MINUTES OF 59TH MEETING (VIRTUAL) OF DRUGS CONSULTATIVE COMMITTEE (DCC) HELD THROUGH WEB CONFERENCE ON 2ND MARCH, 2021 AT CDSCO (HQ)

Inaugural Deliberations

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

Dr. Mandeep Bhandari, Joint Secretary (R), Ministry of Health and Family Welfare, Govt. of India, welcomed the Members of the Committee and emphasized that uploading of information pertaining to license granted for manufacture for sale or distribution of drugs on SUGAM portal as per G.S.R. 19(E), dated 10.01.2019 has to be completed within short period of time, since the progress made till date is not satisfactory despite several communications by Central Government during this period of two years.

He mentioned that, the State Drug Controllers should direct the manufacturers in their jurisdiction to ensure that such information is uploaded at the earliest by 31st March 2021.

While discussing the status of development of software providing a common platform for online submission and processing of applications for grant of various licenses by all the State Licensing Authorities, the Joint Secretary requested the members and CDSCO to complete the development process of software in coordination with CDAC and made it operational by 31st March 2021.

Thereafter, Dr. V.G. Somani stated that, Indian online licensing portal for drug licensing is ready for validation and use and given the details of the portal. It was deliberated in detail that, how the issues of e-payment of fees, use of legacy data till the integration is undertaken are being addressed in the said portal, at this stage of rollout for validation. All the queries of the members were reasonably resolved to ensure the early rollout of the portal. It was also clarified that to begin with, states can use their e-payment system or if not having the one, can use offline payment of fees, in both these cases receipt of payment has to be uploaded on the portal. Further, it was proposed that one common e-payment gateway is being created on portal by entering into MOU with State Bank of India (SBI), so that this option is also available for those who don't have e-payment system in their state/UT. For this, DCGI requested all the State Drugs Controllers to fill up and return the Merchant Information Form given by SBI which was shared with them. This point of filling of Form by SLAs for entering in to MOU by CDSCO with the SBI was reemphasized.

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

AGENDA NO.1

CONSIDERATION FOR APPROVAL OF REPORT OF 58TH MEETING OF DCC HELD ON 14.07.2020 AND ACTION TAKEN IN THE MATTERS ARISING OUT OF THE MEETING.

Approved by the Committee members.

AGENDA NO.2

CONSIDERATION OF THE PROPOSAL FOR EFFECTIVE IMPLEMENTATION OF NATIONAL E-GOVERNANCE PORTAL FOR STATES PHARMACEUTICAL REGULATORY PROCESSES AND MANDATORY UPLOADING OF INFORMATION PERTAINING TO THE LICENSES GRANTED FOR MANUFACTURE FOR SALE OR DISTRIBUTION OF DRUGS IN ONLINE SUGAM PORTAL

2.1 CONSIDERATION OF THE PROPOSAL FOR EFFECTIVE IMPLEMENTATION OF NATIONAL E-GOVERNANCE PORTAL FOR STATES PHARMACEUTICAL REGULATORY PROCESSES

DCC was apprised that, during the inaugural deliberation of the 55th DCC meeting held on 31.01.2019 and 01.02.2019, the issue regarding the online system of licensing of manufacturing and sale of drugs was deliberated. CDSCO and CDAC made detailed presentations on the E-Governance initiatives of the CDSCO including the SUGAM Labs which has been developed recently for the drug testing laboratories. DCC was also apprised about the salient features of the proposed Sales and Manufacturing Licenses Software Management System for all the States in the country. The salient features include online system for licensing of sales and manufacturing premises, post approval changes, issue of certificates and NOC's, monitoring of Not of Standard Quality drugs, enforcement activities, MIS reporting and analytical platform and software administration module. Further the cooperation from all the States/ UTs was sought for the development of the software on its modalities. DCG(I) accordingly had requested on 01.02.2019 to all State/ UT Drugs Controllers to make necessary arrangements for providing the necessary IT infrastructure so that the software can be deployed immediately as and when ready.

The issue was also deliberated in the 56th DCC meeting held on 01.06.2019 wherein after detailed discussion it was decided that the software should be developed and made operational on 01.07.2019. Further, in the 57th meeting of DCC held on 20.08.2019, after detailed review and deliberation on the progress, the Committee recommended that all state drugs control authorities should start utilizing the common software platform **(https://statedrugs.gov.in)** by obtaining log in ID and password and validating all applications formats by getting dummy applications from stakeholders or if already validated shall start using it in full fledged manner. Now, the national e-governance portal for states pharmaceutical regulatory processes has been developed by CDAC in

coordination with Central and State Drugs Regulatory Authorities and is under final stage of its implementation **(https://statedrugs.gov.in).**

Committee has deliberated this issue during beginning of this DCC meeting and again most of the members deliberated on the matter.

After detailed deliberation DCC agreed for rollout of the national e-governance portal for uniform implementation of the provisions under the D&C rules.

The committee also proposed to make provisions in the National portal for migration of the data from the existing state portal and also to integrate with such state portals having single window system in near future, once the rollout has started.

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

Committee was apprised that, Central Government has amended the Drugs and Cosmetics Rules, 1945 vide G.S.R. 19(E) dated 10.01.2019 incorporating Rule 84AB making online submission of data through SUGAM portal as a mandatory requirement under D&C Rules. As per the notification, the licencee shall register with portal SUGAM (www.cdscoonline.gov.in) and upload information, as per the format provided in the said portal pertaining to the licences granted for manufacture for sale or distribution of drugs. The information so provided shall be updated from time to time by the licencee and this information is required to be verified by the concerned State Licensing Authority for confirmation. CDSCO already issued letter to all State Drugs Controllers requesting them to verify the data and approve them at the earliest.

DCC in its 56th meeting held on 01.06.2019 deliberated and recommended that all State Drug Controllers should ensure that uploading of required data as mandated under Rule 84AB is completed by 30.06.2019.

Further, the matter was again deliberated by 57th DCC meeting held on 20.08.2019, wherein DCC recommended that all the State Drugs Control Authorities should ensure uploading of the required data by manufacturers within 15 days by issuing orders under Drugs and Cosmetics Rules.

Also, in 58th meeting of DCC held on 14.07.2020, Dr. Mandeep Bhandari, Joint Secretary (R), Ministry of Health and Family Welfare, Govt. of India, in his opening remarks reminded that uploading of data on SUGAM portal regarding manufacturers and their products has to be completed within short period of time, since the progress made till date is not satisfactory despite several communications by Central Government. It is therefore requested again that all the State Drugs Control Authorities should ensure uploading of the required data and apprise its status to the Committee.

Thereafter, DCC was sensitized that the provisions for mandatory uploading of the licenses pertaining to manufacture, sale and distribution of drugs on the SUGAM portal was made effective from 10.01.2019. However it is observed that the data uploaded by

manufacturer and verified by the SLAs does not reflect the actual number of licenses issued in the Country.

The Members have apprised the committee that their manufactures have been sensitized to upload the data and requested CDSCO to arrange an online training program both to the industry and regulators for smooth uploading of data. Further, members have discussed the simpler method of verification of data by SLAs based on undertaking by the manufacturers.

Accordingly, DCG(I) has proposed a training program on 06.03.2021. Further DCG(I) urged all the SLAs to write to the manufactures in their respective jurisdiction to upload the requisite data at the earliest, subsequently, which shall be verified by SLAs for fulfilling the regulatory requirement. DCGI, further stated that this will bring transparency in the system and facilitate data analytics and will ensure uniformity along with ease of doing business in the country.

After detailed deliberation the committee recommended that the uploading of data should be followed up on priority as it is mandatory provision. It was also discussed and recommended that, since the uploading by manufacturers is mandatory, if it is not undertaken, the necessary action shall be taken by the concerned SLA on the line of Goa, FDA including the steps like subsequent processing of the application request for future permission shall be subject to the compliance of uploading.

AGENDA NO.3

CONSIDERATION OF THE PROPOSAL TO IMPROVE THE PHARMACY PRACTICE IN THE CHEMISTS & DRUGGISTS SHOPS

DCC was apprised that, the practice of medicine is changing rapidly. With these rapidly changing ground realities, the practices of allied professionals such as the “Druggists & Chemists” also need to change synchronously. Professionals associated with this complementary profession too need to adopt “Good Practices” whole heartedly.

In view of the above, several observations were received for improving the current practices at the retail outlets or medicine shops. In this regard a joint meeting was convened by CDSCO and PCI on 05.02.2021 with various stakeholders i.e. AIOCD, AICDF and SCDA wherein the observations which required elaborate deliberations were discussed.

The observations which are identified to be deliberated in DCC for uniform implementation are as follows:

1. The license holder must display the license in shop.
2. The license holder and its employees must not dispense drugs without a valid prescription
3. The license holder must not 'prescribe' the drugs, and must inform the customers by means of a displayed poster/bill that drug prescription is not in his or her domain.

4. The Govt. may prepare a list of drugs which can be dispensed without prescription. This list may be displayed prominently in the shop, permitting the chemist to dispense these drugs without a prescription.
5. There should be a regular (may be quarterly) inspection of the shop premises and the drug inspector doing the inspection must put up his signatures, date of visit for inspection and remarks, if any, on a sheet displayed prominently in the shop premises

Further, observation which requires amendment in the existing Rules is as follow:

1. The license holder must display picture of the license holder in shop.

After examination, DCC observed that some of the observations made regarding improvement in the pharmacy practice are already provided in the Rules. Such observations namely displaying the license, not dispensing the drugs without prescription and inspection of the shops annually are already being implemented and will continued in the future. However, the Committee did not recommended to display the poster that drug prescription is not the domain of the pharmacist as it is already violations of the provisions of the rules and with reference to other points, which were part of annexure of agenda and which has been deliberated with the stakeholders and PCI members as mentioned below, Committee felt that it need to be examined in detail to have a further deliberation.

1. *The license holder must also display the list of all employees/ their qualifications, and the job assigned.*
2. *They (employees) should follow a suitable dress code (if auto and taxi drivers can follow it why can't they?*
3. *They all (employees) must put up a name plate on their chest.*
4. *The license holder must be available almost entire time the shop remain open.*
5. *The license holder must employ a suitably qualified customer manager or drug manager for customer satisfaction.*
6. *The license holder must scan all prescriptions and attach the scanned copy to the print-out of drugs dispensed for confirmation.*
7. *The license holder shall attach a small picture of the scanned copy of license as well as the picture of the license holder on the cash-memo which is handed over to the customer.*
8. *'Over-the-counter' dispensing of drugs should be discouraged.*
9. *The shop owner must dispense the drugs in an envelope with printed details of the shop (such as name, address, license number, etc.).*
10. *If possible shop for medicine/drugs should be separate from shop for cosmetic items.*
11. *Similarly, the shops for allopathic and non-allopathic medicines should be separate with separate dedicated employees for that purpose.*
12. *No child should be employed by the License holder.*
13. *Drug shall not be dispensed to Children (< 12 years of age).*
14. *The license holder must have a computer with suitable large hard-disk for storage of data.*

15. *All billing must be computerised.*

With regard to the increase in the frequency of inspections from the present annual inspections to quarterly inspections, the committee opined that existing man power is not adequate for such frequency. Further, it is not in line with the policy of the Central Government to reduce the compliance burden.

The Committee recommended that the Drugs and Cosmetics Rules may be amended to provide provision for display of the picture of the license holder in the shop.

AGENDA NO.4

CONSIDERATION OF THE PROPOSAL FOR THE FORMS (LICENSES) SPECIFIED IN SCHEDULE A OF D&C RULES FOR REDUCING THE REGULATORY COMPLIANCE BURDEN (ONLINE PAYMENT / SELF CERTIFICATION / DIGITALISATION)

Committee apprised that, Central Government has recently taken up a huge exercise on rationalizing/simplifying and minimizing regulatory compliance burden on businesses in order to improving cost and ease of doing business in the India in a strategic manner and has made Department for Promotion of Industry and Internal Trade (DPIIT), Ministry of Commerce and Industry, as a Nodal Ministry for this exercise.

DPIIT has requested all Ministries and departments to prepare a plan of action and roadmap for reducing and rationalizing the overall compliance burden:

a. By examining Acts and compliances which are out dated in order to remove redundant laws and compliances.
b. To do business process reengineering to reduce, rationalize and simplify the multitude of Acts, Rules and Administrative orders.
c. To digitize all processes so as to do away with all physical submission of papers.

Further, DPIIT has requested to identify their respective area of compliance and focus on executing the identified points to reduce the compliance burden within the timeline of 31st March, 2021(Phase-I) in case of Rules and Regulations and within the timeline of 15th August, 2021 (Phase-II) in case of compliances related to the Act.

Accordingly, CDSCO and Ministry of Health and Family Welfare has identified following compliances for reducing compliance burden;

1. No. of compliances proposed to become less burdensome before 31st March 2021;

    i. Auto renewals with online payment –06 compliances
    ii. Licences/approval kept on self-certification (Risk –based classification)- 01 compliance
    iii. To be digitized- 10 compliances

2. No. of compliances proposed to become less burdensome before 15th August, 2021;

    i. Laws identified for decriminalization-02 compliances

ii. Any other- 01 compliances

Also, DPIIT has forwarded a data received from Team Lease, a Third Party which has identified 1132 compliances related to Drugs and Cosmetics Rules, 1945; Medical Devices Rules, 2017 and New Drugs and Clinical Trials Rules, 2019 as burdensome, which are categorized as follows;

- Rules or regulations based-3 compliances
- Rule based and reviewable-399 compliances
- Procedural Guidelines-730 compliances

CDSCO and MoHFW after comprehensive review of these 1132 compliances have identified 8 compliances as redundant, which are required to be removed from the Rules.

CDSCO has also convened consultation meetings with Drugs Manufacturers Associations, Chemists and Druggists Associations and Consumer Associations on this matter for their views.

After examining the Act and Rules along with whole issue, the committee agreed that the compliance burden should be reduced to enable ease of doing business and further observed that information technology should be adopted wherever feasible.

Committee deliberated all the points of D&C Act and Rules in detail and identified that how much compliance burden could be reduced & finally agreed to reduce the compliance burden as identified. Committee also recommended that medicines safety, efficacy and quality is very vital for patients/consumers. Therefore, other checks and balances provided in the Act and Rules shall also be maintained, while reducing compliance burden.

Committee recommended for changes/amendments as proposed.

AGENDA NO.5

CONSIDERATION OF THE PROPOSAL FROM NCPCR REGARDING JOINT ACTION PLAN

The DCC was apprised that, the wellbeing of children is a universal aspiration. However, drugs and substance abuse among children and adolescents is becoming a global health issue. Therefore, the issue needs a concerted effort to prevent its spread as well as provide necessary services including de-addiction facilities to those already afflicted. The concerned individual, his/her family and friends, the society, the government and the legal system, all must work in tandem to tackle the menace. Thus the need for a Joint Action Plan (JAP) was felt at the highest level to streamline the strategies and efforts of various authorities, institutions and agencies to bring a paradigm shift in the direction if drugs and substance abuse prevention amongst the children in the country.

In this regard, a committee was set up to draft a JAP to address the issue. This committee comprised of Narcotics Control Bureau (NCB) and National Commission for Protection of Child Rights (NCPCR). The committee invited several other concerned Ministries including, MoHFW, DGHS and CDSCO. This JAP is a framework of various

issues amongst which following issues are related to Drugs and Cosmetics Act, 1940 and Rules thereunder:

The issues of concern is that minors are availing Schedule H, H1 or X drugs without prescription and consuming them which is further resulting in drug dependency. Currently, there is no proper monitoring mechanism or strict adherence to guidelines.

Therefore, there is need to develop a robust monitoring system through:

3.1 Mobile app based Information System (MIS)

For better monitoring, register under rule 26(vi) of D& C Rules shall be digitalized for the recording of production, supply and selling of Schedule H, H1 and X drugs by retail chemist or medical stores into a mobile app based Management Information System (MIS). On this MIS details shall be fed by the drug companies making and supplying such drugs and also by the wholesale and retail medical store. This app based MIS software may be developed within a month's time period. Access of this app-based MIS shall be given to NCB. In case it is needed, NCPCR may also develop an MIS.

3.2 Installation of CCTV at medical shops.

To keep a vigil on all medical /pharmacy stores selling schedule H, H1 and X drugs, should mandatorily install CCTV cameras in their shops. This shall be randomly checked by District Drug Controller Authority. In case such medical stores are functioning without CCTV camera, time period of 6 months shall be given to existing medical stores to install CCTVs. This shall be included in licensing rule of pharmacist and chemist selling schedule H, H1 and X. It may be mentioned here that, for time being, District Collector, as empowered under section 133 of the Code of Criminal Procedures, 1973, can issue order with respect to the installation of CCTV cameras at the pharmacy/chemist shop selling Schedule H, H1 and X drugs.

Access of CCTV cameras with internet connection of recording of medical/pharmacy stores selling schedule H, H1 and X drugs shall be given to CWPO of the particular area where such medical stores exists. The district drugs control authority shall conduct periodic meeting with CWPOs. Subsequently, the list and monitoring reports of such medical stores with CCTV camera installation shall be shared with respective state drug controller on a quarterly basis.

In this context Chairman of the NCPCR made a detailed presentation on the Joint Action Plan abuse of drugs by the Children. Further, he also informed that under Juvenile Justice Act, it is a crime to sell psychotropic or drug of abuse to children without prescription & police can take action against such crimes and urged the members to take measures for sharing the data of H, H1 and X drugs with the NCB through a mobile app which will be developed for this purpose. Further he also requested to take measures to mandatorily install CCTV cameras in all such shops selling H, H1 and X drugs to monitor sale of drugs illegally to children.

The members shared their experiences and views to tackle this problem. The members apprised the chairman that all chemists and druggists do not maintain a separate register of sale of H and H1 drugs but the data is maintained in the sale invoices. Therefore the chemists has to upload this data on Mobile app based information system (MIS) separately only for this purpose which require lot of resources. It was also suggested that

the medicines which are abused by the children should be separated from Schedule H& Schedule H1 and to carve out a new Schedule for this purpose for effective monitoring.

With regard to installation of CCTV it is observed that there is no such provision in the rules for enforcement. Further, as proposed above if the drugs of abuse are separated into a new Schedule & separate licensing is introduced for such shops, the shops selling such drugs can be reduced for effective monitoring.

However this needs in depth study and stakeholders (including medical experts) consultation as per Good Regulatory Practices.

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

Accordingly, the sub-committee constituting of following members under Chairmanship of Dr. H.G. Koshia, Commissioner, FDCA, Gujarat is formed to examine the issue and give its recommendation.

1. Dr. H.G. Koshia Commissioner, FDCA, Gujarat	*Chairman*
2. Mr. D.R. Gahane, Joint Commissioner, FDA, Maharashtra	*Member*
3. Mr. Navneet Marwaha, Drugs Controller, Himachal Pradesh	*Member*
4. Mr. Amaresh Tumbagi, Drugs Controller, Karnataka	*Member*
5. Dr. K. Bangarurajan, Advisor, CDSCO	*Member*
6. Dr. Santosh Indraksha, ADC(I), CDSCO(HQ)	*Convener*

Further, meanwhile it was requested to Chairman, NCPCR to provide the list of districts and locations to respective State Drugs Controller to initiate action in co-ordination.

AGENDA NO.6

CONSIDERATION OF THE PROPOSAL FOR AGENDA TO AMEND RULE 64(1) OF THE DRUGS AND COSMETICS RULE, 1945 TO GRANT A PHARMACY LICENCE, MEDICAL SHOP LICENCE OR A WHOLESALE LICENCE ONLY TO A FIRM WHERE A REGISTERED PHARMACIST IS THE SOLE PROPRIETOR OR A MANAGING PARTNER OR A MANAGING DIRECTOR

DCC was apprised that, Ministry of Health and Family welfare has forwarded a representation of President, Karnataka State Registered Pharmacist's Organization on the subject cited above.

In the said representation, it has been stated that as per the provisions of Drugs and Cosmetics Rules, 1945, any person can run a pharmacy or a medical shop or a wholesale distributor shop, irrespective of his educational qualifications, professional

qualifications or experience. Further, the said organisation also requested to amend the Rule 64(1) of the Drugs and Cosmetics Rules, 1945, so as to grant a pharmacy licence, medical shop licence or a wholesale licence, only to a firm, where a registered pharmacist is the sole proprietor or a managing partner or a managing director.

After deliberation, the Committee expressed that, mandating grant of retail and wholesale license only to a firm where a registered pharmacist is the sole proprietor or a managing partner or a managing Director may be desirable, however expressed that the issue need to be examined in details so as to achieve intended objective as the said facts are not yet been brought in the agenda.

Hence, committee deferred the agenda for examination at appropriate time.

AGENDA NO.7

CONSIDERATION OF THE RECOMMENDATIONS OF SUB-COMMITTEE FOR THE MATTER OF BRINGING UNIFORMITY IN RESPECT OF QUANTITY OF SAMPLE REQUIRED TO BE DRAWN BY DRUGS INSPECTORS FOR TEST OR ANALYSIS OF DRUGS, COSMETICS, VACCINES& MEDICAL DEVICES AT CENTRAL DRUGS TESTING LABORATORIES

Committee apprised that, DCC in its 56th meeting held on 01.06.2019 constituted a sub-committee 2019 under the chairmanship of Shri. Shobhit, Deputy Drugs Controller, Madhya Pradesh to examine the subject matter.

*Accordingly, the sub-committee examined the matter and submitted following recommendations for bringing uniformity in respect of quantity of sample required to be drawn by drugs inspectors for test or analysis of drugs, cosmetics, vaccines& medical devices at central drugs testing laboratories**:-***

1. *As per mandate of the sub-committee, it focuses on legal sample only. The Sub-committee examined and discussed in detail the quantity of samples required under each category by various laboratories namely NIB, RDTL, CDL for test or analysis purpose. After detailed examination, the sub-committee has concluded the list of drugs, vaccines, cosmetics and medical devices viz-a-viz quantity to be drawn by the inspectorate staff for test or analysis purpose.*
2. *In case of minimum/lesser quantity of samples or subject to availability of samples quantity, Government Analyst will decide and perform the test.*
3. *This report will provide guidance only and will be dynamic as constituted under the Drugs and Cosmetics Act and Rules made there under. As per availability and condition of sampling, Drugs Inspector can draw any quantity, as and when required.*
4. *Central as well as every State Govt. laboratories should be upgraded by adopting advanced instruments and technologies required for test/analysis*
5. *Scientists/Technicians/Chemist from Central as well as State laboratories also required training to empower the enforcement of Drugs and Cosmetics Act and Rules made there under.*

The Sub-Committee presented its report on the quantity of sample of Drugs/Cosmetics/ Vaccines/medical devices required to be drawn by Drugs Inspectors for test or analysis.

The Committee recommended that the quantity of the sample mentioned in the report is only a suggestion and is not mandatory. Further the Drugs Inspector may draw lower quantities as samples for test or analysis if the indicated quantity is not available or if the situation is warranted.

In principle Committee agreed for the recommendations made by the Sub-Committee. Further, sub-committee has been requested for submitting its final report as per the suggestions made by the DCC during the meeting, which shall be considered as final accepted report by the committee.

AGENDA NO.8

AGENDA FROM GOVERNMENT OF NCT, NEW DELHI

CONSIDERATION OF THE PROPOSAL FOR PERPETUALITY FOR FOLLOWING IN LINE WITH GSR NO. 1337(E) DATED 27.10.2017 IN EFFORTS TO MINIMISE THE REGULATORY COMPLIANCE BURDEN.

DCC was apprised about the agenda that, Vide GSR No. 1337(E) dated 27.10.2017 the words "renewal" has been omitted. Since then, majority of drug licenses/approvals granted under Drugs Rules, 1945 (formerly Drugs and Cosmetics Rules, 1945) and Medical Devices Rules, 2017 with condition that "the license/approval unless sooner suspended / cancelled, shall remain valid perpetually." However, in case of following, the said amendment was not incorporated.

i) Part VIA – Sale of Homeopathic Medicines

ii) Part VIIA - Manufacture for sale or Distribution of Homeopathic Medicines

iii)Part XB –Requirement for the collection, storage, processing and distribution of whole Human Blood, Human Blood Components

Now, Govt. of India in their efforts to minimise the regulatory compliance burden is insisting for auto-retention of licenses / approvals in place of normal renewals. In view of this above provisions are required to be amended accordingly.

After detailed deliberation, with regard to point No. (i) & (ii) the Committee expressed that Homeopathic medicines are also dealt by the Ministry of AYUSH and their opinion may be sought before examination of the proposal. With regard to point no (iii) regarding perpetuality of the licenses for blood banks and blood components, the committee expressed that blood and blood components are life saving drugs and require stringent monitoring and periodical regulatory oversight.

In view of the above, the committee has not recommended for the proposed amendment at present

AGENDA NO. 9

AGENDA FROM STATE OF MAHARASHTRA

9.1 Amendment of Rule 67EE and 85-F, 85-G

DCC was apprised that, amendment of Rule 67EE and 85-F, 85-G to incorporate the provision of retention of licence subject to payment of retention fees. Amendment may be done as per notification dated 27.10.2017

DCC felt that the same proposal has been deliberated under agenda 8(i) & 8(ii).

9.2 Amendment in Rule 65 to make provision for compliance with the Directions issued by Licensing Authority

There is no express provision that licensee shall comply with directions issued by Licensing Authority e.g. FDA M.S. issues stop sale letter when Registered Pharmacist is not present in the drug stores. Hence it is suggested that following Provision may be introduced in Rule 65 namely the licensee shall comply with the directions of licensing Authority, if the Licensing Authority so directs the licensee shall not sell or offer for sale any drug until the Licensing Authority is satisfied about the compliance.

The Committee expressed that provisions are already available under the Rules to address issues regulating the sale of drugs. The committee felt that unfettered power may lead to misuse and suggested that situations in which directions may be given by the Licensing Authority should be specified before considering the proposal.

In view of the above, the committee has not recommended for the proposed amendment at present.

AGENDA NO. 10

AGENDA FROM GOVERNMENT OF GOA

DCC apprised that, as per New Clinical Trial Rules, 2019 Sustained release or Modified Release Dosage form of any Drug in a new Drug as per Definition of New Drug.

Clarification is needed if firm is permitted to manufacture a particular Modified released product prior to New Clinical Trial Rules 2019 and if now firm intends to Manufacturer with additional brand name for export, whether same can be permitted; without DCG(I) clearance for that Company.

DCG(I) clarified the provision pertaining to manufacture of modified release products for exports as per the current provisions. Therefore DCC expressed that no further action is required in this regard as the clarification has been found satisfactory.

AGENDA NO.11

CONSIDERATION OF THE PROPOSAL TO MAKE PROVISIONS FOR SHARING OF TESTING PROTOCOLS BY THE MANUFACTURE OF NEW DRUGS WITH THE GOVERNMENT LABORATORIES

DCC was apprised that, the new drugs definition was modified vide G.S.R 227(E) dated 19.2.2019. In the definition the paradigm change has been enacted for modified or sustained release forms of drugs or novel drugs delivery system as they are out of four year limitation clause i.e. all such products to be granted license only after the manufacturer get the new drug approval from DCG (I). Such products include sustained / extended release dosage form, liposomal dosage form, microsphere based dosage form etc. To further elaborate, if any firm even makes product permission application for nitro-glycerine sustained release tablet which was approved in the year 1975, they need to take new drug approval from DCG (I). As the release patterns may differ from manufacturer to manufacture, it is essential to have these testing parameters (release patterns)/dissolution profile with the Regulators including Government drugs testing laboratories for quick and complete analysis.

In absence of Standard test procedures/dissolution profile laboratories are not carrying out dissolution test (release pattern) and releasing report as "test not done as dissolution profile not provided by the manufacturer" In this way a very important and essential test is not being carried out by the laboratories.

In view of above, such Standard test procedures/ dissolution profile of the products licensed is taken as records and shared with all Government Drugs Testing Laboratories.

After deliberation, DCC expressed that sharing of testing protocols by the manufacturer is indispensible for carrying out testing of the drugs especially non compendial and new drugs. Wherever the manufacturer is not sharing the testing protocols the Government analyst should inform the drugs inspector who has drawn sample and such DI should seek the testing protocol from the manufacturer under the appropriate provisions under the Act. The necessary assistance shall be provided by the drugs regulators/drugs controllers under whose jurisdiction, the manufacturer is located for getting the testing protocol.

AGENDA NO. 12

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

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

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

The Sub-committee presented revised recommendations on the exemption of liquid antiseptics form the requirements of sale license. The committee expressed that the access to liquid antiseptics should not be restricted from licensed premises but should be permitted to sold at all shops especially during the current COVID pandemic. The committee recommended that the D&C rules may be amended as proposed by the sub-committee subject to the conditions mentioned in the report.

Recommendations of the Sub-committee:

The Sub-Committee has examined the issue in detail and had made the following recommendations: -

i) Antiseptics in general are extensively used during post disaster prevention and spread of infection, environmental and social hygiene to prevent disease outbreak, rural maternal health to address infection after child birth. They are also used amongst all age group and amongst all population in different regions, rural and urban areas. They are also recommended by WHO for in prevention and treatment of maternal peripartum infections.

   It is necessary to make antiseptics accessible to the entire population. Restricting sale of antiseptics from only licensed premises denies access and availability to rural and remote areas. Further, the safety of the available antiseptics does not raise any concern.

ii) After careful consideration of the representation of the firms, M/s Reckitt Benckiser and M/s ITC, related judgments, the Sub-Committee recommends that all antiseptic formulations for external use including Dettol and savlon, may be exempted from being covered under a sale license.

iii) Antiseptics should continue to be manufactured under valid licence and there should not be any requirement of licence for its sale as is the case of disinfectant which also does not need sale license.

iv) Accordingly, the Schedule K may be amended by inserting the category of Antiseptics under Sl.No.12.

1. The report of the Sub-committee has been presented in the Drugs Consultative Committee in its 58th meeting held on 14.07.2020. After deliberation the DCC observed that there are numerous such products in the market which the sub-committee did not evaluate due to its specific mandate on three products only. Hence DCC suggested that the scope of the sub-committee shall be revised and broadened to relook the matter for examination all the available liquid antiseptic solutions in the market.
2. Accordingly, the sub-committee examined the products available in the market, the details are available in the annexure to this report. The marketed Liquid antiseptics contain Cetrimide, Chlorhexidine or Chloroxylenol as active ingredients.
3. The Sub-Committee has examined the issue in detail and had made the following recommendations: -
   i) The sub-committee has taken into consideration the concerns of the DCC to prevent misuse/abuse of the product if exempted from the requirement of sale license.
   ii) Enhancing the accessibility of Liquid Antiseptics to remote locations and places which are deprived of the presence of retail medical shops is necessary, especially during pandemics and epidemics .
   iii) Safety of the ingredients of the currently available antiseptics does not raise any concern.
   iv) In view of the above, the sub-committee recommends that the retail sale of the Liquid Antiseptics may be exempted from the requirement of sale license. Accordingly, Schedule K may be amended by inserting the following at appropriate position:

Class of Drugs	**Extent and Conditions of Exemption**
Liquid Antiseptics for household use	The provisions of Chapter IV of the Act and rules thereunder, which require them to be covered with a sale license in Form 20 or Form 20A subject to the following conditions:- (a) The drugs are manufactured by licensed manufacturers (b) The drugs do not contain any substance specified in Schedule G, H, H1 or X (c) The drugs are sold in the original unopened containers of the licensed manufacturer (d) The drugs are purchased from a licensed wholesaler or a licensed manufacturer

DCC after deliberation, agreed for the recommendations made by the sub-committee.

AGENDA NO. 13

CONSIDERATION OF THE PROPOSAL TO REGULATE SALE AND DISTRIBUTION OF REGULATED MEDICAL DEVICES BY SYSTEM OF REGISTRATION OF PREMISES AND SELLER OR DISTRIBUTOR, INVOLVED IN IT.

DCC was apprised that, representations have been received from various Associations/stakeholders for exemption of Drugs Sale Licence for all imported Medical Equipments (Instruments/Equipments/Apparatus/appliances), provided the importer/stockist/retailer of Medical Devices make a registration of such premises where Medical Devices are stocked for sale and distributed.

For this purpose, CDSCO in coordination with CDAC may develop a mechanism/portal of Registration of such traders/hospitals/firms who are involved in the sale/stock/use of Medical Devices. The Registration number thus generated online shall help the Licensing Authority to have data to track and trace the movement of such Medical Devices and Equipment.

PROCESS OF REGISTRATION:

i. Application to be made online or offline with notarized undertaking clearly indicating the name and address of the site to be registered.

ii. Constitution details of the applicant/firm along with ID proof viz; Aadhar card of the Directors/partners/Proprietor of the firm.

iii. Map and area provided for storage of Medical Devices.

iv. Brief description on other activities carried out by applicant, viz; storage of Drugs, Medical items, food products, stationeries etc or any other activities carried out by applicant and the said premises.

v. Qualification details of competent personnel appointed.

CONDITIONS FOR REGISTRATION:

i. This Registration Certificate shall be displayed in a prominent place in a part of the premises open to the public.

ii. The Registration holder shall provide adequate space, equipped with proper storage accommodation for preserving the properties of the Medical Devices such that it does not damage the properties of Medical Devices.

iii. The Registration holder shall maintain requisite temperature and lighting as per requirements of such Medical Devices.

iv. The Registration holder shall conduct the activities under the direction and personal supervision of a competent technical staff consisting of at least one person who is a whole time employee and who has passed the Intermediate Examination from a university recognised by State or Central Government and possess an experience of atleast 1 year in handling/stock/purchase/sale of Medical Devices.

v. The Medical Devices shall be purchased only from Importer or manufacturer licensed or firm registered under these rules.

vi. Separate records of purchases and sales of Medical Devices showing the names and quantities of such Medical Devices, names and addresses of the manufacturers shall be maintained. Such records shall be open to inspection by a Medical Device Officer appointed under the Act, who may, if necessary, make enquiries about purchases and sale of the drugs and may also take samples for testing.

vii. The Registration holder shall maintain an audit or inspection book, to enable the Medical Device Officer to record his observations and non-conformity, if any;

It was noted by the Committee that most of medical devices which are recently taken for regulation in phase wise manner are sold & distributed by distributors (shop-owners) directly to the hospitals or doctors and in-vitro diagnostics (IVDs) and related diagnostic machinery are sold or distributed directly to the pathological laboratories. Very few medical devices or in-vitro diagnostics, which are directly used by consumers, are sold to the consumers and usually prescription is not involved for such purchases by consumers.

Accordingly, there are inherent differences between the sale and distribution of drugs and medical devices as the drugs are usually sold or distributed by wholesalers to retailers and by retailers to the patients/consumers on the basis of prescription while medical devices are sold and distributed mainly to hospitals/doctors or pathological laboratories.

Therefore, looking at above aspects and international practices, Committee recommended to regulate the sale of medical devices in a different manner than the drugs by creating a system of registration of the premises and person involved in the business of sale or distribution of medical devices to maintain the traceability, security and integrity of supply chain of medical devices.

The Committee observed that the sale and distribution of regulated medical devices, which fall under the definition of 3(b)(iv) of "drug" is as such permissible under present rule which can also be allowed to be continued in addition to maintain continuity of already existing system.

Further, Committee recommended to constitute a sub-committee comprising of following members to examine and further frame the system, accordingly, for regulation in a weeks time.

1. Dr. S. Eswara Reddy, JDC(I), CDSCO(HQ)	*Chairman*
2. Dr. H.G. Koshia, Commissioner, FDCA, Gujarat	*Member*
3. Mr. D.R. Gahane, Joint Commissioner, FDA, Maharashtra	*Member*
4. Mr. Amaresh Tumbagi, Drugs Controller, Karnataka	*Member*
5. Mr. N.K.Ahooja, Drugs Controller, Haryana	*Member*
6. Dr. Ravi Kant Sharma, DDC(I), CDSCO(HQ)	*Convener*

AGENDA NO. 14

CONSIDERATION OF THE PROPOSAL FOR AMENDMENT IN THE DEFINITION OF 'NEW DRUG' UNDER NEW DRUGS AND CLINICAL TRIAL RULES 2019 FOR REPLACING THE TERMINOLOGY "STEM CELL DERIVED PRODUCT" WITH "CELLS OR STEM CELL DERIVED PRODUCT"

DCC was apprised that, New Drugs and Clinical Trials Rules, 2019, were published vide G.S.R. 227 (E) dated 19.03.2019. The definition of "New Drugs" prescribed under these rules also includes "stem cell derived products".

In order to provide clarification on "stem cell derived product", the matter was discussed in the DTAB. Based on the recommendation of the 84th DTAB in its meeting held on 27.08.2019 and 85th DTAB held on 29.07.2020, the Central Government vide letter ref no X-11026/21/20107-DRS dated 09.02.2021 has issued directions under 33(P) to all Principal/Health Secretaries of states & UTs for issuance of clarification on stem cell derived product under New Drugs and Clinical Trial Rules, 2019.

The said direction also clarifies that cell based products are covered in the rules as per criteria mentioned in the letter.

The term "cells derived product", however, is missing in the definition of New Drug, which only includes "stem cell derived products".

It is also pertinent to mention here that during various discussions it has been proposed to consider for regulating the **cells or Stem cell derived product** instead of only **stem cell derived products** that will be appropriate terminology to regulate such products. Otherwise cells derived products are not getting clearly covered under the stated terminology i.e. "Stem cell derived products".

In view of above, it is proposed to replace terminology **"stem cell derived product"** in the definition of "New Drugs" published under New Drugs and Clinical Trial Rules 2019 with **"Cells or Stem cell derived product"**.

After deliberation, the committee agreed to replace terminology **"stem cell derived product"** in the definition of "New Drugs" published under New Drugs and Clinical Trial Rules 2019 with **"Cells or Stem cell derived product"**.

AGENDA NO. 15

CONSIDERATION OF THE PROPOSAL FOR AMENDMENT IN COSMETICS RULES, 2020

DCC was apprised that, MoHFW has published separate Cosmetic Rules, 2020 vide G.S.R. 763 (E) dated 15.12.2020 to regulate import and registration, manufacture for sale and distribution of Cosmetics. Various representations have been received from stake holders for consequential minor amendment in the said notification for correction etc.

A. Inclusion of provision for Cancellation and suspension of licence.–
Provisions related to the Cancellation and suspension of licence are not included in the said Cosmetics Rules, 2020. Hence it has been proposed to include the provision as below:

Cancellation and suspension of licence.–

(1) The Licensing Authority may, after giving the licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, cancel a licence issued under these rules or suspend it for such period as he thinks fit, either wholly or in respect of some of the substances to which it relates, if in his opinion, the licensee has failed to comply with any of the conditions of the licence or with any provisions of the Act or the rules made thereunder.

(2) A licensee whose license has been suspended or cancelled may appeal within a period of three months from the date of the order to the State Government which shall after considering the appeal, pass orders, and such orders shall be final.

B. Amendments

S. No.	Rule Position	Cosmetics Rules, 2020	Proposed amendment in the Cosmetics Rules, 2020	Reasons
1.	**3(m)**	"Laboratory" means the Central Cosmetics Laboratory established or notified for carrying out analysis or test of cosmetics by the Central Government under rule 11;	Provision may be omitted as it is already provided in the Act and Rules under heading CDL (Central Drugs Laboratory).	As the rules are overriding the Act, which is not appropriate.
2.	**3(w)**	—Use before or "date of expiry means the date recorded on the container, label or wrapper as the date upto which the cosmetic shall retain its characteristics as per standards at proposed storage condition stated on label;	explanation proviso may be added in Rule 3(w) as below: When use before term is used it shall mean use before first day of month stated on label and date of expiry means the cosmetic will expire on the last day of the month by 24 hrs.	For clarity.
3.	**4(2)(ii)**	(ii) sale, stock, exhibit or offer for sale or distribution of all categories of cosmetics.	May be considered for deletion as the license for sale of cosmetics is exempted as per Twelfth Schedule of the Cosmetics Rules, 2020.	As sale of cosmetics not regulated.
4.	**7**	**Government Analyst-** The Central Government or a State Government may appoint by notification in the Official Gazette, the Government Analyst for the purpose of these rules as provided in section 20 of the Act and rules made thereunder	**Government Analyst-** The Central Government or a State Government may appoint the Government Analyst as provided in section 20 of the Act and rules made thereunder.	Provisions as written needs re-notification, hence to rectify it, present proposal.
5.	**9**	Power, duties and functions of Inspectors specially Authorized to inspect manufacture and sale of	Power, duties and functions of Inspectors specially Authorized to inspect manufacture	To make inline with similar provision in the Drugs and

S. No.	Rule Position	Cosmetics Rules, 2020	Proposed amendment in the Cosmetics Rules, 2020	Reasons
		cosmetics:- (1) subject to the instructions of the **<u>controlling officer</u>**, it shall be the duty of inspector appointed under section 21 of the Act by the State Government, authorized to inspect the manufacture of cosmetics (1) (ii) to send a detailed report after each inspection to the **<u>Controlling officer</u>** indicating the conditions of the licence and provisions of the Act and rules thereunder which are being observed and the conditions and provisions, if any, which are not being observed; (1)(vi) make such enquiries and inspections as may be necessary to detect the manufacture or **<u>sale</u>** of cosmetics in contravention of any provision of the Act and these rules	and sale of cosmetics:- (1) subject to the instructions of the **<u>controlling authority</u>**, it shall be the duty of inspector appointed under section 21 of the Act by the State Government, authorized to inspect the manufacture of cosmetics. (1) (ii) to send a detailed report after each inspection to the **<u>controlling authority</u>** indicating the conditions of the licence and provisions of the Act and rules thereunder which are being observed and the conditions and provisions, if any, which are not being observed; (1)(vi) make such enquiries and inspections as may be necessary to detect the manufacture of cosmetics in contravention of any provision of the Act and these rules.	Cosmetics Rules, 1945. As sale of cosmetics is already exempted under Schedule 12 of the new rules. Therefore the word sale may be deleted.
6.	**11**	**Establishment and functions of the Central**	**<u>Central Cosmetics Laboratory and its</u>**	Present provision in

S. No.	Rule Position	Cosmetics Rules, 2020	Proposed amendment in the Cosmetics Rules, 2020	Reasons
		Cosmetics Laboratory. (1) The Central Government may, by notification, establish Central Cosmetics Laboratory for the purpose of,- (a) to analyse or test such samples of cosmetics as may be sent to it under sub-section (2) of section 11, or under sub-section (4) of section 25 of the Act; or (b) functioning as an appellate laboratory; or (c) to carry out any other function as may be specifically assigned to it. (2) Without prejudice to sub-rule (1), the Central Government may also designate or notify any laboratory under its control and the Director of such laboratory having facility for carrying out test and evaluation of cosmetics as Central Cosmetics Laboratory for the purposes specified in sub-rule (1): Provided that no Laboratory shall be so designated unless it has been duly accredited by the National Accreditation Body for Testing and Calibration Laboratories. (3) The Central Cosmetic Laboratory shall be headed by a Director who shall be appointed or designated by the Central Government.	**function.** (1) The Central drug laboratory established under the Act shall function as Central Cosmetics Laboratory for the purpose of,- (a) to analyse or test such samples of cosmetics as may be sent to it under sub-section (2) of section 11, or under sub-section (4) of section 25 of the Act; or (b) functioning as an appellate laboratory; or (c) to carry out any other function as may be specifically assigned to it. (2) Without prejudice to sub-rule (1), the Central Government may also designate or notify any laboratory under its control and the Director of such laboratory having facility for carrying out test and evaluation of cosmetics as Central Cosmetics Laboratory for the purposes specified in sub-rule (1): Provided that no Laboratory shall be so designated unless it has been certified as GLP compliant or duly	rule overrides the Act. To rectify the same it harmonized with the Act.

S. No.	Rule Position	Cosmetics Rules, 2020	Proposed amendment in the Cosmetics Rules, 2020	Reasons
			accredited by the National Accreditation Body for Testing and Calibration Laboratories. (3) The Central Cosmetic Laboratory shall be headed by a Director who shall be appointed or designated by the Central Government.	
7.	**26 (c)(ii)**	(ii) make arrangements with a laboratory approved by the Central Licensing Authority under Chapter VIII of the rules and accredited by National Accreditation Board for Testing & Calibration Laboratories (NABL) for carrying out such tests.	(ii) make arrangements with a laboratory approved by the State Licensing Authority under Chapter VIII of the rules	As labs are approved by SLA not the CLA.
8.	**26(f)**	The licensee shall keep record of the details of each batch of cosmetic manufactured by him and of the raw materials used therein as per particulars specified in the Eighth Schedule and such records shall be retained for a period of three years after the date of expiry of the batch.	The licensee shall keep record of the details of each batch of cosmetic manufactured by him and of the raw materials used therein as per particulars specified in the Eighth Schedule and such records shall be retained for a period of three years or **six** months after expiry of the batch whichever is later.	The committee agreed that manufacturer shall retain the records for a period of three years or **six** months after expiry of the batch whichever is later.
9.	**26(m) Proviso**	Provided that clauses (c) and (d) shall not apply to the	Provided that clauses (f) and (h) shall not	As it was earlier

S. No.	Rule Position	Cosmetics Rules, 2020	Proposed amendment in the Cosmetics Rules, 2020	Reasons
		manufacture of soap and the procedure for testing of raw materials and the records to be maintained by a manufacturer of soap shall be such as are approved by the Licensing Authority.	apply to the manufacture of soap and the procedure for testing of raw materials and the records to be maintained by a manufacturer of soap shall be such as are approved by the Licensing Authority.	provided in rules.
10.	**49(1)**	Dispatch of samples for test or analysis by order of court :- (1) samples for test of analysis under sub-section (4) of section 25 of the Act shall be sent by registered post or by **courier** or delivered in person in a sealed packet, enclosed , together with a memorandum in Form Cos-20with the outer cover being addressed to the director.	Dispatch of samples for test or analysis by order of court :- (1) samples for test of analysis under sub-section (4) of section 25 of the Act shall be sent by registered post or delivered in person in a sealed packet, enclosed, together with a memorandum in Form Cos-20 with the outer cover being addressed to the director.	Courier needs to be deleted as per court of law Courier is not a recognized mode of sending the samples**.**
11.	**53**	**Confiscation of cosmetics, implements, machinery etc.**– (1) Where any person has been convicted for contravening any of the provisions of Chapter IV of the Act or any Rule made thereunder, the stock of the cosmetics in respect of which the contravention had been made, shall be liable to confiscation. (2) Where any person has been convicted for manufacturing of any cosmetic deemed to be **misbranded**	**Confiscation of cosmetics, implements, machinery etc.**– (1) Where any person has been convicted for contravening any of the provisions of Chapter IV of the Act or any Rule made thereunder, the stock of the cosmetics in respect of which the contravention had been made, shall be liable to confiscation. (2) Where any person	No provision was made for confiscation of cosmetics if they are found to be **spurious as per Section 17D.** Hence this addition**.**

S. No.	Rule Position	Cosmetics Rules, 2020	Proposed amendment in the Cosmetics Rules, 2020	Reasons
		under clause (a), clause (b) or clause (c) of section 17C of the Act, or adulterated cosmetic under section 17E of the Act, or for manufacture for sale of any cosmetic without a valid licence as required under clause (c) of section 18 of the Act, any implements or machinery used in such manufacture and any receptacle, packages, or coverings in which such cosmetic is contained and the animals, vehicles, vessels or other conveyances used in carrying such cosmetics shall also be liable to confiscation.	has been convicted for manufacturing of any cosmetic deemed to be misbranded under clause (a), clause (b) or clause (c) of section 17C of the Act, **or spurious cosmetics under Section 17D of the Act,** or adulterated cosmetic under section 17E of the Act, or for manufacture for sale of any cosmetic without a valid licence as required under clause (c) of section 18 of the Act, any implements or machinery used in such manufacture and any receptacle, packages, or coverings in which such cosmetic is contained and the animals, vehicles, vessels or other conveyances used in carrying such cosmetics shall also be liable to confiscation.	
12.	**60**	**Validity of licence.** (1) A licence issued in Form COS-23 shall remain valid, if the licensee deposits a licence retention fee referred in the Third Schedule before the completion of period of five years from the date of its issue, unless, it is suspended or cancelled by the State Licensing Authority. (2) The licence retention fee referred in sub-rule (1) shall be equivalent to the fee required for grant of such licence as specified in the Third	**Validity of <u>Approval</u>.** (1) **<u>An approval</u>** issued in Form COS- 23 shall remain valid, if the licensee deposits **<u>the approval</u>** retention fee referred in the Third Schedule before the completion of period of five years from the date of its issue, unless, it is suspended or cancelled by the State Licensing Authority. (2) The approval retention fee referred in	Word "**licence"** may be replaced with word "**approval**" as laboratories gets approval as per rule and word licence is inconsistent.

S. No.	Rule Position	Cosmetics Rules, 2020	Proposed amendment in the Cosmetics Rules, 2020	Reasons
		Schedule. (3) If the licensee fails to pay licence retention fee on or before the due date as referred to in subrule (1), he shall be liable to pay licence retention fee along with a late fee calculated at the rate of two per cent of the licence fee for every month or part there of up to six months, and in the event of nonpayment of such fee, the licence shall be deemed to have been cancelled.	sub-rule (1) shall be equivalent to the fee required for grant of such **approval** as specified in the Third Schedule. (3) If the licensee fails to pay **approval** retention fee on or before the due date as referred to in subrule (1), he shall be liable to pay approval retention fee along with a late fee calculated at the rate of two per cent of the approval fee for every month or part there of up to six months, and in the event of non-payment of such fee, the **approval** shall be deemed to have been cancelled.	
13.	**61**	**Inspection for verification of compliance.**— The premises licensed in the manner specified in these rules shall be inspected jointly by Inspector appointed by the Central Government and State Government to verify compliance with the conditions of licence and provisions of the Act and these rules at least once in three years based on risk based approach.	**Inspection for verification of compliance.**— The **approved premises** in the manner specified in these rules shall be inspected jointly by Inspector appointed by the Central Government and State Government to verify compliance with the conditions of **approval** and provisions of the Act and these rules at least once in three years based on risk based approach.	Word "**licence"** may be replaced with word "**approval**" as laboratories gets approval as per rule and word licence is inconsistent.
14.	**62(e)**	The approved institution shall from time to time report to the State Licensing Authority any	The approved institution shall from time to time report to the State	In Rule 62 (e) at the end it is mentioned as

S. No.	Rule Position	Cosmetics Rules, 2020	Proposed amendment in the Cosmetics Rules, 2020	Reasons
		changes in the person-in-charge of testing of cosmetics or in the expert staff responsible for testing and any material alteration in the premises or changes in the equipment used for the purposes of testing which have been made since the date of last inspection made on behalf of the State Licensing Authority before grant or renewal of approval.	Licensing Authority any changes in the person-in-charge of testing of cosmetics or in the expert staff responsible for testing and any material alteration in the premises or changes in the equipment used for the purposes of testing which have been made since the date of last inspection made on behalf of the State Licensing Authority before grant **or end of retention period of approval.**	"-----grant or renewal of approval" but the use of word "renewal" is not right, instead it would have been "---grant or end of retention period of approval", as there is no system of renewal, but there is a system of retention of licence.
15.	**63.**	**Withdrawal and suspension of approval.**– (1) The State Licensing Authority may, after giving the approved laboratory an opportunity to show cause why such an order should not be passed, by an order in writing, stating the reasons therefore, withdraw an approval granted under this Part or suspend it for such period as considered appropriate either wholly or in respect of some of the categories of cosmetics to which it relates, if in his opinion, the approved institution has failed to comply with any of the conditions of the approval or with any provisions of the Act or Rules	**Withdrawal and suspension of approval.**– (1) The State Licensing Authority may, after giving the approved laboratory an opportunity to show cause why such an order should not be passed, by an order in writing, stating the reasons therefore, withdraw an approval granted under this **Chapter** or suspend it for such period as considered appropriate either wholly or in respect of some of the categories of cosmetics to which it relates, if in his opinion, the approved institution has failed to	The words "**Chapter,"** may be considered in place of word "Part", as there are no "Parts" in rules, but there are only "Chapters".

S. No.	Rule Position	Cosmetics Rules, 2020	Proposed amendment in the Cosmetics Rules, 2020	Reasons
		made thereunder.	comply with any of the conditions of the approval or with any provisions of the Act or Rules made thereunder.	
16.	**69.**	**Debarment of applicant.**– (1) Whoever himself or, any other person on his behalf, or applicant submits misleading, or fake, or fabricated documents, may, be debarred by Licensing Authority for such period as deemed appropriate in the facts and circumstances of the case after giving an opportunity to show cause as to why such an order should not be made. (2) Where an applicant is aggrieved by an order made by the Central Licensing Authority under sub-rule (1), such applicant may, within thirty days from the receipt of the order, make an appeal to the Central Government or the State Government, as the case may be, and the Central Government or the State Government, may, after such enquiry as it considers necessary, and after affording an opportunity of being heard, pass such orders in relation thereto as considered appropriate.	**Debarment of applicant.**– (1) Whoever himself or, any other person on his behalf, or applicant submits misleading, or fake, or fabricated documents, may, be debarred by Licensing Authority for such period as deemed appropriate in the facts and circumstances of the case after giving an opportunity to show cause as to why such an order should not be made. (2) Where an applicant is aggrieved by an order made by the **Licensing Authority** under sub-rule. (1), such applicant may, within thirty days from the receipt of the order, make an appeal to the Central Government or the State Government, as the case may be, and the Central Government or the State Government, may, after such enquiry as it considers necessary, and after affording an opportunity of being heard, pass such orders in relation thereto as considered	The said clause is applicable for central and state licensing authorities, but state licensing authority was missing, therefore to bring consistency with clause (1) of Rule 4 word "Central Licensing Authority" replaced by "Licensing Authority".

S. No.	Rule Position	Cosmetics Rules, 2020	Proposed amendment in the Cosmetics Rules, 2020	Reasons
			appropriate.	
17.	**First Schedule (Clause 6)**	In case of any violation of Drugs and Cosmetics Act, 1940 and Rules thereunder, the authorised agent shall continue to be responsible even after withdraw of this **Power of Attorney** for the cosmetics imported in India.	In case of any violation of Drugs and Cosmetics Act, 1940 and Rules thereunder, the authorised agent shall continue to be responsible even after withdraw of this **authorization** for the cosmetics imported in India.	To make similar provision in line with the Drugs and Cosmetics Rules, 1945.
18.	**Twelfth Schedule (Clause 2)**	**Hair Fixers**, namely mucilaginous preparations containing gums, used by men for fixing beard.	Clause 2 to be omitted from D&C rules, 1945	The provision is already covered by the new rules. Therefore same may be deleted from D&C rules, 1945

DCC after detailed deliberation, agreed for the above amendments.

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ANNEXURE-A

List of the participants of 59th Drugs Consultative Committee meeting held on 02.03.2021 under the Chairmanship of Dr. V.G. Somani, Drugs Controller General (India) via Video Conference

A. STATE/UTs DRUGS CONTROL ORGANIZATIONS

S. No.	STATE/UT	NAME	DESIGNATION
1.	Andhra Pradesh	Shri. M.B.R. Prasad	Director, DCA
2.	Arunachal Pradesh	Dr. M. Lego	DGHS, Arunachal Pradesh
3.	Assam	Shri. Hridayanand Mahanta	State Drugs Controller
4.	Bihar	Shri. Ravindra Kumar Sinha	State Drugs Controller
5.	Chhattisgarh	Not represented	
6.	Goa	Smt. Jyothi Sardesai	Director, FDA
7.	Gujarat	Dr. H.G. Koshia	Commissioner, FDCA
8.	Haryana	Shri. N.K. Ahooja	State Drugs Controller
9.	Himachal Pradesh	Shri. Navneet Marwaha	Drugs Controller
10.	Jammu and Kashmir	Smt. Lotika Khajuria	State Drugs Controller
11.	Jharkhand	Smt. Ritu Sahay	Director (Drugs)
12.	Karnataka	Shri. Amaresh Tumbagi	State Drugs Controller (A/C)
13.	Kerala	Shri. K.J.John	State Drugs Controller(I/C)
14.	Madhya Pradesh	Shri. Shobhit	Dy. Drugs Controller, FDA
15.	Maharashtra	Shri. D.R. Gahane	Joint Commissioner
16.	Manipur	Shri. N. Rimot Kumar Meetei	Addl. State Drugs Controller
17.	Meghalaya	Not represented	
18.	Mizoram	Shri. Lal swama	Joint Director (Food & Drugs)
19.	Nagaland	Shri. W H Patton	Jt. Drugs Controller
20.	Odisha	Smt. Mamina Patnaik	Deputy Drugs Controller
21.	Punjab	Shri. Sanjiv Kumar	Joint Commissioner(Drugs)
22.	Rajasthan	Shri. Raja Ram Sharma	Drugs Controller
23.	Sikkim	Dr. T.K. Rai	Joint Drugs Controller
24.	Tamil Nadu	Shri. Sivabalan	Director (Drugs)
25.	Telangana	Shri. Ramdhan	Joint Director (I/C) Drugs Control, Telangana

S. No.	STATE/UT	NAME	DESIGNATION
26.	Tripura	Not represented	
27.	Uttar Pradesh	Shri. Dinesh Kumar Tiwari	Assistant Commissioner (Drug)
28.	Uttarakhand	Shri. Tajber Singh	Drugs Controller
29.	West Bengal	Not represented	
30.	Andaman and Nicobar	Not represented	
31.	Chandigarh	Shri. Amit Duggal	Sr. Drug Control Officer
32.	Dadar and Nagar Haveli	Not represented	
33.	Daman and Diu	Not represented	
34.	Delhi	Shri. K R Chawla	Asst. Drugs Controller
35.	Lakshadweep	Not represented	
36.	Pondicherry	Shri Karthikeyan	State Licensing Authority

B. INVITEE

S. No.	NAME	DESIGNATION
1.	Dr. Mandeep Kumar Bhandari	Joint Secretary, MoHFW
2.	Shri. Priyank Kanoongo	Chairperson, NCPCR
3.	Smt. Shaista	NCPCR
4.	Shri. Uttam Kumar	CDAC Representative
5.	Shri. Rahul	CDAC Representative

C. ZONAL/ SUB ZONAL OFFICES OF CDSCO

S. No.	OFFICES	NAME	DESIGNATION
ZONES			
1.	North Zone, Ghaziabad	Shri. Aseem Sahu	Deputy Drugs Controller (India)
2.	East Zone, Kolkata	Dr. A. Ramkishan	Deputy Drugs Controller (India)
3.	West Zone, Mumbai	Dr. Rubina Bose	Deputy Drugs Controller (India)
4.	South Zone, Chennai	Dr. Manivannan	Deputy Drugs Controller (India)
5.	Hyderabad Zone	Smt. A.Visala	Deputy Drugs Controller (India)
6.	Ahmedabad Zone	Shri. Jayant Kumar	Deputy Drugs Controller (India)
SUB-ZONES			
1.	Baddi Sub-zone	Shri. Arvind Kukrety	Deputy Drugs Controller (India)
2.	Bangalore Sub-zone	Shri. B. Kumar	Deputy Drugs Controller (India)
3.		Shri. Rajsekhar	Asst. Drugs Controller (India)

S. No.	OFFICES	NAME	DESIGNATION
4.	Guwahati Sub-zone	Shri. Shiv Kumar	Asst. Drugs Controller (India)
5.	Indore Sub-zone	Shri. Sunil M Joshi	Deputy Drugs Controller (India)
6.	Varanasi Sub-zone	Shri. Vinay Kumar Gupta	Asst. Drugs Controller (India)
7.	Jammu Sub-zone	Smt. Bharati Bachloo	Asst. Drugs Controller (India)

D. CDSCO (HEAD QUARTERS)

S. No.	NAME	DESIGNATION
1.	Dr. V. G. Somani	Drugs Controller General of India
2.	Dr. S. Eswara Reddy	Joint Drugs Controller (India)
3.	Shri. R. Chandrashekhar	Deputy Drugs Controller (India)
4.	Dr. S.P. Shani	Deputy Drugs Controller (India)
5.	Shri. Sanjeev Kumar	Deputy Drugs Controller (India)
6.	Dr. Ravikant Sharma	Deputy Drugs Controller (India)
7.	Dr. Santosh Indraksha	Asst. Drugs Controller (India)
8.	Shri. Balakumar Mahalingam	Drugs Inspector
9.	Dr. Naveen Mehta	Drugs Inspector
10.	Shri. Shivadev D	Drugs Inspector
11.	Shri. Asheesh Kaundal	Drugs Inspector
12.	Shri. Prakash Kumar Parida	Drugs Inspector
13.	Smt. Gunja Chaturvedi	Asst. Drugs Inspector

E. DRUGS TESTING LABORATORIES

S. No.	OFFICES	NAME	DESIGNATION
1.	CDL, Kolkata	Shri. C. Hariharan	Director/In-Charge
2.	CDL, Kasauli	Dr. Arun Bhardwaj	Director
3.	CDTL, Mumbai	Dr. Raman Mohan Singh	Director
4.	RDTL, Chandigarh	Dr. R.A. Singh	Director
5.	RDTL, Guwahati	Shri. Shiv Kumar	In-charge & Asst. Drugs Controller (India)
6.	CDTL, Chennai	Smt. Vijayalakshmi	Director (In-charge)
7.	CDTL, Hyderabad	Smt. A. Visala	Director (In-charge) & Deputy Drugs Controller (India)