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–110 0 0 2

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-19013/02/2024-DC **Dated:** 30 JUL 2024

To

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

Sub: Minutes of the 64th Meeting of the Drugs Consultative Committee (DCC) held on 19.06.2024 - reg.

Sir/Madam,

The 64th meeting of the Drugs Consultative Committee was held on 19.06.2024.

The minutes of the 64th 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.: Minutes of Meeting

Copy for information to:-

1. PPS to Secretary, MoHFW, Nirman Bhawan, New Delhi
2. PS to Advisor (Cost), MoHFW, Nirman Bhawan, New Delhi

MINUTES OF 64th MEETING (HYBRID MODE) OF DRUGS CONSULTATIVE COMMITTEE (DCC) HELD ON 19th JUNE, 2024 AT CDSCO (HQ), FDA BHAWAN, KOTLA ROAD, NEW DELHI – 110002.

Inaugural Deliberations

Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India), Chairman, Drugs Consultative Committee (DCC), welcomed all the members of the Drugs Consultative Committee (DCC) and thanked them for attending the 64th DCC meeting.

Shri. R. Chandrashekar, Joint Drugs Controller (India) mentioned that this 64th 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. The Committee was also apprised that Ayush Ministry has recruited their own Drugs Inspectors as well as Assistant Drugs Controllers and has started functioning. The Ayush Ministry will be responsible for making all the Policies and Rules related to Ayush department.

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

AGENDA NO.1

ACTION TAKEN REPORT (ATR) OF 63rd DCC MEETING HELD ON 30.01.2024

The Drugs Consultative Committee deliberated the action taken report (ATR) of the agenda items of 63rd DCC meeting held on 30.01.2024.

While deliberating the Agenda No. 5 of the ATR of 62nd DCC meeting held on 26.09.2023, relating to sharing of information on NSQ drugs. The Committee was apprised that only few States are sending the NSQ data on monthly basis. All the States were sensitised to look into the matter and to send the NSQ data periodically and in a timely manner, so as to publish the same on the website for information of all the stakeholders.

No comments were received from the committee members with respect to other agendas and therefore ATR was considered as approved.

AGENDA NO.2

CONSIDERATION OF THE PROPOSAL FOR OPTIMIZING TRAINING PROCESSES AND SUPPORT MECHANISMS FOR REGULATORY OFFICERS

DCC was apprised about the agenda. The committee was also informed that to keep pace with advancements in the pharmaceutical, biological, and medical devices industries, the Training Cell of CDSCO has initiated a comprehensive training program to develop human resources both at CDSCO and the States. These programs include tailored training modules for various levels of induction, as well as basic and advanced courses. The committee was further apprised about the Optimized Training Processes and Support Mechanisms in this regard.

After detailed deliberation, the committee recommended as under: —

1. The nomination details of the participants may be communicated through email instead of the postal delivery
2. Permission from the higher authority may be taken for nomination of the candidate by the State regulator for the domestic training programmes on annual basis.
3. The preparation of Guidelines for selection criteria of the candidates for the training and also the preparation of the checklist to assess the performance evaluation of the candidates before and after the training.
4. Availability of the E-Training modules and certification course modules for the Revised Schedule M, Inspection and Report writing, Prosecution, etc., along with the case studies.
5. SLA's should provide support for **Regional Training Program** for identifying venue, topics, duration etc. to enhance localized training efforts.

AGENDA NO.3

CONSIDERATION OF THE PROPOSAL REGARDING THE ISSUE OF SIMILAR/ SAME BRANDS OF DIFFERENT DRUG FORMULATIONS, OF DIFFERENT THERAPEUTIC CATEGORIES BEING SOLD IN THE COUNTRY AND THE NHRC MATTER REGARDING A NEWS ARTICLE PUBLISHED IN "THE HINDU" ON 25.01.2024, UNDER CAPTION "INDIA'S PROBLEM – DIFFERENT DRUGS, IDENTICAL BRAND NAMES"

The agenda was discussed in length and after detailed deliberation, the committee recommended the following steps to strengthen the measures so that similar brand name does not exist:

1. The data base of all the products with brand names in Sugam Portal may be made accessible to the general public, so that when application for endorsement of brand name in Form 51 is submitted to SLA, they can search the existing brand names from this data base of CDSCO along with the trade mark registry, literature and reference books on details of Drug Formulation in India and Internet, such or similar brand names or trade name is not already in existence with respect to any drug in the country and the proposed brand names or trade names shall not lead to any confusion or deception in the market. Cases of existing same, similar, sound alike, look alike brands, if any available in the market should also be addressed by the concerned State Licensing Authorities with the help of such database etc.

2. In case of existing brands with same name available in the market, whoever has first submitted Form 51 under Drugs Rules, 1945 shall be allowed to continue the marketing and Brand names of other manufacturers shall be withdrawn by the SLAs. In other cases where Form 51 does not apply, the claim of being "First" shall be evaluated by the concerned SLAs on the basis of approval history and take appropriate decision.

3. All the manufacturers should be directed to upload the formulations details along with the brand names on the Sugam Portal (as per rule 84AB).

AGENDA NO. 4

CONSIDERATION OF THE PROPOSAL TO EXCLUDE PRODUCTS COVERED UNDER SCHEDULE-O FROM THE PROVISIONS OF NEW DRUGS AND IMPORT REGISTRATIONS

DCC was apprised about the proposal to exclude products covered under Schedule-O from the provisions of New Drugs and Import Registrations.

The committee was informed that as per Section 3 (b) (ii), Disinfectants are also covered under the definition of Drug. Whenever any drug is imported in the country, the applicant has to obtain Import license together with Registration certificate as per Drugs Rules, 1945 and if any drug attracts the definition of New drug, in that case new drug approval is also required to be obtained as per NDCT Rules, 2019.

After detailed deliberation, the committee recommended to prepare and issue a guidance for specific requirements for obtaining Import Registration Certificate and New Drug Permission (Marketing Authorization) for disinfectants.

AGENDA NO. 5

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 that the matter was earlier deliberated in 61st DCC meeting held on 01.06.2024 and after deliberation, the committee recommended that a consultation meeting with various ophthalmic products (eye drops) producing companies may be conducted.

As per the recommendation of the 61st DCC meeting, a consultation meeting with industry associations was carried out in this regard.

After detailed deliberation, the committee recommended that an advisory may be issued to the SLA's for monitoring the quality of such products.

AGENDA NO. 6

CONSIDERATION OF THE PROPOSAL REGARDING GUIDELINES ON GOOD DISTRIBUTION PRACTICES FOR PHARMACEUTICAL PRODUCTS.

DCC was apprised about the agenda discussed in 63rd DCC meeting held on 30th January 2024 wherein 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. The draft guidelines prepared in this regard was discussed by the Committee.

The DCC observed that and draft guideline for inclusion as schedule under the Drug Rules has been prepared in line with revised WHO TRS guidelines and applicable rules.

After detailed deliberation, the committee opined that the proposed guidance document may be deliberated in consultation with stakeholders before taking further action.

AGENDA NO. 7

CONSIDERATION OF THE PROPOSAL FOR CREATION OF GUIDELINES ON DISPOSAL OF EXPIRED/ UNUSED DRUGS

DCC was apprised that the agenda was discussed earlier in 58th DCC meeting held on 14.07.2020 regarding the disposal of unused/expired medicine and recommended to constitute a sub-committee to examine the issue. Accordingly, a sub-committee was constituted vide OM dated 27.10.2020. Now the sub-committee has submitted its report.

The report of the sub-committee along with the guidance document on safe disposal of unused/expired medicine was deliberated in detail by DCC.

The DCC agreed in principle with the report of the sub-committee and the guidance document and recommended that the sub-committee may also look into the procedures mentioned under the draft guidance document related to disposal of expired/ unused medicine by general public before finalization.

AGENDA NO. 8

CONSIDERATION OF THE PROPOSAL TO REVISIT THE RULE 64 OF DRUGS RULES, 1945 TO MONITOR THE SALE OF DRUGS IN INDIA

DCC was apprised about the Rule 64 prescribes the conditions to be satisfied before a licence in Form 20, Form 20B, Form 20F, Form 20G, Form 21 or Form 21B is granted.

In this regard, it is to mention here that it was decided to constitute a committee to revisit the rule 64 under Part VI of Drugs Rules, 1945 pertaining to sale of drugs other than homeopathic medicines with regards to present scenario.

Accordingly, a committee comprising of Drugs Controller, Odisha, Drugs Controller, Madhya Pradesh, Drugs Controller, Punjab, Drugs Controller, Telangana and DDC (I), Enforcement cell, as Convener has been constituted vide OM dated 20.05.2024.

The committee deliberated the matter and agreed with the proposed committee constituted for the purpose. However, DCC recommended that the report of the committee should be placed before DCC for further discussion and consideration.

AGENDA NO. 9

CONSIDERATION OF THE PROPOSAL TO INFORM THAT ALL THE STATES SHALL FOLLOW THE REVISED SCHEDULE M AND ALL FRESH LICENCE SHALL BE ISSUED ACCORDINGLY

DCC was apprised that the Good Manufacturing Practices (GMP) and Requirements under Schedule M of the Drugs Rule, 1945 have been revised vide G.S.R. 922(E) dated

28.12.2023 published by MoHFW. The revised Schedule M has been made to make the GMP and requirements of Premises, Plant and Equipment for Pharmaceutical Products harmonized with the international Standards.

After detailed deliberation, the committee recommended that the States/ UTs shall ensure that the revised Schedule M is implemented as per the prescribed timelines.

AGENDA NO. 10

CONSIDERATION OF THE PROPOSAL FOR ONLINE NATIONAL DRUG LICENSING SYSTEM (ONDLS) PORTAL FOR ISSUANCE OF LICENCES AND CERTIFICATES FOR DRUGS AND COSMETICS ACROSS THE COUNTRY

DCC was apprised that CDSCO has initiated various online services for implementation of e- governance from time to time including launching of ONDLS portal for the States.

DCC was further apprised that CDSCO has also set up a helpdesk for ONDLS portal for facilitating the stakeholders including the Drug regulators for seamless implementation of the portal.

After detailed deliberation, the DCC recommended that SLAs shall ensure that:

- Applications are received and processed through ONDLS portal only and no physical applications are accepted in case of States/ UTs which are onboarded on ONDLS portal.
- States/ UTs which have not yet on-boarded shall take necessary steps for onboarding on the ONDLS portal.

(AGENDA FROM STATE OF TELANGANA)

AGENDA NO.11

CONSIDERATION OF THE PROPOSAL FOR MANDATING THE INCLUSION OF INTERNATIONAL NOMENCLATURE OF COSMETIC INGREDIENTS (INCI) NAMES ON THE INGREDIENT STATEMENT OF EVERY COSMETIC PRODUCT LABEL.

DCC was apprised about the proposal of using the **International Nomenclature of Cosmetic Ingredients (INCI)** for identification of cosmetic ingredients.

DCC deliberated the proposal in detail and opined that the inclusion of INCI names on label may not be feasible due to space constraint on the label and therefore suggested to follow the BIS standards.

(AGENDA FROM STATE OF TELANGANA)

AGENDA NO. 12

CONSIDERATION OF THE PROPOSAL REGARDING INTERPRETATION OF GASTRO-RESISTANT TABLETS/CAPSULES (DELAYED-RELEASE TABLETS/CAPSULES) AS 'NEW DRUGS' AS PER RULE 2 CLAUSE (W) OF THE NEW DRUGS AND CLINICAL TRIAL RULES, 2019

DCC was apprised about the Manufacturing licences / product approvals of the Gastro-resistant Dosage forms / Delayed-release Dosage forms (Enteric Coated Tablets/Capsules) are considered as 'New Drugs' and shall always be deemed to be new drugs, along with sustained-release, extended-release, prolonged-release, and controlled-release products and their approvals are issued by CDSCO in accordance with the New Drugs and Clinical Trial Rules, 2019.

The committee observed that there is lack of uniform implementation of this rule regarding Gastro-resistant Dosage forms / Delayed-release Dosage forms (Enteric Coated Tablets/Capsules) among the State/UTs.

After detailed deliberation, the committee recommended to issue a Circular to all the States/UTs regarding the interpretation of Gastro-resistant Tablets/Capsules (Delayed-release Tablets/Capsules) as 'New Drugs' as per Rule 2 clause (w) of the New Drugs and Clinical Trial Rules, 2019, for uniform implementation of the provision across the country.

(AGENDA FROM STATE OF PUNJAB)

AGENDA NO.13

CONSIDERATION OF THE PROPOSAL FOR CREATING COMMON PLATFORM FOR AVAILABILITY OF CONSTITUTION OF ALL THE MANUFACTURING FIRMS OF ALL THE STATES / UTS OF THE COUNTRY

DCC was apprised about the time line for completing the investigation and filing of complaints has been fixed in the Not of Standard Quality (NSQ) sample cases for the violation of Section 18(a)(i) of the Drugs and Cosmetics Act 1940 in the State of Punjab.

The committee was informed that for obtaining the constitution from other States takes lot of time and efforts and which results in delay in filing of complaints in the competent Courts. Therefore, requested for a creation of a common platform at CDSCO level, where data related to constitution of the manufacturing firms of all the States may be made available, which will save the time of officers of all the States and the complaints can be filed in a time bound manner in the competent Courts.

The committee deliberated the matter and opined that constitution details of the company is a dynamic document which undergoes various changes.

Accordingly, the committee didn't agree with the proposal of the creation of the common platform at CDSCO level.

ADDITIONAL AGENDA NO.1

CONSIDERATION OF THE PROPOSAL FOR DELIBERATION OF VARIOUS STEPS TO CURB THE ANTIMICROBIAL RESISTANCE (AMR)

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

The committee was informed that the antimicrobials may also be used in other industries such as food, beverages and other non-medicinal, where the sale and use of antimicrobials in non-pharma industries lead to AMR.

The committee further apprised about the proposals to be implemented in order to curb the Antimicrobial resistance.

1. Conditions of License - 3(ii)(c) under Form 20B, Form 20BB and 4(ii)(c) under Form 21B, Form 21BB need to be deleted.
2. Uniform Implementation of Schedule H & H1 drugs by State Drugs Controllers through enforcement activities in order to curb AMR.
3. Insertion of new Rule under Drugs and Cosmetics Act and Rules, for manufacturing Blue colour strips for antimicrobials

After detailed deliberation, the committee opined to amend the conditions at serial no. - 3(ii)(c) under Form 20B, Form 20BB and condition at serial no. 4(ii)(c) under Form 21B, Form 21BB of Drug rules 1945, to include the word ‘except Antimicrobials’.

ADDITIONAL AGENDA NO.2

PRESENTATION BY SUB-COMMITTEE CONSTITUTED TO EXAMINE THE PROPOSAL ON DRUG REGARDING SAMPLING AND TESTING

DCC was apprised about a sub-committee which was constituted in the 62nd DCC to examine the proposal on Drug Sampling and testing.

The committee was informed that so far 2 meetings of the Expert Committee under the Chairmanship of I/c Director CDL, Kolkata and the other members have taken place.

The Final report of the Committee is under Compilation and submission.

In this connection CDAC representative made a presentation on available options including use of 3D QR coding of samples.

The DCC deliberated the matter and opined that the proposal does not appear to be feasible. Further the DCC recommended that the sub-committee may further examine the matter with other available options.

The meeting was ended with vote of thanks to all.

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List of participants enclosed.

LIST OF THE PARTICIPANTS OF 64th DRUGS CONSULTATIVE COMMITTEE MEETING HELD ON 19.06.2024 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. M.V.S.S. Vara Prasad	Deputy Director
2.	Assam	Shri. Biswajit Talukdar	Drugs Controller
3.	Bihar	Shri. Nityanand Kishloya	DDC
4.	Goa	Smt. Jyoti J. Sardesai	Director, FDA
5.	Gujarat	Dr. H.G. Koshia	Commissioner, FDCA
6.	Haryana	Shri. Manmohan Taneja	State Drugs Controller, FDA
7.	Jammu and Kashmir	Mrs. Lotika Khajuria	Drugs Controller
8.	Jharkhand	Smt. Ritu Sahay	Director (Drugs)
9.	Madhya Pradesh	Shri. Mayank Aggarwal & Shri. Shobhit	IAS, Controller FDA DDC, FDA
10.	Maharashtra	Shri. D.R. Gahane	State Drugs Controller
11.	Manipur	Shri. Ronen Singh	Drugs Inspector
12.	Mizoram	Shri. F. Lalliantluanga	Deputy Director (F&D)
13.	Punjab	Shri. Sanjiv Kumar	Joint Commissioner(FDA)
14.	Telangana	Shri. C. Rajavardhana Chary	Deputy Director
15.	Tripura	Shri. Subrata Das	IOD, State Drugs Controller
16.	Uttar Pradesh	Shri. Krishan Gopal Gupta	Asst. Commissioner (Drugs)
17.	Delhi	Shri. K R Chawla	Controlling Authority /Deputy Drugs Controller
		Sundeep B.J.	Asst. Drugs Controller

B. ZONAL/ SUB ZONAL OFFICES OF CDSCO

S. No.	OFFICES	NAME	DESIGNATION
1.	North Zone, Ghaziabad	Shri. K. Narendran	Deputy Drugs Controller (India)
2.	East Zone, Kolkata	Shri. Arup Chatterjee	Deputy Drugs Controller (India)
3.	West Zone - II, Mumbai	Shri. Jayant Kumar	Deputy Drugs Controller (India)
4.	Hyderabad Zone	Dr. Vinay Kumar Gupta	Asst. Drugs Controller (India)

S. No.	OFFICES	NAME	DESIGNATION
5.	Ahmedabad Zone	Dr. Ravi Kant Sharma	Deputy Drugs Controller (India)
6.	Bangalore Zone	Shri. Rajshekhar	Deputy Drugs Controller (India)
7.	Indore Sub-zone	Shri. Gaurav Kumar	Deputy Drugs Controller (India)

C. CDSCO (HEAD QUARTERS)

S. No.	NAME	DESIGNATION
1.	Dr. Rajeev Singh Raghuvanshi	Drugs Controller General of India
2.	Dr. S. E. Reddy	Joint Drugs Controller (India)
3.	Shri. R. Chandrashekar	Joint Drugs Controller (India)
4.	Smt. A Visala	Joint Drugs Controller (India)
5.	Shri. A. K. Pradhan	Advisor
6.	Shri. Aseem Sahu	Deputy Drugs Controller (India)
7.	Dr. Rubina Bose	Deputy Drugs Controller (India)
8.	Shri. Sunil Kulshrestha,	Deputy Drugs Controller (India)
9.	Dr. B. Kumar	Deputy Drugs Controller (India)
10.	Dr. Gouri Shankar	Deputy Drugs Controller (India)
11.	Shri. Ajay Sachan	Deputy Drugs Controller (India)
12.	Smt. Swati Srivastava	Deputy Drugs Controller (India)
13.	Pramod Mesharam	Deputy Drugs Controller (India)
14.	Smt. V. M. Bharathi	Deputy Drugs Controller (India)
15.	Smt. Kavita Sharma	Deputy Drugs Controller (India)
16.	Parthiban J	Asst. Drugs Controller (India)
17.	Shri Ashish Kumar Rai	Asst. Drugs Controller (India)
18.	Shri Ranjeet Singh Patel	Drugs Inspector
19.	Shri. Rohit Sharma	Drugs Inspector
20.	Smt. M. Meena Devi	Asst. Drugs Inspector