of Health and Family Welfare</td>
</tr>
<tr>
<td>2.</td>
<td>Shri. Praveen Deshpande</td>
<td>Deputy Director (Ops), NCB, New Delhi</td>
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<td>3.</td>
<td>Dr. Jai Prakash</td>
<td>Sr. PSO, Indian Pharmacopoeia Commission</td>
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<tr>
<td>4.</td>
<td>Dr. P.L. Sahu</td>
<td>PSO, Indian Pharmacopoeia Commission</td>
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C. DRUG TESTING LABORATORIES

<table>
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<tbody>
<tr>
<td>1.</td>
<td>CDL Kolkata</td>
<td>Shri. C Hariharan</td>
<td>Director/In-Charge</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Shri S. Mukhopadhyay</td>
<td>Deputy Drugs Controller(India)</td>
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<tr>
<td>2.</td>
<td>CDL, Kasauli</td>
<td>Dr. Arun Bhardwaj</td>
<td>Director</td>
</tr>
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<td></td>
<td></td>
<td>Shri. Sumir Rai Bhalla</td>
<td>Asst. Technical Officer</td>
</tr>
<tr>
<td>3.</td>
<td>CDTL, Mumbai</td>
<td>Dr. Raman Mohan Singh</td>
<td>Director</td>
</tr>
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<td>4.</td>
<td>CDTL, Chennai</td>
<td>Dr. N. Murugesan</td>
<td>Director</td>
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<td>5.</td>
<td>CDTL, Hyderabad</td>
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<td>6.</td>
<td>RDTL, Chandigarh</td>
<td>Dr. R. A. Singh</td>
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<td>RDTL, Guwahati</td>
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## D. ZONAL/ SUB ZONAL/PORT OFFICES OF CDSCO

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<td><strong>ZONE</strong></td>
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<tr>
<td>1.</td>
<td>North Zone, Ghaziabad</td>
<td>Shri. Aseem Sahu</td>
<td>Deputy Drugs Controller (India)</td>
</tr>
<tr>
<td>2.</td>
<td>East Zone, Kolkata</td>
<td>Shri. Arup Chatterjee</td>
<td>Asst. Drugs Controller (India)</td>
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<tr>
<td>3.</td>
<td>West Zone, Mumbai</td>
<td>Shri. P.B.N. Prasad</td>
<td>Deputy Drugs Controller (India)</td>
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<tr>
<td></td>
<td></td>
<td>Smt. Rubina Bose</td>
<td>Deputy Drugs Controller (India)</td>
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<tr>
<td>4.</td>
<td>South Zone, Chennai</td>
<td>Smt. Shanthy Gunashekharan</td>
<td>Deputy Drugs Controller (India)</td>
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<td>5.</td>
<td>Hyderabad Zone</td>
<td>Shri. Arvind Kukrety</td>
<td>Deputy Drugs Controller (India)</td>
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<td>Ahmedabad zone</td>
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<td><strong>SUB ZONE</strong></td>
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<tr>
<td>1.</td>
<td>Bangalore Sub-zone</td>
<td>Shri. B. Kumar</td>
<td>Deputy Drugs Controller (India)</td>
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<tr>
<td>2.</td>
<td>Baddi Sub-zone</td>
<td>Shri. B.K. Samantray</td>
<td>Deputy Drugs Controller (India)</td>
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<td>3.</td>
<td>Jammu Sub-zone</td>
<td>Shri Gulshan Taneja</td>
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<td>Shri. R. Chandrashekhar</td>
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<td>5.</td>
<td>Indore Sub-zone</td>
<td>Shri. Sunil M Joshi</td>
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<td>6.</td>
<td>Guwahati Sub-zone</td>
<td>Shri. Shiv Kumar</td>
<td>Asst. Drugs Controller (India)</td>
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<td>7.</td>
<td>Varanasi Sub-zone</td>
<td>Shri. Vinay Kumar Gupta</td>
<td>Asst. Drugs Controller (India)</td>
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<td>1.</td>
<td>IGI Airport, New Delhi</td>
<td>Dr. Naresh Sharma</td>
<td>Asst. Drugs Controller (India)</td>
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<tr>
<td>2.</td>
<td>Kolkata Airport</td>
<td>Shri. Arup Chatterjee</td>
<td>Asst. Drugs Controller (India)</td>
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<td>3.</td>
<td>Kolkata Sea Port</td>
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<td></td>
<td>Ballard Sea Port, Mumbai</td>
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<td>5.</td>
<td>JNPT (Nhava Sheva) Sea Port</td>
<td>V. Rajappan</td>
<td>Asst. Drugs Controller (India)</td>
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<td>7.</td>
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<td>8.</td>
<td>Cochin Sea Port</td>
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<td>S. No.</td>
<td>OFFICES</td>
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<td>DESIGNATION</td>
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<td>9.</td>
<td>Rajiv Gandhi International Airport, Shamshabad, Hyderabad</td>
<td>Shri. Vinod Kumar</td>
<td>Asst. Drugs Controller (India)</td>
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<td>10.</td>
<td>Visakhapatnam Airport</td>
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<td>Krishnapatnam Sea Port</td>
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<td>12.</td>
<td>Bengaluru Airport</td>
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<td>13.</td>
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<td>Kandla Sea Port</td>
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<td>15.</td>
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E. CDSCO HEAD QUARTER

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<thead>
<tr>
<th>S. No.</th>
<th>NAME</th>
<th>DESIGNATION</th>
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<tbody>
<tr>
<td>1.</td>
<td>Dr. S. Eswara Reddy</td>
<td>Drugs Controller General of India</td>
</tr>
<tr>
<td>2.</td>
<td>Dr. V. G. Somani</td>
<td>Joint Drugs Controller (India)</td>
</tr>
<tr>
<td>3.</td>
<td>Dr. K Bangarurajen</td>
<td>Joint Drugs Controller (India)</td>
</tr>
<tr>
<td>4.</td>
<td>Shri. Arun Sharma</td>
<td>Director (Admin)</td>
</tr>
<tr>
<td>5.</td>
<td>Shri A. C. S. Rao</td>
<td>Deputy Drugs Controller (India)</td>
</tr>
<tr>
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<td>Shri. A.K. Pradhan</td>
<td>Deputy Drugs Controller (India)</td>
</tr>
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<td>7.</td>
<td>Dr. S. Manivannan</td>
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<td>Shri Sanjeev Kumar</td>
<td>Deputy Drugs Controller (India)</td>
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<td>9.</td>
<td>Shri A. Senkathir</td>
<td>Deputy Drugs Controller (India)</td>
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<td>10.</td>
<td>Shri. D.K. Chauhan</td>
<td>Asst. Drugs Controller (India)</td>
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<td>Dr. Ravikant Sharma</td>
<td>Asst. Drugs Controller (India)</td>
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<td>Smt. Kavita Sharma</td>
<td>Asst. Drugs Controller (India)</td>
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<td>Dr. D.K. Sable</td>
<td>Asst. Drugs Controller (India)</td>
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<td>Shri Sella Senthil</td>
<td>Asst. Drugs Controller (India)</td>
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<tr>
<td>15.</td>
<td>Mr. Rajesham Pambala</td>
<td>Drugs Inspector</td>
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