**REPORT OF 50TH MEETING OF**

**DRUGS CONSULTATIVE COMMITTEE HELD ON 04 & 05TH NOVEMBER, 2016 AT NEW DELHI**

# Inaugural Deliberations

**(LIST OF PARTICIPANTS IS AT ANNEXURE I)**

1. Dr. G. N. Singh, Drugs Controller General (India) and Chairman, Drugs Consultative Committee, welcomed the participants to the meeting. He briefed the members that the meeting has specifically been convened to discuss issues relating to strengthening of Drug Regulatory System in the country, to examine and recommend the regulations for sale of Drugs over internet and the steps required for revisiting of various rules like Medical Devices Rules, Cosmetics Rules including the up gradation of the GMP to WHO level. DCGI highlighted various measures taken during the last one year for improvement of regulatory systems in CDSCO.

2. In recent WHO workshop in Geneva he raised the issue regarding criteria for defining stringent regulatory authorities by WHO and India has been considered as one of the stringent regulatory authorities. Through SUGAM portal CDSCO has already put the e-governance in respect of more than 60% of the activities relating to grants/ approval of various licences and approvals. This has resulted improvement in efficiency, transparency and accountability in the regulatory system.

3. He requested that all states should join hands with CDSCO to make the regulatory activities on line may be in another 6 months by net working with CDSCO. He also highlighted that the present regulatory process in CDSCO has become hassle free. Clearance of import consignments through ICE Gate on the basis of risk based sampling by port officers of CDSCO through who are working on 24X7 basis.

4. He also highlighted that CDSCO in consultation with the State Regulators has conducted Risk Based GMP/GLP inspections under the guidance of the Ministry of Health & Family Welfare. He stressed that activities related to Post Marketing Surveillance of marketed drugs should be given importance for ensuring the Patient Safety.

5. Shri K. L. Sharma, who joined the meeting post lunch session, thanked the Committee for having invited him for this meeting. He mentioned that he would like to share some of the regulatory issues and actions taken during the last one year.

6. He congratulated all the members for actively participating in the Risk Based Inspections of the manufacturing facilities. He, however, mentioned that the outcome is not giving Rosy picture. The result of compliances has been found in the range of 0 to 0.071% and for non compliances has been found above 90% or so. He also mentioned that GMP compliance in respect of WHO GMP site in certain cases is not satisfactory while in non certain non GMP sites have 100% GMP compliance with respect to WHO GMP.

7. He also congratulated the members for their active participation in the National Drug Survey. The report of the survey is under preparation. In the survey the extent of Nor of Standard Quality drugs is found to be around 3% which is less than the global average.

8. Sh. Sharma mentioned that recently during the visit of Secretary Health to Mozambique, the Mozambique Authority raised quality concerns on the drugs exported from India. The Health Secretary of Mozambique will be visiting India shortly where the quality issue of exported drugs may be raised to the Central Government. He requested the members that pro-active action needs to be taken on priority basis as and when complaints received on the drugs exported from India.

9. He also mentioned that in order to improve the skill and knowledge of the regulators and the Drug Analysts, many training programmes have been conducted. However, certain States have not deputed their officials for the training and few such states have many non-compliances observed during the Risk based Inspections. He also mentioned that Government is working to adopt the training modules being developed by Life Science Skill Sector Development Council.

10. He informed the committee that the Government has recently published the draft Medical Device Rules 2016 seeking suggestions / comments from Stake holders within one month.

11. Sh. Sharma mentioned that there is another area of concern related to regulatory provisions on Clinical Trials. Initiatives have already been taken to prepare separate rules for regulation of Clinical Trials in the country. It is expected that within 2 months draft rules will be published for public comments.

12. He also informed the members that the work is going on to prepare separate rules for regulation of manufacture / import of Cosmetics, as earlier concerns have been raised specially by small cosmetic traders on the regulations.

13. He stressed that the need of data base management system to have comprehensive centralized data of the manufacturers, retailers, wholesalers along with the products with their strength, brand names being manufactured and marketed in the country.

14. As regards to the issue related to on line sale of drugs or e-Pharmacies he mentioned that CDSCO has already written to all the states / UTs that selling of drugs through internet is not permitted and the same status stands today. We have to develop the platform for e-pharmacy. The report of the sub-committee in this regard will be considered for further action needed.

15. While discussing the issue relating to providing the information under RTI Act, Shri Sharma mentioned that as per the RTI act, we are not required to provide the information which is of commercial interest. To the extent the law permit, the PIO may be instructed that no information of commercial nature should be provided.

16. He also emphasized that we are an integral part of a Single System as a whole but not to be seen Centre and the State as different. We should help each other and take the country forward and the position as Pharmacy of World.

17. As regards research and development of a New Drug he mentioned that an Eco System needs to be developed collaborating with the 15 to 20 institutions at National level like NIPER / IITs, who are working good job in this area and we can leverage the resources available in such institutes for R&D and Clinical Research.

18. He also highlighted the issues regarding the dependency on other countries for APIs. Excessive dependency on a single country or single company for API's is not good for the country. If they stop supplying the API, the country will not be in a position to the fill the demand. Dr Katoch Committee has recommended various measures for encouraging the indigenous manufacture of API's. A comprehensive approach needs to be taken in the matter for making self sufficient in API manufacturing.

19. As regards Capacity Building Programme on Central Scheme for strengthening of State Regulatory System, he informed to the members that the Government has received proposals from 19 States so far. Ministry is pursuing the matter with the Finance Ministry for release of funds so that the money can be provided to the states.

20. As regards to the drug testing capacity in the states, he mentioned that many states presently are not able to equip their laboratories with the latest equipments and facilities. He also mentioned that we may consider adopting the RDTL Guwahati model for other such state laboratories. The RDTL Guwahati, which was handed over by the State Government to Centre, has already been equipped with the testing facilities. The States can also avail the services of the Central Drug testing laboratories for testing of samples drawn by their inspectors. He finally mentioned that drug regulatory system in the country has already improved a lot and is going to be improved further.

## AGENDA NO.1

## CONSIDERATION FOR APPROVAL OF REPORT OF 49TH DCC MEETING HELD ON 16.10.2015 AND ACTION TAKEN IN THE MATTERS ARISING OUT OF THE MEETING

The report of the 49th meeting of the DCC was considered approved as there were no comments from the members.

As regards to the strengthening of States under centrally sponsored scheme, it was discussed that 19 States has forwarded their proposal of the Center. The members requested for early release of fund so that the money can be utilized for strengthening their system.

As regards the misuse of oxytocin, the Chairman appreciated the efforts taken by the members for curbing its misuse. He however requested the members to provide the various information sought in the matter and to have continuous monitoring on manufacture and sale of oxytocin.

As regards to the updating of Schedule M the members agreed to revisit the schedule to make it contemporary in light of current WHO GMP guidelines.

As regards to the Risk based inspections, it was emphasized that the State Govt. should depute their regulatory officer for the training programme conducted by the CDSCO and Ministry of Health in this regard.

## *(EXTRACTS OF 5OTH DCC MEETING HELD ON 4TH & 5TH NOV., 2016)*

### AGENDA NO.2

### CONSIDERATION OF THE REPORT OF THE SUB-COMMITTEE CONSTITUTED TO EXAMINE AND RECOMMEND REGULATIONS FOR SALE OF DRUGS OVER INTERNET

The issue of clandestine export and sale of medicines via internet by certain web portals in the country in violation of the provision of the Drugs and Cosmetics Act, 1940 and rules made there under was discussed in the 48th Drugs Consultative Committee (DCC) meeting held on 24.07.2015.

The sub-committee constituted under the chairman ship of Dr. Harshdeep Kamble, Commissioner FDA Maharashtra has submitted its report. The report was presented by Dr. Kamble before the DCC in detail. The presentation covered various aspects such as present scenario regarding sale of medicine, existing network of pharmacies, pros & cons of present healthcare delivery system, different scenario regarding online sale of medicines, concerns and advantage of e-phramcy and the recommendations of the sub-committee including the draft form amendment in the Drugs and Cosmetic Rules.

It was presented that the sub-committee has deliberated the matter is depth in 6 meetings. 368 suggestions comments/received from various stake holders including NGOs, consumer association, industry associations, were considered by the sub-committee. The sub-committee also deliberated with the representatives of the Govt. Depts., such as customs, IT, NIC etc. The salient features of the recommendation of the sub-committee are as under:

- However, online sale of drugs, if properly regulated, has the potential to affect public health positively, but adopting technology should not pose risk to human health.
- There is a need to leverage the technological advancements in e-marketing, ease of doing business and benefits of online sale of medicines to the patients
- The prerequisite for an online market could be the existence of robust system viz. Central portal/clouds, common Apps for patients, physicians, pharmacies, e-pharmacies, etc.

- Some geographical restrictions for supply of drugs are required for effective administrative control on online sale. It will also restrict the entry of prohibited items, spurious medicine.
- Geographical restrictions will help in effective recall of drugs and better pharmacovigilance
- Drugs and Cosmetics Rules, 1945 need to be amended for effective monitoring and proper enforcement of the Act, in achieving its aims and objectives.
- National Portal be created, which will be the nodal platform for transacting and monitoring online sale of drugs.
- Necessary to evolve a mechanism to register e-pharmacy which do not directly indulge in stocking and sale of drugs.
- E-pharmacy may be defined in the Drugs and Cosmetics Rules, 1945
- E-pharmacy shall effect sale only from the respective State from where it has received the order and expected it to be delivered through licensed retail chemist of that State
- All the existing licensees carrying out sale of drugs by way of retail would also be able to register on the National portal for carrying out online sale of drugs.
- They need to be registered with CDSCO under the Drugs and Cosmetics Rules, 1945.
- Online sale of drugs may be permitted either on e-prescriptions or verified scanned copy of the prescription, in compliance with provisions of IT Act, 2000 and rules there under
- Entire audit trail including the name and address of the patient/ physician/ pharmacy shall be digitally stored to prevent abuse and ensure tracking in case of any adverse events
- Database of medical practitioners and pharmacies, data integrity of patients identity and safety, patient counseling, track and trace be maintained
- linking with Aadhaar will ensure the identity of the stakeholders
- As certain categories of drugs viz. the Narcotic and psychotropic drugs, tranquilizers, habit forming drugs and Schedule X drugs are prone for abuse or misuse, such categories may be excluded from sale through e-pharmacies.
- Confidentiality of patient information shall be maintained
- A registry of internet pharmacies should be made available on the National portal. Information to be available on the website of e-pharmacy

- All internet pharmacies should provide a link of the National portal on their homepage for verification of its authenticity by the patient/ consumer.
- Registration with Central Authority shall be mandatory for routing all the transactions through National portal for the online sale of Drugs, whether prescription or non–prescription drugs
- Product advertisements of the Scheduled drugs shall be prohibited on the electronic Medias
- All the provisions proposed for the online sale of drugs will also be applicable to non-prescription drugs also except for the compliance of requirements of prescription

DCC appreciated the efforts taken by the sub-committee to deliberate and capture all aspects comprehensively in such a complex matter and giving recommendations including the draft for amendment in the Rules.

The recommendations of the sub-committee were deliberated by the DCC in detail. Various roadmap /options for implementation regarding sale of medicines through e pharmacies were discussed. Some of the members were of the view that initially only OTC drugs should be allowed to be sold through e pharmacies and based on experience the online sale can be extended to prescription drugs in phased manner. Many of the members, however, were also of the view that the online sale of medicine may help in curbing the problem of misuse / abuse of drugs including the sale of prescription drugs without prescription as, through on line sale it will be easier to track and trace the supply of medicines including suppliers, compliance to the conditions of sales including requirement of prescription to the prescription drugs etc. The technology infrastructure will provide value added information to the regulator, consumers which will also be helpful in restricting the misuse of medicines and ensuring the safety and efficacy of the drug.

It was also deliberated that a centralized platform should be developed and it should be integrated with the entire system of sale of drugs through online as well as through physical means. Initiatives should also be taken for Training & Capacity Building of Regulators on various technological aspects in relation to the sale of drug through on line.

It was also discussed that it is implicitly known that online sale of medicines is not permitted under the existing provisions of Drugs & Cosmetic Act, 1940 & Rules, 1945. However, many companies are involved in online sale of medicines in

the country. Therefore, a direction should go regarding actions to be taken against persons involved in online sale of medicines.

After detailed deliberations, while accepting the report *in-toto*, the DCC recommended that the report of the sub-committee should be forwarded to the Govt. for consideration and further action in the matter.

While deliberating the issues relating the sale of medicines on line, existing regulatory regimes for OTC products was discussed. It was deliberated that presently no definition of OTC under the Act and Rules. However, prescription drugs are considered those which are included in Schedule H, H1 and X are required to be sold under the prescription of RMP. Regulatory provisions that no person dispensing a prescription drug may supply any other preparation, whether containing the same substance or not in lieu thereof provided as one of the conditions of licence for sale of drug was also deliberated by the DCC in light of present scenario of encouraging generic drugs in the health care system. DCC after detailed deliberations recommended for constitution of a sub-committee under Dr. Mrinalini Darswal, Commissioner, Drugs Control Administration, Delhi comprising following members:

1. Dr. Krishna Mohan, DG, Drugs Control Administration, AP
2. Dr. H.G Koshia, Commissioner, FDCA, Gujarat.
3. Smt. A. Visala, DDCI, CDSCO, HQ,

The sub-committee shall recommend regarding classification and regulatory provisions for OTC products. The sub-committee shall also recommend modalities/ amendments needed in the conditions of sale licence so that Pharmacist, while dispensing the prescription drugs may supply any other generic preparations containing the same drug.

**AGENDA NO.3**

**CONSIDERATION OF THE PROPOSAL TO CREATE A COMPREHENSIVE DATA-BASE MANAGEMENT SYSTEM OF ALL MANUFACTURERS, LICENCES ISSUED FOR MANUFACTURE, SALE AND DISTRIBUTION OF DRUGS INCLUDING DRUG FORMULATIONS MARKETED IN THE COUNTRY AND INTEGRATION OF XLN WITH SUGAM PORTAL**

DCC was briefed that the licences for the manufacture, sale and distribution of drugs are issued by the state licensing authorities. Efforts have been made earlier to create a comprehensive database of all the licences issued by the licencing authorities, but without much success. Time and again details about the number of licences granted state wise, along with the constitution of the firm, licence validity, details of the products permitted in case of manufacturing units etc. have been asked at various fora. Lack of authentic data is becoming a handicap while taking policy decisions on various issues pertaining to regulations under the Drugs and Cosmetics Act 1940 and Rule made there under.

The matter has also been under consideration of the Government of India for quite some time and, it has, after consideration of pertinent issues, been decided that an online system be put in place where relevant data including licences issued for sale and distribution by all states in the country is stored and data generated through XLN software is also integrated with the SUGAM portal of CDSCO which will be a single platform for showcasing the entire data.

The CDSCO has already launched an online portal "**SUGAM**" for submission and processing for various categories of applications. To create a National database of the products/ licences/ manufacturers in the country, an online platform with networking of CDSCO with all the State Licensing Authorities in the country with facilities for entering and retrieval of data in respect of **product-wise manufacturers** and **manufacturer-wise products**, **quantities produced**, availability etc., needs to be created. The development of such platforms will be taken up through **SUGAM** portal.

However, to have such a comprehensive database through the development of the platform, the data need to be updated on regular basis and therefore, co-operation and dedication of manufacturers as well as State Licensing Authorities are absolutely necessary.

Therefore, it is proposed that those states who do not have an e-governance program may adopt the XLN software developed by NIC in their states and also integrate the same with the CDSCO portal SUGAM

It was deliberated that so far 14 States have adopted the XLN software which is a good tool for maintaining data base in respect of sale licences. It was discussed that other States should take all necessary measures to adopt the XLN software at the earliest through NIC in their States and integrating with the SUGAM software.

**Recommendations:**

While emphasizing the importance and need of such a comprehensive database DCC recommended that, till such time the online centralized platform through SUGAM is developed and linked with the State Drugs Controllers and State Drug Testing Laboratories, all the States and UTs shall provide the details of manufacturing, sale licenses with name, address and license number to the CDSCO both in hard and soft copies within seven days and further data with the product names and their compositions etc., should be provided within two months of time.

It was also recommended that although the XLN was developed by NIC in 2007, presently it seems that there is no custodian of the system and therefore CDSCO should take necessary steps to become central custodian of the XLN software for proper maintenance and continuous up-gradation as per the need.

While deliberating the above issues, the concerns regarding the dependency on other countries regarding APIs were disused. DCC, therefore, recommended that all State Drugs Controllers should invite the API manufacturers in their states and request them to consider steps for initiating manufacturing of the APIs even in small quantities, for which we are presently fully dependent on other countries to meet eventuality, if any, arisen due to non supply of APIs by the other countries.

## AGENDA NO.4

## CONSIDERATION OF PROPOSAL FOR ENSURING QUALITY OF MEDICINES BY MONITORING OF GMP COMPLIANCE AT MANUFACTURING FACILITIES IDENTIFIED BY THEIR RISK EVALUATION

The members were briefed that Indian drug industry is spread out in the various States and Union Territories. The level of enforcement of provisions of Schedule M in many States has been found to be inadequate. Non-uniformity in the interpretation of the provisions of the law and their implementation, lack of adequate infrastructure and varying level of the competence of the regulatory officials have resulted in inadequate enforcement in many States.

Concerns have been raised from time to time at various fora regarding spurious/adulterated drugs manufactured and marketed in the country. Questions are raised from time to time in the Parliament regarding spurious/adulterated drugs and other quality related issues.

In view of the above, as part of enforcement activities to contain the problem of quality of drugs manufactured in the country, CDSCO, in consultation with the Ministry has devised a system of inspections based on the risk evaluation of the manufacturing facility. A checklist and evaluation tool for conducting and reporting the inspections has been prepared and shared with all the stakeholders.

Training program has been conducted for the Drugs inspectors of the CDSCO and states and also the analyst from various government drugs testing laboratories.

The inspection team comprising of an ADC, one drugs inspector of the state and CDSCO, one assistant drugs inspector and one analyst from laboratory have been jointly conducting inspections. The reports of the inspections are shared with the concerned manufacturers and respective State Drugs Controllers for taking appropriate actions. More such training and inspections are being planned so as to cover all manufacturers identified based on risk assessment.

Four phases of Risk based training programs were conducted. In the said training programme total 124 officials from CDSCO, 64 officials from State Drug Authorities and 42 officials from Drugs Testing Laboratories were trained. Till date 105 Risk based inspection were scheduled in 4 phases, out of which 76 inspections have been carried out. It has been observed that rating of Sch. M and Sch.L-1 compliance varies between 5% to 99.43% with critical rating between 0% to 91.18%.

The purpose of this initiative is to assess the GMP and GLP compliance of manufacturing facilities, to harmonize the procedure and reporting of the conduct

of the inspections across the country, identify the gaps to GMP if any, and communicate the same to the firm for compliance and encourage them further to attain higher standards thereby assuring quality of drugs manufactured in the country for the domestic as well as export markets.

**Recommendation:**

All the States should depute their inspectors for the training programs organised in this respect and also nominate the local drugs inspector to accompany the inspection team for risk based inspections. The training / orientation programme should also be conducted for senior regulatory officials of the States.

Further the State Drugs Controllers should to take appropriate action on the findings of the inspection team as per existing practice under Drugs and Cosmetic Rules and update the action taken in this regards to CDSCO. It was also recommended that the checklist and the tools developed for the risk based inspections should be made dynamic and updated regularly and it should be followed during the GMP inspections.

While discussing the matter relating to Risk based Inspections, the issues regarding strengthening of Drugs Testing Capacities in various states were raised. It was mentioned that in certain states, the laboratories are yet to be equipped with the necessary equipments and facilities for testing of various categories of drug samples. DCC advised that till such time, these laboratories are strengthened, the licensing authorities can avail the testing facilities available with the Central Laboratories. It was also discussed that certain State Laboratories where, strengthening/ updating in terms of latest equipments, etc. Is not happening due to some reason, consideration may be given if these laboratories could be adopted by the centre.

**AGENDA NO.5**

**FEEDBACK ON THE CAPACITY BUILDING PROGRAMME ON CENTRAL SCHEME FOR STENGTHENING OF THE STATES DRUGS DEPARTMENTS UNDER 12TH FIVE YEAR PLAN.**

Members were briefed that the Government has approved a scheme for strengthening of Drug Regulatory Structures in the country at a total cost of Rs. 1,750/- crore to be implemented up to 2017-18. In the 12th Five Year Plan, it has

been proposed that Drug Regulatory mechanism in terms of infrastructure, both physical and human resources at the Centre and the States/ UTs are strengthened.

The component of the scheme includes setting up of new laboratories, provision of additional human resources, creation of training academy for regulators, organisation wise e-Governance with the objective of substantially augmenting the capacity of regulatory structure of CDSCO. Under this programme, the Government has approved the proposal for setting up of mini labs at CDSCO Port offices at Air Cargo complex Mumbai, Nhava Sheva Seaport, Hyderabad, Chennai, Bangalore, IGI and Ahmedabad airports. The proposal of setting up of mini lab at Kolkata Port is under active consideration. CDSCO is being strengthened by filling up various vacant posts, setting up new offices, enhancing drug testing capacities by strengthening 7 existing regular laboratories and human resource development.

For strengthening the State Drug Regulatory Mechanism, a new centrally sponsored scheme under National Health Mission (NHM) Umbrella has also been proposed on 60:40 sharing pattern for providing financial and human resource support to the States / UTs in general and for North-East States, Jammu & Kashmir, Uttarakhand and Himachal Pradesh in particular for whom the sharing pattern would be 90:10. The components of expense heads approved relates to upgradation of State Labs, expansion of existing offices, manpower, accommodation and creation of new labs or mobile labs.

**Recommendations:**

The DCC opined that necessary steps should be taken to release the funds at the earliest so that process of strengthening of the system as per the proposal already forwarded to the Central Govt. by 19 States could be taken up.

**AGENDA NO.6**

**CONSIDERATION OF THE AGENDA OF FIXED DOSE COMBINATIONS OF DRUGS FALLING UNDER THE DEFINITION OF NEW DRUGS NOT APPROVED BY THE LICENSING AUTHORITY UNDER RULE 21- UPDATE**

The members were briefed the Expert Committee, after detailed examination and deliberations categorized these FDCs into 4 categories; which are those FDCs

which have been declared as irrational by the expert committee as these FDCs lacked therapeutic justification; were found to be pharmaco-kinetically or pharmaco-dynamically incompatible; had abuse potential: or could lead to antibiotic resistance in the population etc.

The Expert Committee carried out a comprehensive review of the FDCs keeping in view the contemporary scientific knowledge and expertise. On the basis of the recommendations of the expert committee, the Government examined the matter further and requested the expert committee to provide specific reasons in respect of each FDC that was found irrational. The expert committee accordingly reviewed the matter further and finalized its recommendations. After careful consideration of the matter, show cause notices were issued to the manufacturers whose products were found to be irrational.

Thereafter, after due consideration of the report and replies, the Government vide Gazette Notifications S.O. Nos. 705(E) to 1048(E) dated 10.03.2016 prohibited the manufacture for sale, sale and distribution for human use of 344 FDCs with immediate effect in public interest as these FDCs were likely to involve risk to human beings as safer alternatives were available to these drugs. The banned FDCs that have been held to be irrational had been licensed by the State Licensing Authorities without approval of DCG (I). However, in case of FDCs held to be rational, approvals had also been given by the DCG (I) and in some cases, where more data is required; firms have been asked to conduct Phase IV trials.

It is pertinent to mention here that despite of all above steps taken by the Government, some SLAs are still issuing licenses with respect to FDCs which are not even approved by DCG (I).

**Recommendations**:

DCC reiterated its earlier recommendations that under no circumstances, state licensing authorities should not grant licence for manufacture for sale of any new drugs including FDCs falling under the definition of New Drug with prior approval of DCGI.

The list of the 344 FDCs banned by the Central Govt. which are presently sub-judice should be uploaded by the CDSCO in their website. The consolidated list of FDCs approved by the DCG (I) and also the FDCs which have been recommended by the Kokate Committee as Rational should also be uploaded in the

CDSCO website. It was also recommended that if any FDCs approved by the DCG (I) has been left out in the list already uploaded on the CDSCO website, same may be brought to the notice of CDSCO by the State Licensing Authorities for up-dation.

**AGENDA NO.7**

**CONSIDERATION OF THE AGENDA MAKING THE ENGAGEMENT OF PHARMACIST HAVING RELEVANT QUALIFICATION MANDATORY FOR BLOOD BANKS/ BLOOD STORAGE CENTERS AND ON THE ISSUE TO AVOID UNNECESSARY DELAY IN THE PROCESS OF APPROVAL OF BLOOD BANK LICENCE/RENEWAL CERTIFICATES AND ENDORSEMENT OF ADDITIONAL PRODUCTS (BLOOD COMPONENTS)**

Representations have been received from certain associations for inclusion of presence of Registered Pharmacists in the licenced Blood Banks/Blood Storage Centers.

As the procedure for collection, processing, quality control, compatibility testing are critical for ensuring transfusion of safe blood, services of registered pharmacist may be made mandatory, who can play an important role for quality assurance of blood units during blood collection, processing, storage and issue of blood units after verification of the compatibility test reports of the recipient and donor units.

During the recent months, it has been observed that after joint inspection and subsequent compliance verification, State Licencing Authority are forwarding the licences/renewal certificates for approval of the CLAA to respective Zonal offices of CDSCO, however, the powers of CLAA are with the DCGI for such licences /renewal certificates. Due to said practices, unnecessary delay is observed in the approval of such licences/renewal certificates.

In view of the above, to avoid the unnecessary delay in process of approval of blood bank licence/renewal certificates, all such blood bank licences /renewal certificates for approval of the CLAA should be directly sent to the O/o Drugs Controller General (India), FDA Bhawan, New Delhi.

**Recommendations**:

The DCC agreed to the proposal of making necessary provisions under the Drugs and Cosmetic Rules to make it mandatory for engagement of pharmacist in

blood banks and blood storage centers. DCC also agreed to the proposal of sending the blood bank licensing / renewal certificates directly to the CDSCO HQ without routing it through Zonal /sub zonal offices so as to avoid un-necessary delay in the processing of license.

While deliberating the above issues, the status of earlier recommendation of DTAB for amendment in Drugs and Cosmetics Rules making the engagement of Pharmacist in the Whole Sale premises mandatory was raised. After discussion, the DCC reiterated its recommendation that the competent person for whole sale licence should be a pharmacist.

**AGENDA NO.8**

**CONSIDERATION OF THE PROPOSAL TO PROVIDE FOR LABELLING OF DRUGS IN HINDI AND ENGLISH AND ALSO PROVIDING LEAFLET OF DRUG INFORMATION IN HINDI AND IN BOLD READABLE PRINTS UNDER THE DRUGS AND COSMETICS RULES,1945**

DCC members were briefed that representations have been received by the Government that labels of the drugs are provided only in English and in many cases the prints are not readable with naked eye.

It has therefore been requested that the labels of the drugs should be in Hindi along with English, in bold readable prints and if possible, in regional languages also, so that these are more patients friendly and the consumer is able to read and understand the information provided on the label/Leaflet.

**Recommendations**

DCC did not agree to the proposal of labelling of Drugs in Hindi also, because in many cases due to constraint of space in the label it will be difficult to label in dual language which should be readable. DCC however recommended that the D&C Rules may be amended to provide that the labelling of various informations must be readable with naked eye. DCC also recommended that an advisory

should be issued to all the State Licencing Authorities to advise all the retail outlets to keep the magnifying glass for reading of the information on the label of the products.

While deliberating the above matter, the concerns on the practices of third party manufacturing of drugs were raised wherein a product manufactured by same company is marketed by multiple companies under multiple brands and different prices. In this context, issues regarding present regulatory provisions for granting of licence for manufacture of drugs under proper name were discussed.

The Central Government issued a direction under Section 33P of Drugs and Cosmetics Act, 1940 on 1st October, 2012 to the State Governments that the manufacturing licence for drugs including FDCs should be granted in proper/ generic name without any brand name. Subsequently however, the Drugs and Cosmetics Rules were amended in August, 2014 making it mandatory that an application for grant of manufacturing licence for manufacture of single active ingredient containing products shall be made in proper name only.

In view of above, some of the members were of the opinion that presently granting of licence only in proper name is mandatory for single active ingredient products only, while other members were of a different view that it is mandatory for both Single active ingredient as well as FDCs. DCC after detailed deliberations recommended that legal opinion should be obtained so as to bring clarity in the matter as to whether the mandatory requirement of granting licence in proper name is applicable only for single ingredient products or for both single as well as FDC products.

As regards the concerns on marketing of same drug manufactured by the same company, by multiple firms under multiple brands with different prices, DCC recommended that a sub-committee comprising of the following members should be constituted:

1. Drugs Controller, Himachal Pradesh,
2. Controlling and Licensing Authority, Madhya Pradesh,
3. Drugs Controller, Uttarakhand,
4. Drugs Controller, Jammu & Kashmir,
5. Sh. R. Chandra Sekhar, DDCI, CDSCO, HQ.

The sub-committee shall recommend measures to prevent the misuse of the present day practice in respect of third party manufacturing of drugs in light of the existing regulatory provisions.

**AGENDA NO.9**

**CONSIDERATION OF THE PROPOSAL FOR PARTICIPATION AND ENGAGEMENT IN SKILL DEVELOPMENT PROGRAMME**

Members were briefed that for up gradation of skill sets of persons employed in Pharma manufacturing units, the Government of India had entrusted the work relating to development of qualification packs (National Occupational Standards) to the Life Science Sector Skill Development Council with the objective of upgrading the skills of persons employed in the Life Sciences sector in the country. Accordingly, the Life Science Skill Sector Development Council has, after an elaborate exercise and extensive consultation with the industry, evolved the following modes for certification:

Post fresh skilling and assessment of eligible youth; and Post assessment under 'Recognition of Prior Learning (RPL)' for existing workforce in Industry.

The objective of the certification is to enhance the skills of the workforce engaged in Pharmaceutical and Biotechnology industry and enable organisations to effectively meet quality standards.

Keeping in view the objective of bringing substantial improvement in the quality of the pharmaceutical products, it has become imperative that all personnel employed in Pharmaceutical manufacturing units shall undergo the certification programmes developed by Life Science Skill Sector Development Council and with effect from 01.01.2018, no person shall be employed in any pharmaceutical bio-pharmaceutical manufacturing units unless he has obtained a formal diploma or degree in the relevant area, or has been certified by the Life Sciences Sector Skill Development Council or equivalent organisation in the area in which he has been deployed.

**Recommendations**:-

DCC advised that the members should take all necessary measures to make the skill development programme through Life Sciences Sector Skill development Council programme a success.

**AGENDA NO.10**

**CONSIDERATION OF THE PROPOSAL TO KEEP STRICT VIGIL ON THE DISTRIBUTION AND USE OF THE DUAL USE ITEMS IMPORTED UNDER DUAL USE NOC FOR PATIENT SAFETY IN THE COUNTRY**

The members were briefed that the Zonal offices of CDSCO grant permission in form of Dual Use NOC for drugs imported in bulk for non medicinal use under the provision of Rule 43 of Drugs and Cosmetics Rules. These items imported are of various categories such as Animal Feed Supplement, Feed Premix, Vitamin Premix, Antibiotic/ antibacterial feed additives, anti-ccocidiostatis, Drugs meant for further processing/ conversion to other drug etc.

Port offices of CDSCO inform to the concerned State Drugs Controller & Zonal Offices for post import check. Although the exemption under Schedule D is given with the condition that substances will be imported for non-medical use, but there are reports that certain substances imported under "Dual use NOC" are diverted for medicinal purpose.

In view of this, all state Drugs Controllers may be requested to keep strict vigil on the distribution and use of the substances imported under Dual Use NOC for patient safety in the country.

**Recommendation:**

DCC recommended that continuous monitoring and strict vigil should be put in place so as to ensure that the drug imported under dual use for non medicinal purpose are strictly used for the same and no part of it is diverted for medicinal purpose. DCC also recommended that the D&C Rules should be amended to provide that the formulators of drugs should procure and use the API's only from the sources licensed under the Drugs and Cosmetics Act and Rules there under.

While deliberating the above agenda, concerns regarding misuse of exemption from taking sale licences by the Registered Medical Practitioners for supplying medicines including Vaccines to their patients were discussed. It was mentioned that many RMPs/Clinics/ Nursing Homes stock huge number of medicines of different categories including Vaccines purported to be supplied to their patients. These medicines/ Vaccines are sometimes supplied directly by the manufacturers to these facilities and no records of medicines received, supplied/ used for their pa-

tients etc., are not maintained. Many times, it is difficult for the licensing authorities to take actions against such RMPs/Clinics/Nursing Homes for non compliance with the condition of the exemptions provided under Schedule K.

DCC after detailed deliberations recommended that a sub-committee comprising of the following members shall be constituted namely:

1. Dr. Mrinalini Darshawal, Commissioner, Drugs Control Administration, Delhi.
2. Shri. O. Sadwani, Joint Commissioner and Drugs Controller, FDA, Maharastra,
3. Dr. Krishna Mohan, IPS, DG, Drugs Control Administration, AP,
4. Shri. HS Khoshia, Commissioner, FDCA, Gujarat.
5. Smt. Rubina Bose, DDCI, CDSCO, HQ.

DCC recommended the sub-committee to should review the exemptions provided under Schedule K within 3 to 4 weeks and recommend the safeguards/ amendments in the rules that may be needed to curb the misuse of the exemption. Such clinics/ nursing homes/ RMPs should be regularly monitored to verify the compliance with the conditions of the exemptions provided under Schedule K. It was also recommended that the Clinics / Nursing Homes having more than one Doctor should be insisted to take sale licence for stocking the medicines in their premises.

**AGENDA NO.11**

**CONSIDERATION OF PROPOSAL TO HAVE AN EFFECTIVE RECALL SYSTEM OF DRUGS FOUND NOT OF STANDARD QUALITY**

Concerns have been raised from time to time regarding lack of an effective recall system whereby drugs found to be NSQ by one State are mandatorily recalled across the country from all the States.

A set of draft recall guidelines were discussed at the 45th DCC meeting held on February 4th & 5th, 2013 and then again at 46th DCC meeting on November 12th & 13th 2013 and the same was finalized after detailed deliberations. It was also uploaded on the CDSCO website.

The present system of recalling drugs needs substantial improvement. Two pronged strategy is therefore, proposed to be adopted for the purpose. Firstly, the guidelines on these issues will be re-iterated to all concerned and, to the extent

necessary, the Drugs and Cosmetics Rules, 1940 can be amended. Secondly, 'SUGAM' portal will be suitably prepared to display information regarding drugs recalled by any State regulators for dissemination of information to all concerned.

DTAB in its 72nd meeting held on 27.06.2016 has also considered the matter and recommended to constitute a group to examine in the proposal in detail and suitably incorporate the guidelines in the Drugs and Cosmetics Rules, 1945.

DCC may kindly consider the recommendation of the DTAB for further action.

**Recommendation:**

DCC after detailed deliberation recommended for amendment in the Drugs & Cosmetics Rules for making regulatory provisions in respect of the following:

1. In case of NSQ Drug the manufacturers should be held responsible for re-calling it from the supply chain voluntarily.

2. The manufacturers should have a system of regular market surveillance for monitoring of quality of the drugs placed in the market by drawing the sample from the supply chain and getting it tested to acess the quality and subsequent actions including recall of drug voluntarily in case it is found to be of NSQ.

3. The manufacturers should also have a system of recalling the drug voluntarily from the supply chain in case they find non compliance / deficiencies in their manufacturing, quality control, out of specification observed in ongoing stability studies etc. through their internal audit.

The DCC also recommended that the recall guidelines should be reviewed for updating it in the present day context by a sub-committee consisting of following:-

1. Dr. V.G. Somani , JDC(I),
2. Shri PBN Prasad, DDC(I),
3. Shri Saleem Valjee, Director, F&D Goa.

The sub-committee should submit it report within three weeks. The updated guidelines to be circulated to all the State/ UT Drug Controllers seeking their comments in one week time. The sub-committee should also submit draft for draft rules to be placed before the DTAB.

The Central Drug Laboratories to upload the reports of NSQ drugs within 24 hours of their reporting. Dr. R.A. Singh Director, RDTL, CHD and Dr. Murugesan, Director, CDTL, Chennai shall prepare SOP for declaring a sample as NSQ.

**AGENDA NO.12**

**PROPOSAL TO CONSIDER ISSUES RELATED TO INVESTIGATION INTO MANUFACTURING PLANTS FINED OR BANNED BY FOREIGN REGULATORS.**

The members were briefed that representations had been received that during the last few years several foreign regulators have banned, blocked or blacklisted drug imports from India because of quality issues.

During the last 5 years certain foreign regulatory authorities have imposed import restrictions on certain manufacturing facilities in India due to various issues related to GMP and others. While exporting the drugs, the manufacturers are required to comply with the regulatory requirements of importing countries. However, all cases where the findings of regulators of other countries are relevant from our perspective, required action should be taken by us.

It was deliberated that such matters needs to be addressed promptly with due diligence as the foreign government raises such issues/concerns time and again to the Central Government through diplomatic channels. However, some members raised issues that many-a-time, the complaints/concerns received from the foreign countries are not complete/ lack of clarity.

**Recommendations:**

DCC recommended that as and when CDSCO writes the concern States licensing authority regarding any issues relating to complaints / quality of the drugs exported from India, the authority should promptly investigate the matter within 3 days and strict regulatory actions should be taken, if any non compliance through the regulatory provisions is observed. and actions taken should be intimated to CDSCO for transmitting the Ministry. In case, further clarifications/ issues are required on such complaints/concerns received from the foreign countries, the same may be intimated to CDSCO within the same time frame, so that, the matter could be taken up with the foreign government through the Ministry of Health and Family Welfare.

## AGENDA NO.13

## PROGRESS ON PROPOSAL TO AMEND THE DRUGS AND COSMETICS RULES MAKING BIOEQUIVALENCE STUDIES OF CERTAIN CATEGORIES OF DRUGS MANDATORY

Members were briefed that concerns had been raised from time to time that there is lack of compulsory bioequivalence studies for drug formulations other than new drug and bioequivalence studies are required for ensuring the efficacy of such drug.

It is agreed that pharmaceutical equivalence is not sufficient for ensuring the efficacy of drugs and therefore, Bioequivalence studies should be carried out in cases where generic drugs are approved to be manufactured.

The matter regarding requirement of bioequivalence studies was earlier deliberated in DCC as well as DTAB. The DTAB in its 72nd meeting held on 27.06.2016, after deliberations has again recommended that submission of bioequivalence data should be made mandatory prior to the grant of licence for manufacturing drugs in the country. However, it has suggested that Biopharmaceutics Classification System (BCS) should be adopted and to begin with, conduct of BE study should be made mandatory only for category II and IV of the BCS system. For the drugs already marketed in the country, three years time may be given of submission of BE study data. The Board has further recommended that a Group should be constituted to lay down the modalities for identification of the reference drug for the conduct of BE studies.

DCC may consider the matter for further necessary action.

## AGENDA NO.14

## PROGRESS ON PROPOSAL TO AMEND THE DRUGS AND COSMETICS RULES MAKING STABILITY STUDIES MANDATORY BEFORE GRANT OF MANUFACTURING LICENCE

Representations have been received that there is lack of compulsory stability studies for drugs other than new drug.

It is agreed that all the drugs should be subjected to the required stability studies before grant of manufacturing licence. The issue was earlier deliberated by DCC and DTAB. Based on recommendations of DCC and DTAB, draft rules were

published vide GSR 68(E) dated 03.02.2015 for compulsory submission of stability data before grant of manufacturing licence.

The comments received from various stakeholders have been reviewed by DTAB in its 72nd meeting held on 27.06.2016 and the Board reiterated its earlier recommendation that submission of stability data should be made mandatory, prior to the grant of licence for manufacturing of drugs and recommended that the rules may be finalized at the earliest.

DCC may consider the matter for further necessary action.

**Recommendations for Agenda Nos. 13 & 14:**

Considering the pros and cons of making bioequivalence study mandatory, DCC after detailed deliberations recommended that, NIPER should be requested to conduct a pilot study to assess the problems relating to efficacy of the drugs manufactured and marketed in the country without assessing bioequivalence with the innovators/products approved by DCGI with bioequivalence study.

In respect of Stability Studies, the DCC advised that all the licensing authorities, while granting license to manufacture drugs for sales, should take due consideration regarding need for stability studies for maintaining the safety and efficacy of the products throughout its shelf life and insists the applicants for submission of Stability Data for all products.

The measures needs to be taken for capacity building at the level of state licensing authority, in respect of protocol approval and evaluation of bioequivalence study reports and other related areas as well as at the level of small and medium manufacturers regarding importance of conducting bioequivalence study to ensure the efficacy of the products. It was also decided that all the Nationals Institutions having facilities for formulations / developments should be requested to provide their services to the manufacturers on their need basis.

DCC also recommended that IPC should be requested that while updating the monographs, need for dissolution study for such products should be considered and incorporated in IP. IPC should take initiatives so that, the IP monographs of all the products where dissolution study is necessary, the same may be updated in the next edition of IP going to be published.

While deliberating the above issue, concerns regarding availability of validated specifications and method of analysis (MOA) of P&P products were raised. It was mentioned that many-a-time, the drug analysts faces difficulties in obtaining validated specifications and MOA in respect of such products which causes delays in testing of the samples. It was therefore, decided that the State Licensing Authorities shall take all necessary steps to upload in the XLN Software such information in respect of products licensed by them. In case, it is not available, the concerned manufacturers should be directed to provide the same for uploading in the software. IPC should also be requested to upload all the specifications and MOS of P&P products available with them in their websites.

**AGENDA NO.15**

**PROPOSAL TO CONSIDER ISSUES RELATING TO THE GUIDELINES ISSUED FOR TAKING ACTION ON SAMPLES OF DRUGS DECLARED SPURIOUS OR NOT OF STANDARD QUALITY IN THE LIGHT OF ENHANCED PENALTIES**

Members have been briefed that concerns have been raised from time to time that the "Guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs and Cosmetics (amendment) Act, 2008" issued to all States/Union Territories not only lays down different standards of quality when compared to Section 16 of the Act but also recommends prosecution only in certain cases of NSQ drugs.

DCC may kindly deliberate and give its recommendations in the above matter.

**AGENDA NO.16**

**PROPOSALS TO CONSIDER ISSUES REGARDING LACK OF SOPs AND UNIFORMITY IN ADMINISTRATION OF THE PROVISIONS OF THE DRUGS AND COSMETICS ACT, 1940 AND RULES, 1945**

Issues have been raised regarding lack of SOPs and uniformity in administrative actions taken by different State Drug Controlling Authorities as a result of which each State suspends manufacturing licence for different duration every time a manufacturer violates the regulatory provisions.

In this regard, it may be mentioned that the CDSCO has, with a view to bring uniformity in regulatory practices, commenced conducting common training programmes for regulatory and laboratory personnel of all States and CDSCO.

Standard Operating Procedures for carrying out inspections have also been finalized and shared with the States. Common training programmes on GMP/GLP inspections are also being organized for State and Central Regulators and laboratory personnel.

The MoHFW and CDSCO are continuously engaged in conducting various training programs for regulatory and laboratory officials from various States and Centre on Investigation Techniques and Launching of prosecution, GMP, GLP and GCP.

Further, joint inspection of manufacturing units by teams of officials from CDSCO and States Regulators have been commenced based on risk assessment.

DCC may kindly deliberate and give its recommendations on the issue.

**Recommendations for 15 & 16**

DCC after detailed deliberations recommended that a larger sub-committee under the Chairmanship of Dr. Harshadeep Kamble-**IAS**, **Commissioner FDA Maharash-tra** comprising of following members shall be constituted:

***From States:***

1. Dr. Harshadeep Kamble-IAS, Commissioner FDA Maharashtra
2. Dr. Ravishankar – IPS, Director General, Government of Andhra Pradesh
3. Sh. O Sadhwani – Commissioner FDA Maharashtra
4. Dr. H G Koshia – Commissioner FDA Gujarat
5. Sh. Salim A Veljee – Director, FDA GOA
6. Sh. M Amrutha Rao – Joint Director Drug Controller Administration Telengana
7. Sh. Atul Nasa – Drug Controller Administration Delhi
8. Sh. P Shobhit – Deputy Drug Controller, FDA Madhya Pradesh.
9. Drug Controller Himachal Pradesh
10. Drug Controller Punjab
11. Sh. H Mahapatra – Director Drug Controller Administration, Odisha.
12. Sh. S Abdul Khadir – Director Drug Controller Administration, Tamil Nadu
13. Sh. T Hari Prasad - Director Drug Controller Administration, Kerala

***From CDSCO:***

14. Shri. V.G Somani – JDC (I), CDSCO, HQ
15. Smt. A. Visala - DDC (I), CDSCO, HQ
16. Shri. R. Chandrasekhar – DDC (I), CDSCO, HQ
17. Smt. Swati – DDC (I), CDSCO, HQ
18. Shri. PBN Prasad - DDC (I) ,Hyderabad
19. Shri. Arvind Kukrety - DDC (I), Ahmedabad

The sub-committee shall revisit the guidelines in light of present day context and recommend for necessary amendments in the guidelines. The sub-committee shall also recommend for preparation of guidelines, SOP's for taking administrative actions by the licensing authorities in case of non compliance with the provisions of the regulatory provisions including samples found to be not of standard quality, adulterated declared spurious or not of standard quality.

**ADDITIONAL AGENDA S1**

**CONSIDERATION OF THE PROPOSAL TO FURNISH THE REQUISITE INFORMATION BY ALL THE STATE DRUGS CONTROLLING AUTHORITIES REQUIRED TO BE SUBMITTED FOR NRA ASSESSMENT OF VACCINES BY WHO**

As a part of prequalification of vaccines manufacturers for supply to UNICEF, WHO conducts observed audit to assess the performance of inspectors during GMP inspections of vaccine manufacturing facilities and NRA assessment against the Global benchmarking tool developed by WHO for assessment of Regulatory Functions viz. National Regulatory System, Registration and Marketing Authorization, Vigilance, Market Surveillance and Control, Clinical Trial oversight, Licensing of Premises, Regulatory Inspection, Lab access and Testing/ NRA lot release.

The functions are divided into various indictors/sub T indicators which are categorized as critical or non-critical and evaluate the functions/procedures of NRA on the basis of same. If the vaccine manufacturers deviate from GMP standards and regulatory authorities cannot achieve the bench marks score with respect to

critical indicators, then vaccine manufacturers will not be able to export vaccines through UNICEF.

WHO conducts NRA assessment at every 3 - 4 years and is planning to conduct NRA Assessment of vaccines in the month of February, 2017

**Market Surveillance & Control** is the new functions introduced by WHO which encompass post marketing surveillance and monitoring of the products. It is an important regulatory tool to monitor the supply of safe, efficacious and quality products to the consumer/patients. It is required to ensure that the regular sampling of medical products including vaccines are being carried out as per Drugs and Cosmetics Act & Rules by the Drugs Inspectors of Central and State Drugs Controlling Authorities throughout the supply chain. Accordingly, CDSCO and State inspectors have been directed for regular sampling of vaccines and also all the State Drugs Inspectors responsible for control and monitoring of sales premises are required to ensure that Good Distribution Practices are followed by all the entities in the supply chain with specific emphasis on vaccine transportation and storage as per the Good Distribution Practice Guidelines for Biological Products. All the State Drugs Inspectors may be directed to specifically include the storage and distribution of vaccine in their inspection report wherever applicable.

**Licensing Premises** is the new functions introduced by WHO which encompass the licensing procedures of all manufacturing and sales premises. Accordingly, all the States have been requested to provide updated

1. List of all licensed premises for manufacturing and sales and list/ database of all the licenses approved / withdrawn/cancelled or suspended.
2. Check list and SOP for inspection for grant or renewal of licenses of manufacturing facility and sales premises
3. List of inspections conducted for 2013-2016 onwards for manufacturing and sale premises with date and purpose of inspections.
4. Details of drug samples drawn by the drugs inspector as per the following table for 2013-2016 (till date)

| S. No | Name and designation | Qualification | Experience before joining the State Service | Current regulatory experience | Trainings Attended | Number of vaccine inspections conducted |
|---|---|---|---|---|---|---|

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| | | | | | | |

**Regulatory Inspection** is the critical function of NRA assessment and all the states are requested to provide following information regarding inspectors, planning and conduct along with regulatory action taken after inspections of Manufacturing and sales premises.

1. Details of Drugs Inspectors posted in your State along with requisite qualification, training, skills and experience in the tabular format given below.

| S.No | Name and designation | Area of posting | Qualification | Experience before joining the State Service | Current regulatory experience | Trainings Attended |
|---|---|---|---|---|---|---|
| | | | | | | |

2. Individual job descriptions along with Organogram.

3. All the inspections are to be conducted as per uniform procedures circulated to the States from time to time and as discussed in DCC in strict compliance with GMP and GDP by Qualified, experienced and trained inspectors.

**Recommendations:**

All the members were appraised that CDSCO had already requested all the State Drugs Controllers to provide information relating to the list of licence premises for manufacturing and sale, data base of all licences approved, withdrawn, suspended, cancelled, total number of inspectors with the list of inspectors competent for inspection of vaccine manufacturing facilities with qualification, training scheme, experience, details of list of inspections conducted , list of details of samples drawn and tested and other related information in the tabular form required for the purpose of NRA assessment by WHO scheduled to be held in Feb 2017.

DCC also advised all the State Drugs Controllers that information sought by CDSCO as mentioned above should be provided promptly within a week's time in both hard and soft copies, so that the same could be compiled by CDSCO in a time

bound manner. It was also advised that in light of the upcoming NRA assessment by WHO data base along with SOPs, guidelines regarding the processing of applications for licensing, GMP/GLP inspections, drawing and testing of samples, regulatory action taken in case of non compliance, recall system and other regulatory activities should be put in place which may be seen by the NRA assessment team of WHO.

**Additional Agenda S2**

**Consideration of proposal for making latest edition of Indian Pharmacopoeia (IP) and Indian Pharmacopoeia Reference Substances (IPRS) with all Drug manufacturers and laboratories mandatory at their manufacturing / Quality Control facilities.**

Indian Pharmacopoeia (IP) is for fulfillment of the requirements of Drugs and Cosmetics Act, 1940 and Rules thereunder, the laws governing the activities of import, manufacture, sale & distribution of drugs in India, the standards of identity, purity and strength prescribed in the IP apply to all drugs involved in the aforesaid activities in India.

Therefore, it may be considered necessary that every manufacturing / Quality Control facility in the country should have the latest edition of IP and IPRS for the product manufactured to ensure the quality of the product.

In addition, the instructions may also be given to all the Government laboratories for ensuring the availability of all the required IPRS in their laboratory which are available at Indian Pharmacopoeia Commission.

**Recommendations:**

DCC agreed that every manufacturing / Quality control facility in the country should have the latest edition of IP (original copy). It was also agreed that for maintaining the quality of drugs as per the standards of strength identity and purity as prescribed under drugs and cosmetics Act and Rules, every manufacturer should procure and use the available IPRS from Indian Pharmacopoeia Commission (IPC), list of which are already on the IPC website.

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

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