

**MINUTES OF 60<sup>TH</sup> SPECIAL MEETING (VIRTUAL) OF DRUGS CONSULTATIVE COMMITTEE (DCC) HELD THROUGH WEB CONFERENCE ON 07<sup>TH</sup> APRIL , 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.

DCG(I) appreciated the efforts made by State Drugs Controllers to ensure availability of drugs and vaccine for COVID-19 to supplement the efforts of the Government for addressing the challenges due to COVID-19 pandemic situation in the country. He mentioned that we need to be proactive in addressing all such challenges by ensuring drugs and vaccine including expansion of capacity of COVID vaccine manufacturing facility as per the Drugs and Cosmetic Act 1940 and Rules made thereunder.

Thereafter, DCG(I) mentioned that there are certain important agenda which includes online National Drug licensing system (NDLS), provisions regarding sale of medical devices etc., which are needed to be addressed urgently to ensure uniform implementation of the provisions of the Act and Rules. Therefore, this special 60<sup>th</sup> DCC meeting have been convened to deliberate on this important issues

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

**AGENDA NO.1**

**CONSIDERATION OF THE RECOMMENDATIONS OF SUB-COMMITTEE FOR THE PROPOSAL TO DEVELOP A MECHANISM / PORTAL FOR REGISTRATION OF TRADERS/ HOSPITALS/ FIRMS WHO ARE INVOLVED IN THE SALE/STOCK/USE OF MEDICAL DEVICES FOR EXEMPTION OF DRUGS SALE LICENCE**

Committee was apprised that, DCC in its 59<sup>th</sup> meeting held on 02.03.2021 constituted a sub-committee under the chairmanship of Dr. S. Eswara Reddy, JDC(I),CDSCO to examine the subject matter.

Accordingly, the sub-committee examined the matter and submitted the recommendations. DCC deliberated recommendations in details including the proposed draft Rules as prepared by the sub-committee and accepted the report of the sub-committee with the suggestion to reframe the provision with respect to appeal [proposed Rule 87(D)(2)] as “ A registration certificate holder whose registration has been suspended or cancelled by State Licensing Authority under sub Rule (1) an appeal to the State Government or Authority designated by the State Government”.

## AGENDA NO.2

### **LAUNCHING OF ONLINE NATIONAL DRUG LICENSING SYSTEM (NDLS) PORTAL FOR ISSUANCE OF LICENCES AND CERTIFICATES FOR DRUGS AND COSMETICS ACROSS THE COUNTRY**

The issue of developing an online portal for issuance of sales and marketing licenses has been discussed in various DCC meetings including the 57<sup>th</sup> DCC meeting held on 20.08.2019. The 57<sup>th</sup> DCC in its meeting recommended that all the State Drug Control Authorities should utilize the common software platform by getting dummy applications from the Stake holders. Accordingly, CDSCO has taken this task for development of such online portal to bring uniformity, traceability and accountability in evaluation and disposal procedure of such applications for issuance of licenses/certificates across the country for the benefit of all the stakeholders. Online National Drug Licensing System portal developed by CDAC in coordination with CDSCO & States has been made functional for testing with effect from 31st March 2021 for validation of the system which can be accessed through <https://statedrugs.gov.in>. The system will be shifted from validation mode to operational for all purposes w.e.f. from 15th April 2021.

During the DCC meeting, all the members were requested to test the developed Online National Drugs licensing system (ONDLS) so that it can be made operational from 15<sup>th</sup> April 2021. Some of the members requested to provide adequate number of CDAC officials for answering the query and clarifications for the purpose of hand holding the stake holders. After detailed deliberation, the committee agreed that the developed online licensing system should be made operational by 15<sup>th</sup> April 2021 and all the technical glitches/issues are to be resolved before 15<sup>th</sup> April 2021. Further, for the purpose of hand holding of stakeholders and regulators, three training programmes have to be conducted, one for the regulators on 17<sup>th</sup> April 2021, second and third for the manufacturers and the wholesalers and retailers on 24<sup>th</sup> April 2021 for the seamless working on the developed online portal.

All the members were asked to provide to CDAC and CDSCO their Name and details of single point of contact (State representative) and also to share that what are the division for manufacturing and Sale in their respective jurisdiction along with hierarchy of reporting as was communicated in the mail by DCG(I), so that CDAC can help them to create appropriate login ID & Pass words for respective Zone /district etc. in state (for sale as well as manufacturing)

**ADDITIONAL AGENDA NO. S-1**

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

The agenda was earlier discussed in the 59th DCC held on 02.03.2021. In addition to that agenda 14 issues which were discussed with the stakeholders were placed before the DCC for its consideration and recommendations.

The details of the issues and recommendations of DCC were as under:-

**1. The license holder must employ a suitably qualified customer manager or drug manager for customer satisfaction**

After examining stakeholders opinion/comments, the committee opined that the Pharmacist acts as customer manager for consumer satisfaction. Therefore, there may not be the need of additional such customer manager.

**2. The license holder must scan all prescriptions and attach the scanned copy to the print-out of drugs dispensed for confirmation.**

The Committee after examining stakeholders comments did not agree due to impracticability and cost burden.

**3. The shop owner must dispense the drugs in an envelope with printed details of the shop (such as name, address, license number, etc.).**

The committee was of the opinion that, since the Cash Memo/Bill contains name and address of the Shop, Licence No. etc, and hence, printing the same on envelop is duplication.

**4. No child should be employed by the License holder.**

Already covered under other law

**5. Drug shall not be dispensed to Children (< 12 years of age)**

The Committee after examining stakeholders comments agreed to issue advisory in this regard with provision of consulting the parents/responsible adult relative of child on phone by the Pharmacist before dispensing the Drugs.

- 6. The license holder must have a computer with suitable large hard-disk for storage of data.**

The Committee after examining stakeholders comments recommended issuing advisory only in this regard.

- 7. All billing must be computerised.**

The Committee after examining stakeholders comments recommended issuing advisory only in this regard.

- 8. The license holder must be available almost entire time the shop remain open.**

The Committee opined that the presence of Pharmacist is already mandatory in the Rules, which shall be stringently enforced.

- 9. 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.**

The Committee after examining stakeholders opinion recommended that, an advisory in this regard may be issued with respect to categories provided in Schedule K of Drugs Rules, 1945 which can dispensed without prescription to be displayed.

- 10. 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.**

The Committee after examining stakeholders opinion, did not recommend the proposal due to impracticalities, cost burden and a possibility of providing confusing information to the consumer.

- 11. 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.**

The committee was of the opinion that it was already provided in the law that, Pharmacists dispense the drugs and does not prescribe through prescription. Further, the committee opined to take stringent enforcement measures in such cases.

- 12. 'Over-the-counter' dispensing of drugs should be discouraged.**

It is already provided in Rules, not to dispense the prescription drugs without prescription. The committee re-emphasized to implement strictly not to dispense the prescription drugs over-the-counter and action should be taken in this regard by the Drugs Regulatory Authorities.

**13.If possible shop for medicine/drugs should be separate from shop for cosmetic items.**

After examining stakeholders comments, Committee recommended that separate earmarked areas may be provided in the shop for such items.

**14.Similarly, the shops for allopathic and non-allopathic medicines should be separate with separate dedicated employees for that purpose.**

After examining stakeholders comments, Committee recommended that separate earmarked areas may be provided in the shop for such items.

The DCC after detailed deliberation in principle agreed with the comments of the stakeholders on the issues mentioned above. Specifically, with regards to dispensing of drugs the committee observed that dispensing of prescription drug without valid prescription is illegal and it is already covered under the provisions of the Drugs Rules, 1945. Further, reports of registered pharmacist prescribing the drugs have not been observed. No further amendment need to be made in this regard. Not to employ children is already covered under other laws and with respect to not to dispense drug to children, committee did not agree to proposal, if child is only aid in family, but agreed to issue advisory to consult parents on phone before dispensing.

The committee opined that, the aforesaid mentioned issues should not be made mandatory at this point of time and should be advisory to the registered pharmacist and shop owners. Accordingly, the committee recommended that an Advisory may be issued to the chemist & druggist in this regard.

**ADDITIONAL AGENDA No S-2**

**CONSIDERATION OF THE PROPOSAL FOR AMENDMENT IN RULE 34(10) OF THE 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 stakeholders for consequential amendment in the said notification for correction etc

Provision related to manner of labelling of cosmetics products meant for export purposes under the Cosmetics Rules, 2020 are as under:

**Manner of Labelling:-**

Rule 34(10) provides that “In case, the cosmetics is meant for export then the labels on packages or container of cosmetics shall meet the specific requirements of law of the country to which the cosmetics is to be exported, but the following particulars shall appear in a conspicuous manner on the label of the inner most pack of the cosmetics in which the cosmetics is packed and every other outer covering in which the container is packed:

- (a) name of the cosmetics;
- (b) the distinctive batch number or lot number or serial number preceded by the word Lot No. or Lot or Batch No. or B. No. or Serial No. or B;
- (c) use before or date of expiry, if any;
- (d) the name and address of manufacturer and address of actual premises where the cosmetics has been manufactured;
- (e) licence number preceded by letters Licence No. or Lic. No.;
- (f) Internationally recognised symbols in lieu of text, wherever required:

Provided that where a cosmetic is required by the consignee to be not labelled with the name and address of the manufacturer, the labels on packages or containers shall bear a code number as approved by the State Licensing Authority”.

Representation has been received to amend the above provisions under Rule 34(10) of Cosmetics Rules, 2020 to make it in line with previous Rule, 147 of Drugs and Cosmetics Rules 1945 which was a provisions for exemption of cosmetics not manufactured for consumption on sale in India

The Committee opined that levels of regulations of cosmetics varies from country to county. Some countries do not regulate cosmetics. Therefore, labelling provisions may vary from country to country. Hence for export, labelling provision should be as per the Rules and Regulations of the importing Country.

DCC after detailed deliberation, agreed to amend the said Rules i.e 34(10) as stated below:

***Rule 34(10) - In case, the cosmetics is meant for export then the labels on packages or container of cosmetics shall meet the specific requirements of law of the country to which the cosmetics is to be exported.***

**Provided that where a cosmetic is required by the consignee to be not labelled with the name and address of the manufacturer, the labels on packages or containers shall bear a code number as approved by the state Licensing Authority.**

DCC after detailed deliberation, agreed for the above amendments.

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**ANNEXURE-A**

**List of the participants of 60<sup>th</sup> (Special) Drugs Consultative Committee meeting held on 07.04.2021 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. K.V.S.N Gupta	Joint Director, DCA, A.P.
2.	Assam	Shri. Hridayanand Mahanta	State Drugs Controller
3.	Bihar	Shri. Ravindra Kumar Sinha	State Drugs Controller
4.	Goa	Smt. Jyothi Sardesai	Director, FDA
5.	Gujarat	Dr. H.G. Koshia	Commissioner, FDCA
6.	Haryana	Shri. N.K. Ahooja	State Drugs Controller
7.	Himachal Pradesh	Shri. Navneet Marwaha	Drugs Controller
8.	Pradesh	Dr. Manish Kapoor	Drugs Control Department, H.P.
9.	Jharkhand	Smt. Ritu Sahay	Director (Drugs)
10.	Karnataka	Shri. Amaresh Tumbagi	State Drugs Controller (A/C)
11.	Kerala	Shri. K.J.John	State Drugs Controller(I/C)
12.	Maharashtra	Shri. D.R. Gahane	Joint Commissioner
13.	Manipur	Shri. N. Rimot Kumar Meetei	Addl. State Drugs Controller
14.	Meghalaya	Shri. Antony Laloo	Senior DI, Licensing & Controlling Authority
15.		Shri. I.T.D. Toi	Senior Inspector of Drugs
16.	Mizoram	Representative	Attended
17.	Nagaland	Shri S. Lithungo Lotha	Dy. Drugs Controller
18.	Odisha	Shri. Annanda Das	Drugs Controller
19.		Smt. Mamina Patnaik	Deputy Drugs Controller
20.	Punjab	Shri. Sanjiv Kumar	Joint Commissioner(Drugs)
21.	Rajasthan	Shri. Raja Ram Sharma	Drugs Controller
22.	Tamil Nadu	Shri. Karthikeyan	Deputy Director (Drugs)
23.	Telangana	Shri. Ramdhan	Joint Director (I/C) Drugs Control, Telangana

S. No.	STATE/UT	NAME	DESIGNATION
24.	Tripura	Representative	Attended
25.	Uttar Pradesh	Shri. Dinesh Kumar Tiwari	Assistant Commissioner (Drug)
26.	West Bengal	Shri. Sukumar Chandra Das	Assistant Drug Controller, Drugs Control , West Bengal
27.	Chandigarh	Shri. Amit Duggal	Sr. Drug Control Officer
28.	Dadar and Nagar Haveli	Representative	Attended
29.	Daman and Diu	Shri. Dharmesh Agarwal	Drug Licensing Authority
30.	Delhi	Shri. Atul Nasa	Controlling & Licensing Authority and Deputy Drugs Controller
31.		Shri. K R Chawla	Asst. Drugs Controller
32.	Pondicherry	Dr. Ananda Krishnan	Senior Drugs Inspector

#### B. INVITEE

S. No.	NAME	DESIGNATION
1.	Dr. K. Bangarurajan	Advisor
2.	Shri. Uttam Kumar	CDAC Representative

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

S. No.	OFFICES	NAME	DESIGNATION
<b>ZONES</b>			
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. S. 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)
<b>SUB-ZONES</b>			
1.	Baddi Sub-zone	Shri. Arvind Kukrety	Deputy Drugs Controller (India)
2.	Bangalore Sub-zone	Shri. B. Kumar	Deputy Drugs Controller (India)
3.	Guwahati Sub-zone	Shri. Shiv Kumar	Asst. Drugs Controller (India)
4.	Indore Sub-zone	Shri. Sunil M Joshi	Deputy Drugs Controller (India)
5.	Varanasi Sub-zone	Shri. Vinay Kumar Gupta	Asst. Drugs Controller (India)
6.	Jammu Sub-zone	Smt. Bharati Bachloo	Asst. Drugs Controller (India)

S. No.	OFFICES	NAME	DESIGNATION
<b>PORT OFFICES</b>			
1.	Mumbai (Air and Sea port)	Shri. Abhishek Chawla	Asst. Drugs Controller (India)
2.	Chennai (Air Port)	Smt. V.M. Bharathi	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.	Dr. P.B.N. Prasad	Joint Drugs Controller (India)
4.	Shri. A. K. Pradhan	Deputy Drugs Controller (India)
5.	Shri. Ranga Chandrasekhar	Deputy Drugs Controller (India)
6.	Shri. Sanjeev Kumar	Deputy Drugs Controller (India)
7.	Dr. Ravikant Sharma	Deputy Drugs Controller (India)
8.	Smt. Shraddha Srivastava	Assistant Drugs Controller (India)
9.	Shri. Vijay Vitthalrao Chandankar	Assistant Drugs Controller (India)
10.	Shri. Rajesh Verma	Assistant Drugs Controller (India)
11.	Shri. Balakumar Mahalingam	Drugs Inspector
12.	Shri. V. Sooraj	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)