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केन्द्रीय औषधि मानक नियंत्रण संगठन
स्वास्थय सेवा महानिदेशालय
स्वास्थय एवम् परिवार कल्याण मंत्रालय
भारत सरकार
एफ.डी.ए. भवन, कोटला रोड़,
नई दिल्ली-११०००२

सत्यमेव जयते

Dr. V. G. Somani
Drugs Controller General (India)
Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare
Government of India
FDA Bhawan, Kotla Road,
New Delhi-110002 (India)

F. No. X-19013/02/2019-DC **Dated: 12 -09-2019**

To

All State/UT Drugs Controllers

Sub: Minutes of the 57th Meeting of the Drugs Consultative Committee held on 20.08.2019 at Goa - reg.

Sir/Madam,

57th meeting of the Drugs Consultative Committee was held on 20.08.2019 at Goa.

The minutes of the 57th meeting of the Drugs Consultative Committee is annexed herewith for your information and taking further necessary action, wherever required as per recommendations decided therein.

Yours faithfully,

(Dr. V. G. Somani)
Drugs Controller General (India)

Encl. Copy of the minutes

Copy for information to:-

1. PPS to Secretary, MoHFW, Nirman Bhawan, New Delhi
2. PPS to DGHS, MoHFW, Nirman Bhawan, New Delhi
3. PPS to AS, MoHFW, Nirman Bhawan, New Delhi
4. PPS to JS(R), MoHFW, Nirman Bhawan, New Delhi
5. Directors of CDL/ CDTL/ RDTL of CDSCO
6. Zonal / Sub-zonal/ Port Offices of CDSCO

MINUTES OF 57TH MEETING (SPECIAL) OF DRUGS CONSULTATIVE COMMITTEE HELD ON 20TH AUGUST, 2019 AT GOA

Inaugural Deliberations

Dr. V.G. Somani, Drugs Controller General (India), Chairman, Drugs Consultative Committee (DCC), welcomed the participants and thanked them for attending the special meeting. He also extended a warm welcome and thanked Dr. Mandeep K. Bhandari, Joint Secretary, MoHFW for his presence in the meeting in spite of his busy schedule.

DCG (I) in his address stated that the DCC, a statutory body, has been very active in deliberating various agenda of national importance and public interest for continuous strengthening of drug regulatory system in the country. He opined that each and every state and zonal/subzonal offices should be empowered with intelligence cell like CDSCO(HQ) to curb illicit activities. Further he also stated that very close co-ordination and regular dialogue between state and central regulators by deputing/nominating one person from each side shall be established for ensuring effective enforcement activities, operationalization of online activities, clearance of pendencies related to joint responsibilities and any other pending issues of clarification etc. and strengthening of regulatory system under capacity building programme.

DCGI emphasized the recent major amendments to the Drugs and Cosmetics Rules such as compulsory submission of BA/BE data, stability data and uploading manufacturing license details in online SUGAM portal. He opined that DCC as mandated under section 7 of Drugs and Cosmetics Act should fulfill its responsibilities to advise Central Government, State Governments and the Drug Technical advisory Board on any matter tending to secure uniformity throughout India in the administration of this Act by convening meeting as and when required and by regulating its own procedures. Accordingly, henceforth DCC shall adopt a methodology to ensure adequate oversight of regulatory system by self assessment and by using good regulatory practices and risk based approach in regulation with the objective to become a robust regulatory system as per national and international expectation. He also requested all states, Central and Laboratory officials for effective implementation of 12th five year plan for Regulatory System Strengthening ensuring utilization of funds by personally facilitating completion of administrative formalities on top priority. DCG(I) also requested all officials to take stringent measures against malpractices. He then requested Dr. Mandeep K. Bhandari, Joint Secretary to address the August gathering.

Dr. Bhandari, Joint Secretary (R), Ministry of Health and Family Welfare, Govt. Of India, welcomed all the Committee members and thanked Government of Goa for hosting the meeting. He welcomed Dr. V.G. Somani as the new DCG (I) and complemented Dr Eswara Reddy for the efforts towards strengthening of the regulatory systems made during the period he held additional charge as DCGI.

Dr. Bhandari, noted with concern that progress made towards uploading of the information regarding manufacturing licences on the online SUGAM portal as per G.S.R. 19(E), dated 10.01.2019 is far from satisfactory. He called upon the State Drug Controllers to sensitive the manufacturers in this regard and ensure compliance to the GSR in letter

and spirit within next 15 days. Members requested Central Government to also issue a letter in this regard to the State Chief Secretaries of each state.

JS(R) also observed that all the State Drugs controllers need to be expediting the process of issuing disability certificates in case of faulty hip implants and requested them to provide the details to Central level Expert Committee on a priority basis. He also stressed that the Government has zero tolerance towards the malpractices and that such issues shall be dealt with most seriously by the Ministry of Health and Family Welfare and CDSCO.

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

AGENDA NO. 1

CONSIDERATION FOR APPROVAL OF REPORT OF 56TH MEETING OF DCC HELD ON 01.06.2019 AND ACTION TAKEN IN THE MATTERS ARISING OUT OF THE MEETING

While deliberating Action Taken Report of the 56th meeting of DCC, State Drug Controller, Haryana has raised the concern on Agenda No. 16.2 of the 56th DCC for which an advisory has been issued by CDSCO on 09.08.2019 with respect to labelling requirements for combi kit of Misoprostol and Mifepristone tablets for Medical Termination of Pregnancy (MTP). In this regard he requested that instead of labelling requirements a restriction to be imposed that the wholesalers shall supply the kits only to the recognised centres to prevent the misuse of this kit in line with the provisions of MTP Act 2002 & MTP Rules 2003.

Taking it into consideration, DCC recommended the following points:

1. To make provisions in Drugs and Cosmetics Rules for empowering DCGI to issue the advisories on the matters related to implementation of Drugs and Cosmetics Act and Rules made thereunder in the Country.
2. Subsequently, advisory should be circulated to all manufacturers.
3. All State Drugs Controllers are requested to include the prescribed conditions issued as advisory as a condition while granting licences and for old licences.
4. All SDCs may interact with all the stakeholders for making awareness about the advisories issued by DCG(I) specially Chemist and Druggist Association, Manufacturers and other relevant players.

DCC agreed the Action Taken Report of the 56th meeting of DCC.

AGENDA NO. 2

PROPOSALS FOR RECOGNITION OF INDIAN DRUG REGULATORY SYSTEM AS STRINGENT REGULATORY AUTHORITY AS PER WHO SPECIFIED CRITERIA.

DCC was apprised on the proposal of becoming Indian drug regulatory system as a Stringent Regulatory Authority as per WHO specified criteria as under:

The term Stringent Regulatory Authority is commonly recognised term for Regulatory Authorities having a well developed Regulatory System. The term is commonly used for a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) or is associated with an ICH member through a legally binding mutual recognition agreement.

The concept of a Stringent Regulatory Authority or SRA was developed by the WHO Secretariat and the Global Fund to guide medicine procurement by the international regulatory and procurement community. The concept has additionally served to promote reliance on the product evaluations and decisions of SRAs by other authorities when making their own regulatory decisions.

The International Council for Harmonisation (ICH) describes a “Stringent Regulatory Authority (SRAs)” as a member of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) or is associated with an ICH member through a legally binding mutual recognition agreement. The ICH is unique in bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration.

Since its inception in 1990, ICH has gradually evolved, to respond to the increasingly global face of drug development. ICH's mission is to achieve greater harmonisation worldwide to ensure that safe, effective, and high quality medicines and vaccines are developed and registered in the most resource-efficient manner.

India has been an Observer in ICH since 2015 and is exploring to move forward to become full member. As Member of the ICH Association, a regulatory authority and the regulated industry are required to follow the ICH guidelines of Technical Requirements for Pharmaceuticals for Human Use (ICH). ICH guidelines are widely recognized and are increasingly applied by many Countries. Indian industry association are represented as a Member in certain industry members groups at ICH. However the Indian National Regulatory Authority (NRA) is not a member.

The Regulatory system can be assessed by its maturity level in the implementation of the various Regulatory Functions like National Regulatory System, Registration and Market Authorisation, Vigilance, Clinical Trial Oversight, Laboratory Access and testing, NRA lot release, Market Surveillance and Control. Licensing Premises and Regulatory Inspections.

There is a need to have a common Quality Management System for three functions namely regulatory inspections, market surveillance and control, licensing of premises to be governed at the State level. The Regulatory Inspections serving as model of uniting the Centre and States in common regulatory practices could serve as an example and should be taken on the priority.

The Global Benchmarking Tool (GBT) followed by WHO for NRA assessment represents the primary means by which the WHO objectively evaluates regulatory systems, as mandated under WHA Resolution 67.20 on Regulatory System Strengthening for medical products. The tool and benchmarking methodology enables the WHO and regulatory authorities to:

- identify strengths and areas for improvement;
- facilitate the formulation of an Institutional Development Plan (IDP) to build upon strengths and address the identified gaps;
- prioritize IDP interventions; and
- monitor progress and achievements.

The Committee deliberated the matter at length. During deliberation, some members pointed out whether the proposal for recognition of Indian Regulatory system as SRA comes under the purview of the committee. The committee deliberated that the agenda is actually aimed to strengthen the drug regulatory system in the Country through identification of gaps and monitoring regulatory activities, so as to gain trust of public on the system ensuring that the drug manufactured and marketed in the country are safe and effective.

After detailed deliberation, the Committee recommended for Regulatory System Strengthening and opined that to become SRA/ICH or other international members, consultations should be held with stakeholders and other concerned Ministerial departments (like Department of Pharmaceuticals, Department of Industrial Policy and Promotion, Department of commerce) etc. in this regard. Further, it was felt that a dedicated cell may be created preferably in for self assessment, gap analysis and preparation of plan for strengthening the drug regulatory system in the country. Advice of experts/ consultants for Regulatory System Strengthening may be required in this endeavour.

AGENDA NO. 3

CONSIDERATION OF THE RECOMMENATIONS SUBMITTED BY SUB-COMMITTEE OF DRUGS CONSULTATIVE COMMITTEE (DCC) ON OVER-THE-COUNTER (OTC) DRUGS

DCC was apprised that the sub-committee under chairmanship of Shri. N.K. Ahooja, Drugs Controller, Haryana has submitted its recommendations to the DCC. The Sub-Committee is of the opinion that there is an urgent need for defining the Over-the-Counter (OTC) drugs and to lay down specific provisions for the regulation of OTC drugs in the country. For these purposes following recommendations were suggested:

Promote self-care without compromising patient safety thereby reducing the treatment cost.

- The definition for OTC drug must be laid down in the Drugs & Cosmetics Rules-1945
- Basic Characteristics of OTC Drugs should be incorporated

- Classification of OTC drugs into OTC-1 and OTC-2 based on the extent of evidence of safety, therapeutic index, need for accessibility to patients, availability, non-habit forming nature, present supply chain mechanism, socioeconomic conditions of the country.
- Initial list of OTC Drugs should be prepared
- Regulation of switch of prescription Drugs to OTC Drug
- Regulation of New OTC Drug Approval
- Distribution & Sale of OTC Drugs
- Advertisement of OTC Drugs

After detailed deliberation, DCC recommended that the recommendations of the Sub-committee should be considered for suitable amendment in the Schedule K of the Drugs and Cosmetics Rules, 1945 to incorporate necessary provisions for such drugs for providing exemptions from requirements of Sale license/ prescription of RMP etc. subject to appropriate conditions. Accordingly, the DCC further recommended that the subcommittee should identify such list along with conditions and frame draft for amendments in the Rules.

AGENDA NO. 4

CONSIDERATION OF THE PROPOSAL TO PROVIDE SECURITY MEASURES TO THE DRUGS REGULATORS ENGAGED IN THE ENFORCEMENT ACTVITIES OF DRUGS AND COSMETICS ACT, 1940 AND RULES MADE THEREUNDER.

DCC apprised that there are repeated cases in news where intimidation, threat, looting and lynching with the drugs regulators have come to the knowledge. In one of the recent case, one officer of the FDA-Punjab was killed in the office due to her actions against the unaccounted and unauthorised sale of habit forming drugs by a chemist. All such incidences are making it unsafe to work individually by the regulators without adequate protection.

DCC deliberated the matter and suggested that, Drug Control department of every state should be empowered with the police force of their respective state in line with Andhra Pradesh, Maharastra, Haryana etc. to protect the drug regulators from the threats. Accordingly, Drug Controllers may request their respective State Authorities for making such arrangement or ensure that in every district at least one police officer is assigned for support in regulatory work related to Drugs and Cosmetics Act and other Act being enforced by State Drugs Control authorities.

AGENDA NO. 5

CONSIDERATION OF THE RECOMMENDATIONS OF SUB-COMMITTEE FOR AMENDMENT OF PROVISIONS REGARDING ADVERTISEMENTS FOR TREATMENT OF THE AILMENTS MENTIONED IN SCHEDULE J OF DRUGS AND COSMETICS RULES, 1945 AND ALSO FOR AILMENTS INCLUDED IN DRUGS AND MAGIC REMEDIES (OBJECTIONABLE ADVERTISEMENTS) ACT, 1954 & RULES 1955

The Committee was apprised that the sub-committee constituted for the purpose under the chairmanship of Shri. H. Mahapatra, Former Drugs controller, Odisha has submitted following recommendations:

Part A: To amend the Drugs and Cosmetics Rule, 1945, as under:

1. Amendment in Rule 106 and addition of Rule 106C in part IX of Drugs and Cosmetics Rules, 1945
2. Amendment in Rule 74, 74A, 74B, 78, 78A (all are in part VII), 85H (in part VIIA) and 157 (in part XVI) of Drugs and Cosmetics Rules, 1945.
3. Inclusion of definition of Advertisement in the Drugs and Cosmetics Rules, 1945.
4. The sub-committee also proposed that some disease, disorder or conditions from Schedule J of Drugs and Cosmetics Rules, 1945 are required to be deleted / added to align it with Schedule of DMROA.

Part B: To amend the Drugs and Magic Remedies (Objectionable Advertisements) Rules 1955 as under:

1. To include following definitions in the Rule 2 of DMROA Rules

   Definitions of Ayurvedic medicines, Homoeopathic Medicines, Phytopharmaceutical drug, registered medical practitioner, Registered Homeopathic medical practitioner, Patent or proprietary medicine, Schedule and Medicine in DMROA Rules.

The sub-committee has also recommended for certain amendments in the DMROA Act, 1954.

After detailed deliberation, DCC recommended for constituting a sub-committee to examine the recommendations in details for further action to bring alignment between the Drugs and Cosmetics Rules, 1945 and the DMROA Act and Rules in this regard.

AGENDA NO. 6

CONSIDERATION OF THE RECOMMENDATIONS OF SUB-COMMITTEE FOR EFFECTIVE RECALL SYSTEM OF NOT OF STANDARD QUALITY (NSQ) DRUGS

Drugs Consultative Committee (DCC) in its 55th meeting held on 31.01.2019 & 01.02.2019 constituted a sub-committee under the chairmanship of Shri. K.V. Rajendranath Reddy, IPS, Ex-DG, DCA, Andhra Pradesh to to examine the issues

regarding effective recall system of drugs found 'Not of Standard Quality (NSQ)' and to review the recall guidelines for updating the same in the present context.

The sub-committee examined the matter in its 1st and 2nd meeting held on 16th April, 2019 and 13th-14th May, 2019 respectively, considered all the parameters and submitted following recommendations:

(1) Strengthening of existing system (short term and immediately achievable goal)

- To be done immediately with present infrastructure, IT support system, online system, published guidelines to ensure effective recall of NSQ drug and uniform implementation of the same by all the SLAs, UTs and CDSCO e.g. appointment of nodal officers in each state, UT, CDSCO zones and subzones, constitution of special committee at the central level etc, amendment in Rules, use of currently available electronic media like whatsapp group etc.

(2) Further strengthening within the shortest possible time (medium term goal)

- Creation of Drugs Control websites for uploading Not of Standard Quality reports, development of Mobile App based system etc.

(3) Future plan (long term Goal)

- Development of online portal/ web-based services connecting pan India - all stakeholders – Heads of Government testing laboratories at Central and state levels, regulators at all levels - Drugs Inspectors, their Controlling or Licensing Authorities and Nodal Officers in case they are different from LA/CA, supply chain (Stockist/ distributors/ wholesalers/ C and F/ retailers as association and individual entity, all association of manufacturers etc.

After detailed deliberation, DCC agreed to the recommendations of the sub-committee for making Rules/guidelines. Further, to protect the public from potential use of Not of Standard Quality (NSQ) Drugs after its declaration, the committee recommended that CDSCO shall immediately publish such data/reports on its website for which the State and Central Drug Control Authorities shall inform such cases of NSQ to the CDSCO by email at enforcecell.div@cdsco.nic.in immediately after such declaration by the Govt Analysts. It shall also be ensured that the reports of NSQ drugs after declaration shall be informed by the State or Central laboratories immediately to the concerned Drug Control authorities.

Further during the discussion in continuation to this point, it was also recommended to update the status of action taken (upto its logical conclusion as per Drugs and Cosmetics Act and Rules) by the respective authorities on Not of Standard Quality drugs specially those identified under the National Drug Survey programme

During the deliberation members raised the concern about recording of storage condition by Drugs Inspector while drawing the sample for test or analysis. To make it a uniform practice, DCC recommended to include provision for recording storage condition in Form-17 of Drugs and Cosmetics Rules. Further Committee also recommended to

make the provisions under the Drugs and Cosmetics Rules to mention the storage conditions on the label and that while supplying the drugs the distributors/suppliers shall ensure and record on the supply documents or bills that drugs are supplied as per storage conditions on the label. Similarly, receiver/purchaser for further sale/ distribution shall ensure and record on the receiving document that drugs were received in the appropriate conditions as per label. Further the recall of drugs whenever required shall also be the responsibility of wholesalers/ distributors/ retailers.

For maintenance of proper supply chain storage condition while medicines are sold and are expected to remain with patients for certain period of time, it is imperative to counsel the patient about the drug in the prescription for his safety. Therefore, DCC also recommended that provisions shall be made under the Drugs and Cosmetics Rules that, medicines which are required to be sold on prescription of RMP, shall be dispensed with counselling by the Registered Pharmacist.

Subsequently, members also raised concerns about uniformity in test reports. DCC felt that detailed examination is required to take further action in this regard. Therefore, DCC constituted a subcommittee under Chairmanship of Shri Hariharan, Director(I/c), CDL, Kolkata to examine and give recommendation in the matter about sampling, testing and test reports.

Composition of sub-committee:

1.	Shri. C. Hariharan, Director(I/c), CDL, Kolkata	(Chairman)
2.	Dr. Raman Mohan Singh, Director, CDTL, Mumbai	(Member)
3.	Director/Representative of CDTL, Chennai	(Member)
4.	Dr. R. A. Singh, Director, RDTL, Chandigarh	(Member)
5.	State Drugs Controller, Gujarat	(Member)
6.	State Drugs Controller, Maharashtra	(Member)
7.	State Drugs Controller, Andhra Pradesh	(Member)
8.	Director/Representative of CDL, Kasauli	(Member)
9	Dr. A. Ramkishan, DDC(I), CDSCO(East Zone)	(Convener)

The sub-committee shall examine the report and submit their recommendations within three months to the DCC for further consideration.

AGENDA NO. 7

CONSIDERATION OF PROPOSAL FOR IMPLEMENTATION OF MEDICAL DEVICE RULES 2017 FOR EXISTING MANUFACTURERS LICENSED BEFORE IMPLEMENTATION OF MDR, 2017

The Ministry of Health & Family Welfare, Government of India has notified the Medical Devices Rules 2017 vide G.S.R. 78(E) dated 31.01.2017 under the provisions of the Drugs and Cosmetics Act, 1940.

In the notified Rules, the time up to Sep 2018 was given to the manufacturer's to upgrade and get license under MDR 2017. It has been noticed that several manufacturers

had paid fees for the retention of license under the old scheme and has not made application for license under MDR 2017. It may be mentioned that there is no specific provision in the Rules for the licensee to have their license valid for another five years without any inspection on payment of fees.

In recent raid in the country it was observed that these manufacturers of medical devices are operating in non-compliance to the current regulation. There may be some manufacturers whose product may be classified as Category C but earlier, these were not regulated under CLAA scheme. Such licensees are operating under the old licensing system and are in noncompliance to current regulation. Hence it needs to be considered as to who will take action against such licensees.

The following points were suggested to the DCC:

1. A public notice may be issued giving three months' time to manufacturers who are licensed earlier under SLA and their products have now been categorised at C or D under the Medical Device Rules(MDR), 2017 to make application in compliance to the Rules. In overall nine months, all such firms should get fresh licenses under the new Rules.

2. A public notice may be issued giving six months time to all the manufacturers licensed earlier under CLAA scheme to get license as per the requirements of MDR, 2017.

3. In cases where the firm is already licensed under CLAA scheme and found to be operating under non compliance mode, show cause notice may be issued by the Licensing Authority for medical devices (category C and D) and further action may be initiated based on the CAPA submitted by the firm as per the applicable Rules

DCC deliberated the matter and agreed for the proposals that firms shall get licenses as per New MDR, 2017 preferably in 9 months and essentially, before expiry of existing license and for the licensees, which are continuing on old licenses based on saving clause in MDR, in case of non-compliance, action shall be taken by the authority under whose licence, the licensee is operating. If the medical device falls in C & D category and licensee is continuing with SLA license, action shall be taken by SLA after such time the licence issued by SLA remains valid due to the saving clause.

AGENDA NO. 8

CONSIDERATION OF PROPOSAL FOR AMENDMENT OF MEDICAL DEVICE RULES 2017 REGARDING TRANSITION PERIOD FOR MANUFACTURERS LICENSED BEFORE TO IMPLEMENT PROVISIONS OF MDR, 2017.

The Ministry of Health & Family Welfare, Government of India has notified the Medical Devices Rules 2017 vide G.S.R. 78(E) dated 31.01.2017 under the provisions of the Drugs and Cosmetics Act, 1940 which is effective from 01.01.2018 to regulate the Clinical Investigation, Manufacture, Import, Sale and Distribution of the medical devices in the country.

Clause (i) of Rule 97 under Medical Device Rules, provides as under-

“the licence or registration certificate, issued under the provisions of the Drugs and Cosmetics Act and Rules 1945, prior to commencement of these rules shall be deemed to be valid till its expiry or for a period of eighteen months from the date these rules are notified whichever is later under the corresponding provisions of these rules.”

It is pertinent to mention that CDSCO has received representation from Sh.Rajiv Nath, Forum Coordinator, Association of Indian Medical Device Industry (AiMeD) wherein it is stated that license issued or renewed for Medical Devices under Drugs and Cosmetics Rules, 1945 before implementation of MDR, 2017 which is still valid and obtained a license as per MDR, 2017; such manufacturer should be allowed a transition time up to 6 months to implement the new provisions for switching inventory of labelling/packaging from earlier license to new license.

AiMeD has requested for amendment in Rule 97 of Medical Device Rule 2017, as under-

the license issued under the provision of these rules shall be effective before expiry of the license issued under Drugs and Cosmetics Rules, 1945 or on completion of six months from the date new license is issued under the provision of Medical Device Rules, whichever is earlier to enable smooth transition and clearance of packaging inventory labelled with earlier Manufacturing licence number.

However, there is no provision in the MDR, 2017 to permit such transition period and the new license number is applicable the day it is issued by SLA and it is unreasonably expected that manufacturer will overnight switch labelling on packaging to the new license number. This is not practical nor can old inventory be destroyed or wasted needlessly.

In view of the above, it was proposed that the MDR, 2017 may appropriately be amended to provide following:-

A. The license issued under the provisions of these rules shall be effective before expiry of the license issued under Drugs and Cosmetics Rules, 1945 or on completion of six months from the date new license is issued under the provisions of Medical Device Rules, whichever is earlier

B. For the purpose of export, in case of change of constitution or name change of the firm, the licensee shall obtain the permission from Licensing Authority to use the old name for the purpose of exhausting transition time of registration in foreign countries. Such permission will be given initially for one year and extendable for further period as per the request of applicant.

DCC deliberated the matter of such transition from one old license to another new license due to change in Rules while the old license is still having its residual shelf life and recommended that only one license shall be operational till its expiry and which one the licensee would like to continue with, shall be indicated by the licensee/applicant himself. If the licensee want to use old license till expiry, then the new license shall be made effective from the next day of expiry of the old license.

AGENDA NO. 9

CONSIDERATION ON THE STATUS OF STATE LEVEL EXPERT COMMITTEES FOR PAYMENT OF COMPENSATION TO PATIENTS IMPLANTED WITH ASR HIP IMPLANT MANUFACTURED BY M/S DEPUY INTERNATIONAL LTD (JOHNSON & JOHNSON)

The Central government has constituted Central Expert Committee and advised for State Level Committees to implement the recommendations of Dr. Aggarwal Committee. The Central Expert Committee was constituted under the chairmanship of Dr. R.K. Arya to determine the quantum of compensation. In this regard, all State and Union Territories were required to form State Level Committees vide order no. X.11035/25/2015-DFQC dated 30.08.2018 for assisting patients for the examination and evaluation of affected patients. It was also required that the report of the individual shall be submitted by the State Level Committees to the Central Expert Committee including its recommendations within a period of 60 days from the date of the receipt of the application from Central Expert Committee.

It was emphasized in the meeting 56th DCC held on 01.06.2019 that all the states should constitute the state level committees for ASR implant issue with State Drugs Controller as member secretary to identify the patients who have undergone the revision surgery and to forward such cases to the central committee for examination. In the meeting it was requested that all the State Drugs Controllers should put extra miles and efforts to ensure that such patients are given the compensation as per the interim order of Hon'ble Delhi High Court.

In this regard DCC emphasized again that all the State Drugs Control Authorities should facilitate the process of compensation to patients implanted with ASR hip implant by M/s Depuy international Ltd (Johnson & Johnson) expeditiously by holding regular meetings at frequent intervals and conducting hand holding of claimants in getting disability certificate and application completed or submitted properly.

AGENDA NO. 10

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

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

to all State Drugs Controllers requesting them to verify the data and approve them at the earliest.

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

DCC therefore recommended that all the State Drugs Control Authorities should ensure uploading of the required data by manufacturers within 15 days by issuing orders under Drugs and Cosmetics Rules.

AGENDA NO. 11

CONSIDERATION OF THE PROPOSAL FOR A COMMON SOFTWARE PLATFORM FOR DRUG LICENSES MANAGEMENT FOR ALL THE STATES IN THE COUNTRY

DCC in its 56th meeting held on 01.06.2019 deliberated the development of the Common software platform. CDAC made a detailed presentation on online filing and processing of application for the grant of drug manufacturing licence.

After detailed deliberation, it was decided that the development of the common software platform should be completed and the programme should be rolled out on 01.07.2019. DCC also deliberated the need of imparting training to the state regulatory officials on the proposed software system

Accordingly, training was provided to 3-5 officials of various State Drugs Control departments by the CDAC on 10.06.2019.

After detailed review and deliberation on the progress, the committee recommended that all the State Drugs Control Authorities should start utilizing the common software platform (statedrugs.gov.in) by obtaining login ID and password and validating all application formats by getting dummy application from stakeholders or if already validated shall start using it in full-fledged manner. In case of any problem, they shall contact CDAC main contact person Mr Rahul Gautam (mobile no. 8527890789) or alternatively Ms Payal Saluja (mobile no.7042906655) or Mr Sanjeev (mobile no. 9540346888),or Mr Rishi Prakash (mobile no. 9873719691), IT helpdesk at ithelpdesk.sugam@gmail.com and can also take support from Zonal/ Subzonal heads of CDSCO.

ADDITIONAL AGENDA NO. S1

CONSIDERATION OF PROPOSAL ON MEASURES NEED TO BE TAKEN TO ADDRESS THE ISSUE OF REPACKING OF ACTIVE PHARMACEUTICAL INGREDIENTS (API) INTO SMALLER PACKS BY THE WHOLESALERS FOR SALE

Active Pharmaceutical Ingredients (Bulk drugs) can be manufactured and sold directly to the formulator or through the wholesaler in accordance with the provisions of Drugs and Cosmetics Act, 1940 and Rules made there under.

It has been observed that in some cases the wholesalers repack the Active Pharmaceutical Ingredients into smaller packs and sale the same to the formulators for manufacturing the finished formulation.

After detailed deliberation, DCC recommended that repacking of Active Pharmaceutical Ingredients by wholesaler is as such not allowed under the Drugs and Cosmetics Rules, 1945 and it has a potential for breach of integrity and quality of the product. Therefore, it was opined that the authorities shall take the information from licensee in their jurisdiction about such activities by issuing letters/notices within 15 days and this compiled information along with executive summary shall be submitted to CDSCO within next 15 days i.e., 30 days after issue of the Notices and then hold national level stakeholders consultation with the representatives/ associations of these licensees by involving the states where such activities are happening, prominently to decide further course of action in consultative manner by understanding the views of stakeholders and spreading the awareness about the provisions of the Rules .

NOTE: ANNEXURE-A: List of Participants

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ANNEXURE-A

List of the participants of 57th Drugs Consultative Committee meeting held on 20.08.2019 at Goa under the Chairmanship of Dr. V.G. Somani, Drugs Controller General (India)

A. STATE/UT DRUGS CONTROL ORGANIZATIONS

S. NO.	STATE/UT	NAME	DESIGNATION
1.	Andhra Pradesh	Shri. P. Vinay Kumar	Joint Director, DCA
2.	Arunachal Pradesh	Not represented	
3.	Assam	Shri. Ashim Kumar Nath	State Drugs Controller
4.	Bihar	Shri. Ravindra Kumar Sinha	State Drugs Controller
5.	Chhattisgarh	Shri. Styanarayana Rathore	State Drugs Controller
6.	Goa	Smt. Jyothi Sardesai	Director, FDA
7.	Gujarat	Not represented	
8.	Haryana	Shri. N.K. Ahooja	State Drugs Controller
9.	Himachal Pradesh	Not represented	
10.	Jammu and Kashmir	Not represented	
11.	Jharkhand	Smt. Ritu Sahay	Director (Drugs)
12.	Karnataka	Shri. Bhagoji T.Khanapure	State Drugs Controller
13.	Kerala	Ravi S Menon	State Drugs Controller
14.	Madhya Pradesh	Shri. Ravindra Singh	CFDA
		Shri. Shobhit	Dy. Drugs Controller, FDA
15.	Maharashtra	Shri. V.K. Biyani	Joint Commissioner
16.	Manipur	Shri. N. Rimot Kumar Meetei	Addl. State Drugs Controller
17.	Meghalaya	Shri. Antony Laloo	Licensing & Controlling Authority
		Shri. Devistone Swer	Asstt. Drug Controller
18.	Mizoram	Shri. Lal sawma	Joint Director
19.	Nagaland	Shri. Athembemo Ezung	Drugs Inspector
20.	Odisha	Smt. Mamina Patnaik	State Drugs Controller (I/C)
21.	Punjab	Shri. Gurbinder Singh	
22.	Rajasthan	Not represented	
23.	Sikkim	Not represented	
24.	Tamil Nadu	Shri. Sivabalan	Director (Drugs)
25.	Telangana	Dr. B. Venkateswarlu	Joint Director, DCA
26.	Tripura	Dr. N. Goswami	Dy. Drugs Controller
27.	Uttar Pradesh	Shri. Dinesh Kumar Tiwari	Assistant Commissioner (Drug)
28.	Uttarakhand	Not represented	

S. NO.	STATE/UT	NAME	DESIGNATION
29.	West Bengal	Shri. Swapan Kumar Mondal	Director (Drugs)
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. Atul Kumar Nasa	DDC & Controlling Authority
35.	Lakshadweep	Not represented	
36.	Pondicherry	Not represented	

B. INVITEES

S. No.	NAME	DESIGNATION
1.	Dr. Mandeep Kumar Bhandari	Joint Secretary, MoHFW
2.	Dr. Madhur Gupta	Technical Officer, WHO

C. ZONAL/ SUB ZONAL OFFICES OF CDSCO

S. No.	OFFICES	NAME	DESIGNATION
ZONE			
1.	North Zone, Ghaziabad	Shri. AseemSahu	Deputy Drugs Controller (India)
2.	East Zone, Kolkata	Dr.A.R. Ramkishan	Deputy Drugs Controller (India)
3.	West Zone, Mumbai	Dr P.B.N. Prasad	Deputy Drugs Controller (India)
		Dr Rubina Bose	Deputy Drugs Controller (India)
4.	South Zone, Chennai	Smt. Shanthy Gunasekaran	Deputy Drugs Controller (India)
5.	Hyderabad Zone	Smt. A.Visala	Deputy Drugs Controller (India)
6.	Ahmedabad Zone	Shri. Arvind Kukrety	Deputy Drugs Controller (India)
SUB ZONE			
1.	Baddi Sub-zone	Shri. B.K. Samantray	Deputy Drugs Controller (India)
2.	Bangalore Sub-zone	Dr. B. Kumar	Deputy Drugs Controller (India)
3.	Guwahati Sub-zone	Shri. A. Senkathir	Deputy Drugs Controller (India)
4.	Indore Sub-zone	Not represented	
5.	Varanasi Sub-zone	Not represented	Asst. Drugs Controller (India)
6.	Jammu Sub-zone	Not represented	
7.	Goa Sub-zone	Shri. Surender Kumar Kaswan	Drugs Inspector

D. CDSCO HEAD QUARTER

S. No.	NAME	DESIGNATION
1.	Dr. V. G. Somani	Drugs Controller General of India
2.	Dr. K Bangarurajan	Joint Drugs Controller (India)
3.	Shri. A.K. Pradhan	Deputy Drugs Controller (India)
4.	Dr. S. Manivannan	Deputy Drugs Controller (India)
5.	Dr. S.P. Shani	Deputy Drugs Controller (India)
6.	Shri. R. Chandrashekhar	Deputy Drugs Controller (India)
7.	Ms. Swati Srivastava	Deputy Drugs Controller (India)
8.	Shri. Jayant Kumar	Deputy Drugs Controller (India)
9.	Dr. Santosh Indraksha	Asst. Drugs Controller (India)
10.	Shri. Mukesh Kumar	Drugs Inspector
11.	Shri. Shivadev D	Drugs Inspector
12.	Shri. Prakash Kumar Parida	Drugs Inspector
13.	Shri. Gunda Raghuvaran	Drugs Inspector
14.	Smt. Minakshi	Drugs Inspector
15.	Shri. Ranjeet Singh Patel	Drugs Inspector
16.	Smt. Smrithi Sharma	Drugs Inspector

E. DRUG TESTING LABORATORIES

S. No.	OFFICES	NAME	DESIGNATION
1.	CDL Kolkata	Shri. C. Hariharan	Director/In-Charge
2.	CDTL, Mumbai	Dr. Raman Mohan Singh	Director
3.	RDTL, Chandigarh	Dr. R.A. Singh	Director