REPORT OF 54TH MEETING OF DRUGS CONSULTATIVE COMMITTEE HELD ON 30TH JULY, 2018 AT NEW DELHI

Inaugural Deliberations

Dr. S. Eswara Reddy, Drugs Controller General (India), Chairman, Drugs Consultative Committee, welcomed the participants and thanked them for sparing time for deliberations on the proposals to improve quality of drugs manufactured/marketed in the country.

All the members of the committee and special invitees introduced themselves to the Chair. The Chair set the context of meeting by providing briefs about agenda points to be discussed.

Chair stressed the problems related to Schedule M compliance are mostly confined to small-scale pharmaceutical units as large-scale firms have shown greater willingness to comply with the revised norms in order to increase their competitiveness in the global arena. Chair opined that there is necessity of building the brand image of India by increasing confidence in the drugs manufactured in India. Chair also opined that there is a need of upgrading and strengthening the regulatory mechanism for quality product on par with the international standards.

The Chair quoted that the Drug Regulatory Authorities are required to have more interaction, transparency in working, coordination among the States and with the Central and use of IT facilities for an effective quality control over drugs. It is essential that only safe and effective drugs are permitted to be marketed to safeguard the public health. There should be an effective recall system so that the drugs found not of standard quality are withdrawn from the market at the earliest.

In order to monitor the quality of such drugs moving in the market, samples are drawn by the drug control officials of the States as well as CDSCO randomly as well as risk based strategy and tested in Government laboratories.

Chair pointed out the importance of implementing the various provisions like Stability Studies, Bioequivalence studies, Good Distribution Practices, Recall system etc. to become in line with the international regulatory agencies.

Chair also informed to the members about submission of report of the subcommittee constituted under the chairmanship of Dr. Nilima Kshirsagar to examine the banned 344 FDC +5 FDC and recommendations of 80thDTAB in this regard by Central Government.

Chair informed the committee on recent actions taken up by the Central Government on restriction of Oxytocin and stated that Ministry of Health and Family Welfare issued notification vide G.S.R. No.411 (E) dated 27.04.2018, to restrict the manufacture for sale, sale or distribution of Oxytocin under section 26A of the Drugs& Cosmetics Act,1940 provided that manufacturing of Oxytocin formulations for domestic use shall be by public sector undertakings or companies only and the labels of the products shall bear barcodes.

Ms. Preeti Sudan, Secretary, Ministry of Health and Family Welfare spared time from her busy schedule to address the meeting. While reviewing the status of FDCs, Secretary stressed on the action to be taken on FDCs considering 80th DTAB recommendation in light of order of Hon. Supreme Court.

She also highlighted the restriction on manufacturing, sale of oxytocin to be effective from 01.09.2018 and requested the State Drug Controllers to make sure the availability of Oxytocin in their States by placing the purchase order in time with Karnataka Antibiotics &. Pharmaceuticals Limited (KAPL), Karnataka for its uninterrupted supply. She requested all State Licensing Authorities to ensure that there is no artificial shortage of Oxytocin in their respective States and Union Territories. Drugs Controller, Tripura raised concern on Oxytocin supply in North Eastern States. In response, she advised to take necessary precautions to avoid unavailability of Oxytocin to North Eastern States by sensitizing KAPL for establishing effective distribution channel. She once again reminded that all the State Licensing Authorities shall ensure implementation of various measures taken by Central Government from time to time including issues related to sale of anti-TB drugs.

DCG (I) and State Drugs controllers informed the Secretary regarding various initiatives on e-governance like establishment of software platform for online applications and modules & draft rules for comprehensive database of the manufacturing sites, licensed products along with their details of dosage strengths etc.

In her reply to SLAs regarding disbursement of remaining fund for strengthening of Drugs Regulatory for capacity building in the states, she requested the members to submit the fund utilization certificate for further disbursement process.

Dr. S. Venkatesh, DGHS, Ministry of Health and Family Welfare also addressed the meeting. In his address, he mentioned the importance of formulation development including stability testing, quality testing and Bioequivalence studies of drug formulations in manufacturing of quality drugs in the Country. He also pointed out the importance of Good Distribution Practices for Pharmaceuticals Products and requested all state licensing authorities about the guidelines prepared by CDSCO which needs to be followed at every level of supply chain.

Mr. R.K. Vats, Additional Secretary, Ministry of Health and Family Welfare also addressed the meeting. In his address, he pointed out the importance of regulating quality of drugs by both Central and State Governments. He also emphasized about the promotion of Make in India and Ease of doing business by making new regulatory provisions. He mentioned about initiatives being taken to empower the consumers and medical practitioners for testing of drugs independently in quality testing laboratories in collaboration with IPC.

He stated that drug regulators should take measures to ensure the availability of drugs in the country and also requested the State Drug Controllers to monitor the manufacturing units meticulously for ensuring sufficient production of drugs under NPPA.

Mr. Sudhir Kumar, Joint Secretary, Ministry of Health and Family Welfare also addressed the meeting. In his address, he requested the members to ensure that Oxytocin Orders reach well in advance to KAPL to avoid shortage. He mentioned that DCC may take measures to encourage the usage of generic drugs by the public. He suggested that the regulatory authorities should strengthen their enforcement activities including drawing and testing of drug samples from market. He also highlighted the need of efficient measures for ensuring the safety of Cosmetics.

DCG (I) initiated the deliberations point wise on the issues to improve the quality of drugs manufactured/marketed in the country.

AGENDA NO. 1

CONSIDERATION FOR APPROVAL OF REPORT OF 53rd DCC MEETING HELD ON 09.04.2018 AND ACTION TAKEN IN THE MATTERS ARISING OUT OF THE MEETING

DCG(I) briefed point wise on the Action Taken Report of the 53rd meeting of DCC, the same was approved by the members.

AGENDA NO. 2

CONSIDERATION OF PROPOSALS TO IMPROVE THE QUALITY OF DRUGS MANUFACTURED/MARKETED IN THE COUNTRY

1. Formulation Development

a) Making requirement of Form-29 mandatory before grant of manufacturing licence
b) Facility- Own/Contract
c) Developmental studies
    i) Safety and compatibility of excipients
    ii) Stability
    iii) Process Validation
    iv) Analytical Method Validation
    v) Quality/Organic Volatile Impurity/Impurity Profiling of APIs
    vi) Dissolution Study / BA-BE Study

Members deliberated the above matter. Drugs Controller, Himachal Pradesh suggested to prepare Guideline Document on Formulation Development for uniform implementation of the Regulatory requirements. In this regard, DCG (I) constituted a sub-committee under the chairmanship of Drugs Controller, Punjab with following members.

1. Drugs Controller, Haryana
2. Drugs Controller, Telangana
3. Dr. A. Ramkishan, DDC (I), CDSCO (EZ)
4. Prof. Mukesh C. Goel, Former Director, Head of Pharmaceutics, LM College of Pharmacy, Ahmedabad, Gujarat.
5. Two experts in the field of Formulation Research & Development

2. Manufacture for Sale

Compliance of GMP:

i) Quality Assurance Division
ii) Utilities: HVAC/Water/Steam
iii) Validation Master Plan - Process Validation, Analytical Method Validation, Cleaning Validation
iv) Annual Product Review
v) Stability Studies

Further DCG (I) stated that at present the applicants are not providing the 'Product and Process Failure Data' to the regulatory authorities. In this regard, DCG(I) suggested to all State Licensing Authorities to encourage manufacturers for reporting of such raw data along with applications. Also mentioned the importance of contemporaneous documentation as a part of data integrity and requested for its strict enforcement across country.

3. Good Distribution/ Storage Practices

Members deliberated the matter and Dr.V.G. Somani, JDC(I) suggested to take necessary provisions to impart legal sanctity to the 'Good Distribution Practice Guidelines'. P.B.N. Prasad DDC (I) suggested to incorporate the Good Distribution Practice Guidelines as Schedule to the Rules to penalise the offenders.

4. Market Surveillance for quality monitoring

I. Drawing of samples by DIs
II. Testing in laboratories
III. Specification and reference standard
IV. Timelines for issue of test reports
V. Regulatory action in case of NSQ drugs
VI. Direction and follow up for Recall of NSQ drugs

Members deliberated the matter andraised the issue regarding sampling of some cosmetics in the name of AYUSH product. To address issues of cosmetics safety raised by JS, he suggested DCG (I) to invite the representative from AYUSH for next DCC meeting.

Dr. V.G. Somani, JDC (I) briefed about the quality system to be improved in coordination with State and Central Government regulators quoting clause 16.10, 26.2 to 26.5 and 27.1 of Schedule M wherein it was emphasized to focus the inspection on design of quality of product, its validation, establishment of shelf life through stability studies prior manufacturing. With regard to testing of non-pharmacopoeial drugs by drug testing laboratories, he suggested to make provisions to obtain related documents from manufacturer of such drugs by the Licensing Authorities and to have common database and protocol for testing of such products by all labs. In response to which Director CDL, Director RDTL stated that such methods submitted by manufacturer shall be inspected with respect to their validation and reproducibility during inspection.

Dr. K. Bangarurajan, JDC (I) informed about the GLP status of public sector laboratories and requested State Licensing Authorities to take necessary action on such laboratories who fails to meet Schedule L1 compliance. Lab representatives opined that all the state laboratories need to be upgraded with respect to infrastructure and manpower. They also requested that all laboratories should be provided with sufficient fund.

Members suggested to incorporate the definition for 'thermolabile and thermostable' in the rules. DCG (I) opined that this may be discussed in the next DCC meeting.

5. Quality monitoring in Government Supply

I. GMP compliance in case of manufacture of drugs only for Govt. supply
II. Drawing and testing of samples from Govt. supply chain
III. Handling of NSQ and recall of NSQ drugs

Members deliberated the matter about higher percentage of NSQ in govt. supplies and opined that it could be largely related to procurement policy of Lowest Price Bidder to get the tender (L1 Policy). Members felt that there is

an urgent need to reformulate the existing procurement policy such that quality would be primary factor by mandatorily purchasing from WHO-GMP certified companies.

6. Sale of Drugs

Grant of Sale Licence:

a) Adequate storage facility – Cold chain
b) Availability of pharmacist
c) Sale of drugs without prescription-AMR
d) Maintenance of records of sale and distribution

Members requested DCG (I) to make the provisions for differentiation of generic and branded drugs.

Members raised the concerns about the absence of pharmacist, sale of drugs without prescription and maintenance of records especially bills. In this regard, DCG (I) requested each state licensing authority to conduct awareness programme with the medical associations and consumer associations for proper implementation of these provisions.

Drugs Controller, Haryana raised concerns about anomaly between Indian Pharmacopoeia and Drugs and Cosmetics Rules, 1945 with respect to the storage conditions of Oxytocin. DCG (I) clarified that the provisions of Drugs and Cosmetics Rules shall prevail in such cases and requested IPC representative to look into the matter for necessary changes in Indian Pharmacopoeia.

7. Prompt and effective Product Recall System of defective products

Members deliberated the obstacles on complete recovery of NSQ drugs from market. In this regard Dr. Shani, DDC(I) suggested State Governments to allot dedicated ADC(I) to look after implementation of recall system meticulously so as to ensure that every single unit of the defective drugs is recalled by manufacturer from supply chain and proper reconciliation of the stocks of manufacture, distribution and recall shall be maintained.

8. Any other issue relating to quality monitoring of drugs

Representatives from C-DAC demonstrated the on line portal for uploading the data by manufacturer and their authentication by state licensing authorities.

DCG (I) informed the proposal regarding the formation of independent expert committee to audit all regulatory authorities and laboratories.

DCG (I) pointed out the need of strengthening regulatory provisions for import of the Active Pharmaceutical Ingredients.

Shanthi Gunashekaran, DDC(I) expressed her concerns on misuse of imported excipients and suggested to strengthen the D&C act to regulate import, manufacture and sale of excipients.

Arvind Kukrety DDC (I) opined that there is urgent need to take the measures to strengthen the regulatory provisions in respect of supply chain of active pharmaceutical ingredients and excipients.

DCG (I) informed the members that, he may request the Central Government to write a letter to the chief secretary of each state for implementing the recent notifications and necessary measures to improve the quality of drugs marketed in the country.

The meeting ended with the vote of thanks to the Chair.

NOTE: ANNEXURE-A: List of Participants

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ANNEXURE-A

List of the participants of 54thDrugs Consultative Committee meeting held on 30thJuly, 2018 at New Delhi under the Chairmanship of Dr. S. Eswara Reddy, Drugs Controller General (India)

A. STATE/UTs DRUGS CONTROL ORGANIZATIONS

S. NO.	STATE	NAME	DESIGNATION
1.	Andhra Pradesh	Dr. Ravi Shankar	DG, DCA
2.	Arunachal Pradesh	Not represented	
3.	Assam	Not represented	
4.	Bihar	Shri. Ravindra Kumar Sinha	State Drugs Controller
5.	Chhattisgarh	Shri. Hiren Patel	Asst. Drugs Controller
6.	Goa	Not represented	
7.	Gujarat	Dr. H.G. Koshia	Commissioner, FDCA
8.	Haryana	Shri. N.K Ahuja Sh. Man Mohan Taneja	State Drugs Controller Asst. 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	Additional Drugs Controller
13.	Kerala	Shri. Ravi S. Menon	Drugs Controller
14.	Madhya Pradesh	Shri. Shobhit	Dy. DC, FDA
15.	Maharashtra	Shri. A.T. Nikhade	Jt. Commissioner (HQ), FDA
16.	Manipur	Shri. Akoijam Singhajeet Singh	State Drugs Controller
17.	Meghalaya	Shri. Devistone Swer	Asst. Drugs Controller
18.	Mizoram	Shri. Lal Sawma	Joint Director, FDA
19.	Nagaland	Not represented	
20.	Odisha	Not represented	
21.	Punjab	Shri. Pradeep Kumar	Jt. Commissioner, FDA
22.	Rajasthan	Shri. Raja Ram Sharma	Drugs Controller
23.	Sikkim	Not represented	
24.	Tamil Nadu	Shri. K. Sivabalan	Director, DCA
25.	Telangana	Dr. B. Venkateswarlu	Deputy Director

S. NO.	STATE	NAME	DESIGNATION
26.	Tripura	Dr. N. Goswami	State Drugs Controller
27.	Uttar Pradesh	Shri. Rajesh Srivastava	Assistant Commissioner (Drug)
28.	Uttarakhand	Shri. Tajber Singh	Drugs Controller
29.	West Bengal	Shri. Swapan Kumar Mondal	Acting Director of drugs control
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. A.K. Kaushal Shri. Atul Kumar Nasa	Spl. Secretary, H&FW HOD & Controlling Authority
35.	Lakshadweep	Not represented	
36.	Pondicherry	Not represented	

B. SPECIAL INVITEES

S. No.	NAME	DESIGNATION
1.	Smt. Preeti Sudan	Secretary, MoHFW
2.	Dr. S. Venkatesh	DGHS, MoHFW
3.	Dr. R.K. Vats	Additional Secretary & DG (CGHS), MoHFW
4.	Shri. Sudhir Kumar	Joint Secretary, MoHFW
5.	Dr. P.L. Sahu	PSO, Indian Pharmacopoeia Commission
6.	Dr. V. Kalaiselvan	PSO, Indian Pharmacopoeia Commission

C. DRUG TESTING LABORATORIES

S.No.	LABORATORY	NAME	DESIGNATION
1.	CDL Kolkata	Shri. C Hariharan	Director/In-Charge
2.	CDL, Kasauli	Shri. Sumir Rai Bhalla	Asst. Technical Officer
3.	CDTL, Mumbai	Dr. Raman Mohan Singh	Director
4.	CDTL, Chennai	Dr. N. Murugesan	Director
5.	CDTL, Hyderabad		
6.	RDTL, Chandigarh	Dr. R. A. Singh	Director
7.	RDTL, Guwahati	Not represented	

D. ZONAL/ SUB ZONAL/PORT OFFICES OF CDSCO

S. No.	OFFICES	NAME	DESIGNATION
		ZONE	
1.	North Zone, Ghaziabad	Shri. Aseem Sahu	Dy. Drugs Controller (India)
2.	East Zone, Kolkata	Dr. A. Ramkishan	Dy. Drugs Controller (India)
3.	West Zone, Mumbai	Shri. P.B.N. Prasad	Dy. Drugs Controller (India)
4.	South Zone, Chennai	Smt. Shanthy Gunashekharan	Dy. Drugs Controller (India)
5.	Hyderabad Zone	Dr. S. Manivannan	Dy. Drugs Controller (India)
6.	Ahmedabad zone	Shri. Arvind Kukrety	Dy. Drugs Controller (India)
		SUB ZONE	
1.	Bangalore Sub-zone	Shri. B. Kumar	Dy.Drugs Controller (India)
2.	Baddi Sub-zone	Shri. B.K. Samantray	Dy.Drugs Controller (India)
3.	Jammu Sub-zone	Shri. Gulshan Taneja	Dy.Drugs Controller (India)
4.	Goa Sub-zone	Not represented	
5.	Indore Sub-zone	Shri. Sunil M Joshi	Asst. Drugs Controller (India)
6.	Guwahati Sub-zone	Shri. Shiv Kumar	Asst. Drugs Controller (India)
7.	Varanasi Sub-zone	Shri. Vinay Kumar Gupta	Asst. Drugs Controller (India)
		PORTS	
1.	IGI Airport, New Delhi	Dr. Naresh Sharma	Dy.Drugs Controller (India)
2.	Kolkata Airport	Not represented	
3.	Kolkata Sea Port		
4.	Chhatrapati Shivaji International Airport, Mumbai	Not represented	
	Ballard Sea Port, Mumbai		
5.	JNPT (Nhava Sheva) Sea Port	Not represented	
6.	Chennai Airport	Not represented	
7.	Chennai Sea Port	Not represented	
8.	Cochin Sea Port	Not represented	
9.	RGI Airport, Hyderabad	Not represented	
10.	Visakhapatnam Airport	Not represented	
	Visakhapatnam Sea Port		

S. No.	OFFICES	NAME	DESIGNATION
11.	Krishnapatnam Sea Port	Not represented	
12.	Bengaluru Airport	Not represented	
13.	Ahmedabad Airport	Not represented	
14.	Kandla Sea Port	Not represented	
15.	Goa Airport	Not represented	

E. CDSCO HEAD QUARTER

S. No.	NAME	DESIGNATION
1.	Dr. S. Eswara Reddy	Drugs Controller General of India
2.	Dr. V. G. Somani	Joint Drugs Controller (India)
3.	Dr. K Bangarurajan	Joint Drugs Controller (India)
4.	Shri. Arun Sharma	Director (Admin)
5.	Shri. A. C. S. Rao	Deputy Drugs Controller (India)
6.	Dr. S.P. Shani	Deputy Drugs Controller (India)
7.	Shri. A.K. Pradhan	Deputy Drugs Controller (India)
8.	Shri. R. Chandrashekhar	Deputy Drugs Controller (India)
9.	Shri. Sanjeev Kumar	Deputy Drugs Controller (India)
10.	Shri. A. Senkathir	Deputy Drugs Controller (India)
11.	Shri. Jayant Kumar	Deputy Drugs Controller (India)
12.	Dr. Santosh Indraksha	Asst. Drugs Controller (India)
13.	Dr. Ravikant Sharma	Asst. Drugs Controller (India)
14.	Smt. Kavita Sharma	Asst. Drugs Controller (India)
15.	Shri Sunil Kulshreshta	Asst. Drugs Controller (India)
16.	Shri. Sidharth Malhotra	Asst. Drugs Controller (India)
17.	Shri. Sella Senthil	Asst. Drugs Controller (India)
18.	Shri. Ashish Rai	Drugs Inspector
19.	Shri. Gunda Raghuvaran	Drugs Inspector
20.	Shri. Shivadev D	Drugs Inspector
21.	Shri. Asheesh Kaundal	Drugs Inspector
22.	Shri. Prakash Parida	Drugs Inspector
23.	Shri. Rajesham Pambala	Drugs Inspector
24.	Ms. Gunja Chaturvedi	Asst. Drugs Inspector