# MINUTES OF 56TH MEETING OF DRUGS CONSULTATIVE COMMITTEE HELD ON 01ST JUNE, 2019 AT NEW DELHI

## Inaugural Deliberations

Before starting the proceedings of the meeting the members observed two minutes silence to express condolence over the death of Ms. Neha Shoree, Drugs Inspector, FDA, Punjab and Mr. Rahul S. Shakhapure, ADC(I), CDSCO (HQ).

Dr. S. Eswara Reddy, Drugs Controller General (India), Chairman, Drugs Consultative Committee (DCC), welcomed the participants and thanked them for attending the meeting at a very short notice. He also extended a warm welcome and thanked Dr. Mandeep K. Bhandari, Joint Secretary, MoHFW for his presence in the meeting in spite of his busy schedule. DCG (I) in his address stated that the DCC, a statutory body, has been very active in deliberation of various agenda of national importance for continuous strengthening of drug regulatory system in the country. He emphasized the need for effective implementation of the provisions related to requirements of BA/BE study and Stability Study for ensuring Quality of the drugs manufactured in the country. He also stressed the need of continuous upgradation of knowledge & skill of the regulators in light of scientific and technological advancement in the field of pharmaceutical science. Keeping this in view CDSCO & Ministry has started nominating the State regulators to participate at various international conferences. DCG(I) then requested Dr. Mandeep K. Bhandari, Joint Secretary to address the gathering.

The Joint Secretary in his remarks highlighted the importance of this forum where diverse problems of each State in drug regulation are deliberated and it brings the experiences from across the country at one place. He opined that Hon'ble courts also take the cognizance of deliberations of this forum while addressing the various court cases related to drug regulation. He stated that the deliberations and outcomes of this forum goes for policy decisions at the higher levels of the Government. DTAB also consider many issues based on deliberation in this forum.

While emphasizing various measures for ensuring quality of drugs, he complimented the members that all the State Licensing Authorities are implementing the requirement of BA/BE and Stability studies in the process of granting manufacturing licenses of the drugs. He also stated that we should work together as a nation to strengthen the drug regulatory system so that in days to come, we become one of the stringent regulatory authorities in the world. He stressed upon the need to implement the regulatory provisions in letter and spirit to ensure quality of the drugs manufactured and marketed in the country.

Thereafter, he addressed the members on following specific issues.

1) **State Level Committees for compensation in case ASR implant of Johnson and Johnson:**

   He emphasized that all the states should constitute the state level committees for ASR implant issue with State Drugs Controller as member secretary to identify the patients who have undergone the revision surgery and to forward such cases to the central committee for examination. He also apprised the

members that Hon'ble Delhi High Court has given an interim order for giving compensation of ₹ 25 lakhs for such cases. As on date, 67 cases were identified and there are still many cases yet to reach CDSCO. He requested all the members to put extra miles and efforts to ensure that such patients are given the compensation as per the procedures and we must not lose this opportunity to help out the patients.

2) **Central Data base for manufacturing licenses and drug products**

While mentioning the importance of creating a comprehensive data base of the licenses and drug products, the Joint Secretary requested the members to put all efforts to ensure that such data are uploaded in the SUGAM portal as per mandatory requirement under the Rule 84AB of the Drugs and Cosmetics Rules, 1945. He expressed concerns regarding slow progress on uploading the information. He mentioned that the State Drug Controllers should discuss with the industry associations in the matter and ensure that such information is uploaded within a stipulated time line. After interaction with the State Drug Controllers, it was agreed that uploading of the information should be completed by end of this month i.e., 30.06.2019.

**3) Common platform for online submission and processing of applications:**

While discussing the status of development of software providing a common platform for online submission and processing of applications for grant of various licenses by all the State Licensing Authorities, the Joint Secretary requested the members and CDSCO to complete the development process at the earliest. After detailed discussion it was decided that the software should be developed and made operational on 1$^{st}$ July 2019.

**4) Enforcement activity to prevent misuse of Oxytocin:**

While discussing the issue of Oxytocin, he stressed upon the need of continuous enforcement activities to prevent its misuse. He requested the members to adopt appropriate mechanism in the respective states for strong vigil and continuous enforcement activities to prevent the illegal import, manufacture and sale of oxytocin in the country. He also emphasized that Oxytocin, being an essential medicine for induce labor, should be available in every nook and corner of the country. He requested the members to take all measures to ensure availability of the medicine.

**5) Strengthening of Indian Drug Regulatory System:**

He mentioned that under the scheme of "Strengthening the State Regulatory System", so far funds have been provided to around 26 States/UTs. Other States/UTs are yet receive any funds due to either non submission of their proposal or not signing the MOU. He stated that the State Drug controllers should follow up and sensitize their government for expediting the process under the scheme so that the fund could be provided to the remaining states at the earliest. He also mentioned that the funds provided should be utilized for the

intended purpose only. There may be third party evaluation about utilization of the funds in those states who have received it.

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 55TH MEETING OF DCC HELD ON 31.01.2019 & 01.02.2019 AND ACTION TAKEN IN THE MATTERS ARISING OUT OF THE MEETING

DCC agreed the Action Taken Report of the 55th meeting of DCC.

## AGENDA NO. 2

## PROPOSAL FROM STATE OF HARYANA

## CONSIDERATION OF THE PROPOSAL THAT THE ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS) INCLUDING E-CIGARETTES (EC), HEAT NOT BURN DEVICES, VAPE, E-SHEESHA, E-NICOTINE FLAVOURED HOOKAH AND THE LIKE DEVICES THAT ENABLE NICOTINE DELIVERY ARE COVERED UNDER THE DEFINITION OF 'DRUG' UNDER THE DRUGS AND COSMETICS ACT, 1940

DCC deliberated that Electronic Nicotine Delivery Systems (ENDS) are devices that heat a solution to create an aerosol, which contains nicotine and frequently many other chemical flavours, dissolved usually in a solvent of Propylene Glycol and/or Glycerin. ENDS come in different glamorous shapes and sizes. ENDS do not burn or use tobacco leaves but instead heat to vaporise a solution, which the user then inhales. The main constituents of the solution, in addition to nicotine when nicotine is present (which is usually the case), are multiple flavouring agents dissolved in propylene glycol with or without glycerol. ENDS solutions and emissions, therefore, contain chemicals, many of which are common with traditional tobacco and of known toxicity and several others which are being subjected to studies. Although ENDS is generally talked of as a single product class, these products constitute a diverse group with potentially significant differences in the production of toxicants and mechanisms for delivery of nicotine. A typical ENDS user therefore, uses these devices that heat a solution to create an aerosol, which frequently contains nicotine and other numerous flavours usually dissolved into propylene glycol and/or glycerin.

There are various types of ENDS, the most common being what is known as electronic cigarettes or E-cigarettes. Therefore, e-cigarettes can resemble like traditional tobacco products like cigarettes, cigars, pipes or common gadgets like flashlights, flash drives/pen-drives or pens. Currently, there are more than 460 different e-cigarette brands with varied configuration of nicotine delivery (first generation or so-called cigar likes, second- generation tank systems and even larger third-generation or personal vaporisers) available in the market with over 7,700 flavours.

The state Government of Punjab, Haryana and Union Territory of Chandigarh have declared/ notified ENDS or e-cigarettes as an unapproved drug under the Drugs and Cosmetics Act and Rules, 1945 and have commenced prosecutions of sellers of ENDS under the Drugs and Cosmetics Act, 1940.

The Food & Drugs Administration, Haryana has taken action after conducting raids and collected samples of above mentioned products considering these products as un-approved drugs manufactured without licence and launched 37 prosecutions in the competent Courts of Hon'ble Chief Judicial Magistrates of various districts. These actions taken reports were submitted by the Department of Food & Drug Administration, Haryana, in the matter of Public Interest Litigation of Burning Brain Society Vs. Union of India CWP No. 14597 of 2007 and Hon'ble High Court never objected to this action taken by the Department. Rather, as mentioned above, recently, the Hon'ble Punjab and Haryana High Court in CRM-M-39328-2015 + 16 other connected cases vide its order dated 06.03.2019 has dismissed the petitions which were filed to quash the order of summoning the traders/ manufacturers of ENDS from different districts of Haryana. The petitioners had contended that they were dealing with the product Hookah, Molasses and it can't be treated as drug and can't fall under the purview of the D&C Act. The petitioners also contended that they had a valid licence for Tobacco and they are not required to have a manufacturing licence for drugs. The Hon'ble High Court after going through the issue in detail did not agree with their contention and dismissed the case. Also, some court case is ongoing on this issue before the Delhi High Court and the Hon'ble Court had passed various orders in this regard.

In another case, State through DCO, Gurugram Vs Sh. Parkash Chandi Verma Manager & Sh. Rahul Yadav owner of M/s Kasba pool Snooler Snaks point, M-28, Basement, Opposite of Bank of India, Old DLF Colony, Gurgaon, Chief Judicial Magistrate, Gurugram vide order dated 20.01.2017 convicted the accused persons and sentenced the convict for Rigorous Imprisonment (RI) for a period of three years and a fine of Rs. One Lakh.

The State of Haryana has also notified 'Nicotine in its pure chemical form' as 'Poison' vide notification No. S.O.152/C.A.12/1919/S.2 and 8/2015 dated 15.10.2015 at S. No. 20 under the Poisons Act. Also, the State Governments of Karnataka, Kerala, Mizoram, Maharashtra, Jammu & Kashmir, Uttar Pradesh and Bihar have issued necessary orders banning the manufacture, distribution and sale of e-cigarettes as unapproved drug, under the Drugs and Cosmetics Act, 1940.

The Government of India had on 28.08.2018 issued an Advisory on Electronic Nicotine Delivery System (ENDS) including E-cigarette, Heat-Not burn devices, Vape, e-Sheesha, e-Nicotine, Flavoured Hookah and the like products. This advisory had inter alia advised that in the larger public interest and in order to prevent the initiation of ENDS by non-smokers and youth with special attention to vulnerable groups, to ensure that any ENDS including e-cigarette, Heat-Not burn devices, Vape, e-Sheesha, e-Nicotine, Flavoured Hookah and the like devices that enable nicotine delivery are not sold (including on line sale), manufactured, distributed, traded, imported and advertised in their jurisdiction, except for the purpose and in the manner and to the extent, as may be approved under the Drugs and Cosmetics Act 1940 and Rules made thereunder.

Based on this advisory, the CDSCO on 22.02.2019 had issued letters to all State/ UT Drug Controllers that no Electronic Nicotine Delivery Systems (ENDS) including e-cigarette, Heat-Not burn devices, Vape, e-Sheesha, e-Nicotine, Flavoured Hookah and the like products has yet been approved under the Drugs and Cosmetics Act 1940 and Rules made thereunder and requested them to therefore ensure that any ENDS including e-cigarette, Heat-Not burn devices, Vape, e-Sheesha, e-Nicotine, Flavoured Hookah and the like devices that enable nicotine delivery were not sold (including on line sale), manufactured, distributed, traded, imported and advertised in their jurisdictions.

Standards and specifications of 'Nicotine' have been provided in BP, USP, EP and other Pharmacopeias. 'Nicotine is covered as 'Drug' u/s 3(b) of Drugs Act and licenses to manufacture, COPPs on recommendation of joint inspection team have been found issued to various firms.

Nicotine Chewing gums and Lozenges upto 2 mg of 'Nicotine' are exempted from sale licence under chapter IV of Drugs Act under provisions of schedule-K read with Rule 123 but the formulation can be manufactured only under Drugs manufacturing Licence (added through GSR 549(E) dated 16.07.2003.

Various "Nicotine" preparations such as Nicotine Transdermal Patches 36 mg/78 mg/ 114 mg; Nicotine Lozenges 2mg/4mg with the indication to reduce withdrawal symptoms including nicotine craving associated with quitting the smoking; Nicotine ploacrilex lozenges with the indication to reduce withdrawal symptoms including nicotine craving associated with quitting the smoking and quitting chewed tobacco and guthka containing tobacco are approved by DCG(I) under Drugs and Cosmetics Act and rules made thereunder.

Under the regulation 2.3.4 of the Food safety and Standard (Prohibition and Restrictions on sales) Regulations, 2011 and Act, 2006 clearly prohibits:

*"Product not to contain any substance which may be injurious to health: Tobacco and nicotine shall not be used as ingredients in any food products."*

'Nicotine' is also included in list of insecticides under the Schedule of The Insecticide Act, 1968'

Till now Electronic Nicotine Delivery System (ENDS) including e-Cigarettes, Heat-Not Burn devices, Vape, e-Sheesha, e-Nicotine Flavoured Hookah and the like devices that enable nicotine delivery has not been approved under the Drugs and Cosmetics Act and Rules made thereunder.

ENDS including e-cigarettes are promoted by the industry body as a smoking cessation aid but their efficacy and safety as a quitting aid has not yet been firmly established. Though, some smokers claim to have cut-down smoking while using ENDS, the total nicotine consumption seems to remain unchanged. Moreover, a considerable number of ex-smokers who have reported stopping cigarette use with the aid of ENDS continue using the latter product, thus, sustaining nicotine dependence. There have been various surveys and studies which reported that ENDS is used as a way to obtain nicotine in smoke-free spaces, indicating that ENDS were being used to satisfy nicotine addiction during periods of temporary or forced abstinence.

It was observed that, under the provisions of 'Drugs' in the Drugs and Cosmetics Act, 1940, any product intended to be used as aid for smoking cessation is covered under the definition of drugs and various drugs have been approved as aid for smoking cessation under the provisions of the Drugs and Cosmetics Act, 1940 and Rules made thereunder.

In view of above and after revisiting the earlier deliberations by DCC in its 48th meeting, the DCC recommends that, since Electronic Nicotinic Delivery Systems (ENDS) including e-cigarette, Heat-Not burn devices, Vape, e-Sheesha, e-Nicotine, Flavoured Hookah and the like products are used as a tobacco [especially smoking forms such as cigarettes] cessation product and functions for nicotine delivery for reasons including nicotine de-addiction; hence these devices and products falls under the definition of "drug" as defined under Section 3(b) of the Drugs and Cosmetics Act, 1940.

## AGENDA NO.3

## CONSIDERATION OF THE PROPOSAL OF CONCEPT OF DOSSIER APPROVAL FOR FORMULATION DEVELOPMENT AND FOR GRANT OF MANUFCTURING LICENCE

The Drugs and Cosmetics Rules, 1945 have been amended vide G.S.R. 327(E) dated 03.04.2017 mandating the submission of BA/BE studies for grant of manufacturing licence. As per the GSR 327 (E), applicant shall submit the result of bioequivalence study along with the application for grant of manufacturing licence of oral dosage form of drugs falling under the Category II and Category IV of the Biopharmaceutical Classification System.

The Rules have also been amended vide G.S.R. 360(E) dated 10.04.2018 making it mandatory to submit evidences of stability, safety of excipients, etc. to State Licensing Authority along with application before grant of product manufacturing licenses.

In this context DCC in its 56th meeting held on 01.06.2019 deliberated the concept of the "Dossier Approval" in respect of formulation development data, including stability data and BA/BE data, generated under the valid licence under the Drugs and Cosmetics rules, 1945.

It was deliberated that any person/ institution can develop a drug formulation and can generate dossier of the product development containing detailed data on formulation development, BA/BE study data, stability data, excipients compatibility, etc, and submit to the licensing authority for approval. Once such dossier is approved by licensing authority under Drugs and Cosmetics Rules, 1945, the same may be submitted by a manufacturer under an agreement for technology transfer etc. between the person/institution who has developed the formulation and the manufacturer seeking for grant of manufacturing license for the same product subject to submission of following:

1. Equivalency report showing the similarity of source and specifications of Raw Materials, API & excipients, Packaging Materials Specifications, SOPs, Testing Methods, Manufacturing and Packaging Processes, Equipment Design and Principle, Batch Size and finished product specifications between manufacturers product and the product developed by the person/institution.

2. Comparative evaluation data including Multimedia comparative dissolution profile to show the similarity between the two products.
3. Six Months Accelerated and Long Term stability data for the drug formulation generated at the applicants manufacturing site.

DCC after detailed deliberations, recommended to amend the Drugs and Cosmetics rules to make necessary provisions in this regard.

## AGENDA NO.4

## CONSIDERATION OF THE PROPOSAL FOR AMENDMENT OF THE EXEMPTIONS PROVIDED UNDER SCHEDULE K REGARDING SUPPLYING OF MEDICINES BY REGISTERED MEDICAL PRACTITIONERS TO THEIR PATIENTS

DCC was apprised that Registered Medical Practitioners (RMP) can supply different categories of medicines including vaccines to their patients as per the exemption provided with certain conditions under Schedule K of the Drugs and Cosmetics Rules, 1945. Currently, there is no specific category which can be supplied by RMP to their patients.

It is proposed that, the following additional conditions may be incorporated under the conditions of exemption to prevent the misuse of the exemption:

1. The Registered Medical Practitioner shall supply generic medicines only.
2. The Registered Medical Practitioners shall supply the 'Physicians Samples' at free of cost.

DCC deliberated the proposal and agreed to amend Schedule K of the Drugs and Cosmetics Rules, 1945 to specify the medicines to be supplied by RMP to their patients.

## AGENDA NO. 5

## CONSIDERATION OF HON'BLE DELHI HIGH COURT DIRECTIONS GIVEN THROUGH ORDER DATED 06.02.2019; CORRECTED AND RELEASED ON: 13.02.2019; IN THE MATTER OF CS (COMM) 1071/2018 TITLED AS M/S. CUREWELL DRUGS & PHARMACEUTICALS PVT. LTD & ANR. VS RIDLEY LIFE SCIENCES PVT. LTD & ANR

DCC was apprised that, the Hon'ble High Court of Delhi through its order dated 06.02.2019; corrected and released on: 13.02.2019; in the matter CS (COMM) 1071/2018 titled as M/S. Curewell Drugs & Pharmaceuticals Pvt. Ltd & Anr. Vs Ridley Life Sciences Pvt. Ltd & Anr., has directed to publish the Draft Rules to deal with the regulation of identical brand names to ensure that medicines with identical brand names and identical packaging are not allowed to be manufactured or sold.

Apart from the Draft Rules, the Hon'ble Delhi High Court has given further directions, the extract of the Order is reproduced below-

*"13. Under the Drugs and Cosmetics Act, 1940 (`DC Act'), the DCGI and the State FDAs are vested with powers to supervise and overlook the manufacture and*

*sale of drugs. Section 17 and Section 17A of the DC Act deal with misbranded and adulterated drugs. The Central and State Governments are empowered to appoint inspectors who have vast powers as stipulated under Section 22. They have powers to inspect any premises, take samples, search any premises, search any vehicle, seek production of records. In fact, the powers are extremely wide so as to ensure that sub-standard medicines are not manufactured and sold. Such inspectors, therefore, ought to keep regular supervision on all the manufacturing units falling within their territories, to ensure maintenance of the quality of medicines. The draft rules which are under consideration ought to take into consideration the situation of the ground and ensure that medicines with identical brand names and identical packaging are not allowed to be manufactured or sold.*

14. *Apart from the draft Rules, the following directions are issued for consideration by the authorities in order to regulate and better supervise the quality of medicines being manufactured and sold.*

    i. *Creation of a secured platform, to be under the supervision of the DCGI, which is accessible to all State FDAs, both for access of data and for uploading of data;*

    ii. *Creation of a 'master electronic database' of all the approved brand names for manufacture and sale of drugs issued both by the DCGI and the State FDAs and making the same available to all state FDAs and Drug controllers through a secured platform. The list to be maintained and made available both brand wise and manufacturer wise, on the secured platform;*

    iii. *List of registered trademarks under Class 5 for pharmaceutical and medicinal preparations be obtained from the Controller General of Patents, trademarks and designs and be made available to the approving authorities at the Central level and State level. The said list ought to be updated bi-annually i.e., on 1st January and 1st July every calendar year;*

    iv. *Access to the data be given to Drug Inspectors/Drug Controllers across the country;*

    v. *Drug Inspectors/Drug Controllers to conduct regular and periodic inspections as per the Act and the Rules to ensure that the drugs that are being manufactured in a particular unit are duly licensed for. The reports of the said inspections to be submitted through the secured platform;*

    vi. *Periodic and regular reports of drug inspectors should be compulsorily submitted to the respective licensing authorities on the secured platform and a mechanism be set up for review of the said reports at the State level;*

    vii. *Periodic meetings ought to be held at the central level, to review the status of manufacture and sale of drugs across the country, under the aegis of the DCGI;*

    viii. *Strict action in accordance with law ought to be taken against those manufacturers who manufacture drugs without licences, who indulge in*

*adulteration or contamination of drugs etc. A periodic report as to the number of actions taken, ought to be uploaded on the secured platform of the DCGI.*

15. *It is clarified that the above directions are not exhaustive in nature.*

16. *The DCGI/DCC/DTAB and the Ministry of Health and Family Welfare, to take a comprehensive decision in respect of the draft rules and notify the draft rules for public comments within a period of three months from today. The draft rules so notified shall also be placed on the record of this Court. Copies of the same shall be supplied to the Ld. Counsels for the parties. After the draft rules are put up for public comments and are finalised, authorities to take expeditious action to amend the rules, notify the same in accordance with law, not later than 31st December, 2019. If the draft rules are not placed before this Court within three months, the suit shall be listed by the Registry before the Court on 15th May, 2019. No further orders are called for in this suit. Decree sheet be drawn qua Defendant No.1 in terms of paragraph 4 above."*

In this regard, a draft notification has been published vide G.S.R. 152(E) dated 26.02.2019 inviting for objections and suggestions, if any. While submitting the reply, the same has been brought to the notice of Hon'ble High Court of Delhi. Further, the Hon'ble Court in its order dated 15.05.2019 directed that the case need not be listed further.

DCC noted the Court directions for compliance and the status of the draft notification of the above said rules which is under consideration for finalization.

**AGENDA NO. 6**

**CONSIDERATION OF THE PROPOSAL ON ACTION TAKEN FOR IMPLEMENTATION OF G.S.R. 19(E) DATED 10.01.2019 REGARDING MANDATORY UPLOADING OF INFORMATION PERTAINING TO THE LICENSES GRANTED FOR MANUFACTURE FOR SALE OR DISTRIBUTION OF DRUGS IN ONLINE PORTAL SUGAM**

DCC was apprised that Central Government has amended the Drugs and Cosmetics Rules, 1945 vide G.S.R. 19(E) dated 10.01.2019 incorporating Rule 84AB making online submission of data through SUGAM portal as a mandatory requirement under D&C Rules.

As per the notification, the licencee shall register with portal SUGAM (www.cdscoonline.gov.in) and upload information, as per the format provided in the said portal pertaining to the licences granted for manufacture for sale or distribution of drugs. The information so provided shall be updated from time to time by the licencee and this information is required to be verified by the concerned State Licensing Authority for confirmation. CDSCO already issued letter to all State Drugs Controllers requesting them to verify the data and approve them at the earliest.

DCC in its 55$^{th}$ meeting held on 31.01.2019 & 01.02.2019 deliberated the matter and recommended that all State Drug Controllers should ensure for effective implementation of Rule 84AB introduced vide G.S.R. 19(E) dated 10.01.2019.

The issue regarding lack of comprehensive data base of information related to licences granted has been raised from time to time in various fora to ensure quality of the drugs manufactured and marketed in the country. The amendments in the rules have been made with the objective of having such a data base at the earliest as part of overall strengthening of drug regulatory system in the country. Considering that such a data base is of paramount importance, the implementation of the rule 84AB in letter and spirit at the earliest is absolutely necessary.

It is, therefore, emphasized again that all the State Drugs Control Authorities should ensure the effective implementation of Rule 84AB under the Drugs and Cosmetics Rules, 1945.

DCC after deliberation recommended that all State Drug Controllers should ensure that uploading of required data as mandated under Rule 84AB is completed by 30.06.2019.

## AGENDA NO. 7

## CONSIDERATION OF PROPOSAL FOR EFFECTIVE IMPLEMENTATION OF REQUIREMENT OF BA/BE STUDIES AND STABILITY STUDIES AS MANDATED BY GAZETTE NOTIFICATIONS G.S.R. 327(E) DATED 03.04.2017 AND G.S.R. 360(E) DATED 10.04.2018 RESPECTIVELY

DCC was apprised that Central Government has amended the Drugs and Cosmetics Rules, 1940 vide G.S.R. 327(E) dated 03.04.2017 making it mandatory to submit results of BA/BE studies for oral formulations of Biopharmaceuticals Classification System (BCS) class II & class IV drugs to State Licensing Authority along with application before grant of product manufacturing licenses.

The Government also amended the Drugs and Cosmetics Rules, 1940 vide G.S.R. 360(E) dated 10.04.2018 making it mandatory to submit evidences of stability, safety of excipients, etc. to State Licensing Authority along with application before grant of product manufacturing licenses.

In 55$^{th}$ meeting of the DCC held on 31.01.2019 & 01.02.2019, Additional Secretary pointed towards the responsibility of bringing quality in generic medicines for which the manufacturers are required to submit the bioequivalence data and stability data mandatorily with a view to build the confidence amongst the doctors and consumers. He also requested all State Drugs Controllers to create the awareness amongst the manufacturers about the importance of conducting the bioequivalence studies and stability studies.

In the above said meeting, DCG(I) also pointed out the challenges in the States in implementing the mandatory provisions for submitting the bioequivalence data and stability data while applying for manufacturing license. Therefore, DCG(I) reiterated the need for the State Governments to be sensitized about effective implementation of the mandatory requirements to ensure quality of generic drugs.

Accordingly, considering the importance of BA/BE and stability studies, the Ministry of Health and Family Welfare has issued Advisory on 06.03.2019 to the Chief Secretaries

of all States and UTs for continued support and guidance to the Drugs Control Organization in their respective State/UT in enforcement of the Drugs and Cosmetics Act, and Rules to ensure quality, safety and efficacy of drugs manufactured and marketed in the country.

DCC deliberated the matter and again emphasized that all the State Drugs Control Authorities should ensure the effective implementation of G.S.R. 327(E) dated 03.04.2017 and G.S.R. 360(E) dated 10.04.2018.

## AGENDA NO. 8

## CONSIDERATION OF THE PROPOSAL FOR A COMMON SOFTWARE PLATFORM FOR DRUG LICENSES MANAGEMENT FOR ALL THE STATES IN THE COUNTRY

DCC was apprised about the progress of development of the Common software platform.

CDAC made a detailed presentation on online filing and processing of application for the grant of drug manufacturing licence.

DCC deliberated that there should be a time line for rolling out the programme. DCC also deliberated the need of imparting training to the state regulatory officials on the proposed software system.

After detailed deliberation, it was decided that the development of the common software platform should be completed and the programme should be rolled out on 01.07.2019.

Regarding training programme, it was decided that 3-5 officials of various levels from each State Drugs Control office should be nominated for training by the CDAC on 10.06.2019. Accordingly, a communication was forwarded by CDSCO to all State Drugs Controllers to depute the officials for the program.

## AGENDA NO. 9

## CONSIDERATION OF THE PRESENT STATUS OF REGULATION OF SALE AND DISTRIBUTION OF DRUGS OVER INTERNET (E-PHARMACY) IN LIGHT OF CONCERNS RAISED IN VARIOUS FORA

DCC was apprised that, the Department of Health and Family Welfare has issued a draft notification vide G.S.R. 817(E) dated 28.08.2018 proposing to amend the Drugs and Cosmetics Rules, 1945 by incorporating separate part for the regulation of e-Pharmacies in the country.

In response to the draft notification a large number of comments have been received. Central Government has decided to carry out wider consultations before finalising the draft notification.

However, a large number of PIL’s have been filed in various Hon’ble High Courts of the various states. The Hon’ble High Courts have issued directions with regards to the regulation of sale of drugs over internet.

DCC deliberated the matter and suggested that, all the State Drugs Controllers shall take necessary action as per directions of various Hon'ble High Courts.

In one such instance, a copy of the order of the Hon'ble High Court of Delhi in W.P. (C) No.11711 of 2018 in the matter of Zaheer Ahmed vs Union of India & Ors has been circulated to all the State Drugs Controllers on 8.5.2019.

Further, in various matters referred above, the Hon'ble High Courts were seeking the details of action taken by the State Drugs Controllers.

DCC after deliberation recommended to take action as per the existing provisions of the Drugs and Cosmetics Rules, 1945 for any violations on online sale of drugs and also recommended to include the provision for uploading the e-prescription in the rules on e-pharmacy to be finalized.

## AGENDA NO. 10

## CONSIDERATION OF PROPOSAL ON STATUS OF UPGRADATION AND SYNCHRONIZATION OF SCHEDULE M UNDER THE DRUGS AND COSMETICS RULES, 1945 WITH THE WHO-GMP COMPLIANCE STANDARDS

DCC was apprised that the matter pertaining to up gradation/ synchronization of Schedule M with WHO-GMP standards has been under consideration of the Ministry of Health and Family Welfare for quite some times now.

Good Manufacturing Practices (GMP) requirements were incorporated under Schedule 'M' to the Drugs and Cosmetics Rules, 1945 in 1988. Subsequently, Schedule 'M' was amended on 11.12.2001. Schedule 'M' is broadly based on general principles of WHO-GMP Guidelines.

WHO has, however, also laid down separate GMP guidelines for Biological Products, Hazardous Substances like certain Hormones, Cytotoxic substances, Radio Pharmaceuticals, Herbal products, Investigation of products for Clinical trial, etc and also detailed guidelines on various aspects such as water system, Heating Ventilation And Air Conditioning (HVAC) system, Validation for Process, Testing, Cleaning, Stability, Study etc.

The matter was deliberated in 74th DTAB meeting held on 15.11.2016 and agreed for amendment in the rules to upgrade the Schedule M to make it on par with the WHO-GMP.

Based on the recommendations of DTAB, the Ministry has published draft notification vide G.S.R. 999(E) dated 05.10.2018 for up gradation of Schedule M inviting comments/ suggestions from the stakeholders. Many stake holders have however raised objections/ concerns on the proposed amendments.

DCC deliberated the status of finalization of the draft notification and recommended for appropriate action in the matter.

## AGENDA NO. 11

## CONSIDERATION OF PROPOSAL ON STATUS OF INCLUSION OF PROVISIONS ON GOOD DISTRIBUTION PRACTICES (GDP) OF PHARMACEUTICAL PRODUCTS IN THE DRUGS AND COSMETICS RULES, 1945

The objective of the quality control over drugs is to ensure that the patients get quality drugs. For this purpose it is necessary to ensure the quality and identity of pharmaceutical products during all aspects of the distribution process which includes procurement, purchasing, storage, distribution, transportation, and associated documentation/ record keeping practices. Each activity in the distribution system is required to be carried out in accordance to the principles of Good Distribution Practices. The involvement of unauthorized entities in the distribution and sale of pharmaceutical products is a matter of concern as it leads to introduction of spurious drugs in the supply chain. It is the responsibility of all parties involved in the distribution of pharmaceutical products to ensure that the quality of pharmaceuticals products and the integrity of the distribution chain are maintained throughout the distribution process.

The said matter was deliberated earlier in 47$^{th}$ Drugs Consultative Committee held on 30.07.2014 and 31.07.2014 wherein report of the sub-committee constituted for preparation of Guidelines on GDP of Pharmaceutical Products was considered. Recently, the matter was also deliberated in 54$^{th}$ meeting of DCC held on 30.07.2018 and the DCC suggested to take necessary provisions to impart legal sanctity to the suggested guidelines as a Schedule to the Drugs and Cosmetics Rules, 1945 to penalise the offenders.

Subsequently, a notice was issued on 25.09.2018 inviting comments/ suggestions on the draft guidelines from the stakeholders. A number comments/ suggestions have been received.

DCC deliberated the proposal and found that there has been no comment received from the State Drug Controllers and recommended to make necessary provisions for Good Distribution Practice under the Drugs and Cosmetics Rules, 1945.

## AGENDA NO. 12

### CONSIDERATION OF THE PROPOSAL FOR MAKING UNIFORM QUANTITY OF SAMPLE REQUIREMENT TO BE DRAWN BY DRUGS INSPECTORS FOR TEST OR ANALYSIS OF DRUGS, COSMETICS, VACCINES & MEDICAL DEVICES AT CENTRAL DRUGS TESTING LABORATORIES

DCC was apprised that, a meeting with Heads of Zonal, Sub-Zonal & Port Offices and the Directors of all laboratories of CDSCO was held on 30.01.2019 at New Delhi, wherein the issue regarding quantities of samples required to be drawn by the drugs inspectors for testing at drugs testing laboratories under the provisions of the Drugs and Cosmetics Act and Rules was discussed.

It was decided to prepare and circulate the sample quantities required for testing or analysis of Drugs, Cosmetics, Vaccines & Medical Devices for uniformly following the procedures in CDSCO.

Accordingly, sample quantities required for analysis of Drugs, Cosmetics, Vaccines & Medical Devices submitted by the Directors of CDL-Kolkata and RDTL-Chandigarh was placed before the Committee.

DCC deliberated the matter and opined that detailed examination is required to take further action in this regard. Therefore, DCC constituted a subcommittee under chairmanship of Shri. Shobhit, Dy. Drugs Controller, Madhya Pradesh to examine and give recommendation in the matter.

**Composition of sub-committee:**

1. Shri. Shobhit, Dy. Drugs Controller, Madhya Pradesh (Chairman)
2. Representative from State Drugs Testing Laboratory Andhra Pradesh (Member)
3. Representative from State Drugs Testing Laboratory Gujarat (Member)
4. Dr. R. A. Singh, Director, RDTL, Chandigarh (Member)
5. Dr. S.P. Shani, DDC(I), CDSCO(HQ) (Convener)

The sub-committee shall examine the report and submit their recommendations within three months to DCC for further consideration.

## AGENDA NO. 13

## PROPOSAL FOR AMENDMENT IN SCHEDULE H OF DRUGS AND COSMETICS RULES TO PROVIDE EXEMPTION FROM LABELLING REQUIREMENTS AS PER SCHEDULE H FOR THE CHEMICAL CONTRACEPTIVE MENTIONED UNDER ENTRY NO. 15 OF SCHEDULE K OF THE DRUGS AND COSMETICS RULES, 1945

"Schedule K" of the Drugs and Cosmetics Rules, under the entry no. 15 provides exemption from taking a sale licence for chemical contraceptive having the following composition per tablet:

(1) DL-Norgestrel-0.30 mg,
Ethinyloestradiol-0.30 mg

(2) Levonorgestrel-0.15 mg,
Ethinyloestradiol-0.03 mg

(3) Centchroman-30 mg

(4) Desogestrel-0.150 mg,
Ethinyloestradiol-0.03 mg

(5) Levonorgestrel-0.1 mg,
Ethinyloestradiol-0.02 mg

However, drugs centchroman and ethinyloestradiol are specified in the Schedule H of Drugs and Cosmetics Rules, at the entry no. 101 and 186 respectively.

A representation has been received from HLL Lifecare Limited mentioning that the company is manufacturing and supplying regular oral contraceptive pills to the Ministry of Health and Family Welfare under National Family welfare Programme since 1993 under various brand names of contraceptive like Mala N, Mala D, Apsara, Choice, Ecroz, Khushi,

Sunheri etc. containing drug composition Levonorgestrol I.P. 0.15 mg, Ethinyloestradiol I.P. 0.03 mg, combo packed with Ferrous Fumarate I.P. 60 mg.

The firm has submitted that labelling of the above said products were initially done by mentioning “Schedule K” on all the packing material as these products are covered under the “Schedule K” of Drugs and Cosmetics Rules, 1945.

However, objections have been raised by one of the State Drugs Controller Office on the labelling of these products with following remarks:

1. “Labelling part of above products shall be in line with Schedule H requirements: viz., printing of Rx, red box and Schedule H warning in the primary and secondary packages of the products.
2. The labelling shall not include “Schedule K” as this is not a labelling requirement.”

Accordingly, the company has implemented the labelling requirements as per “Schedule H” in its packing artwork.

However, the company is facing difficulties to sell and supply these products under various schemes of MoHFW due to following constraints:

a. “Schedule H drug cannot be advertised, which is very essential for Social Marketing to educate the people about proper use of the product.
b. Schedule H drug can only be sold with a prescription of a registered medical practitioner whereas Social marketing products are meant for providing affordable contraceptive in the remotest area of the country where availability of registered medical practitioners is a constraint.
c. The selling of Schedule H drug requires proper retail licence for selling medicines which is not possible for Social marketing Organization, as their products are sold under Govt. schemes through Over the Counter (OTC) and not through prescription.”

In this regard, the HLL Lifecare Limited has requested to make necessary amendment in the Drugs and Cosmetics Rules, 1945 to remove “Schedule H” labelling requirements on products containing;

(i) Levonorgestrol I.P. 0.15 mg, Ethinylestradiol I.P. 0.03 mg
(ii) Centchroman 30 mg

Therefore, it is proposed to make the following amendments in respect of item no.101 & 186 in “Schedule H” of the Drugs and Cosmetics Rules, 1945:

“101. Centchroman (except for strength 30 mg in Tablet)
186. Ethinyloestradiol (except for strength Ethinyloestradiol I.P. 0.03 mg in combination with Levonorgestrol I.P. 0.15 mg in Tablet)”

DCC deliberated the proposal and agreed to amend ‘Schedule H’ of the Drugs and Cosmetics Rules, 1945 to exempt Centchroman 30mg tablets and Ethinyloestradiol I.P. 0.03 mg in combination with Levonorgestrol I.P. 0.15 mg in Tablet from schedule H.

## AGENDA NO. 14

## CONSIDERATION OF THE PROPOSALS FROM STATE OF BIHAR

The agenda was deferred.

## AGENDA NO. 15

## CONSIDERATION OF THE PROPOSALS FROM STATE OF GOA

The agenda was deferred.

## AGENDA NO. 16

## CONSIDERATION OF THE PROPOSALS FROM STATE OF HARYANA

**1. Recommendation to Prohibit/Ban Creamy Snuff (Misused as Toothpaste Containing Tobacco) and Powdered Tobacco (Misused as Toothpowder Containing Tobacco)**

DCC deliberated the matter and opined that necessary letter may be issued to Tobacco Control Division of the Ministry for appropriate action to consider prohibit/ban of the following:

1. Creamy Snuff as manufactured and misused as toothpaste containing tobacco which appears at sr. no. 7 of the Schedule u/s 3(p) of COTP Act, 2003.
2. Toothpowder containing Tobacco as manufactured and misused as toothpowder containing tobacco which appears at sr. no. 10 of the Schedule u/s 3(p) of COTP Act, 2003.

**2. Sale of MTP (Medical Termination of Pregnancy) kits containing Misoprostol and Mifepristone by Wholesalers only to the approved MTP centres having required facilities and services of duly qualified and experienced Registered Medical Practitioner under MTP Act**

DCC was apprised that the combi kit of Misoprostol and Mifepristone tablets for MTP have been approved by CDSCO with following warning:

***"Warning: product is to be used only under the supervision of a service provider and in a medical facility as specified under MTP Act 2002 & MTP Rules 2003"***

DCC deliberated the matter and suggested that a letter should be issued by CDSCO to all State Drug Controllers about the above requirement and also to ensure the effective implementation of labelling requirements as per MTP provisions.

**3. Prohibition of Aceclofenac for veterinary use for saving vultures**

DCC was apprised that Dr. Vibhu Parkash, 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. GSR 499 (E) dated 04$^{th}$ July,

2008 and permitted 'Diclofenac injection for human use shall be in single unit dose pack only' vide notification No. GSR 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.

DCC deliberated the matter and recommended that Drugs Controller, Haryana may write letter to Dr. Vibhu Parkash, Principal Scientist & Deputy Director, BNHS, Vulture Conservation Breeding Centre to provide detailed supporting scientific data in this regard for further action.

## AGENDA NO. 17

## CONSIDERATION OF THE PROPOSALS FROM STATE OF MAHARASHTRA

**1. Penal clause for violation of provision of the D & C Act and Rule for approved testing laboratory.**

At present under the Drugs and Cosmetics Act, 1940 there is no specific penal clause under Section 27 of the Act for the violation of any provisions by the private approved testing laboratories holding approval under Form 37/ Form 48. If such laboratories grossly violate any provision of the Act and issue Certificate of analysis to any manufacturer/ person who brought their product in market for sale and distribution as drugs/ Ayurvedic drugs/ cosmetics cannot be not penalized. Hence is necessary to amend the Act for bringing penalty clause for approved testing laboratory for such violations.

DCC deliberated the proposal and opined that it is related to amendment in the Drugs and Cosmetics Act and the issue may be taken up when amendment of the Act is considered.

**2. Amendment in the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 and Rules thereunder for authorizing Drugs Inspector for institution of prosecution on the line of D & C Act. (Sec.32) for the violations of any provision of this Act.**

At present officers are instituting prosecution under the DMR (OA) Act as authorized under Section 8 but during trail the question of authority for filing prosecution is raised by the defence in most of the cases. At present in this Act there is no clear authorization for filing the prosecution under this Act like as mentioned in Section 32 of the D & C Act. Hence the provision for authorization for institution of prosecution may be made in DMR (OA) Act.

DCC deliberated the proposal and opined that it is related to amendment in the Drugs and Cosmetics Act and the issue may be taken up when amendment of the Act is considered.

**3. Amendment in Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 for enhancement in penalty.**

At present the penalty mentioned under Section 7 of this Act for the violation of provision of section 3, 4 and 5 are very less hence, there is no expected deterrent

effect on the offender which tempts them to advertise their products in any manner for their financial benefit and the very purpose of this Act is defeated. Hence the penalty clause may be amended with higher fine and imprisonment on the line of Section 53 of FSS Act., 2006.

DCC deliberated the proposal and opined that it is related to amendment in the Drugs and Cosmetics Act and the issue may be taken up when amendment of the Act is considered.

**4. Amendment in the rules for labelling provisions for medicines for Govt., / Institutional supply.**

DCC deliberated the matter and recommended that strict enforcement activities should be adopted to prevent non-compliance of provisions of Drugs and Cosmetics Act, 1940 and Rules, made thereunder.

**5. Amendment in Schedule K exemption regarding for the Quantity and Category for stocking medicines by the RMPs in their own Hospitals/ Clinic for their patient use.**

The proposal was already discussed under Agenda No. 4.

**6. Sale of drugs (Medicine by E-Pharmacy, more stringent regulation to be made.**

The proposal was already discussed under Agenda No. 9.

**7. Strict regulation for E-Cigarette is to be made by the Central Govt.**

The proposal was already discussed under Agenda No. 2.

**8. Training of the Regulatory officers/ Drugs Inspectors:**

DCC deliberated the matter and agreed for separate module for training of all the regulators.

**9. Publishing of Drugs Reference data:**

DCC deliberated the matter and suggested to publish newsletter or bulletin on quarterly basis capturing amendments in the Drugs and Cosmetics Act, 1940 and the rules made thereunder.

**10. Availability of Reference Standard/ Working Standard for regulatory analysis.**

The State Drugs Testing laboratories are continuously facing constraint of the reference and working standards for the regulatory analysis of the quality surveillance drugs samples and the test reports cannot be delivered in the prescribed time frame. In view of above, it may be proposed to develop a central depository of Reference/ Working Standard with the help Drugs Manufacturers. The R.S/ W.S as and when required by any of the Govt. Laboratory can be issued on their request.

DCC deliberated that presently IPC, Ghaziabad is maintaining and distributing the reference standards. The State laboratories may approach the IPC in this regard.

**11. Strengthening of State Drugs Regulatory system -change of project work under the sanctioned grant-in-aid.**

The matter has already covered in the inaugural address of the meeting.

## AGENDA NO.18

## CONSIDERATION OF THE PROPOSALS FROM STATE OF MADHYA PRADESH

## CONSIDERATION OF THE PROPOSAL TO INCORPORATE PROVISION FOR INCLUSION OF COMMON TESTING FACILITY CENTRE IN THE DRUGS AND COSMETICS RULES, 1945 TO PROVIDE THE FACILITY LIKE TESTING LABORATORY FOR CLUSTER OF PHARMACEUTICAL INDUSTRIES TO FACILITATE MSME/SSI

DCC deliberated that already there are provisions under Part XV(A) of Drugs and Cosmetics Rules for approval of Institutions for carrying out tests on Drugs, Cosmetics and Raw materials used in their manufacture on behalf of licensees for manufacture for sale of drugs and cosmetics.

## AGENDA NO. 19

## CONSIDERATION OF THE PROPOSALS FROM STATE OF PUNJAB

**1. Amendment in Rule 124 - Standards of Drugs**

The Rule 124 of the Drugs and Cosmetics Rules deals with the standards of drugs, this rule directs to follow the Indian Pharmacopeia or any other Pharmacopeia for the time being enforced for the purpose of purpose of Standards for identity, purity & strengths of the drugs. There is no time limit specified under this Rule that after how much time, the standards mentioned in Pharmacopeia is to be followed by the manufacturer/ labs/ regulators from the date of introduction of such Pharmacopeia. The manufacturer/ testing labs has to validate/ revalidate the various process(s) involved in the manufacturing & testing, which needs minimum time to validate/ revalidate process/ methods/ change control. It has been observed that the manufacturer/ drugs testing labs do not adopt/ follow the new edition of Pharmacopeia for months or years together. It is proposed that the provisions of time limit to follow the new edition of Pharmacopeia may be made under the said Rule.

DCC, after deliberation recommended that the regulators should ensure proper implementation of the existing provisions of standards for drugs provided under Second Schedule of the D&C Act.

**2. Amendments in Rule 64 - This rules deal with conditions to be satisfied before a sale licence is granted or renewed/retained**

(i) Under this rule, the clear provisions in speaking terms with respect to proper storage accommodation for preserving the properties of the drugs has not been defined. In many of the States in summer, the room temperature exceeds more than 30 degree Celsius especially in the months of May to July. The thermolabile drugs get affected with the high temperature and the deterioration of such products get catalysed. It is recommended that there shall be specific conditions under rule 64 that the premises/ accommodation should be equipped with suitable capacity of air conditioner along with power backup arrangements and suitable capacity refrigerator.

DCC deliberated the proposal and opined that it is already covered in the Good Distribution Practices (GDP) guidelines.

(ii) In many of the States, there is mushrooming of drugs sales units, due to the reason that there is no restriction under rule 64 for grant of sale licence that as many as licence can be granted even in the small area, where there may not be any viability or need for such sale licences. The increasing number of drugs sale licences may be one of the reasons for sale of scheduled drugs without the supervision of pharmacists, unauthorised sale of drugs and non maintenance of storage conditions, sale of scheduled drugs without prescription etc. It is recommended that there shall be some fixed criteria for considering the application for grant of sale licence (retail sale & wholesale licence) to control the mushrooming of such licences. The minimum criteria for grant of licence may be population of the area, type of health institution/prescribers in the proposed area etc.

DCC, after deliberation opined that individual State may take appropriate action in this regard.

(iii) The qualifications to be a competent person in wholesale licence need to be replaced with registered pharmacist as in the wholesale dealing the storage conditions of the drugs needs to be maintained for which the pharmacist have good knowledge.

DCC deliberated the proposal and opined that the matter is already under consideration of the MoHFW.

**3. Amendments in Rule 66 - This rule deals with the suspension/ cancellation of drugs sale licences.**

(i) Under the proviso there is need to include action against the qualified person - pharmacist beside the action against agent/employee/licencee, where in the case the licencee found selling scheduled drugs without under the supervision of qualified person, the inclusion of such provisions may prove to be useful in ensuring the presence of pharmacists in the chemist shops.

DCC deliberated that pharmacists are regulated by the Pharmacy Council of India and accordingly action could be taken in this regard.

(ii) In the proviso 1 (b),there is need to include the provisions that the licence/agent/employee had not been guilty of similar act or omission within 3 years in place of 12 months before the date on which the act or omission took place etc. It is not feasible by the Drugs Inspector to inspect each & every shop once in a year with the present strength of Drugs Inspectors; moreover they are dealing with multifarious activities. The chemists take the advantage of this proviso during the hearing of appeal before the Government and the action taken by the State Licensing Authority does not sustain.

DCC, after deliberation opined that measure should be taken by the Licensing Authority for proper enforcement of the existing provisions in this regard.

(iii) There is no provision for disposal of seized drugs in the event of taking action under rule 66 it is recommended that the adequate provisions may be made.

DCC, after deliberation opined that the disposal of the seized drug should be as per the order of the Court.

## AGENDA NO. 20

## CONSIDERATION OF THE PROPOSALS FROM STATE OF TELANGANA

1) **Amendment of Rule 35, Clause (xii) and Rule 37 of New Drugs and Clinical Trials Rules, 2019 for mandating inspections of bioavailability and bioequivalence study centres by officers authorized by State Licensing Authorities:**

DCC after deliberation opined that New Drugs and Clinical Trial Rules, 2019 is applicable for Clinical trials and BA/BE studies of new drugs regulated by CDSCO on behalf of Central Government.

2) **Amendment of New Drugs and Clinical Trials Rules, 2019 for mandating inspections regarding Clinical Trials by officers authorized by State Licensing Authorities:**

DCC after deliberation opined that New Drugs and Clinical Trial Rules, 2019 is applicable for Clinical trials and BA/BE studies of new drugs regulated by CDSCO on behalf of Central Government.

3) **Amendment of Conditions of Manufacturing Licences under the Drugs and Cosmetics Rules, 1945 for mandating Prior Approval for 'Major' post-approval changes from the Licensing Authority:**

DCC deliberated the proposal to have a schedule regarding "Post Approval Changes" shall be incorporated under Drugs and Cosmetics Rules, 1945.

DCC after deliberation, recommended to constitute a subcommittee under chairmanship of Dr. B. Venkateswarlu, Joint Director, DCA, Telangana to frame the guidance document.

**Composition of sub-committee:**

1. Dr. B. Venkateswarlu, Joint Director, DCA, Telangana — (Chairman)
2. Dr. H.G. Koshia, Commissioner, FDCA, Gujarat — (Member)
3. Shri. Dinesh Kumar Tiwari, Assistant Commissioner (Drug), Uttar Pradesh — (Member)
4. Shri. Arvind Kukrety, DDC(I), Ahmedabad Zone, CDSCO — (Convener)

The sub-committee shall examine the matter and submit their recommendations within three months to DCC for further consideration.

4) **Amendment of Conditions of Manufacturing Licences under the Drugs and Cosmetics Rules, 1945 for mandating intimation of occurrence of any suspected unexpected Serious Adverse Event to the Licensing Authority:**

DCC, after deliberation opined that the proposal may be considered while finalizing the draft rules for upgradation of Schedule M already notified by the Government.

5) **To restrict the Batch Number printing to a Maximum of 4 (Four) digit Numerical/ Alpha-numerical only on the Labels of Drugs by making necessary amendment to Rule 96 (1) (v) of the Drugs and Cosmetic Rules 1945.**

DCC after deliberation opined that restriction of batch no. to maximum 4 numbers may not be appropriate in overall perspective of manufacturing of drugs.

6) **To Notify both the Medical Examination Gloves and Surgical Disposable Latex Gloves as "Drugs". To prescribe manufacturing /testing standards on par with the parameters equivalent to Schedule R of similar Drug Item "Condom" by Inserting Schedule R 2 for Medical Examination Gloves and Sterile Disposable Surgical Latex Gloves.**

DCC deliberated and opined that roadmap to bring all medical devices under regulation is already under consideration.

## AGENDA NO. 21

## CONSIDERATION OF THE PROPOSALS FROM STATE OF TRIPURA

The agenda was deferred.

## ADDITIONAL AGENDA NO. S-1

## CONSIDERATION OF THE PROPOSALS FROM STATE OF GUJARAT

## CONSIDERATION OF THE PROPOSAL FOR MAKING PROVISION FOR GRANTING OF LICENCE TO SELL DRUGS BY RETAIL FROM A MOTOR VEHICLE UNDER THE 'PRADHAN MANTRI BHARTIYA JANAUSHADHI PARIYOJANA' (PMBJP) SCHEME

Proposal has been received from the Commissioner, Food & Drugs Control Administration, Gujarat State and stated that to achieve the objective of making available quality generic medicines at affordable prices to all, 'Jan Aushadhi Scheme' launched by the Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India in November, 2008 across the counthy. Now, the 'Jan Aushadhi Scheme' has been revisited and renamed as 'Pradhan Mantri Bhartiya Janaushadhi Pariyojana' (PMBJP).

The Product Basket of the scheme now covers more than 800 medicines and 154 surgicals & consumables in all major therapeutic categories such as Anti-infectives, Anti-allergics, Antidiabetics, Cardiovasculars. Anti-cancers, Gastro-intestinal medicines, etc. PMBJP has resulted in 50-90% savings to patients in the area of healthcare by selling generic medicines through its PMBJP Kendras across the country.

As per the Drugs and Cosmetic Act 1940 and Rules, 1945 made thereunder, Rule 62-C and Rule 62-D describe about the application for licence to sell drugs by wholesale or to distribute the same from a motor vehicle and form of licences to sell drugs by wholesale or distribute drugs from a motor vehicle respectively.

To promote the PMBJP Scheme particularly in rural areas where it is hard to find any medical store, it is proposed to amend the rules for making the provision to issue licence to sell drugs by retail from a motor vehicle to help the needy person and fulfil the objective, vision and mission of the scheme.

DCC deliberated the proposal and opined that it may not be feasible to control the misuse of such regulatory provisions if incorporated in the rules.

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

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

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# ANNEXURE-A

**List of the participants of 56th Drugs Consultative Committee meeting held on 01.06.2019 at New Delhi under the Chairmanship of Dr. S. Eswara Reddy, Drugs Controller General (India)**

## A. STATE/UTs DRUGS CONTROL ORGANIZATIONS

| S. NO. | STATE/UT | NAME | DESIGNATION |
|---|---|---|---|
| 1. | Andhra Pradesh | Shri. P. Vinay Kumar | Joint Director, DCA |
| 2. | Arunachal Pradesh | Not represented | |
| 3. | Assam | Not represented | |
| 4. | Bihar | Not represented | |
| 5. | Chhattisgarh | Not represented | |
| 6. | Goa | Not represented | |
| 7. | Gujarat | Dr. H.G. Koshia | Commissioner, FDCA |
| 8. | Haryana | Shri. N.K. Ahooja | State Drugs Controller |
| 9. | Himachal Pradesh | Shri. Navneet Marwaha | State Drugs Controller |
| 10. | Jammu and Kashmir | Smt. Lotika Khajuria | Controller, Drugs & Food |
| 11. | Jharkhand | Smt. Ritu Sahay | Director (Drugs) |
| 12. | Karnataka | Shri. P.Ramesh | Deputy Drugs Controller (I/C) |
| 13. | Kerala | Not represented | |
| 14. | Madhya Pradesh | Shri. Shobhit | Dy. Drugs Controller, FDA |
| 15. | Maharashtra | Dr. Pallavi Darare | Commissioner, (HQ), FDA |
| | | Shri. Amrut Nikhade | Jt. Commissioner (HQ), FDA |
| 16. | Manipur | Not represented | |
| 17. | Meghalaya | Not represented | |
| 18. | Mizoram | Not represented | |
| 19. | Nagaland | Not represented | |
| 20. | Odisha | Smt. Mamina Patnaik | State Drugs Controller (I/C) |
| 21. | Punjab | Shri. Pradeep Kumar | Jt. Commissioner, FDA |
| 22. | Rajasthan | Not represented | |
| 23. | Sikkim | Not represented | |
| 24. | Tamil Nadu | Not represented | |
| 25. | Telangana | Dr. B. Venkateswarlu | Joint Director, DCA |
| 26. | Tripura | Not represented | |
| 27. | Uttar Pradesh | Shri. Dinesh Kumar Tiwari | Assistant Commissioner (Drug) |
| 28. | Uttarakhand | Shri. Tajber Singh | State Drugs Controller |
| 29. | West Bengal | Not represented | |
| 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 |
| 35. | Lakshadweep | Not represented | |
| 36. | Pondicherry | Not represented | |

**B. INVITEES**

| S. No. | NAME | DESIGNATION |
|---|---|---|
| 1. | Dr. Mandeep Kumar Bhandari | Joint Secretary, MoHFW |
| 2. | Ms. Payal Saluja | Principal Technical Officer, CDAC |
| 3. | Ms Shruti Gupta | Project Engineer, CDAC |
| 4. | Shri. Anant Patel | Project Engineer, CDAC |

**C. ZONAL/ SUB ZONAL OFFICES OF CDSCO**

| S. No. | OFFICES | NAME | DESIGNATION |
|---|---|---|---|
| **ZONE** | | | |
| 1. | North Zone, Ghaziabad | Shri. AseemSahu | Deputy Drugs Controller (India) |
| 2. | East Zone, Kolkata | Shri. Shyam Narayan Singh | Drugs Inspector |
| 3. | West Zone, Mumbai | Shri. P.B.N. Prasad | Deputy Drugs Controller (India) |
| | | Smt. Rubina Bose | Deputy Drugs Controller (India) |
| 4. | South Zone, Chennai | Not represented | |
| 5. | Hyderabad Zone | Smt. A.Visala | Deputy Drugs Controller (India) |
| 6. | Ahmedabad Zone | Shri. Arvind Kukrety | Deputy Drugs Controller (India) |
| **SUB ZONE** | | | |
| 1. | Baddi Sub-zone | Shri. B.K. Samantray | Deputy Drugs Controller (India) |
| 2. | Bangalore Sub-zone | Not represented | |
| 3. | Guwahati Sub-zone | Shri. A. Senkathir | Deputy Drugs Controller (India) |
| 4. | Indore Sub-zone | Not represented | |
| 5. | Varanasi Sub-zone | Shri. Vinay Kumar Gupta | Asst. Drugs Controller (India) |
| 6. | Jammu Sub-zone | Not represented | |
| 7. | Goa Sub-zone | Not represented | |

**D. CDSCO HEAD QUARTER**

| S. No. | NAME | DESIGNATION |
|---|---|---|
| 1. | Dr. S. Eswara Reddy | Drugs Controller General of India |

| S. No. | NAME | DESIGNATION |
|---|---|---|
| 2. | Dr. V. G. Somani | Joint Drugs Controller (India) |
| 3. | Dr. K Bangarurajan | Joint Drugs Controller (India) |
| 4. | Shri A. C. S. Rao | Deputy Drugs Controller (India) |
| 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. | Dr. Naresh Sharma | Deputy Drugs Controller (India) |
| 12. | Shri. Jayant Kumar | Deputy Drugs Controller (India) |
| 13. | Dr. Ravikant Sharma | Deputy Drugs Controller (India) (I/C) |
| 14. | Shri. Rishi Kant Singh | Legal Consultant, CDSCO |
| 15. | Dr. Santosh Indraksha | Asst. Drugs Controller (India) |
| 16. | Shri. Ankit Sharma | Asst. Drugs Controller (India) |
| 17. | Shri. K.Narendran | Asst. Drugs Controller (India) |
| 18. | Shri. Sushanta Sarkar | Asst. Drugs Controller (India) |
| 19. | Shri. Ashish Rai | Drugs Inspector |
| 20. | Shri. Shivadev D | Drugs Inspector |
| 21. | Shri. Gunda Raghuvaran | Drugs Inspector |
| 22. | Shri. RajeshamPambala | Drugs Inspector |
| 23. | Shri Ashish Kaundal | Drugs Inspector |
| 24. | Shri. Prakash Parida | Drugs Inspector |
| 25. | Shri. Ashish Chauhan | Drugs Inspector |
| 26. | Shri. D.Kumara Swamy | Drugs Inspector |