MINUTES OF 58TH MEETING (VIRTUAL) OF DRUGS CONSULTATIVE COMMITTEE HELD THROUGH WEB CONFERENCE ON 14TH JULY, 2020 AT CDSCO (HQ)

Inaugural Deliberations

Dr. V.G. Somani, Drugs Controller General (India), Chairman, Drugs Consultative Committee (DCC), welcomed the participants and thanked them for attending the meeting through web conference in wake of COVID-19. He also extended a warm welcome and thanked Dr. Mandeep K. Bhandari, Joint Secretary, MoHFW for his participation in the meeting through online conference in spite of his busy schedule.

Dr. Mandeep Bhandari, Joint Secretary (R), Ministry of Health and Family Welfare, Govt. Of India, in his opening remarks acknowledged the efforts made by Central and State regulatory agencies to maintain the manufacturing and supply of essential medicines by keeping a rigorous daily monitoring of the stocks of essential medicines, seamless supply of KSMs, intermediates excipients to the manufacturing facilities and facilitating production & distribution schedules; to avoid any potential shortage of essential medicines, medical devices, PPE kits, sanitizers, etc in the Country in COVID-19 pandemic situation. He also appreciated the members for taking steps to prevent black marketing of the COVID-19 drugs such as Remdesivir Inj., etc. In light of the few instances reported in the media. He further reminded that uploading of data on SUGAM portal regarding manufacturers and their products has to be completed within short period of time, since the progress made till date is not satisfactory despite several communications by Central Government. Due to the current pandemic situations, he wished all the members to take necessary precautions to stay safe and healthy.

DCG (I) in his address stated that the regulatory approach has been changed to meet the current pandemic situation. He mentioned about various measures taken for ensuring the availability of COVID-19 related critical drugs, medical devices and diagnostic kits for COVID to the consumers/institutions in the Country by way of close coordination with manufacturing industry and distribution channel. He appreciated about the surveys conducted to assess the current production capacity of manufacturing firms as compared to pre COVID production capacity of manufacturing firms, import of the Active Pharmaceutical Ingredients, availability of COVID related drugs like Hydroxychloroquine, Paracetamol, Azithromycin, Methylprednisolone, Dexamethasone, Enoxaparin at retail level, etc. He thanked all the State Drugs Controllers for the extensive support to the Industry by coordinating local administration, police, etc to continue the manufacturing operations and facilitate the supplies including interstate movements, which otherwise was prohibited due to lockdown situations. He acknowledged the contributions made by the SDCs in various manufacturing and availability surveys of essential medicines including critical drugs for COVID-19 across country to avoid potential shortages. He further updated the Committee about recent regulatory developments in the Country in the light of COVID-19 situations and various steps to promote early research of drugs/vaccines in the country.

Many States have lauded the steps taken by Central Government to combat prevailing pandemic situation and appraised the committee with steps taken by their respective Governments.

Thereafter, DCC deliberated the agenda items one by one. The details of agenda and recommendations are as under:

AGENDA No.1

CONSIDERATION FOR APPROVAL OF REPORT OF 57TH MEETING OF DCC HELD ON 20.08.2019 AND ACTIONS TAKEN IN THE MATTERS ARISING OUT OF THE MEETING

While deliberating Action Taken Report of the 57th meeting of DCC,

(i) State Drug Controller, Haryana raised for discussion on the Point No.1 of Action Taken Report (ATR) for which an advisory has been issued by CDSCO on 09.08.2019 with respect to labelling requirements for combi kit of Misoprostol and Mifepristone tablets for Medical Termination of Pregnancy (MTP). In this regard he requested that instead of labelling requirements a restriction should be imposed that the wholesalers shall supply the kits only to the recognised centres to prevent the misuse of this kit in line with the provisions of MTP Act 2002 & MTP Rules 2003. DCC after deliberation considered the points for further deliberation in totality to take a balanced view on the restriction to prevent misuse and ensure availability of the drug.

(ii) Members of the committee have raised their concerns regarding the safety measures to the drugs regulators engaged in the enforcement activities of drugs and cosmetics act, 1940 and rules made thereunder.

DCC recommended to issue a letter from DCG(I) to all State Authorities to look into the matter positively.

(iii) The committee deliberated Point No.8 of the ATR that if a provision can be made so that mfg license no. granted under Drugs and Cosmetics Rules, 1945 can be used for Medical Devices Rules (MDR), 2017 after MDR come into effect. Committee felt further detailed deliberation on the matter.

AGENDA No. 2

CONSIDERATION OF THE PROPOSAL FOR PROHIBITION OF ACECLOFENAC FOR VETERINARY USE FOR SAVING VULTURES

DCC was apprised that, Principal Scientist & Deputy Director, BNHS, Vulture Conservation Breeding Centre, B-3, Forest Complex, Pinjore, Panchkula, Haryana has given a research note on 'Metabolism of Aceclofenac in cattle to Vulture-killing Diclofenac'. Earlier Government of India has prohibited 'Diclofenac and its formulations for animal use' vide notification No. G.S.R 499 (E) dated 04th July, 2008 and permitted

'Diclofenac injection for human use shall be in single unit dose pack only' vide notification No. G.S.R 558(E) dated 17th July, 2015. In view of this, Vulture Conservation Breeding Centre has requested the appropriate action in this matter for prohibition of Aceclofenac for veterinary use for saving vultures.

Committee was also apprised that, in its 56th meeting deliberated the matter and recommended that Drugs Controller, Haryana may write letter to Principal Scientist & Deputy Director, BNHS, Vulture Conservation Breeding Centre to provide detailed supporting scientific data in this regard for further action.

Accordingly, upon request said research paper has been received and kept for review of the committee. Drug Controller, Haryana has apprised the committee on how the Aceclofenac and Diclofenac are posing problems for the survival of vultures leading to the environmental issue due to the dead forest animals, since vultures are the Scavenger and thus protecting the environment from dead animals. By banning the said drug, committee shall be contributing the "Swatchha Bharat Abhiyaan" by Hon'ble PM of India.

DCC, examined the issue and after detailed deliberation, recommended for making provisions in the rules for prohibition of Aceclofenac for veterinary use to save vultures and to contribute the "Swatchha Bharat Abhiyaan" by Hon'ble PM of India.

AGENDA No. 3

CONSIDERATION OF THE PROPOSAL OF REPRESENTAION FROM HON'BLE MP(LS), DATED 02.10.2019 REGARDING DIAGNOSIS OF PHARMACIST PROBLEMS ARISING IN BIHAR

DCC was apprised that, a representation by Hon'ble MP (Lok Sabha), requesting to look into the issue of non-availability of registered pharmacists in the retail stores of medicines in Bihar was received.

In the representation, issue were raised regarding several concerns with respect to the non-availability of the registered pharmacists in Bihar and has requested to provide relaxation in qualification of the registered pharmacists for the persons who are having the experience in selling of medicines in his own retail stores.

DCC deliberated the issue thoroughly and observed that there are abundant registered pharmacists in the country who are in the need of the job, lakhs of pharmacists are coming out every year to serve the profession, there are numerous and sufficient pharmacy colleges in the country including Bihar and the number is increasing every year. Also the crucial and critical role of pharmacist has been deliberated during dispensing of medicines, who counsels the patients on Dosage, Administration, Drug Safety, Adverse effect, Allergies or reactions and the response by patients to such conditions etc.. This critical role cannot be fulfilled by the non-pharmacy persons due to

their inherent lack of knowledge on medicines, pharmacology and toxicology. By considering the issue holistically, DCC did not agree for relaxation in qualification for the registered pharmacists for the persons who are having the experience in selling of medicines in his own retail stores.

AGENDA No. 4

CONSIDERATION OF THE PROPOSAL REGARDING FORMULATION OF GUIDELINES FOR LABELLING OF PERFORMANCE ENHANCING DRUGS (DOPING DRUGS)

DCC was apprised that, a representation has been received by this office wherein it is requested that the list of doping drugs which are banned by World Anti-Doping Agency (WADA) and National Anti-Doping Agency (NADA) should be made available to the public, teachers, parents, students, sports persons, doctors etc. for their knowledge and to further distinguish these drugs from others either by “Orange line” or any other colour line or marking with “D” or “Doping drugs” etc. should be done on the label for easy and convenient identification, so that these drugs should not be used without medical supervision/advice.

DCC was also apprised about opinion of the industry associations/representatives on the labelling of Performance enhancing drugs (Doping drugs) during the virtual meeting held on 23.06.2020 by CDSCO and shared the minutes of the meeting, wherein the industry was not in favour of such labelling stating that the issue is not related to labelling but an awareness by the coaches or parents etc. should suffice along with strict enforcement of the sale provisions of such prescription drugs.

DCC after detailed deliberation did not agree for the labelling changes to distinguish performance enhancing drugs (doping drugs) from other drugs. Committee also opined that sale of these drugs are regulated under Schedule H and Schedule H1 of the Drugs and Cosmetics Rules, 1945 and required to be sold at retail stores only on the prescription of Registered Medical Practitioner.

AGENDA No. 5

CONSIDERATION OF THE PROPOSAL REGARDING PROBLEM FACED BY THE BLIND OR VISUALLY IMPAIRED PEOPLE TO READ MEDICINES TABLETS/CAPSULES STRIPS

DCC was apprised that, a representation has been received by this office, wherein the problem faced by visually impaired people in reading the strips of tablets is highlighted. It was mentioned that strips of the tablets or capsules are not available with information in Braille and hence difficult to identify by the visually impaired people. The printed matter on such drugs has very small font and has poor legibility which even poses difficulty to the persons having normal vision. At present, there is no labelling provision in the Drugs

and Cosmetics Act and Rules, which take into consideration the needs of the blind or visually impaired people. As a result these special category of people face difficulty to know the name and expiry date of the medicines. Hence, requested that a provision shall be made to label the drugs with Braille inscriptions.

DCC was also apprised that, this matter was deliberated with the industry stakeholders in a virtual meeting held on 23.06.2020 to devise a mechanism in this regard. Industry submitted that it is difficult to provide necessary information on the label of medicines in Braille due to space constraints. Further, industry submitted that it is not aware whether internationally such practices are adopted and at this stage such proposal is difficult to accept.

After thorough deliberation, DCC recommended for constituting a sub-committee to examine the issue in detail for its further consideration.

AGENDA No. 6

CONSIDERATION OF THE PROPOSAL FOR AMENDMENT OF RULE 85, RULE 66 & RULE 74, RULE 64 OF DRUGS & COSMETICS ACT, 1940 REGARDING CANCELLATION OF LICENSES FOR VIOLATING DRUG PRICE CONTROL ORDER (DPCO), 2013 WITH RESPECT TO OVERCHARGING OF PRICES OF DRUGS/ MEDICINES

DCC was apprised that, Parliament Standing Committee in its 54th Report on the subject 'Pricing of Drugs with special reference to Drugs (Prices Control) Order, 2013' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated that for violation of Drug Price Control Order (DPCO), 2013 with respect to overcharging, the National Pharmaceuticals Pricing Authority had issued various Demand Notices but the actual amount recovered from manufacturing firms is too meagre in comparison to the amount due to be recovered.

In this regard, the Committee strongly recommended that if the manufacturer do not deposit the demanded amount within the prescribed time limit given by NPPA, cancellation of licenses of such companies to manufacture that medicine/drug may be considered. Similar action may also be taken on retailers who indulge in overcharging of drugs/ medical devices.

Earlier, the DTAB in its 82nd meeting held on 02.04.2019 deliberated and denied the said proposal. However, based on the action taken submitted by the Government on the recommendations of 54th PSC, the Parliamentary Standing Committee recommended that the relevant provision of DPCO, 2013 and Drugs & Cosmetics Rules, 1945 should be revisited by the Ministry of Health & Family Welfare and necessary action should be taken for the amendment of these orders/ Acts/ Rules so as to make these provisions more stringent and effective.

DCC deliberated the issue and did not agree to the proposal due to the lack of the enabling power in the Drugs and Cosmetics Act to regulate the prices of medicines, as its objective is to regulate the import, manufacture, distribution and sale of drugs and cosmetics in the country.

AGENDA No. 7

CONSIDERATION OF THE PROPOSAL EXAMINATION OF THE NEED FOR CONTINUING WITH THE NOTIFICATION: G.S.R. 144(E) DATED 17.02.2017

DCC was apprise that, the Government of India has issued a Gazette notification vide G.S.R. 677(E) dated 15.09.2009 (copy enclosed) under Section 26B of the Drugs & Cosmetic Act, 1940 and restricted that, the manufacturing and sale of the drugs 'Oseltamivir Phosphate' and 'Zanamvir' should follow the conditions as specified for Schedule X to the Drugs and Cosmetics Rules, 1945 and permission from the Central Government is required to be given each time for the export of these drugs.

Subsequently, the matter was deliberated by the Drugs Technical Advisory Board (DTAB) in its 68th meeting held on 15.02.2016 and 74th meeting held on 15.11.2016, recommended that the Gazette notification G.S.R. 677(E) dated 15.09. 2009 may be withdrawn and notification under Section 26B of the Act permitting the sale of the drug with conditions as applicable for Schedule H1 Drugs keeping all other conditions same in that notification may be issued.

Accordingly, the Government of India has issued a Gazette notification vide G.S.R. 144 (E) dated 17.02.2017 under Section 26B of the Drugs & Cosmetic Act, 1940 and restricted that, the manufacturing and sale of the drugs 'Oseltamivir Phosphate' and 'Zanamvir' should follow the conditions as specified for Schedule H1 to the Drugs and Cosmetics Rules, 1945 and permission from the Central Government is required to be given each time for the export of these drugs.

In this regard, DCC examined the issue of continuing the notification especially in respect of requirement of NOC from DCG(I) for manufacture of the drugs for domestic as well as for export purpose in the current context.

After detailed deliberation, considering the matter in current context, DCC recommended for revoking the notification, G.S.R. 144(E) dated 17.02.2017. Further, Committee also recommended that these drugs should be notified under Schedule H1 of the Drugs and Cosmetics Rules, 1945 for their sale regulation in the Country.

AGENDA No. 8

CONSIDERATION OF THE PROPOSAL REGARDING FORMULATION OF REGULATORY GUIDELINES FOR EFFECTIVE ADMINISTRATION OF CARBETOCIN SOLUTION FOR INJECTION 100 mcg/mL IN AMPOULE / VIAL

DCC apprised that, a representation received from the Ministry regarding formulation of regulatory guidelines for effective use of Carbetocin as this issue was raised under Rule 377 dated 19.07.2018 in Lok Sabha by Smt. Poonam Mahajan M.P.

CDSCO after consultation with Subject Expert Committee (SEC)-Reproductive & Urology, in its meeting held on 15.10.2019 and reviewing the application for the grant of permission to manufacture and marketing of Carbetocin solution for injection 100 mcg/ml ampoule/vial recommended to grant the sought permission. Further, as desired by the ministry, a regulatory guideline for effective use of the drug in the country was prepared and approved by the said SEC.

These guidelines were placed before the DCC for its review and approval.

DCC after examination, agreed for the guidelines finalized by SEC of CDSCO for effective administration of Carbetocin solution for injection 100 mcg/ml in ampoule / vial as per the Drugs and Cosmetics Rules,1945. The guidelines shall be made available to the stakeholders.

AGENDA No.9

CONSIDERATION OF THE PROPOSAL TO AMEND DRUGS AND COSMETICS RULES, 1945 REGARDING THE QUALIFICATION OF TECHNICAL SUPERVISOR AND BLOOD CENTRE TECHNICIANS IN BLOOD CENTRES

DCC was apprised that, a letter was issued by then Drug Controller General (India) in 2005 to Joint Commissioner, Maharashtra and copy to all State Licensing Authorities as well as all Zonal and Sub-Zonal office of CDSCO, on subject “Qualification of ex-serviceman to be recognized as technician in Blood banks”.

The blood centre technicians and technical supervisors serving in Defence Services have done BTA class I to III course. There are large number of technicians in the Defence Services, those have done BTA class III/II/I, Diploma in Blood Transfusion Techniques (DBTT) courses in accordance with Defence Services Qualification Regulation,1958 and have adequate experience of working in military hospitals. Although having technical knowledge and experience, at many occasions, they are facing difficulty to prove that their qualifications are at par with DMLT/BMLT.

However, the qualification viz. BTA class III/II/I and DBTT (in accordance with defence services qualification regulation 1958) is not mentioned in Schedule F part XIIB of Drugs and Cosmetics Act, neither in Rule 122G (where qualification of Medical officer is

mentioned). Also, it was not included in recent GSR 166(E) dated 11 March 2020, where qualification of the technician and technical supervisor and experience is mentioned.

In this regard it was proposed to amend the Rule 122G or Schedule F XIIB or any other place or any suitable action deemed fit. DCC after detailed deliberation agreed for the proposal.

AGENDA No. 10

(CONSIDERATION OF THE PROPOSALS FROM STATE OF MAHARASHTRA)
AMENDMENT OF PART VIII OF THE DRUGS AND COSMETICS RULES, 1945 TO INCLUDE PROVISIONS FOR LOAN LICENSEES FOR MANUFACTURE OF DRUGS FOR EXAMINATION, TEST OR ANALYSIS IN FORM 29:

The applicants have to submit 06 months stability data prior to product approval. However there is no specific provision for grant of licence to manufacture of drugs for examination, test or analysis in Form 29 for loan licensees. The provisions of Part VIII of the Drugs and Cosmetics Rules, 1945, in Rule 86 to Rule 93 may be amended suitably.

DCC after detailed deliberation clarified that there is no bar under the Drugs and Cosmetics Rules, 1945 for granting the Form 29 for loan licensees as per the Drugs and Cosmetics Rules, 1945.

AGENDA No.11

(CONSIDERATION OF PROPOSALS FROM UNION TERRITORY OF JAMMU & KASHMIR)
CONSIDERATION OF PROPOSAL FOR INCORPORATION OF STATUTORY FORMS FOR CLASS C AND CLASS D MEDICAL DEVICES

A) DCC was apprised that, Medical Device Rules framed vide G.S.R. 78(E) , Notification dated 31.01.2017 , under Chapter III “AUTHORITIES, OFFICERS AND BODIES” provides that “ The State Drugs Controller, by whatever name called, shall be the State Licensing Authority and shall be the competent authority for enforcement of these rules in matters relating to,-
(i) manufacture for sale or distribution of Class A or Class B medical devices;

(ii) sale, stock, exhibit or offer for sale or distribution of medical devices of all classes.

The said rules does not make any mention of provisions related to sale, stock, exhibit or offer for sale or distribution of medical devices of all classes viz. Statutory forms as provided for manufacture for sale or distribution of Class A or Class B medical devices.

DCC after detailed deliberation stated that as per the Section 3b(iv) of the Drugs and Cosmetics Act, 1940, all medical devices are defined as drugs. Hence, sale of all classes of medical devices viz. Class A, Class B, Class C and Class D can be regulated by the

State Licensing Authority. Hence, there is no requirement for the separate Statutory Forms.

B) DCC was apprised that, Rule 71 (8) / 76 (9) of Drugs & Cosmetics Rules , 1945 provides for grant of Product License in proper name only for a formulation containing single active ingredient only. A further clarification is required whether Product Licenses granted for formulations containing more than one active ingredient can be endorsed with Brand Names as well as per Form-51details provided by the applicant firm.

DCC after detailed deliberation opined that there is no explicit provision for approval/endorsement of the brand names along with licenses granted by the licensing authority.

AGENDA No.12

(CONSIDERATION OF PROPOSALS FROM STATE OF WESTBENGAL)

Whether SBTC NOC is required mandatorily for renewal of voluntary organizations and charitable trusts only? As stated in GSR, all hospitals (Government & Private) and Red Cross Society do not require submitting NOC from SBTC.

DCC after detailed deliberations clarified that SBTC NOC for grant/ renewal of license is required for blood centre run by Charitable Trust or Voluntary Organization only. Further, for renewal, it includes renewal of such licenses which are granted after 21.12.2005.

ADDITIONAL AGENDA No. S-1

CONSIDERATION OF PROPOSAL FOR CREATION OF DRUG DISPOSAL POLICY FOR PUBLIC AND SUPPORT FOR PHARM ECOVIGILALNCE

DCC was apprised that a letter received from AIIMS referred an article contains the study aimed to assess the extent of exposure of Active Pharmaceutical Compounds (APCs) in the hydrologic cycle in and around New Delhi. This study analyzed the presence of 28 drugs from different classes in the surface water. The study further revealed that apart from therapeutic usage main source of ecological exposure could be due to the disposal of unused and expired pharmaceutical compounds into landfills. It revealed the existence of antimicrobial agents and other APCs in the aquifers of Delhi with levels >0.1µg/L. Placement of appropriate strategies is expected to reduce the burden of APCs and other pollutants into hydrologic cycle.

It has also been stated that un-segregated drug disposal could be a reason for the emergence of drug resistance with special reference to antibiotics. Hence, drug disposal policy for public and hospitals where people can dispose used, unused, expired drugs and drug formulation safely is required.

After detailed deliberation, DCC recommended for constituting a sub-committee under chairmanship of State Drugs Controller, Kerala to examine the issue.

ADDITIONAL AGENDA S-2

CONSIDERATION OF PROPOSAL ON MEASURES NEED TO BE TAKEN FOR STRONG IMPLEMENTATION OF THE PROVISIONS OF THE DRUGS AND COSMETICS RULES, 1945 TO ENSURE THAT NO DRUGS INCLUDING ANTIBIOTICS IN SCHEDULE H & H1 ARE SOLD BY RETAIL WITHOUT PRESCRIPTION OF RMP

Antimicrobial Resistance (AMR) is an increasingly serious threat to public health. Concerns have been raised from time to time regarding sale of prescription drugs by retail without prescription of Registered Medical Practitioners (RMP).Ministry of Health and Family Welfare in consultation with various stakeholders developed National Action Plan on AMR (NAP-AMR), which was officially released on 19.04.2017.

The NAP-AMR outlines the priorities and interventions planned which consider harmonized approach across various sectors to address the use of and resistance to antimicrobial agents in human health, agriculture, food products and the environment including certain strategic priorities as below. The priorities related to drug regulation are as under:

I. Strengthen and enforce regulations to minimise the sub standards, spurious, falsely labelled and falsified antimicrobials..

II. Strengthen legislation to regulate prescription and dispensing of antimicrobials.

III. Identify additional regulatory interventions or support needed to effectively implement Schedule H1 and X restrictions.

IV. Ensure prescription sale of antibiotics and their use under supervisions; regulate bulk selling, importation and labelling for species specific use.

Therefore, effective measures are required for strong implementation of the provisions of the Drug & Cosmetics Rules to ensure that no drugs including antibiotics in Schedule H & H1 are sold by retail without prescription of RMP.

After detailed deliberation, DCC felt its absolute necessity for strong implementation of the provisions of the Drug & Cosmetics Act, 1940 and Rules to ensure quality, safety and efficacy of drugs including antibiotics sold in the Country and also to ensure that no drugs in Schedule H & H1 are sold by retail without prescription of RMP.

ADDITIONAL AGENDA S-3

RECOMMENDATIONS OF THE SUB-COMMITTEE CONSTITUTED BY THE DRUGS CONSULTATIVE COMMITTEE (DCC) FOR CLARIFICATION ON EXEMPTION OF DETTOL ANTISEPTIC LIQUID (CLOROXYLENOL, TERPINEOL AND ALCOHOL) AS ANTISEPTIC LIKE THAT OF DISINFECTANT IN THE COUNTRY UNDER SCHEDULE K (RULE 123) OF DRUGS AND COSMETICS RULES 1945 AND IDENTIFY SUCH SIMILAR TYPE OF PRODUCTS

The Drugs Consultative Committee in its 55th meeting held on 31.01.2019 & 01.02.2019 has constituted a sub-committee for clarification on exemption of Dettol antiseptic liquid (cloroxylenol, terpineol and alcohol) as antiseptic and disinfectant in the country under Schedule K (Rule 123) of Drugs and Cosmetics Rules 1945 and identify such similar type of products and give its recommendations.

The sub-committee was constituted vide Office Memorandum vide X-19013/04/2018-DC (1) dated 20.02.2019 & 05.03.2019, under the chairmanship of Shri. N.K.Ahooja, Drugs Controller, Haryana.As per the terms of reference, the Sub-committee in its meeting held on 26.07.2019 invited the representatives from (1) M/s. Reckitt Benckiser (Manufacturer of Dettol antiseptic liquid) (2) M/s. ITC Limited (Manufacturer of Savlon antiseptic liquid), both leading manufacturers for antiseptic liquids to offer their views.

After consideration of the available technical and legal information and detailed deliberations the sub-committee submitted its report for DCC review and deliberations.

DCC after detailed deliberation, it was observed that there are numerous such products in the market which the sub-committee did not evaluated due to its specific mandate on three products only. Hence DCC suggested that the scope of the sub-committee shall be revised and broadened to relook the matter for examination all the available liquid antiseptic solutions in the market.

NOTE: ANNEXURE-A: List of Participants

ANNEXURE-A

List of the participants of 58th Drugs Consultative Committee meeting held on 14.07.2020 under the Chairmanship of Dr. V.G. Somani, Drugs Controller General (India) Via Web Conference

A. STATE/UT DRUGS CONTROL ORGANIZATIONS

S. NO.	STATE/UT	NAME	DESIGNATION
1.	Andhra Pradesh	Not represented	
2.	Arunachal Pradesh	Not represented	
3.	Assam	Not represented	
4.	Bihar	Shri. Ravindra Kumar Sinha	State Drugs Controller
5.	Chhattisgarh	Not represented	
6.	Goa	Smt. Jyothi Sardesai	Director, FDA
7.	Gujarat	Dr. H.G. Koshia	Commissioner, FDCA
8.	Haryana	Shri. N.K. Ahooja	State Drugs Controller
9.	Himachal Pradesh	Shri. Navneet Marwaha	Drugs Controller
10.	Jammu and Kashmir	Shri. Lotika Khajuria	State Drugs Controller
11.	Jharkhand	Smt. Ritu Sahay	Director (Drugs)
12.	Karnataka	Shri. Amaresh Tumbagi	State Drugs Controller (A/C)
13.	Kerala	Sri.K.J.John	State Drugs Controller(I/C)
14.	Madhya Pradesh	Shri. Shobhit	Dy. Drugs Controller, FDA
15.	Maharashtra	Shri. Jugalkishore Mantri	Joint Commissioner
16.	Manipur	Shri. N. Rimot Kumar Meetei	Addl. State Drugs Controller
17.	Meghalaya	Not represented	
18.	Mizoram	Pu F.Lalliantluanga	Dy. Director
19.	Nagaland	Not represented	
20.	Odisha	Smt. Mamina Patnaik	State Drugs Controller (I/C)
21.	Punjab	Not represented	
22.	Rajasthan	Shri. Raja Ram Sharma	Drugs Controller
23.	Sikkim	Dr. T.K. Rai	Joint Drugs Controller
24.	Tamil Nadu	Shri. Sivabalan	Director (Drugs)
25.	Telangana	Dr. Y. Naveen Kumar	Joint Director, DCA
		Dr. B. Venkateswarlu	Deputy Director, DCA
26.	Tripura	Not represented	
27.	Uttar Pradesh	Shri A.K. Gupta	Assistant Commissioner (Drugs)
28.	Uttarakhand	Not represented	
29.	West Bengal	Mr. Tarapada Das	Director of Drugs Control
30.	Andaman and Nicobar	Not represented	
31.	Chandigarh	Shri. Amit Duggal	Sr. Drug Control Officer

S. NO.	STATE/UT	NAME	DESIGNATION
32.	Dadar and Nagar Haveli	Not represented	
33.	Daman and Diu	Not represented	
34.	Delhi	Shri. Atul Kumar Nasa	DDC & Controlling Authority
		Shri. K R Chawla	Asst. Drugs Controller
35.	Lakshadweep	Not represented	
36.	Pondicherry	Not represented	

B. INVITEE

S. No.	NAME	DESIGNATION
1.	Dr. Mandeep Kumar Bhandari	Joint Secretary, MoHFW

C. ZONAL/ SUB ZONAL OFFICES OF CDSCO

S. No.	OFFICES	NAME	DESIGNATION
ZONE			
1.	North Zone, Ghaziabad	Shri. Aseem Sahu	Deputy Drugs Controller (India)
2.	East Zone, Kolkata	Not represented	
3.	West Zone, Mumbai	Dr Rubina Bose	Deputy Drugs Controller (India)
4.	South Zone, Chennai	Smt. Shanthy Gunasekaran	Deputy Drugs Controller (India)
5.	Hyderabad Zone	Smt. A.Visala	Deputy Drugs Controller (India)
6.	Ahmedabad Zone	Shri. Jayant Kumar	Deputy Drugs Controller (India)
SUB ZONE			
1.	Baddi Sub-zone	Shri. B.K. Samantray	Deputy Drugs Controller (India)
2.	Bangalore Sub-zone	Dr. B. Kumar	Deputy Drugs Controller (India)
3.	Guwahati Sub-zone	Shri. A. Senkathir	Deputy Drugs Controller (India)
4.	Indore Sub-zone	Shri. Sunil M Joshi	Asst. Drugs Controller (India)
5.	Varanasi Sub-zone	Shri. Vinay Kumar Gupta	Asst. Drugs Controller (India)
6.	Jammu Sub-zone	Not represented	
7.	Goa Sub-zone	Shri. Surender Kumar Kaswan	Drugs Inspector

D. CDSCO HEAD QUARTER

S. No.	NAME	DESIGNATION
1.	Dr. V. G. Somani	Drugs Controller General of India
2.	Dr. S. Eswara Reddy	Joint Drugs Controller (India)
3.	Dr P.B.N. Prasad	Joint Drugs Controller (India)
4.	Dr. K Bangarurajan	Advisor
5.	Shri. A.K. Pradhan	Deputy Drugs Controller (India)
6.	Dr. S. Manivannan	Deputy Drugs Controller (India)
7.	Dr. S.P. Shani	Deputy Drugs Controller (India)
8.	Shri. R. Chandrashekhar	Deputy Drugs Controller (India)
9.	Shri. Sanjeev Kumar	Deputy Drugs Controller (India)
10.	Ms. Swati Srivastava	Deputy Drugs Controller (India)
11.	Shri. B.K. Samantray	Deputy Drugs Controller (India)
12.	Dr. Ravikant Sharma	Deputy Drugs Controller (India)
13.	Dr. Santosh Indraksha	Asst. Drugs Controller (India)
14.	Dr. Rikta Saha	Asst. Drugs Controller (India)
15.	Sh.Y K Shelar	Asst. Drugs Controller (India)
16.	Sh. Pramod M Patil	Asst. Drugs Controller (India)
17.	Shri. Suresh Kumar Kalwania	Drugs Inspector
18.	Shri. Shivadev D	Drugs Inspector
19.	Shri. Asheesh Kaundal	Drugs Inspector
20.	Shri. Gunda Raghuvaran	Drugs Inspector
21.	Shri. Rajesham Pambala	Drugs Inspector

E. DRUG TESTING LABORATORIES

S. No.	OFFICES	NAME	DESIGNATION
1.	CDL, Kolkata	Shri. C. Hariharan	Director/In-Charge
2.	CDL, Kasauli	Dr. ArunBhardwaj	Director
3.	CDTL, Mumbai	Dr. Raman Mohan Singh	Director
4.	RDTL, Chandigarh	Dr. R.A. Singh	Director
5.	RDTL, Guwahati	Dr. Parthajyoti Gogoi	Director

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