डॉ. राजीव सिंह रघुवंशी
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केंद्रीय औषधि मानक नियत्रंण संगठन
स्वास्थ्य एवम परिवार कल्याण मंत्रालय
भारत सरकार
एफ.डी.ए. भवन, कोटला रोड
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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-19013/01/2024-DC **Dated:** 14/2/2024

To

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

Sub: Minutes of the 63rd Meeting of the Drugs Consultative Committee (DCC) held on 30.01.2024 through Hybrid mode - reg.

Sir/Madam,

63rd meeting of the Drugs Consultative Committee was held on 30.01.2024 through Hybrid mode.

The minutes of the 63rd 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. PS to Adviser (Cost), MoHFW, Nirman Bhawan, New Delhi

MINUTES OF 63rd MEETING (HYBRID MODE) OF DRUGS CONSULTATIVE COMMITTEE (DCC) HELD THROUGH WEB CONFERENCE ON 30th JANUARY, 2024 AT CDSCO (HQ)

Inaugural Deliberations

Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India), Chairman, Drugs Consultative Committee (DCC), welcomed all members and thanked them for attending the meeting.

DCG(I) mentioned that this 63rd DCC meeting has been convened to deliberate on some of the important agendas in order to ensure uniform implementation of the provisions of the Act and Rules.

DCG(I) also stressed upon following points which needs to be implemented/ ensured by the States:

- DCG (I) apprised the State Drugs Controllers for the urgent need of onboarding of SLAs on the Online National Drugs Licensing System (ONDLS) for online receiving applications and issuance of blood center licenses. He informed that no physical applications will be accepted w.e.f. 01.04.2024.
- DCG(I) stressed for addressing the issue of similar/ same brands of different drug formulations of different therapeutic categories being sold in the domestic market by different manufacturers and there is an urgent need to take action by States against such manufacturers.
- DCG(I) also highlighted about the concerns with respect to multiple NSQ drugs manufactured by same manufacturer (repeated offenders). It was discussed about black listing of such manufacturers and prepare a list of such offenders so that Govt. procurement agencies become careful before procurement of drugs from such manufacturers.
- DCG(I) requested all the SLA's to strengthen/upgrade their State Drug Testing Laboratories with the funds released by the Central Government as the Central Drugs Laboratories are overburdened with the cough syrup samples and others sent by the CDSCO Drugs Inspectors. It was also informed that after a certain period of time, samples will not be accepted.

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

AGENDA NO.1

CONSIDERATION FOR APPROVAL OF REPORT OF 62nd MEETING OF DCC HELD ON 26.09.2023 AND ACTION TAKEN IN THE MATTERS ARISING OUT OF THE MEETING

Committee was apprised regarding the action taken report (ATR) on the agenda items of 62nd DCC meeting held on 26.09.2023.

The DCC was apprised on the Agenda No. 3 of the ATR regarding the proposal to bring uniformity in enforcement through Risk Based Inspection of drug manufacturing sites as

per the guidance document shared by CDSCO with all the States/UTs LAs requesting for sharing their comments on the guidance document. As no comments were received, therefore the DCC considered the Guidance document as approved.

Further, DCGI also requested to strengthen the infrastructure required for regulation of Medical Devices in the States including the manpower, laboratory, etc., as it is an emerging area.

With respect to Agenda No. 5 of the ATR relating sharing of information on NSQ dugs, the DCC was apprised that only few States are sending the NSQ data on monthly basis. All the States were sensitised to look into the matter regarding any difficulties and to send the NSQ data periodically and timely manner, so that the information so received can be compiled and published on the website for information of all the stakeholders.

No comments were received from the committee members w.r.t to other agendas and therefore ATR was considered as approved as above.

AGENDA NO.2

CONSIDERATION OF THE PROPOSAL FOR PHARMACEUTICAL WASTE MANAGEMENT

DCC was appraised that pharmaceuticals wastes are drugs and medicines, which are generated during manufacturing and maintenance operations, which can no longer be used. The improper disposal of unused medicines including antimicrobial is a growing problem throughout the world and traces of these wastes were found in environment which may cause serious health effect including Antimicrobial Resistance (AMR) to the human life.

There are various provisions under Drugs & Cosmetics Act in this regard and including following–

Sub-clause 16 of Part 1, Revised Schedule M of Drugs Rules 1945:

“Waste Material-

16.1 Provision shall be made for the proper and safe storage of waste materials waiting disposal. Toxic substances and flammable materials shall be stored in suitably designed, separate, enclosed cupboards.

16.2 Waste material shall not be allowed to accumulate. It shall be collected in suitable receptacles for removal to collection points outside the buildings and disposed of safely and in a sanitary manner at regular and frequent intervals.

16.3 The disposal of sewage and effluents (solid, liquid and gas) from the manufacturing area shall be in conformity with the requirements of the guidelines issued by the Environmental Pollution Control Board.

16.4 All bio-medical waste shall be destroyed as per the provisions of the Bio-Medical Waste (Management and Handling) Rules, 2016.

16.5 Rodenticides, insecticides, fumigating agents and sanitising materials shall not be permitted to contaminate equipment, starting materials, packaging materials, in-process materials or finished products.

Details of the proposal in context of AMR placed before the committee

1. Implementation of appropriate regulatory provisions under Schedule M.
2. Have regular stakeholders interactions for implementation of GMP principles to ensure monitoring of antimicrobial waste in industrial effluents,
3. Implementing recommendations/expectations of Pharmaceutical manufacturers regarding waste management to mitigate and prevent potential AMR
4. Developing guidance for the state Drugs Controllers and especially, the GMP inspectors for management of waste and waste water from the production of Antimicrobials.
5. The role and contribution of State Drugs Controllers on SAPCAR (State Action Plans for Containment of AMR)
6. Augmentation of enforcement activities.

The matter was deliberated in the DCC, and it was opined that provisions of waste disposal are available in the revised Schedule M and it was emphasized that the same need to be implemented in letter and spirit and it was also opined that it needs to be addressed by the Drugs Inspectors while carrying out the inspections especially the manufacturing units manufacturing Antimicrobials. Regarding disposal of the antimicrobials specifically on account of growing concerns regarding antimicrobial resistance being developed in the general population, States were also requested to provide inputs regarding current practices in their respective states. Further, it was proposed to create dedicated Nodal cell at each State level for handling issues relayed to Antimicrobials Resistance. It was further opined that States will be requested to share current practices on the disposal of antimicrobial drugs and accordingly a SOP will be prepared by CDSCO and shared to States for their comments.

AGENDA NO. 3

CONSIDERATION OF THE PROPOSAL FOR INFORMATION ABOUT FORTHCOMING GLOBAL BENCH MARKING OF VACCINES (NRA ASSESSMENT)

DCC was apprised that the Global bench marking is the tool followed by WHO for assessment or benchmarking of a country with respect to various regulatory functions, this being a pre-requisite for procurement of vaccines by UN agencies from Indian manufacturers and CDSCO along with other relevant institutions like CDL etc. are assessed by WHO.

In compliance with various questions in the tools number of communications were sent to the states and zones with respect to following viz.

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.

It was stressed that many States have not yet provided the data to CDSCO in response to the letter issued by CDSCO in the matter. Further, the committee was informed that the data submission is a continuous activity and updated data needs to be provided regularly as per checklist and SOP shared by CDSCO for manufacturing as well as sales premises for following the common practice on inspection process and preparation of uniform inspection reports among the States. Accordingly, all the state / UT Drugs Controllers were once again requested to provide the information at the earliest.

AGENDA NO. 4

CONSIDERATION OF THE PROPOSAL TO MAKE GUIDELINES ON GOOD DISTRIBUTION PRACTICES FOR PHARMACEUTICAL PRODUCTS UNDER SEPARATE SCHEDULE TO THE DRUGS RULES, 1945

DCC was apprised that according to Drugs & Cosmetics Act 1940 and Drugs Rules 1945, Rules 64 and 65 specify the conditions to be fulfilled to sell, stock, exhibit or offer for sale or distribute the drugs. It shall be the responsibility of all parties involved in the distribution of pharmaceutical products to ensure that the quality of pharmaceutical

products and the integrity of the distribution chain are maintained throughout the distribution process from the site of the manufacturer to the entity responsible for dispensing or providing the product to the patient or his or her agent. Thus in order to maintain the quality of the Pharmaceutical Products, adequate control over the entire chain of distribution is required to be maintained.

CDSCO had already published draft Guidelines on Good Distribution Practices of Biological Products and implemented in the year 2012 after consultation with stakeholders in line with WHO guidelines.

Further, the implementation of Good distribution /storage practices was deliberated in 54thmeeting of Drugs Consultative committee held on 30.07.2018 and it was suggested to take necessary provisions to impart legal sanctity to the suggested Guidelines as Schedule to the Drugs & Cosmetics Rules, 1945. In this regard, CDSCO had drafted guidelines on Good Distribution practices on Pharmaceutical Products in the year 2018 and same was published for stakeholders' comments. The draft guidelines is now under further revision in line with the revised WHO guidelines (2020).

The matter was deliberated in the DCC and it was stressed that due to non-mandatory nature of guidelines, the maintenance of storage condition of drugs during transit till whole sale and retail level is not being ensured by the manufacturers. DCC agreed that revised Good Distribution Practices (GDP) guidelines should be circulated to all States/ UTs before finalizing and once it is finalized, it should be made part of the Rules to provide legal backing and accordingly DCC recommended for inclusion of the GDP guidelines in the Drugs Rules, 1945.

AGENDA NO. 5

CONSIDERATION OF THE PROPOSAL FOR APPRISAL OF THE DRUGS CONSULTATIVE COMMITTEE ON THE REVISION WORK UNDERTAKEN WITH RESPECT TO CERTAIN GUIDELINES

In light of the New Drugs and Clinical Trials Rules, 2019, published in 2019, and various amendment in the rules from time to time, it has been decided by CDSCO to revise the following guidelines to align with current regulations, procedures and practices

1. Indian Good Clinical Practices Guidelines
2. Guidance documents for Zonal, Sub-Zonal & Port Offices.

DCC was apprised regarding revision work being undertaken by CDSCO. It was also requested that States/ UTs may also provide their comments if any which will be helpful in revising these guidelines.

AGENDA NO. 6

CONSIDERATION OF THE PROPOSAL FOR CONSIDERING BAN ON THE IMPORT & PRODUCTION OF CHLORAMPHENICOL AND NITROFURAN DRUGS FOR USE IN ALL FOOD-PRODUCING SYSTEM

DCC was apprised that the representation from MPEDA to propose ban of import & production of subject drugs was placed to the Department of Animal Husbandry & Dairying on 22.05.2023. The Empowered Committee on Animal Health (EACH) had decide whether to ban bulk packing of these two substances or to ban their usage entirely for food producing animal rearing systems.

Accordingly, the EACH committee has accepted the proposal of MPEDA and Ministry of Fisheries, Animal Husbandry & Dairying, Krishi Bhavan New Delhi had issued a Memorandum dated 06.10.2023 to MPEDA, which states that "in light of suggestions proffered by MPEDA, the regulatory subcommittee of the EACH of DAHD in its meeting held on 1309.2023 observed that the committee has no objection on the total ban on import, production, distribution and sales of Chloramphenicol and Nitrofurans drugs for use in any food producing animal rearing system.

The MPEDA has requested the Ministry of Health & Family Welfare to take the necessary steps to implement a complete ban on the import, production, distribution & sales of Chloramphenicol and Nitrofurans drugs for use in any food-producing animal rearing system “as observed by Regulatory subcommittee of the EACH of DAHL”.

In this regard, it is pertinent to mention that according to notification No. 1-100/SP(PAR)-notification/Enf/FSSAI/2014 dated 20.07.2018 issued by Food safety and Standard Authority of India (FSSAI), MoH&FW, various antibiotics and veterinary drugs including Nitrofurans i.e. Furaltadone, Furazolidone, Nitrofurantoin Nitrofurazone and Chloramphenicol are not permitted to be used at any stage of processing of meet and meet product, poultry, and eggs, sea food including shrimps, prawns or any variety of fish and fishery products. The extraneous maximum residue limit of 0.001 mg/kg will be applicable except for Chloramphenicol for which it shall be 0.0003mg/ kg (0.3microgram/ kg).

The matter was discussed and members opined that many a times drugs are being misused for poultry and other animal feed supplements and therefore the committee agreed with the proposal for ban on the import, production, distribution & sales of Chloramphenicol and Nitrofurans drugs for use in any food-producing animal rearing system.

AGENDA NO. 7

CONSIDERATION OF THE PROPOSAL FOR IMPORT OF INDUSTRIAL/TECHNICAL GRADE API OR DRUG SUBSTANCES THROUGH DUAL USE NOC FOR NON MEDICINAL USE

DCC was apprised regarding the issue and essentiality of Dual Use NOC for Industrial/technical grade API or Drug Substances to be imported for Non Medicinal Use to be treated as chemicals and exempted from Schedule D to be read with Rules 43 of Drugs and Cosmetics Rules, 1945 and uniform regulation under Chapter III and IV of Drugs and Cosmetics Act and Rules thereunder. There are concerns as well as court cases related to import of Salicylic Acid (industrial/ technical grade) in this regard.

The matter was deliberated by DCC in detailed in light of Schedule D to be read with Rules 43 of Drugs Rules, 1945. The committee opined that the rule position is very clear and therefore substances intended to be used as drugs after further purification or rendering them sterile is not exempted under Rule 43 from the provision of Chapter III of the Drugs and Cosmetics Act, 1940 and rules made thereunder.

Further, DCC also opined that any substance imported in a chemical name irrespective of any grade or congaing higher amount of impurities intended to be used as a drug is also not exempted under Rule 43 and Schedule D.

AGENDA NO. 8

CONSIDERATION OF THE PROPOSAL FOR LICENSING OF CELL OR STEM CELL DERIVED PRODUCTS, GENE THERAPEUTIC PRODUCTS OR XENOGRAFTS, ETC. THROUGH CLAA ENDORSEMENT

DCC was apprised that at present there are provisions under the Drugs & Cosmetics Act for grant of manufacturing permission for Vaccine, LVPs and r-DNA products under Form 28D and Form 28DA with the CLAA endorsement. However, there is no provision for grant of manufacturing license by the SLA & CLAA in Form 28D for approval of Cell and Stem cell derived products, Gene therapy products, modified release dosage forms, and such other new drugs.

A revised Form and Format including amendment to Form 27D, 27DA and Form 28D and Form 28DA for inclusion of the words cell or stem cell derived products, gene therapeutic products or xenografts, etc. was proposed.

The DCC deliberated and agreed with the proposal w.r.t cell or stem cell derived products, gene therapeutic products or xenografts, etc.

AGENDA NO. 9

CONSIDERATION OF THE PROPOSAL FROM BOTSWANA AND BURKINA FASO, ON BEHALF OF THE AFRICA REGION, TO AMEND PART I AND PART II OF ANNEX A OF THE MINAMATA CONVENTION ON MERCURY ON COSMETICS TO BE CONSIDERED BY THE CONFERENCE OF THE PARTIES AT ITS FIFTH MEETING

Minamata Convention on Mercury is to communicate to the Parties and the signatories to the Minamata Convention on Mercury; the text of the amendment to Annex A to the Convention as proposed by Botswana and Burkina Faso on behalf of the Africa region. The proposal was putforward for consideration by the Conference of the Parties at its fifth meeting, which is scheduled to take place from 30th October to 3rd November 2023 in Geneva, Switzerland is summarized below.

1. **Proposal by the Africa region to amend Part I of Annex A to the Minamata Convention on Mercury.**

The Africa region proposes to insert the following text in Part I of Annex A (deleting the 1 ppm mercury threshold for cosmetics):

Mercury-added products	Date after which the manufacture, import or export of the product shall not be allowed (phase-out date)
Cosmetics, including skin lightening soaps and creams, and not including eye area cosmetics where mercury is used as a preservative and no effective and safe substitute preservatives are available.	2025

2. Proposal by the Africa region to amend Part II of Annex A to the Minamata Convention on Mercury.

The Africa region proposes to insert the following text in Part II of Annex A:

Mercury-added Products	**Provisions**
Cosmetics including skin lightening soaps and creams, and not including eye area cosmetics where mercury is used as a preservative and no effective and safe substitute preservatives are available 1/.	Measures to be taken by a Party to phase out the sale and offering of sale of mercury-added cosmetics from both local markets and online platforms shall include the following measures: i. Setting national objectives to phase out sales and offering of sales including, but not limited to carrying out two or more of the following: (a) Developing and implementing strategies to discourage marketing, advertising and display; (b) Developing and publicizing advisories, detention and prohibited substances lists of mercury-added cosmetics; (c) Licensing and product ingredient approvals for manufacturing facilities for cosmetics and beauty products; (d) Engaging online platforms in developing and implementing product safety pledges. ii. Coordinating and collaborating on phase out initiatives inter-ministerially and bilaterally and/or regionally; iii. Raising public awareness about the hazards of SLP use among physicians, dermatologists and beauty centers, as well as consumers and family

	members.

1/ The intention is not to cover cosmetics, soaps or creams with trace contaminants of mercury:

The matter was deliberated in the DCC, and it was opined that a sub-committee may be constituted which may also include medical health hazard experts dealing with elemental impurity, an expert from the Ministry of Environment & Forest. Further, it was also opined that the sub-committee may also look into India's obligations in respect of the Minamata Convention on Mercury, if any.

AGENDA NUMBER 10 TO 13 WAS DELIBERATED IN REFERENCE TO THE COMMUNICATION RECEIVED FROM THE MINISTRY OF COMMERCE

AGENDA NO. 10

CONSIDERATION OF THE PROPOSAL FOR GRANT OF ONE-TIME EXPORT NOC & MANUFACTURING LICENSE FOLLOWED BY CERTIFICATE OF PHARMACEUTICAL PRODUCT (CoPP) FOR PHARMACEUTICAL AND BIOLOGICAL PRODUCTS UNDER UNAPPROVED/ BANNED DRUGS/ NEW DRUGS CATEGORY SOLELY FOR EXPORT PURPOSE

DCC was apprised on the following issues raised by the industry.

a) **For pharmaceutical products:**

Currently, as per DCGI notification No. 7-5/2018/Misc./034 (NOC) dated 02.08.2018, export NOC and manufacturing license are granted by State Licensing Authority (SLA) for manufacture of unapproved/banned/new drugs solely for export purpose. This process is a time-consuming approach which renders delay in the export consignment since for each PO (for repetitive export purchase orders), applicants need to obtain export NOC (specific to quantity, country & buyer) & Mfg. license from SLA which takes a considerable amount of time and eventually CoPP from SLA based on joint inspection takes further additional time, leading to delays in getting the CoPP required for Export purposes.

Therefore, it was proposed weather grant of one-time export NOC and manufacturing license followed by CoPP may be considered.

b) **For Biological products:**

Currently, export NOC from CDSCO HQ, New Delhi is a prerequisite to obtain Mfg. license including counter sign from CLA to manufacture unapproved/banned drugs/New drugs derived r-DNA technology (biological products) solely for export purpose and followed by COPP from SLA. It takes about 8 to 10 months to get these approvals and the entire process is very cumbersome and time consuming to approach every time to apply for repetitive export orders as is conveyed by the Industry.

It is to mention that as per the earlier procedure for manufacture of Unapproved/Banned drugs/New drugs, the manufacturer were required to take NOC from CDSCO prior to obtaining manufacturing license from States for export purpose. In light of that, one-time export NOC and manufacturing license was insisted by the manufacturers.

The matter was discussed in 48th DCC held on 24.07.2015, it was recommended that NOCs for export of drugs which are prohibited for marketing in the country are only required to be issued country specific and quantity specific. In other cases for repetitive export orders, office of DCGI may review the guidelines in consultation with MoHFW.

In order to streamline the export, the process to grant NOC as well as manufacturing license for Unapproved/Banned drugs/New drugs were delegated to States vide letter dated 02.08.2018 with the approval of the Ministry.

Therefore, it was proposed weather grant of one-time export NOC and manufacturing license followed by CoPP may be considered.

Committee deliberated the matter and discussed that grant of such one-time export NOC may be considered for certain categories of drugs like approved/ unapproved new drug, and not for the banned drugs. However, the committee opined that due to misuse potential, the current practice for issuance of NOCs for export of drugs may continue. However, DCC recommended for constituting a sub-committee to examine the pros and cons involved for taking further decision in the matter.

AGENDA NO. 11

CONSIDERATION OF THE PROPOSAL REGARDING REQUEST FOR RELAXATION OF NOC CONDITION OF PHYSICAL DESTRUCTION OF ALL UN-EXPORTED QUANTITY OF THE DRUG(S) IN THE NO OBJECTION CERTIFICATE (NOC) FOR EXPORT OF UNAPPROVED/APPROVED NEW DRUGS

DCC was apprised that the concerns have been raised that the excess quantity manufactured under Test License and un-exported, needs to be destroyed by the manufacturer as per NOC conditions, which leads to great economical loss to the industry and in turn to the Nation.

It is to mention that as per DCGI circular no. 7-5/2018/Misc./034 (NOC) dated 02.08.2018, the applicant shall ensure that the drugs manufactured on the basis of the permission granted is exported and no part of it is diverted for domestic sale in India and the applicant shall ensure physical destruction of all un-exported quantity of drugs.

DCC deliberated the matter in detailed and recommended that the same sub-committee constituted as per recommendations given in Agenda no. 10 above shall also examine this issue and submit the report.

AGENDA NO. 12

CONSIDERATION OF THE PROPOSAL FOR UNIFORM COPP FORMAT (RECOMMENDED BY WHO) AND WHO GMP CERTIFICATE THROUGHOUT THE COUNTRY

DCC was apprised that the concerns have been raised that Certificate of the Pharmaceutical product (CoPP) & WHO GMP certificate are the preliminary documents to be submitted for obtaining product approval/Market Authorization and to export the pharmaceuticals to most of the overseas markets. The industry is facing difficulties while exporting because of lack of uniformity in the COPP & WHO GMP format issued by various State Licensing Authorities. Many importing countries such as Vietnam are seeking verification of COPPs by the State Licensing authorities due to different formats being used by SLAs.

The matter was discussed in detail among the members and it was opined that the states are issuing WHO CoPP certificates as per WHO guidelines. It was requested to States to share the formats of WHO CoPP certificates being issued by them currently to examine the issue of non uniformity and deciding the matter. Zonal offices of CDSCO shall coordinate with States for obtaining the formats.

AGENDA NO. 13

CONSIDERATION OF THE PROPOSAL FOR HARMONIZATION IN PROCESSING AND ISSUANCE OF LICENSES/ CERTIFICATESAT SLA LEVEL

The matter is regarding separate mechanisms of application procedures in various state drug control offices for grant of licenses using different formats for licenses and certificates (GLP/GMP/FSC etc.). Some states are using software, some require physical submission of documents and some are endorsing the letter heads of the companies. Suggestion regarding harmonized systems across different states.

It was requested to States to share the formats being issued by them currently to examine the issue of non uniformity and deciding the matter. Zonal offices of CDSCO shall coordinate with States for obtaining the formats.

AGENDA NO. 14

CONSIDERATION OF THE REPORT SUBMITTED BY COMMITTEE FOR PREPARATION OF “NATIONAL DRUGS DATABASE”

DCC was apprised that the under the Drugs & Cosmetics Act, 1940 and Rules made thereunder, different authorities have different responsibilities and the data of the drugs manufactured, sold and distributed is present in different forms under the custody of multiple regulatory authorities, which in turn leads to a need for a central database of the drugs. At present, there is no comprehensive national database which provides details of

medicines available in the country. A comprehensive database is crucial not only to empower consumers but also to improve the monitoring mechanism for ensuring quality, safety and efficacy of drugs.

At the moment, many states have their own databases on different software platforms and all that data needs to be integrated into a centralized database which will provide near real-time and comprehensive information to the authorities.

In order to have such a database for the drug formulations licensed by the State Licensing Authority in the Country, Rule 84AB was incorporated providing that the manufacturers will register and upload the data regarding manufacturing and formulation details as per the Format provided in the SUGAM Portal and the information uploaded by the licensee with SUGAM portal, shall be verified by the concerned Licensing Authority.

Central Drugs Standard Control Organization (CDSCO) constituted a Committee vide O.M No. ED/Misc.-365/2022 dated 27.10.2022to prepare a comprehensive 'National Drugs Database' of drug formulations manufactured and marketed in the country.

The Committee deliberated the matter in various meetings and finalised the report along with recommendations. Copy of Committee report dated 30.11.2023 is enclosed.

As on 30.11.2023, the manufactures have uploaded data of **total 492995**drug formulations on the SUGAM Portal out of which **175337** formulations are with brand name and **317658** formulations are without brand name. However, out of **491527** drugs formulations only 33094 (out of which **18978**with brand name and **14116**without brand name**)** have been verified and approved by the SLA so far. Also, **2706** drugs formulations (out of which **1838** with brand name and **868** without brand name**)** have been verified and rejected by the SLA so far. The State-wise details about number of formulations etc. are provided in enclosed report.

As per the Format in SUGAM Portal, various details of drug formulations are to be uploaded as under**: -**

1. Manufacturing License No.
2. Manufacture Name & Address
3. Loan Premises Name & Address
4. License issue date
5. License expiry date
6. License first date
7. Type of license
8. Generic Name
9. Strength
10. Brand Name
11. Pack size
12. Dosage Form
13. Composition
14. Therapeutic Category, etc.

The drug can be searched by using product name, brand name, name of manufacturer etc. in the SUGAM portal database. Further, the SUGAM portal data can be exported in Excel Sheet and the same can be used for searching.

Recommendations of the Committee are mentioned as below:

- The details of the drug formulations in the database of the SUGAM portal should be verified and approved by the respective State Drugs Control Authorities at the earliest before its use.
- For verification of the legacy data, the committee recommends that the Government may consider hiring of appropriate agency/manpower for coordinating with the State Drug Authorities for carrying out this exercise.
- The drug database should be used in strengthening, streamlining the regulatory as well as the healthcare system in many aspects as mentioned in the Committee report.
- The State Drugs Control Authorities should regularly direct the manufacturers under their jurisdiction to upload the data on real time basis as per the requirements.
- Consideration may be given to amend the Rules incorporating suitable provision so that in case any manufacturer of any drug does not upload and update the data as per the requirements, the manufacturer cannot sale/distribute the said product.
- The Government has initiated the process for creation of a unified IT platform for all regulatory activities, to assess regulatory capacity across the States and Centre, to promote 'Ease of Doing Business', etc. The database created under the SUGAM portal may be considered for integration with the database under the unified IT Platform as and when the Platform is implemented.

DCC deliberated the matter and apprised that already enough time have passed (almost 5 years) mandating manufacturers to update details of product licenses and permissions in SUGAM portal as required under rule 84B of Drugs Rules, 1945. However, till date manufacturers have not updated the details of all the products in the SUGAM database. DCC recommended that States shall carry out meeting with industry associations and a deadline may be set for uploading of all the formulation details.

AGENDA NO. 15

CONSIDERATION OF THE PROPOSAL FOR CHECKING ANTIMICROBIAL RESISTANCE AS PER THE EXPECTATION NAP-AMR 2.0

DCC was apprised that the Antimicrobial Resistance (AMR) has been recognised as a serious and growing threat to the public health Globally.

The problem of Antimicrobial Resistance (AMR) has been highlighted as a global health priority in multiple high-level fora ranging from the UNGA, G7 to G20. Under the Indian Presidency, the G-20 New Delhi Leaders Declaration states the following in this regard: "*Implement and prioritise tackling Antimicrobial Resistance (AMR) following the One Health approach, including through research and development, infection prevention and control, as well as antimicrobial stewardship efforts within respective national action*

plans through AMR and antimicrobial consumption surveillance" (vide section 28(iv), page 9 pf the declaration).

The following measures are proposed to the State Drugs Controller for uniform implementation in order to curb the Antimicrobial resistance.

1. Develop and implement mechanism for safe disposal of expired antimicrobials.
2. **Track & trace system** has been implemented for top 300 brands w.e.f. 01.08.23. It may be expanded to Antimicrobials.
3. Develop guidelines for ensuring the Quality Management System to be implemented by the CDSCO and SDCs in order to curb AMR.
4. Development of guidance for SDCAs to ensure implementation of Schedule H & H1 drugs through enforcement activities.
5. Issuing advisory to manufacturers to use their digitalised well developed supply chain network, for manufacture and sale of antimicrobials.

The matter was apprised to the committee in detailed and the committee recommended for actions as recommended under Agenda no. 2 above. It was further opined that SLAs shall issue directions to manufacturing associations, chemist associations and enforcement officials for sensitizing them regarding the issue and visible concrete action need to be taken by the States. It was decided that each State shall provide Action Taken Report on AMR to CDSCO. Further, CDSCO will also hold a dedicated consultation with States on the issue. States shall share the practices followed by them presently to combat AMR.

AGENDA NO. 16

CONSIDERATION OF THE PROPOSAL FOR NEED OF JOINT TASK FORCE FOR FIGHTING THE MENACE OF SPURIOUS/ ADULTERATED DRUGS IN THE COUNTRY

DCC was apprised that various measures are ongoing to address the issue. The matter needs to be examined critically in respect of specific Terms of reference, activities to be performed, modalities, etc.

However, DCGI requested all the States for informing about the implementation of G.S.R 823(E) dated 17.11.2022 regarding Bar Code/ QR Code on the label of top 300 Brands of drugs in Drugs Rules, 1945.

AGENDA NO. 17

CONSIDERATION OF THE PROPOSAL TO AMEND DRUGS RULES, 1945 FOR REMOVAL OF THE EXEMPTIONS FOR THE DRUGS SUPPLIED BY REGISTERED MEDICAL PRACTITIONERS TO HIS OWN PATIENTS IN LIGHT OF HON'BLE SUPREME COURT IN SLP(CRL) NO. 9978 of 2022 AND THE CENTRAL GOODS AND SERVICE TAX 2017

DCC was apprised about the proposal.

The matter was discussed at length by the DCC. It was observed that the matter pertains to supplying of medicines by practicing physicians wherein the cost of medicines collected above MRP along with the consultation fees and GST/tax evasion and opined that the issue of tax evasion are beyond the scope of DCC. As regards to overcharging beyond the ceiling price fixed under DPCO, States are empowered to take action under DPCO, 2013. The committee didn't agree with the proposal.

AGENDA NO. 18

CONSIDERATION OF THE PROPOSAL TO AMEND DRUGS RULES, 1945 TO PROVIDE EXEMPTION FOR RECOGNIZED MEDICAL INSTITUTION FROM THE PROVISION OF SALE LICENCES UNDER DRUGS RULES 1945 IN RESPECT OF SUPPLY AND DISTRIBUTION OF ESSENTIAL NARCOTIC DRUGS NOTIFIED UNDER THE NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES ACT 1985 FOR ADEQUATE ACCESS TO SUCH OPIOIDS FOR PALLIATIVE CARE AND DE-ADDICTION TREATMENT

DCC was apprised about the proposal.

The matter was discussed at length by the DCC. DCC opined that the existing provisions does not bar for recognizing Medical Institutions for supply of essential Narcotic Drugs. Therefore, the committee didn't agree with the proposal.