डॉ. राजीव सिंह रघुवंशी
औषधि महानियंत्रक (भारत)
केंद्रीय औषधि मानक नियत्रंण संगठन
स्वास्थ्य एवम परिवार कल्याण मंत्रालय
भारत सरकार
एफ.डी.ए. भवन, कोटला रोड
नई दिल्ली–110002

सत्यमेव जयते

Dr. Rajeev Singh Raghuvanshi
Drugs Controller General (India)
Cental Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare
Government of India
FDA Bhawan, Kotla Road
New Delhi - 110002 (India)

F. No. X-19013/01/2023-DC

Dated: 14/07/2023

To

All State/ UT Drug Controllers/ DDC (I) of Zonal & Sub-zonal offices/ Directors of Labs of CDSCO

Sub: Minutes of the 61st Meeting of the Drugs Consultative Committee (DCC) held on 01.06.2023 through Hybrid mode - reg.

Sir/Madam,

61st meeting of the Drugs Consultative Committee was held on 01.06.2023 through Hybrid mode.

The minutes of the 61st meeting of the Drugs Consultative Committee is annexed herewith for your kind information and taking further necessary action, wherever required as per recommendations decided therein.

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

Encl. Copy of the minutes

Copy for information to:-

1. PPS to Secretary, MoHFW, Nirman Bhawan, New Delhi
2. PPS to JS(R), MoHFW, Nirman Bhawan, New Delhi

MINUTES OF 61ST MEETING OF DRUGS CONSULTATIVE COMMITTEE (DCC) HELD THROUGH HYBRID MODE ON 01ST JUNE, 2023 AT CDSCO (HQ)

Inaugural Deliberations

Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India), Chairman, Drugs Consultative Committee (DCC), welcomed and thanked Ms. Aradhana Patnaik, Joint Secretary (Regulations), MoHFW, GoI and all State/UT Drugs Controllers for sparing their valuable time and participating in 61st DCC meeting and informed that some important agenda points will be taken for deliberations for the uniform administration of the provisions of Drugs and Cosmetics Act, 1940. He further requested, Ms. Aradhana Patnaik, Joint Secretary (Regulations) to give her opening remarks and share the expectations of Govt. of India from DCC.

Ms. Aradhana Patnaik thanked all the Members of the DCC for their participation and desired that there shall be more and more coordination between the officials of Central and State Regulatory Authorities. Framing of Standard Operating Procedures (SOPs) or guidance documents etc. for regulatory procedures would help both the Central and State Regulatory Authorities for harmonized administration and regulatory actions.

She emphasized that quality of medicines is of paramount importance to ensure patient safety and the miscreants should be strictly dealt with as per the laid down procedures. She stated that the monitoring of quality of medicines through drawing and testing of samples should be carried out through systematic approach. Multiple samples should not be drawn by a Drugs Inspector from a specific place to fulfil the monthly quota.

Further, Ms. Aradhana Patnaik appreciated the efforts of both the Regulatory Authorities in successful planning and execution of Risk Based Inspections (RBI). The 2nd phase of the RBI being more streamlined, it will be further strengthened during the 3rd phase. She also emphasized that all State/UT Governments should be on board to the 'SUGAM LABS', which is an online portal for Government Drug Testing Laboratories.

Regarding the disbursement of remaining funds by the Central Government for strengthening the drug regulatory system., she urged all the State/UT Drugs Controllers to submit Utilization Certificates (UCs) so that next instalment can be released at the earliest.

Finally, she wished all the members to have fruitful deliberations and recommend some concrete action plans to streamline and strengthen the regulatory system in the country.

Thereafter, the committee started deliberations on the Agenda items as under.

AGENDA NO.1

ACTION TAKEN REPORT OF 59th & 60th MEETING OF DCC HELD ON 02.03.2021 & 07.04.2021

The Committee members in principle approved the ATR of 59th and 60th DCC meetings.

However, while deliberating Action Taken Report of the 59th DCC meeting, for Agenda No. 5, the sub-committee constituted under Chairmanship of Dr. H.G. Koshia, Commissioner, FDCA, to examine the proposal from NCPCR regarding Joint Action Plan (Mobile app based Information System (MIS) & Installation of CCTV at medical shops), submitted its recommendations before the DCC.

The DCC reviewed the report of the sub-committee and accepted the recommendations made therein for necessary action.

Further, DCC also requested the sub-committee to recommend actions in case of non-compliance. Accordingly, the sub-committee may deliberate and submit its report within three months.

AGENDA NO.2

CONSIDERATION OF PROPOSAL FOR MEASURES NEED TO BE TAKEN FOR UNIFORM IMPLEMENTATION OF DOCUMENT/ DOSSIER BASED APPROVAL FOR LICENSING OF DRUGS TO ENSURE QUALITY, SAFETY AND EFFICACY OF DRUGS IN THE COUNTRY

DCC was apprised that concerns have been raised from time to time regarding Quality, Safety and Efficacy of the drugs and uniform implementation of the provisions of Drugs and Cosmetics Act, 1940 and Rules thereunder, including safety of the excipients used in the formulations.

Further, Committee was informed about the need to take measures for uniform implementation of document/ dossier based approval for licensing of drugs to ensure quality, safety and efficacy of drugs in the country.

It was deliberated that uniform implementation of document based licensing will be able to address many issues relating the quality of drugs manufactured in the country. It was also deliberated that a specified checklist / format may be developed which can be adopted uniformly across the country. The checklist presently being used for approval of subsequent new drug in CDSCO may be used after appropriate modification required as per the Drugs rules, 1945.

The committee after detailed deliberation recommended that the dossier / document based licensing of the drugs should be implemented uniformly across the country and the checklist for submission of documents by the applicant may be prepared

based on the checklist of subsequent new drugs followed at CDSCO. The draft Checklist should be circulated to all the members for their comments within seven days. The committee also recommended that a letter should be issued by DCG (I) advising the State Licensing Authorities to implement the documents based licensing uniformly across the country.

AGENDA NO.3

CONSIDERATION OF PROPOSAL TO BRING UNIFORMITY IN ENFORCEMENT THROUGH RISK BASED INSPECTION OF DRUG MANUFACTURING SITES

DCC was apprised that the Indian drug industry is spread out in the various States and Union Territories, the enforcement has been found to be of varying level among the states. Non-uniformity in the interpretation of the provisions of the law and their implementation, lack of adequate infrastructure and varying level of the competence of the regulatory officials have resulted in varying level of performance.

The Committee deliberated that in order to optimize the allocation of resources ensuring better quality products, compliance to the Good Manufacturing Practices (GMP) should be uniformly checked through a risk-based approach to inspections. The facilities that need to be inspected based on history of inspection, risk associated with the product, findings of past inspections, NSQ drugs etc.

A draft guidance document for risk based inspection of drug manufacture sites was placed before the committee for deliberations. The committee perused the guidance document and discussed in detail the quality risk management tools which may be adopted for identifying the manufacturing site through risk rating based on intrinsic risk, and compliance risk as well as details of classifications of the inspections findings like critical, major and other than major deficiencies and actions to be taken based on inspection findings in a uniform manner across the country.

After detailed deliberation the committee recommended that the guidance document including the details of actions to be taken based on inspection findings should be forwarded to all the members for their suggestions / comments within seven days for further necessary actions for finalization of the same.

AGENDA NO.4

CONSIDERATION OF THE PROPOSAL FOR UNIFORM IMPLEMENTATION OF MARKET SURVEILLANCE FOR QUALITY MONITORING OF MEDICINES IN THE SUPPLY CHAIN

DCC was apprised about the importance of ensuring uniform implementation of market surveillance for quality monitoring of medicines in the supply chain.

The Committee deliberated that presently, about one lakh drugs samples were tested. However, in case of samples tested and declared as not of standard quality, spurious/

adulterated drugs, due to lack of comprehensive common database of details of the Licensees, the products, inspections and enforcement activities, etc. and proper coordination, information sharing amongst various States/UT, there have been major challenges in carrying out investigations and launching of prosecutions.

After detailed deliberation, the committee recommended that uniform implementation in drawing of samples of drugs / cosmetics / medical devices through a guidance document will enhance the market surveillance for better monitoring of the quality of the drugs. Therefore, the committee recommended to develop a guidance document in consultation with the stakeholders.

AGENDA NO. 5

CONSIDERATION OF THE PROPOSAL FOR UNIFORM IMPLEMENTATION OF CONDITIONS OF SALE OF DRUGS ACROSS THE COUNTRY

&

AGENDA NO. 7

PROPOSAL FOR ACTIONS TO BE TAKEN FOR IMPLEMENTATION OF THE INTERVENTIONS/ACTIVITIES AS PER THE NATIONAL ACTION PLAN (NAP-AMR) RELATING TO REGULATORY AGENCIES

DCC was apprised that concerns have been raised from time to time regarding the sale of prescription drugs without valid prescription of RMP especially antimicrobial drugs leading to misuse / overuse/ abuse of such drugs posing serious risk to public health and in this regard a concrete strategy and Plan of Action may be recommended.

The Committee was further apprised that the Ministry of Health and Family Welfare in consultation with various stakeholders has 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 along with responsible agencies and expected timelines towards operationalizing NAP-AMR for Anti-Microbial Resistance (AMR) containment.

The list of interventions/activities as per the NAP-AMR which are related to regulatory agencies, are as under:

- *Regulatory enforcement to prohibit sale of antimicrobials as OTC under Drugs & Cosmetics Act, and Rules;*
- *Ensure prescription sale of antibiotics and their use under supervision regulate bulk selling importation and labelling for species-specific use;*
- *Identify additional regulatory interventions or support needed to effectively implement Schedule H, H1 and X restrictions;*
- *Review the categorization of high end antimicrobials as well as new antibiotics in Schedule X/H1 of national regulations;*

- *Strengthen and enforce regulations to minimize substandard, spurious, falsely labelled and falsified antimicrobials;*
- *Develop policy & implementation mechanisms on extended producers responsibility for expired/unused antibiotics;*
- *Restrict antibiotics in animal feed, feed premix; ensure registration and use of registered products only; regulate their importation, direct distribution and online marketing ensure appropriate labelling;*
- *Restrict and phase-out non therapeutic use of antimicrobials such as their use as growth promoters and disease prevention in animals;*
- *Expedite regulatory processes to ensure uninterrupted supply of quality assured antimicrobials;*
- *Organize a consultation with regulatory bodies to review current legislations on antimicrobial prescription and feasibility to strengthen existing legislations and introduce new legislations;*
- *Registration of farms, factories, slaughter houses, wet markets, aquaculture units, food processing units, feed manufacturers, health care facilities, veterinary care facilities to be done;*
- *Ensure registration of and data collection from manufacturers, sellers, prescribers and bulk users (farmers and feed manufactures) of antibiotics;*
- *Restrict and gradually eliminate the use of restricted antibiotics, which are critically important for humans in non-human sectors especially food-producing animals;*
- *Develop national plan on restricting (ban/phase off) use of critically important antibiotics*

  - Evidence based policy guided by data generated from well implemented antimicrobial stewardship programmes across various sectors".

- *Implement and monitor national plan to restrict and use of critically important antibiotics in animals and agriculture.*

  - Existing advisory on use of antibiotics in food producing animals 2014, should be updated clearly stating a plan for implementation, backed up by strong legislative support; develop national level monitoring targets and indicators for critically important antibiotics in animals/agriculture.

The strategy and its importance needed to be adopted for addressing the issue of AMR was discussed. DCC deliberated intensively the specific activities/interventions as per the NAP-AMR relating to prohibition of retail sale of antimicrobials without prescription; identifying additional regulatory intervention to effectively implement the conditions of sales of antimicrobials included in Schedule H and Schedule H1; strengthening the enforcement measures to ensure quality of antimicrobials; restriction of use of antibiotics in animal feed/feed premix as growth promoter and disease prevention in animals; feasibility to strengthen existing sale related legislation; restricting and gradually eliminating critically important antibiotics in food producing animals etc.

The committee was sensitized for strict implementation of the regulatory provisions related to manufacture, sale and distribution of antimicrobials and need to take proactive measures for their effective implementation to ensure proper manufacture, sale, distribution and use of antibiotics. The committee also stressed the need for strict enforcement to prevent diversion for illegal use of Active Pharmaceutical Ingredients of antimicrobials in non-human sector like food producing animals as growth promoter and prevention of disease in animals.

Considering the need for concrete strategy to address this issue of AMR, the committee after detailed deliberation, recommended for constitution of an Expert-committee under the Chairmanship of Commissioner FDCA Gujarat comprising of following members namely-

1. Dr. H.G. Koshia Commissioner, FDCA, Gujarat	Chairman
2. Drugs Controller, Uttar Pradesh	Member
3. Drugs Controller, Telangana	Member
4. Drugs Controller, Goa	Member
5. Representative from CDSCO	Convener

The committee will examine the issue in consultation with various concerned Stakeholders and give its recommendation in three months.

AGENDA NO.6

CONSIDERATION OF PROPOSAL OF HAVING REGULATORY OVERSIGHT ON POST-APPROVAL CHANGES TO THE LICENSED PRODUCTS TO ENSURE THEIR QUALITY, SAFETY AND EFFICACY THROUGHOUT THE PRODUCT LIFECYCLE

DCC was apprised that any change to a licensed product may impact on the quality, safety and efficacy of the product and any change to the information associated to the product may impact on the safe and effective use of the product. However, these changes may be made for the purpose of maintaining routine production, improving the quality attributes or improving the efficiency of manufacture or updating product labelling information. Therefore, the regulation of such post approval changes or change control, is one of the most important key elements of regulation of pharmaceutical products by the regulatory authorities in ensuring quality, safety and efficacy.

The Committee deliberated the issue in detail and recommended for preparation of a guidance document for execution of existing provisions of the rules, comparison of base dossier with the major/ critical post approval changes, verification about the post approval changes during the audit and make it mandatory as a part of inspection checklist.

The Committee also recommended that the rules should be amended to incorporate appropriate provisions under the Conditions of license to make it mandatory that the manufacturers provide the details of the critical/ major Post –approval changes to the licensing authority.

AGENDA NO. 8

CONSIDERATION OF THE PROPOSAL TO INCORPORATE PROVISION FOR INCLUSION OF DETAILS OF EXCIPIENT ON EVERY STRIP OF MEDICINES

DCC was apprised about the grievance received on the usage of parabens in pharmaceutical products as preservatives, which is one of the product used as excipients and that there is no clear cut indication of composition of excipient on strips of medicines available on retails medical shops which causes inconvenience to the patients who are allergic to such excipients.

The Committee was also informed that through the representation it has been requested to rectify this problem to stop suffering of such patients/consumers and suggested to add details of excipient or INS codes of excipient on every strip of medicines.

The Committee deliberated that the details of the excipients should be in the package inserts of the medicines. However, presently there is no provision which make it mandatory for the manufacturers to provide package inserts along with the drugs manufactured/ marketed in the country. The criteria to mandate mentioning of the details of excipients on drug formulations have to be evaluated at length for its implementation.

Considering overall perspective, the committee after detailed deliberation recommended to issue an advisory for mentioning details of excipients on drug formulation by various means/ modality on voluntary basis.

AGENDA NO. 9

CONSIDERATION OF THE PROPOSAL TO AMEND DRUGS RULES, 1945 TO REGULATE ALCOHOL CONTENT IN TINCTURES/ OTHER ALCOHOLIC PREPARATIONS TO CURB THEIR ILLEGAL SALE ACROSS PHARMACIES

DCC was apprised about the representation received to take necessary action to amend the provisions in the Drugs and Cosmetics Act and Rules thereunder with respect to the misuse of the drugs containing alcohol/ tincture.

The Committee was informed that Aromatic Cardamom Tincture and other alcoholic preparations in which content of alcohol is very high are being sold from medical stores and are being misused as country liquor. The alcohol content in Aromatic Cardamom Tincture is in the range of 84%v/v to 87%v/v and are being sold in 100ml packs. They are specified under class 10(iv) of Schedule K of the Drug Rules, 1945 and are being misused due to exemptions as per the said Schedule. Being cheap, they are misused as liquor by economically weaker people posing a big concern for public health.

After detailed deliberation, DCC opined that there is a need for amendment in Drugs Rules, 1945 to regulate alcohol content in tinctures/ other alcoholic preparations to curb their illegal sale across pharmacies.

After detailed deliberation, the Committee recommended that the rules may be amended and exemption provided for alcoholic preparations containing the alcohol content 30ml or above in Schedule K may be removed and such preparation may be included in Schedule H1. The Committee recommended for suitable amendments in Drugs Rules, 1945 to restrict pack size of these item to maximum 30ml.

AGENDA NO.10

CONSIDERATION OF THE PROPOSAL TO AMEND THE DRUGS RULES, 1945 WITH RESPECT TO THE PACKING OF EYE DROPS IN OPAQUE PLASTIC VIALS/ BOTTLES BY PHARMACEUTICAL COMPANIES

DCC was apprised about the representation received to amend the Drugs Rules, 1945 with respect to concerns raised on the packing of eye drops in opaque plastic vials/ bottles by pharmaceutical companies on the basis of historical testing results of eye drops sampling which showed that most of the samples failed in description due to particulate matter and contamination. This was the trend when Eye drops were either packed in glass vials or transparent plastic vials.

Therefore, it was requested to ensure that Eye Drop Formulations are packed in transparent plastic vials/ Bottles, so that the consumer can ensure the clarity of Eye Drop before instilling.

After detailed deliberation, DCC recommended that a consultation meeting with various ophthalmic products (eye drops) producing companies may be conducted.

AGENDA NO.11

CONSIDERATION OF THE PROPOSAL REGARDING COMPETENT TECHNICAL STAFF HAVING DEGREE IN BIOTECHNOLOGY, BIOCHEMISTRY, MICROBIOLOGY, ZOOLOGY, BOTANY AND LIFE SCIENCE STUDY

DCC was apprised about the representation was received regarding the proposal for approval of Competent Technical Staff having degree in Biotechnology, Biochemistry, Microbiology, Zoology, Botany and Life Science Study with relevant experience for manufacturing & testing of Cell or Stem Cell derived product.

The Committee was informed that for manufacturing the desired product, the firm required staffs that have Degree or Post Graduate Degree in Biotechnology, Biochemistry, Microbiology, Zoology, Botany and Life Science Study and/or experience in manufacturing of Biotechnology Products and the present Rule 76 of Drugs Rules, 1945 does not mention the educational qualification requirements of Competent Technical Staff to manufacture Cell Therapy/ Stem Cell derived product viz. Degree or Post Graduate

Degree in Biotechnology, Biochemistry, Microbiology, Zoology, Botany and Life Science study and/ or experience in manufacturing of Biotechnology products.

After detailed deliberation, DCC recommended to amend the Drugs Rules, 1945 incorporating specific requirement of competent technical staff for cell or stem cell derived products as a separating category.

AGENDA NO.12

CONSIDERATION OF THE PROPOSAL FOR ISSUANCE OF FREE SALE CERTIFICATE(FSC), MARKET STANDING CERTIFICATE (MSC) AND NON CONVICTION CERTIFICATE (NCC) TO CLASS A (NON STERILE AND NON MEASURING) DEVICES BASED ON REGISTRATION NUMBER CARRIED OUT AS PER CHAPTER IIIB OF MEDICAL DEVICES RULES (MDR), 2017

DCC was apprised about the concerns raised regarding varying level of implementation for issuance of Free Sale Certificate (FSC), Market Standing Certificate (MSC) and Non Conviction Certificate (NCC) to Class A (non sterile and non measuring) medical devices based on registration number carried out as per Chapter IIIB of Medical Devices Rules (MDR), 2017.

The Committee was further informed that for Class A (non sterile and non measuring) devices, no licence in Form MD-3 and MD 4 is required to be obtained from State Licensing Authority and Free Sale Certificate (FSC), Market Standing Certificate (MSC) and Non Conviction Certificate (NCC) for such Class A (Non Sterile and Non measuring) device may be issued by Concerned State Licensing Authority, based on the registration carried out by the manufacturer which is generated on the portal (www.cdscomdonline.gov.in)

After detailed deliberation, DCC opined that suitable and necessary changes may be incorporated in the MD online portal so that the details of the registrations are visible and accessible to the SLAs and SLAs can review the details of the registration certificate, if required, to issue the Free Sale Certificate (FSC), Market Standing Certificate (MSC) and Non Conviction Certificate (NCC).

AGENDA NO.13

CONSIDERATION OF THE PROPOSAL FOR NO REQUIREMENT OF LOAN LICENSE APPLICATION FOR STERILIZATION PURPOSE BY A MANUFACTURER, WHO HAS LICENSE IN FORM MD-3/4 OR IN FORM MD-9/10, AT THE STERILIZATION SITE HAVING VALID LICENSE FOR STERILIZATION IN FORM MD-3 OR FORM MD-9.

DCC was apprised about the representation regarding the waiver to obtain loan license for sterilization, by a manufacturer holding valid manufacturing license in Form MD-3/4 or

Form MD-9/10, to carry out sterilization at a site, which is holding valid manufacturing license in Form MD-3 or Form MD-9 for Sterilization (by EO or by Gamma Radiation).

After detailed deliberation, the Committee opined that a Sub-Committee should be constituted for in depth examination of the issue and to propose suitable recommendations in this regard.

Accordingly, a Sub-Committee constituting of following members is formed to examine the issue and give its recommendation and submit its report in three months.

1. Drugs Controller, NCT, Delhi	Chairman
2. Drugs Controller, Karnataka	Member
3. Drugs Controller, Jharkhand	Member
4. Representative from CDSCO	Convener

AGENDA NO.14

CONSIDERATION OF THE PROPOSAL FOR SMOOTH TRANSITION OF CLASS A & B MEDICAL DEVICES TO LICENSING REGIME AND ADHERENCE TO THE TIMELINES PRESCRIBED IN MDR, 2017

DCC was apprised about the concerns regarding disposal of various applications which were filed for Grant of License in Form MD-3 or Form MD-4 and that the relaxation period of six months is completed on 31.03.2023, hence such application needs to be disposed off on priority basis.

The Committee deliberated the proposal and requested all the SLAs to clear the pendency within prescribed timeline.

AGENDA NO.15

AGENDA FROM STATE OF KERALA

DCC was apprised about the agenda from the State of Kerala:

1. With regard to sampling of drugs, cosmetics & medical devices, necessary steps may be taken to develop an online software for sampling of the same, to be implemented through the country.

2. Centralised registration software for registration of names of traders/ distributors/ wholesalers with their status of drug license may be maintained for verification of the genuineness of drug supplied to each state.

In this regard, the Committee after detailed deliberation opined that the above issues may be considered for inclusion while developing a unified national portal.

ADDITIONAL AGENDA NO. 1

CONSIDERATION OF THE PROPOSAL ON RECOMMENDATION OF INTER-MINISTERIAL COMMITTEE ON "DUAL USE" AND ILLICIT TRAFFICKING OF PRESCRIPTION DRUGS AND PRECURSORS

DCC was apprised about the recommendation of Inter-Ministerial Committee on "Dual Use" and illicit trafficking of prescription drugs and precursors and that the committee recommended to introduce digital track and trace system through block chain technology Bar coding/QR Coding System for the identified pharmaceutical ingredients (API) / formulations (list below) on the line of recent introduction of similar mechanism for API / 300 branded formulations by MoH&FW to get information like Unique Product identification code, Name of the API, Brand name (it any), Name and address of the manufacturer, Batch no, Batch Size, Date of manufacturing, Date of expiry or retesting, Serial shipping container code, manufacturing License no. or import license no. Special storage condition required (if any) etc.

1. Codeine based Cough Syrups,
2. Fentanyl & its analogues,
3. Buprenorphine injections
4. Tramadol,
5. Alprazolam,
6. Nitrazepam,
7. Diazepam,
8. Lorazepam,
9. Clonazepam,
10. Zolpidem and
11. Ketamine

The Committee was further informed that, for introducing bar code/QR code on all formulations containing listed 11 APIs, requires amendment to the Drugs Rules, 1945, which will be helpful in real time tracking & tracing of the same to prohibit illicit manufacturing as well as sale and purchase at supply chain level of these 11 APIs containing formulations.

After a detailed discussion, the committee recommended that the provisions made vide G.S.R 823(E) dated 17.11.2022 enlisting top 300 Brands of drugs may be extended to cover the drug formulations of the above listed 11 APIs.

ADDITIONAL AGENDA NO. 2

AGENDA FROM SUB-ZONE CHANDIGARH

DCC was apprised that concerns have been raised from time to time for bringing uniformity in implementation of the provisions of the Rule 73-AB (1) and 84-C (1) and 73-AB (2) and 84-C (2) of Drugs Rules, 1945, by all State/UT Licensing Authorities as well as Central with respect to the procedures of joint inspections for grant of fresh manufacturing license, grant of additional license in existing facility, addition of new

dosage form, extension or modification of the existing facility, change of constitution, tech staff, compliance verifications, Risk Based Inspections & their compliances etc.

After detailed deliberation, the Committee opined that there is need of an advisory / guidelines for execution of the provisions of the Rule 73-AB (1) and 84-C (1) and 73-AB (2) and 84-C (2) of the Drugs Rules, 1945 for its uniform implementation throughout the country.

Accordingly, the DCC constituted a Sub-Committee comprising of following members for examination of the matter and give its recommendation and submit its report in three months.

1. Drugs Controller, Uttarakhand
2. Drugs Controller, Himachal Pradesh
3. Drugs Controller, Uttar Pradesh
4. Shri. Ranga Chandrashekhar, DDC(I) CDSCO (Baddi)

ADDITIONAL AGENDA NO. 3

AGENDA FROM THE STATE OF PUNJAB

DCC was apprised about the following issues:

(1) Guidelines framed under Section 33-P for taking action in the Not of Standard Quality cases require detailed deliberation for taking uniform action in such cases.

(2) Categorization of Thermostable and Thermolabile drugs.

(3) Making provisions under Drugs & Cosmetics Act, 1940 and Rules, 1945 for taking action in cases of overcharging by the Blood Centres.

(4) Matter regarding bar-coding of the formulations having potential of misuse for intoxication, containing the salts like Tramadol, Buprenorphine, Diphenoxylate, Alprazolam, Benzodiazepenes i.e. Diazepam, Lorazepam etc.

(5) Regarding application of provisions of NDPS Act along with Drugs & Cosmetics Act, 1940 on the licensed chemists from where drugs formulations containing Narcotic drugs & Psychotropic substances are seized.

(6) Regarding making uniform guidelines / SOPs (like sealing of chemist shops) for effective implementation of suspension orders issued under Rule 66 of the Drugs & Cosmetics Rules, 1945 where the erring chemists are having other licences like homoeopathic drugs sale licences, food licences etc. in the same premises.

(7) Amendment in various Forms on which different licences are issued with respect to addition of column for constitution details.

After detailed deliberation, the committee gave following recommendations on aforesaid issues: -

(1) To re-visit widely the guidelines framed and issued under Section 33-P for taking action on cases of NSQ/ spurious/ adulterated drugs.

(2) For Categorization of Thermostable and Thermolabile drugs, a sub-committee comprising experts from NIPER under the Chairmanship of Prof. Arvind Kumar Bansal, NIPER Mohali should be constituted to look into the matter in depth to prepare a science based indicative list of Thermostable and Thermolabile drugs.

(3) In regard to the issue of overcharging by the Blood Centers, the Committee opined that a letter may be written to NPPA in this regard.

(4) to (7) This issue was discussed alongwith the Additional Agenda No. 1 and DCC provided clarity on the issues related to bar-coding & NDPS issues & other issues as raised above.

ADDITIONAL AGENDA NO. 4

AGENDA FROM THE STATE OF DELHI

DCC was apprised regarding the concern raised with respect to clarity on Section 23(4)(iii), Section 25(2), Section 18A, Section 32 (2), Section 36 AB of D&C Act, 1940.

DCC opined that the matter is related to amendments in the Sections of the present Act and a draft bill is already under consideration by the government for a new Act.

ADDITIONAL AGENDA NO. 5

CONSIDERATION OF THE PROPOSAL REGARDING WHO GLOBAL BENCHMARKING TOOL (GBT) FOR EVALUATION OF NATIONAL REGULATORY SYSTEMS

DCC was apprised about the Global Bench Marking (GBT) tool followed by WHO for assessment or benchmarking of a country with respect to various regulatory functions and that this being a pre-requisite for procurement of vaccines by UN agencies from Indian manufacturers, CDSCO alongwith other associated institutions like Central Drugs Laboratory etc. are assessed by WHO.

The Committee was further informed that WHO may plan the re-benchmarking of CDSCO very soon with respect to vaccines, once agreed by the Ministry.

Accordingly, the DCC requested all the State/UT drugs Controllers that in compliance with various parameters in the tool, following documents/ details/ information may be provided to CDSCO at the earliest. List of documents enclosed at **Annexure A**.

1. List of Officials in your department with details of qualification, experience before joining, current regulatory experience, training attended, which should be updated from time to time, number of inspections conducted in vaccine facilities
2. Recruitment Rules, plan and procedures
3. Organogram with job responsibilities under QMS which was decided in 49th DCC meeting
4. Risk based sampling plan and sampling of vaccines on basis of quarterly plan with guidance on same and submission of same with reports of vaccines storage facilities.
    - Quarterly plan to be made for sampling of vaccine from
    - Private hospitals/distribution chains of the manufacturers for private supply
    - Whole sale/retail premises where are vaccines are stored
    - Government hospitals/PHC/ Community Health Centres under jurisdiction
    - Special attention to imported vaccines and it shall be considered for sampling, if it has exhausted 60% shelf life in supply chain
    - If information/evidences received from any source on the integrity of the vaccine supply chain and the quality of vaccine, samples shall be drawn
5. Submission and maintenance of database of licensed vaccine manufacturing premises with list of products, licensed premises for sales, details of inspection performed of manufacturing and sales by states, action taken (approved, suspended, withdrawn, cancelled), list /database of all license approved/withdrawn/suspended/cancelled of vaccine manufacturers and sales premises):
6. Details of samples drawn with test results, regulatory action.

ADDITIONAL AGENDA NO. 6

CONSIDERATION FOR INCLUSION OF REGIONAL DIRECTOR TO BE INVOLVED AS A MEMBER OF THE TEAM FOR INSPECTION OF BLOOD CENTERS AT THE TIME LICENSING / RENEWAL

As per minutes of 31st meeting of Governing Body of National Blood Transfusion Council (NBTC) held on 26.11.2022 under the Chairmanship of DGHS, it was suggested to amend the Drugs Rules, 1945 for involvement of the Regional Director (RD), ROHFW in the Blood Transfusion Services Programme as a member of the team for inspection of blood centres at the time licensing/ renewal.

DCC deliberated that provision is there under the Drugs Rules, 1945 and as per the current provisions, under Rule 122-I, the Blood Centres at the time licensing/ renewal. shall be inspected by one or more inspectors, appointed under the Act and/or alongwith Experts in the field concerned. Therefore at the time of inspection, experts may be included in the inspection team

The meeting was ended with vote of thanks to all.

The End

List of participants enclosed.

LIST OF THE PARTICIPANTS OF 61ST DRUGS CONSULTATIVE COMMITTEE MEETING HELD ON 01.06.2023 THROUGH HYBRID MODE UNDER THE CHAIRMANSHIP OF DR. RAJEEV SINGH RAGHUVANSHI, DRUGS CONTROLLER GENERAL (INDIA)

A. STATE/UTs DRUGS CONTROL ORGANIZATIONS

S. No.	STATE/UT	NAME	DESIGNATION
1.	Andhra Pradesh	Shri. K.V.S.N. Gupta	Joint Director, DCA, A.P.
2.	Arunachal Pradesh	Shri. Ibom Ete	ZLA, A.P.
3.	Assam	Shri. Biswajit Talukdar	Sr. DI, GHTY (LA)
4.	Bihar	Shri. Ghanshyam Bhagat	Drugs Controller
5.	Chhattisgarh	Shri. Basanth Kumar Kaushik	DDC & SLA
6.	Goa	Smt. Jyoti J. Sardesai	Director, FDA
7.	Gujarat	Dr. H.G. Koshia	Commissioner, FDCA
8.	Haryana	Shri. Manmohan Taneja	State Drugs Controller, FDA
9.	Himachal Pradesh	Shri. Navneet Marwaha	Drugs Controller
10.	Jammu and Kashmir	Mrs. Lotika Khajuria	Drugs Controller
11.	Jharkhand	Smt. Ritu Sahay	Director (Drugs)
12.	Karnataka	Shri. Bhagoji. T Khanapure	Drugs Controller (A/C)
13.	Kerala	Dr. Sujith Kumar K	Drugs Controller (I/C)
14.	Madhya Pradesh	Shri. Shobhit	Deputy Drug Controller, FDA
15.	Maharashtra	Shri. Bhushan Patil	State Drugs Controller
16.	Manipur	Not Represented	
17.	Meghalaya	Shri. Larap. T.D. TOI	State Licensing Authority
18.	Mizoram	Not Represented	
19.	Nagaland	Not Represented	
20.	Odisha	Shri Nilamadhaba Dash	Drugs Controller
21.	Punjab	Shri. Sanjiv Kumar	Joint Commissioner(Drugs)
22.	Rajasthan	Shri. Ajay Pathak	Drugs Controller
23.	Sikkim	Shri. B. Iyangain Martin Targain	State Licensing Authority
24.	Tamil Nadu	Shri. Thiru. M.N. Sridhar	Director of Drugs Control (i/c)
25.	Telangana	Shri. G. Ramdhan	Deputy Director
26.	Tripura	Smt. Kanchan Sinha	Deputy Drugs Controller, Tripura
27.	Uttar Pradesh	Shri. Dinesh Tiwari	FSDA , UP
28.		Shri. S.K. Chaurasia	DLCA, UP
29.	Uttarakhand	Shri. Tajber Singh	Drugs Controller
30.	West Bengal	Smt. Sumana Pyne	Drugs Controller
31.		Shri. Tapan Kanti Rudra	IAS, DC
32.	Andaman and Nicobar	Not Represented	
33.	Chandigarh	Not Represented	

S. No.	STATE/UT	NAME	DESIGNATION
34.	Dadar and Nagar Haveli	Not Represented	
35.	Daman and Diu	Not Represented	
36.	Delhi	Shri. K R Chawla	Head of Office / Licensing Authority /Deputy Drugs Controller
37.	Lakshadweep	Not represented	
38.	Pondicherry	Dr. E. Anandakirouchenane	Controlling Authority cum Licensing Authority
39.	Ladakh	Smt. Nasreen Bano	ADC

B. INVITEE

S. No.	NAME	DESIGNATION
1.	Ms. Aradhana Patnaik	Joint Secretary(R), MoHFW

C. ZONAL/ SUB ZONAL OFFICES OF CDSCO

S. No.	OFFICES	NAME	DESIGNATION
1.	North Zone, Ghaziabad	Shri. Sanjeev Kumar	Deputy Drugs Controller (India)
2.	East Zone, Kolkata	Dr. Kamal Krishna Halder	Asst. Drugs Controller (India)
3.	West Zone, Mumbai	Shri. A. Senkathir	Deputy Drugs Controller (India)
4.	South Zone, Chennai	Dr. B. Kumar	Deputy Drugs Controller (India)
		Smt. C. Thiruvidha	Drugs Inspector
5.	Hyderabad Zone	Smt. B. Saraladevi	Asst. Drugs Controller (India)
6.	Ahmedabad Zone	Shri Jayant Kumar	Deputy Drugs Controller (India)
7.	Baddi Sub-zone	Shri. R Chandrashekar	Deputy Drugs Controller (India)
8.	Bangalore Sub-zone	Shri. N. A. Mahesh	Deputy Drugs Controller (India)
9.	Guwahati Sub-zone	Shri. Shiv Kumar	Asst. Drugs Controller (India)
10.	Indore Sub-zone	Represented	Asst. Drugs Controller (India)
11.	Varanasi Sub-zone	Shri. Vinay Kumar Gupta	Asst. Drugs Controller (India)
12.	Jammu Sub-zone	Smt. Bharati Bachloo	Asst. Drugs Controller (India)

D. DRUGS TESTING LABORATORIES

S. No.	OFFICES	NAME	DESIGNATION
1.	CDL, Kolkata	Dr. Saroj Kumar Ghosh	Director-in-Charge
2.	CDL, Kasauli	Shri. Sushil Kumar Sahu	Director-In-Charge

S. No.	OFFICES	NAME	DESIGNATION
3.	CDTL, Mumbai	Mrs. Sayali U. Warde	Director-in Charge
4.	RDTL, Chandigarh	Dr. Debasis Maiti	Director-in Charge
5.	RDTL, Guwahati	Shri. Shiv Kumar	In-charge & Asst. Drugs Controller (India)
6.	CDTL, Chennai	Smt. C Vijayalakshmi	Director-in Charge
7.	CDTL, Hyderabad	Smt. A. Visala	Director -in-charge & Deputy Drugs Controller (India)

E. CDSCO (HEAD QUARTERS)

S. No.	NAME	DESIGNATION
1.	Dr. Rajeev Singh Raghuvanshi	Drugs Controller General of India
2.	Dr. V. G. Somani	Joint Drugs Controller (India)
3.	Dr. S. E. Reddy	Joint Drugs Controller (India)
4.	Shri. A. K. Pradhan	Joint Drugs Controller (India)
5.	Dr. S. Manivannan	Joint Drugs Controller (India)
6.	Shri. Sunil M Joshi,	Deputy Drugs Controller (India)
7.	Dr. Ravikant Sharma	Deputy Drugs Controller (India)
8.	Shri. Aseem Sahu	Deputy Drugs Controller (India)
9.	Shri. B K Samantaray	Deputy Drugs Controller (India)
10.	Dr. Rubina Bose	Deputy Drugs Controller (India)
11.	Smt. A Visala	Deputy Drugs Controller (India)
12.	Smt. Swati Srivastava	Deputy Drugs Controller (India)
13.	Dr. Santosh Indraksha	Deputy Drugs Controller (India)
14.	Dr. Naveen Mehta	Drugs Inspector
15.	Shri. Abhinav Kapoor	Drugs Inspector
16.	Smt. Gunja Chaturvedi	Asst. Drugs Inspector
17.	Dr. Nagendra Kumar	Asst. Drugs Inspector