डॉ. स. ईश्वरा रैड्डी एम.फार्म,पीएच.डी.
औषधि महा नियंत्रक (भारत)
केन्द्रीय औषधि मानक नियंत्रण संगठन
स्वास्थ्य सेवा महानिदेशालय
स्वास्थ्य एवम् परिवार कल्याण मंत्रालय
भारत सरकार
एफ. डी. ए. भवन, कोटला रोड,
नई दिल्ली-११०००२

सत्यमेव जयते

Dr. S. Eswara Reddy M.Pharm, Ph.D.
Drugs Controller General (India)
CENTRAL DRUGS STANDARD CONTROL, ORGANISATION
DIRECTORATE GENERAL OF HEALTH SERVICES
MINISTRY OF HEALTH & FAMILY WELFARE
GOVERNMENT OF INDIA
F.D.A. BHAWAN, KOTLA ROAD,
NEW DELHI-110002

F.No. 22-01/2019-DC

Date: 11-04-2019

To

Members of DTAB

Subject: Minutes of the 82nd meeting of the Drugs Technical Advisory Board (DTAB) held on 02 April, 2019 at Nirman Bhawan, New Delhi.

Sir/Madam,

A copy of the minutes of the 82nd meeting of Drugs Technical Advisory Board held on 02 April, 2019 at Nirman Bhawan, New Delhi, duly approved by the Chairman, is annexed for your information and perusal please.

Yours faithfully

(Dr. S. Eswara Reddy)
Drugs Controller General (India)
Member Secretary (DTAB)

Encl: Copy of the Minutes

MINUTES OF THE 82nd MEETING OF DRUGS TECHNICAL ADVISORY BOARD HELD ON 02.04.2019 AT DGHS, NIRMAN BHAWAN, NEW DELHI

PRESENT

1.	Dr. S. Venkatesh Director General of Health Services, Nirman Bhawan, New Delhi	Chairman
2.	Dr. S. Eswara Reddy Drugs Controller General (India), FDA Bhawan, New Delhi	Member Secretary
3.	Shri C. Hariharan Director (I/C), Central Drugs Laboratory, Kolkata	Member
4.	Dr. A. K. Tahlan Director, Central Research Institute, Kasauli, Himachal Pradesh	Member
5.	Dr. Tapas K. Kundu Director, CDRI, Lucknow	Member
6.	Shri. A.K. Nath Drugs Controller (I/C), Assam	Member
7.	Prof. M. D. Karvekar Bangalore, Karnataka	Member
8.	Shri. Pankaj Patel Chairman and Managing Director, Zydus Cadila Group, Ahmedabad	Member
9.	Dr. Nilima Kshirsagar Chair in Clinical Pharmacology, ICMR, Mumbai	Member
10.	Dr. R.N. Tandon Past Honorary Secretary General, IMA, New Delhi	Member
11.	Prof. Dr. T.V. Narayana President , IPA, Bengaluru	Member
12.	Shri. M.S Lokesh Prasad Scientific Officer & Govt. Analyst, Bengaluru, Karnataka	Member
13.	Dr. Vaishali N Patel Govt. Analyst, Food & Drugs Laboratory, Vadodara, Gujarat	Member

INVITEES

1. Dr. Arun Bhardwaj
   Director, Central Drugs Laboratory, Kasauli
2. Dr. S.R. Chinta
   Deputy Adviser (H),
   Ministry of AYUSH, New Delhi

CDSCO REPRESENTATIVES

1. Shri. A C S Rao
   DDC (I), CDSCO (HQ), New Delhi
2. Shri. R. Chandrasekhar,
   DDC (I), CDSCO (HQ), New Delhi
3. Dr. Santosh Indraksha
   ADC (I), CDSCO (HQ), New Delhi
4. Shri. Milind P. Patil
   Drugs Inspector, CDSCO (HQ), New Delhi
5. Shri. Shivadev .D
   Drugs Inspector, CDSCO (HQ), New Delhi
6. Shri. G. Raghuvaran
   Drugs Inspector, CDSCO (HQ), New Delhi
7. Shri. Rajesham Pambala
   Drugs Inspector, CDSCO (HQ), New Delhi

The Director, Indian Veterinary Research Institute, Izatnagar; President, Pharmacy Council of India, New Delhi; Dr. Pallavi Jain Govil, Commissioner, FDA, Madhya Pradesh and Elected member by MCI could not attend the meeting because of their other commitments.

Dr. S. Venkatesh, Director General of Health Services & Chairman DTAB welcomed the Board members and invitees. Dr. S. Eswara Reddy, DCG(I), Member-Secretary apprised that Ministry had published 26 draft, 23 final notifications in 2018 and 6 draft, 14 final notifications till date in 2019. Thereafter, DCG(I) with the permission of the chairman initiated the deliberation on DTAB agenda along with Action Taken Reports on previous DTAB recommendations.

AGENDA NO.1

ACTION TAKEN REPORT (ATR) FOR 81st DTAB MEETING HELD ON 29.11.2018

The Action Taken Report (ATR) on the recommendations of DTAB in 81st meeting was approved by the Board.

AGENDA NO. 2

CONSIDERATION OF THE PROPOSAL FOR EVALUATION OF PROF. C. K. KOKATE COMMITTEE REPORT SUBMITTED WITH RESPECT TO FIXED DOSE COMBINATIONS (FDCs) CONSIDERED AS IRRATIONAL IN 2ND ASSESSMENT REPORT OF THE COMMITTEE

DTAB was apprised that, the Ministry of Health & Family Welfare (MoHFW) vide Order No. X11035/53/ 2014-DFQC dated. 16.09.2014 constituted a committee under the chairmanship of Prof. C. K. Kokate, Former Vice-Chancellor, KLE University, Belgaum, Karnataka for examining the Safety and Efficacy of unapproved FDCs which were licensed by State Licensing Authorities without due approval of DCG(I).

After holding a series of meetings the Kokate Committee had submitted its second assessment report to the MoHFW on 27.05.2016 categorizing FDCs into "irrational (category 'a')", "requiring further deliberation (category 'b')", "rational (category 'c')" and "FDCs requiring generation of data (category 'd')". Accordingly Show Cause Notices (SCNs) were issued by CDSCO to the applicants in respect of FDCs which were considered as irrational (category 'a') to the concerned manufacturers. This was 4th lot/ final assessment of such FDCs considered by the Kokate Committee.

Replies, so received against SCNs with respect to FDCs considered as irrational under category 'a', were placed before the Kokate Committee for examination. It was decided by the Kokate Committee to examine these FDCs along with subject experts in the respective field, wherever necessary.

The Kokate Committee discussed each FDC in detail in consultation with subject experts of relevant therapeutic area. The Kokate Committee discussed total 418 such applications of FDCs. The Kokate Committee examined all the data submitted by the applicants and also checked/ reviewed the scientific data. While examining the replies to the SCNs of such FDCs, the Kokate Committee considered following points:

a. Scientific clinical evidence to justify the use of FDC
b. Epidemiological data on co-existence of diseases/ symptoms for which FDC is indicated
c. Patients Safety and Risk Benefit assessment
d. Drug Toxicity/ Adverse effect
e. Misuse of drug/ Prescription error
f. Abuse Potential
g. Pharmacokinetic and Pharmacodynamic interaction/ Compatibility
h. Dosage compatibilities of FDCs vis-à-vis that of single ingredients
i. Issue of antimicrobial Drug Resistance
j. Recent Standard Treatment Guidelines (STG)
k. Patient Compliance
l. International status particularly in ICH countries.

After examining 418 applications of FDCs, the Kokate Committee has found 324 FDCs as irrational, after evaluating all the data submitted and available information, 28 FDCs as rational, 2 FDCs which require further generation of data and 4 FDCs which require further deliberation. It was also observed that 60 FDCs have already been either prohibited (48 FDCs) or have been already declared as rational (11 FDCs), or fall under sub-judice category (1 FDC) by the Kokate Committee which were placed in the list of these 418 applications of FDCs inadvertently. Therefore, the Kokate Committee did not make any recommendations on these 60 applications of FDCs.

The report of the Kokate Committee has been placed before the DTAB for deliberation. The Kokate Committee in its report has opined that these FDCs wherever recommended as “irrational (category ‘a’)” should not be allowed for their continued manufacturing and marketing in the country. The FDCs which have been declared as irrational needs to be prohibited under Drugs and Cosmetics Act, 1940 as other safer alternatives to those combinations are available.

DTAB after deliberation recommended to constitute a sub-committee under the chairpersonship of Dr. Nilima Kshirsagar with following composition to evaluate Prof. C.K. Kokate Committee report submitted with respect to Fixed Dose Combinations (FDCs) considered as irrational in the 2nd assessment report of the Committee:

1. Dr. Nilima Kshirsagar The Chair in Clinical Pharmacology, ICMR, Mumbai	Chairperson
2. Prof. Dr. T.V. Narayana President, IPA, Bengaluru	Member
3. Dr. Sandeep Bavdekar Former Prof. Head Pediatrics, T.N Medical College & BYL Nair Ch. Hospital, Mumbai	Member
4. Dr. Nirmala Rege Former Prof. & HOD Pharmacology Seth G S Medical College & KEM Hospital, Mumbai	Member
5. Dr. R.N.Tandon Immediate Past Honorary Secretary General, IMA, New Delhi	Member
6. Dr. B. Gupta Professor & Head, Dept. of Medicine, NDMC Medical College & Hindu Rao Hospital, New Delhi	Member
7. Shri H.Mahapatra Former Drugs Controller, Odisha	Member
8. Shri. Sanjeev Kumar DDC(I), CDSCO (HQ), New Delhi	Convener

The Chairperson of the sub-committee may co-opt other experts from relevant field as deemed necessary for the purpose. The Sub-committee shall furnish its report within three months.

AGENDA No. 3

CONSIDERATION OF THE PROPOSAL FOR EXEMPTION OF OBTAINING FORM 29 FOR TEST OR ANALYSIS OF APPROVED DRUGS, IF THE MANUFACTURER HOLDS VALID PRODUCT PERMISSION FOR MANUFACTURE OF SAME DOSAGE FORMS

The Board was apprised that, licence to manufacture drugs for the purposes of examination, test or analysis is granted in Form 29 under Rule 89 of the Drugs and Cosmetics Rules, 1945 and licence to manufacture of drugs for sale or for distribution is granted in Form 25 or Form 28 under the said rules.

Rule 89 of the Drugs and Cosmetics Rules, 1945 is reproduced below:-

> ***"89.*** *Licence.–If the person proposing to manufacture a drug for the purpose of examination, test or analysis does not hold a licence in Form 25 or Form 28 in respect of such drugs he shall, before commencing such manufacture, obtain a licence in Form 29."*

It was proposed to exempt for obtaining licence in Form 29 for manufacture of approved drugs for the purposes of examination, test or analysis by the manufactures who are already holding valid product permission for manufacturing of same dosage form of any drug in Form 25 or Form 28.

DTAB deliberated the proposal in detail and agreed to exempt for obtaining licence in Form 29 for manufacture of approved drugs by the manufactures who are already holding licence in Form 25/Form 28 to manufacture any drug in same dosage form subject to the condition that the information about the manufacturing of such drugs for examination, test or analysis shall be uploaded on the SUGAM Portal. Accordingly the Drugs and Cosmetics Rules shall be amended.

AGENDA NO. 4

CONSIDERATION OF THE PROPOSAL FOR INCORPORATION OF QR CODING ON PACKING OF ACTIVE PHARMACEUTICAL INGREDIENTS (APIs) FOR TRACKING AND TRACING IN THE SUPPLY CHAIN

The Board was apprised that, the Active Pharmaceutical Ingredient (API) is most important constituent of any drug formulation. The supply chain with respect to its security and integrity in proper storage condition plays very important role to enhance quality supply of APIs.

In various fora, stake holders suggested to have a system of QR code on packing of APIs for tracing the origin and movement of APIs from manufacturers to formulators through a system of networking.

DTAB after detailed deliberation, recommended to include necessary provisions under the Drugs and Cosmetics Rules, 1945 for making it mandatory to have QR coding on labels of APIs for tracing the origin and movement of APIs from manufacturers to formulators through a system of networking.

AGENDA NO. 5

CONSIDERATION OF THE PROPOSAL TO AMEND SCHEDULE K OF DRUGS AND COSMETICS RULES, 1945

The Board was apprised that, a proposal was received to make following amendment in Schedule K of Drugs and Cosmetics Rules, 1945.

S. No.	Existing Rule	Proposed Rule
23.	Drugs supplied by (i) Multipurpose Workers attached to Primary Health Centres/Sub-Centres, (ii) Community Health Volunteers under the Rural Health Scheme. (iii) Nurses, Auxiliary Nurses, Midwives and Lady Health Visitors attached to Urban Family Welfare Centres/Primary Health Centres/ Sub-Centres and (iv) Anganwadi workers.	Drugs supplied by: (i) Health Functionaries attached to Primary Health Centres/ Sub-Centres/ Health & Wellness Centres, (ii) Community Health Volunteers under the National Health Mission, (iii) Nurses, Auxiliary Nurse Midwives and Lady Health Visitors attached to Government Primary Healthcare Facilities in urban areas.

DTAB deliberated the proposal and agreed for amendment in the Schedule K of the Drugs and Cosmetics Rules, 1945.

AGENDA No. 6

CONSIDERATION OF THE REPORT SUBMITTED BY SUB-COMMITTEE FOR REVISION OF THE FEES FOR THE TEST OR ANALYSIS BY AMENDING SCHEDULE B AND SCHEDULE B-1 OF THE DRUGS AND COSMETICS RULES, 1945

The Board was apprised that, DCC in its 53rd meeting held on 09.04.2018 constituted a sub-committee under the chairmanship of Dr. N. Murugesan, Director, CDTL, Chennai, for amending Schedule B and Schedule B-1 of Drugs and Cosmetics Rules, 1945 in respect of the proposed hike in fees for test or analysis of drugs.

The sub-committee submitted this report and also presented the same before DCC in its 55th meeting. Major recommendations of the sub-committee are as under:

1. Revision of fees for test or analysis by the Central Drugs Laboratories, Central and State Drugs Testing Laboratories under Schedule B of Drugs and Cosmetics Rules, 1945.

2. Revision of fees for the test or analysis by the Central Drugs Laboratory, Government Analyst of Central/ State Drugs Testing Laboratories under Schedule B1 of Drugs and Cosmetics Rules, 1945.

3. Inclusion of a separate schedule in the Medical Device Rules, 2017 for the test or analysis fees of notified medical devices.

DCC agreed to the recommendations of the sub-committee and recommended to initiate process for necessary amendment in the Rules. Accordingly, the recommendations of the sub-committee were placed before the DTAB.

DTAB deliberated the recommendations of the sub-committee in detail and recommended to revise the fees for the test or analysis by amending Schedule B and Schedule B-1 of the Drugs and Cosmetics Rules, 1945 as per the recommendations of DCC. The Board also recommended to include a separate Schedule in the Medical Device Rules, 2017 for the test or analysis fees of notified medical devices as recommended by the sub-committee of the DCC.

AGENDA NO. 7

CONSIDERATION OF THE RECOMMENDATIONS OF THE SUB-COMMITTEE ON LABELING OF IRON TABLETS AND POLIO DROPS DISTRIBUTED TO THE CHILDREN UNDER GOVERNMENT PROGRAMMES WITH NAME AND EXPIRY DATE IN HINDI ALSO

The Board in its 78th meeting held on 12.02.2018 considered the proposal to amend Rule 96 of the Drugs and Cosmetics Rules, 1945 for labelling of iron tablets and polio drops distributed to the children under Government programmes with name and expiry date in Hindi also and constituted a sub-committee under the chairmanship of Dr. R.N. Tandon, Honorary Secretary General, IMA, New Delhi to examine and give recommendations to streamline the labelling requirements of drugs so as to provide the requisite information to the consumer.

The sub-committee members and co-opted experts, as per the terms of references, examined the feasibility of printing the name of medicine and expiry date in Hindi on label of the drug products and submitted the minutes of meetings along with recommendations.

The sub-committee had submitted its recommendations that name of medicines shall be printed both in English and Hindi for open market, whereas for medicines procured by any Government agencies are at liberty to ask for regional language on label of drug products along with English.

DTAB deliberated the recommendation of the sub-committee and did not agree for making it mandatory to include drug name and expiry date in Hindi/ Regional language along with English. However, the Board recommended that Government Procurement Agencies take necessary steps in tendering process to include drug name and expiry date in Hindi/ Regional language along with English on the label of Iron tablets and Polio drops in Government programmes in addition to

the existing conditions of Rule 96 of Drugs and Cosmetics Rules. It is further recommended that an advisory may be issued by Government in this regard.

The Board further recommended that the sub-committee may co-opt the representatives from Pharmaceutical manufacturing industry and Indian Pharmaceutical Association for further deliberations on the overall issues related to labelling requirements of drugs.

AGENDA NO. 8

AGENDA RELATED TO AMENDMENT OF MEDICAL DEVICES RULES (MDR), 2017

8.1 CONSIDERATION OF THE PROPOSAL TO AMEND SCHEDULE V (QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES AND *IN-VITRO* DIAGNOSTIC MEDICAL DEVICES) OF MEDICAL DEVICE RULES, 2017 IN LINE WITH ISO 13485: 2016

The Board was apprised that, Schedule V of Medical Device Rules, 2017 deals with Quality Management System for Medical Devices and in-vitro diagnostic medical devices and it is largely based on requirements of ISO 13485:2003. These provisions have been updated by ISO in its third edition which is effective from 01.03.2019. Therefore, it was proposed for amendment of Schedule V of Medical Device Rules, 2017 in line with ISO 134185: 2016.

DCC in its 55th meeting held on 31.01.2019 & 01.02.2019 deliberated the proposal and recommended to prepare the necessary provisions or guidelines.

DTAB deliberated the proposal and agreed to amend the Schedule V of the Medical Device Rules, 2017 to incorporate necessary provisions in this regard.

8.2 CONSIDERATION OF PROPOSAL TO INCORPORATE THE PROVISION FOR DETAILS OF THE COMPETENT TECHNICAL STAFF RESPONSIBLE FOR THE MANUFACTURE AND TESTING OF MEDICAL DEVICES IN FORM MD-3, FORM MD-4, FORM MD-5, FORM MD-6 FORM MD-7 & FORM MD-8 AND ABOUT SCOPE OF ACCREDITATION IN FORM MD-39 & FORM MD-40 IN THE MDR-2017

The Board was apprised that, 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.Said rules are effective from 01.01.2018 to regulate the Clinical Investigation, Manufacture, Import, Sale and Distribution of the medical devices in the country.

In the said rules, it is observed that the names, qualifications and experience of the competent technical staff responsible for the manufacture, testing and evaluation of medical device(s) are not mentioned in the following forms:

i. MD-3 (Application for Grant of Licence to Manufacture for Sale and Distribution of Class A or Class B medical device)

ii. MD-4 (Application for Grant of Loan Licence to Manufacture for Sale or for Distribution of Class A or Class B medical Device)

iii. MD-5 (Licence to Manufacture for Sale or for Distribution of Class A or Class B Medical Device)

iv. MD-6 (Loan Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device)

v. MD-7 (Application for Grant of Licence to Manufacture for Sale or for Distribution of Class C or Class D)

vi. MD-8 (Application for Grant of Loan Licence to Manufacture for Sale or for Distribution of Class C or Class D)

vii. MD-39 (Application for grant of registration to Medical Device Testing Laboratory for carry out Test or Evaluation of a medical device on behalf of manufacturer)

viii. MD-40 (Certificate of registration to Medical Device Testing Laboratory for carry out Test or Evaluation of a medical device on behalf of manufacturer).

The details of names, qualifications and experience of the competent technical staff responsible for the manufacture, testing and evaluation of medical device(s) is not generated in licence issued to the applicants because it is not mentioned in application.

Chapter X in said rules specifies the provisions for registration of laboratory for carrying out test or evaluation. As per Rule 81, an application for grant of registration of a medical device testing laboratory to carry out testing or evaluation of a medical device on behalf of a manufacturer shall be made to the Central Licensing Authority through online portal of the Central Government in Form MD-39. The application shall be accompanied with the following information, namely:-

(i) constitution of the medical device testing laboratory;

(ii) premises showing location and area of the different sections

(iii) qualification, experience of technical staff employed for testing and the person in-charge of testing;

(iv) list of equipment; and

(v) valid accreditation certificate issued by the National Accreditation Body for Testing and Calibration Laboratories or any other similar body as may be notified by the Central Government;

As per sub rule (3) of Rule 83 of said rules, the Central Licensing Authority may grant registration in Form MD-40. However, scope of accreditation is not mentioned in MD-39 & MD-40.

In view of the above, it is proposed that we may amend the form MD-3, MD-4, MD-5, MD-6, MD-7, MD-8, MD-39 & MD-40 to insert the names,

qualifications and experience of the competent technical staff in the said forms and scope of accreditation in MD-39 & MD-40.

DTAB deliberated the proposal and agreed to amend the Medical Device Rules, 2017 to incorporate the names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of medical devices and scope of accreditation in respective forms.

AGENDA NO. 9

CONSIDERATION OF THE PROPOSAL TO AMEND SCHEDULE-V OF THE DRUGS AND COSMETICS RULES, 1945 TO REVISE THE LIMIT OF "FREE SALICYLIC ACID TEST" FOR MEDICINES CONTAINING ASPIRIN

The Board was apprised the proposal of revising the limit of "Free Salicylic Acid Test" for patent and proprietary medicines containing aspirin. It is mentioned that current provision under Schedule-V of the Drugs and Cosmetics Rules, 1945 as:

'All patent and proprietary medicines containing aspirin shall be subjected to "Free Salicylic Acid Test" and the limit of such acid shall be 0.75 per cent. Except in case of soluble type aspirin in which case the limit of such acid shall be 3 per cent.'

Aspirin and Aspirin containing FDCs are widely used formulations, and several such single ingredient, formulations and FDCs are covered under various Pharmacopoeia and the "Free Salicylic Acid" content limit specified in such Pharmacopoeia are as under:

1. IP 2018 : Maximum 3 per cent
2. BP 2018 : Maximum 3 per cent
3. USP 41 : Not more than 3 per cent
4. USP 41 : Not more than 8 per cent (for Aspirin Effervescent Tablets for Oral Solution)

DTAB deliberated the proposal and agreed to amend Schedule-V of the Drugs and Cosmetics Rules, 1945 to revise the limit of free salicylic acid content in medicines.

Therefore, it is proposed to revise the free salicylic acid limits under Schedule-V of the Drugs and Cosmetics Rules, 1945 as:

'All medicines containing aspirin shall be subjected to "Free Salicylic Acid Test", and the limit of "Free Salicylic Acid" content shall be not more than 3.0 per cent.'

AGENDA NO. 10

CONSIDERATION OF THE PROPOSAL TO AMEND RULE 127 OF THE DRUGS AND COSMETICS RULES, 1945 TO PERMIT BIS STANDARD IS-4707 (PART I) COLOURS IN DISINFECTANTS

The Board was apprised that, a representation was received from one manufacturing company that they had introduced a disinfectant in early 1980s with Hydrochlorite base with distinctive blue colour. As colourant, the company had been using Acid Blue 80(CI No. 61585) and Acid Red (CI No. 45100) since its introduction and the same colourants are being used, without any change, till date. The colours specified in the proviso of Rule 127 of the Drugs and Cosmetics Rule are unstable on Hydrochlorite based disinfectants. Hence, the company after research introduced their disinfectant with Acid Blue 80(CI No. 61585) and Acid Red (CI No. 45100), both being non-staining.

On 13.04.2005, the Drug Controller, Maharashtra took a view that since this disinfectant falls under Rule 126 of Drugs & Cosmetics Rules, 1945; hence a drug within the meaning of Section 3(b)(ii) of Drugs & Cosmetics Act,1940. Therefore the company was advised by the Drugs Controller, Maharashtra to apply for manufacturing licence. Further, a complaint was made by a competitor company and representation was submitted to the Licensing Authority, Himachal Pradesh stating that the colours used in the manufacturing of the above mentioned disinfectant are not listed in Rule 127 of Drugs & Cosmetics Rules, 1945.

Based on the complaint, the Licensing Authority, Himachal Pradesh issued a Show Cause Notice to the Company on 28.10.2009. The company had challenged the Show Cause Notice and filed Writ Petition (CWP No. 4424 of 2009) before the Hon'ble High Court, Himachal Pradesh and stay had been granted by the Hon'ble High Court.

Further, the same company had also filed a petition for the permission to use colours in the manufacture of Disinfectants (used on inanimate surfaces) mentioned under Rule 127 of Drugs & Cosmetics Rules 1945. The Hon'ble High Court in the order dated 13.03.2018 directed the respondent-Union of India/ MoHFW to submit instructions qua decision, if any, taken in the representation of the petitioner.

Accordingly, an Expert committee was constituted to give their recommendations/ opinion to DCG(I) based on the representation of the company to amend the Rule 127 of the Drugs and Cosmetics Rules, 1945 to permit BIS IS-4707 (Part I) colours in disinfectants under the chairpersonship of Shri. Amrut Nikhade, Joint Commissioner, FDA Maharashtra. In the meeting held on 07.12.2018, the Expert Committee recommended to amend the proviso under Rule 127 of Drugs and Cosmetics Rules, 1945 to permit use of BIS IS-4707 (Part I) Colours in disinfectants.

DTAB deliberated the proposal and agreed to amend the Rule 127 of Drugs and Cosmetics Rules, 1945 to permit use of colours specified in BIS IS-4707 (Part I) in the manufacturing of disinfectants.

AGENDA NO. 11

CONSIDERATION OF THE PROPOSAL TO REPLACE THE WORDS "CHEMISTS & DRUGGISTS" BY "PHARMACY" IN RULE 65(15)(b) & RULE 65(15)(c) OF THE DRUGS AND COSMETICS RULES, 1945

The Board was apprised that, representation was received to remove the words "Chemists and Druggists" from Rule 65(15)(b) of the Drugs and Cosmetics Rules and replace it with "Pharmacy" in order to give trade of medicines a better professional recognition.

As per Rule 65(15)(b) of the Drugs and Cosmetics Rules, the description "Chemists and Druggists" shall be displayed by those licensees who employ the services of a Registered Pharmacist but who do not maintain a "Pharmacy" for compounding against prescriptions. Similarly in Rule 65(15)(c) of the Drugs and Cosmetics Rules, the description "Pharmacy", "Pharmacist", "Dispensing Chemist" or "Pharmaceutical Chemist" shall be displayed by such licensees who employ the services of a Registered Pharmacist and maintain a "Pharmacy" for compounding against prescription.

However, in the current scenario, the compounding of medicines by registered pharmacists hardly exists due to capable pharma industry in place in the country. The term 'Chemists and Druggists' was coined in 1945 and is quite old and has lost relevance and also, at present the word 'drug' is looked upon as more clandestine and as addiction for chemicals, hence not suit to refer a professional pharmacist.

It was requested to amend the Rule 65(15)(b) and Rule 65(15)(c), so that medical shops may be called Pharmacy as this is in concurrence with the international practice of calling a medical shop selling medicines by this name and also provide an identity and sense of value to the practicing pharmacist at the outlets.

This matter was deliberated in 55th DCC meeting held on 31.01.2019 & 01.02.2019 and recommended to replace the words 'Chemists and Druggists' by 'Pharmacy' in Rule 65(15)(b) of the Drugs and Cosmetics Rules, 1945. Accordingly, the proposal is placed before the DTAB for deliberation.

DTAB deliberated the matter and agreed to amend Rule 65(15) of the Drugs and Cosmetics Rules, 1945 to provide that all licensees in Form 20/Form 21, they should display the word "Pharmacy".

AGENDA No. 12

CONSIDERATION OF THE PROPOSAL TO AUTHORISE LICENSING AUTHORITY FOR SALE LICENSES TO ISSUE STOP SALE ORDER

The Board was apprised that, at present, as per Rule 85(2) of Drugs and Cosmetics Rules, 1940 the Licensing Authority for manufacturing are empowered to stop manufacturing, sale or distribution of the drug if in his opinion the licensee has

failed to comply with any of the conditions of the licence or with any provisions of the Act or Rules made thereunder.

A proposal was received that similar provision should be made for Licensing Authority for sale by amending Rule 66 in the following manner.

“The licensing Authority may direct the licensee to stop sale or distribution of the drugs and if in his/her opinion the licensee has failed to comply with any of the condition 'of the licence or with any provisions of the Act or rules made thereunder.”

This matter was deliberated in 55th DCC meeting held on 31.01.2019 & 01.02.2019 and the DCC recommended for incorporating a provision under Rule 66 providing that the Licensing Authority may direct the licensee to stop sale or distribution of the drugs, if, in his/her opinion, the licensee has failed to comply with any of the conditions of the licence or any provisions of the Act or Rules made thereunder.

DTAB deliberated the matter and agreed to amend Rule 66 of the Drugs and Cosmetics Rules, 1945 for incorporating a provision to authorized the Licensing Authority to issue stop sale order.

AGENDA No. 13

CONSIDERATION OF THE PROPOSAL TO INCORPORATE THE PROVISION FOR NAME OF COMPETENT PERSON-IN-CHARGE IN FORM 20D UNDER SCHEDULE A OF THE DRUGS AND COSMETICS RULES, 1945

The Board was apprised that, in the Drugs and Cosmetics Rules, 1945, there is a provision in Form 20C i.e. ‘Licence to sell, stock or exhibit or offer for sale, or distribute Homoeopathic medicines by retail’ and Form 20E i.e. ‘Certificate of Renewal of Licence to sell, stock or exhibit or offer for sale, or distribute Homoeopathic medicines’, to mention the name of competent person-in-charge but no such provision is there in Form 20D i.e. ‘Licence to sell, stock or exhibit or offer for sale, or distribute Homoeopathic medicines by wholesale’.

Representation was received from one of the State Drugs Controllers for incorporation of the provision for mentioning the name of competent person-in-charge in Form 20D.

The matter was deliberated in 55th DCC meeting held on 31.01.2019 & 01.02.2019 and the DCC recommended for incorporating a provision in Form 20D for mentioning the name of competent person-in-charge in line with that in Form 20C and Form 20E.

DTAB deliberated the matter and agreed to amend the Drugs and Cosmetics Rules, 1945 to have provision to mention the name of the competent person-in-charge in Form 20D.

AGENDA NO. 14

CONSIDERATION OF PROPOSAL TO INCLUDE THE PROVISION IN DRUGS AND COSMETIC RULES, 1945 FOR REQUIREMENT OF KEEPING THE CONTROL SAMPLES OF THE DRUGS IMPORTED BY THE IMPORT LICENCE HOLDER AGAINST THE IMPORT LICENSE ISSUED BY CDSCO

DTAB was apprised that, the manufacturing licence holders are required to comply with the one of the conditions of licence as prescribed in Rule 74(l) of the Drugs and Cosmetic Rules, 1945 which is reproduced below:

> *"74(l) the licensee shall maintain reference samples from each batch of the drugs manufactured by him in a quantity which is at least twice the quantity of the drug required to conduct all the tests performed on the batch. In case of drugs bearing an expiry date on the label, the reference samples shall be maintained for a period of three months beyond the date of expiry or potency. In case of drugs where no date of expiry of potency is specified on the label, the reference samples shall be maintained for a period of three years from the date of manufacture."*

The above condition is applicable for indigenous manufacturers who are manufacturing and marketing the drugs in the country. However, there is no such condition available in the import licence under the Drugs and Cosmetics Rules, 1945. In situations when there is any spurious, misbranded or sub standard drugs found in the market, it becomes very difficult to verify the authenticity of such drugs as the control samples of these imported drugs are not available with the import licence holder.

Therefore, in order to remove this discrepancy, it was proposed to amend the Rule 26 of the Drugs and Cosmetics Rules, 1945 i.e., 'Conditions of import licence' for incorporating the following condition:

> *"26(viii) the licensee shall maintain reference samples from each batch of the drugs imported by him in a quantity which is at least twice the quantity of the drug required to conduct all the tests performed on the batch. In case of drugs bearing an expiry date on the label, the reference samples shall be maintained for a period of three months beyond the date of expiry or potency. In case of drugs where no date of expiry or potency is specified on the label, the reference samples shall be maintained for a period of three years from the date of manufacture."*

DTAB deliberated the proposal and agreed to amend the Drugs and Cosmetics Rules, 1945 to incorporate necessary provision, making it mandatory for import licence holders to maintain the control samples of imported drugs.

AGENDA NO. 15

CONSIDERATION OF THE PROPOSAL TO AMEND THE DRUGS AND COSMETICS RULES, 1945 PERTAINING TO QUALIFICATION OF THE COMPETENT TECHNICAL STAFF FOR GRANT OF LICENCE FOR MANUFACTURING AND TESTING OF DRUGS

The Board was apprised that, a representation has been received from Pharmacy Council of India (PCI), New Delhi regarding amendment of the Drugs and Cosmetics Rules pertaining to qualification of the competent technical staff for grant of licence for manufacturing of drugs.

Central Council of the PCI in its 104th meeting held in August, 2018 noted the following:

a. Advancement in the field of Pharmaceutical Sciences has led to many quality challenges.

b. Besides a graduate in Pharmacy, a graduate in Science or graduate in Chemical Engineering or Chemical Technology or Medicine is also defined as a competent technical staff for manufacturing of drugs.

c. Approximately one lakh B. Pharmacy graduates are passing out from various pharmacy institutions in the country and hence there is no dearth of B. Pharmacy graduates in the country.

Subsequently, Central Council of the PCI unanimously resolved to suitably amend the conditions for grant of licence for manufacturing of drugs to the effect that only graduate in Pharmacy shall be defined as a competent staff for manufacturing of drugs.

Accordingly, PCI has requested to amendment the Drugs and Cosmetics Rules, 1945, providing that the qualification of competent technical staff to supervise the manufacturing of the drugs shall be a Graduate in Pharmacy/ Pharm.D. from an institution approved by the Pharmacy Council of India under the Pharmacy Act 1948 (VIII of 1948).

This matter was deliberated in 55th DCC meeting held on 31.01.2019 & 01.02.2019 and the DCC has recommended for addition of Pharm.D as one of the qualification for competent technical staff to supervise the manufacturing of drugs to the existing qualifications by amending the Drugs and Cosmetics Rules, 1945 wherever applicable. Accordingly, the proposal is placed before the DTAB.

DTAB deliberated the matter and agreed to amend the Drugs and Cosmetics Rules, 1945 to include Pharm. D degree as one of the qualifications for competent technical staff for manufacturing and testing of drugs.

AGENDA NO. 16

CONSIDERATION OF THE PROPOSAL TO CANCEL THE LICENSES OF THE MANUFACTURERS WHO DOES NOT DEPOSIT THE DEMANDED AMOUNT WITHIN THE PRESCRIBED TIME LIMIT GIVEN BY NPPA UNDER DPCO AND SIMILAR ACTION ON RETAILERS WHO INDULGE IN OVERCHARGING OF PRICING OF DRUGS/ MEDICAL DEVICES

The Board was apprised that, there is a recommendation that on 'Pricing of Drugs with special reference to Drugs (Prices Control) Order, 2013' to incorporate the necessary provisions under the Drugs and Cosmetics Rules, 1945 to enable the Licensing Authority to cancel the manufacturing licences for drugs, in case of the manufacturers fails to deposit the demanded amount within the prescribed time limit given by NPPA under DPCO and also requested to make similar cancellation provision for licences of retailers who indulge in overcharging of drugs/ medical devices.

Currently there is no provision under the Drugs and Cosmetics Act, 1940 and Rules, 1945 for cancellation and suspension of licences on pricing issue.

DTAB deliberated and did not agree to the proposal, as the objective of the Drugs and Cosmetics Act is to regulate the import, manufacture, distribution and sale of drugs and cosmetics.

ADDITIONAL AGENDA NO. S-1

CONSIDERATION OF THE PROPOSAL TO INCLUDE SURGICAL GOWNS, SURGICAL DRAPES AND INCISION DRAPES UNDER THE PURVIEW OF SECTION 3(B)(IV) OF THE DRUGS AND COSMETICS ACT, 1940 AS MEDICAL DEVICES

The Board was apprised that, the Ministry of Health and Family Welfare, Govt. 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. At present 23 notified medical devices are regulated under the said act. Further, Department of Health and Family Welfare, Ministry of Health and Family Welfare vide G.S.R. 5980(E) dated 03.12.2018 in pursuance of sub-clause (iv) of clause (b) of Section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, the following devices intended for use in human beings as drugs with effect from 01.01.2020, namely:

1. Nebulizer
2. Blood Pressure Monitoring Devices
3. Digital Thermometer and
4. Glucometer

Moreover, Department of Health and Family Welfare, Ministry of Health and Family Welfare vide G.S.R. 775 (E) dated 08.02.2019 In pursuance of sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the

Central Government, after consultation with the Drugs Technical Advisory Board has the following devices intended for use in human beings as drugs with effect from 01.04.2020, namely:

1. All implantable medical devices
2. CT scan Equipment
3. MRI Equipment
4. Defibrillators
5. Dialysis Machine
6. PET Equipment
7. X-Ray Machine and
8. Bone marrow cell separator

In addition to these initiatives, the Central Government under the chairmanship of DGHS w.r.t. the implementation of the decisions taken by Committee of Secretaries on Technical Textiles, it is proposed that surgical gowns, surgical drapes can be considered for notification under the said act in the meeting convened by the South India Textile Research Association (SITRA) on 05.10.2018 at Nirman Bhawan, New Delhi.

In this connection, a public notice was uploaded on CDSCO website on dated 27.11.2018 for the aforesaid matter and requested all the stakeholders to forward their comments/ suggestions within 45 days of the issue of this public notice.

Further, a meeting was held on 27.03.2019 for the regulation of surgical drapes and surgical gowns under the Section 3(b)(iv) of the Drugs and Cosmetics Act, 1940 wherein stakeholders were agreed for the regulation of said products. Therefore, it is proposed to regulate the surgical gowns, surgical drapes and incision drapes under the said Act.

DTAB deliberated the proposal and agreed to notify surgical gowns, surgical drapes and incision drapes under the Section 3(b)(iv) of the Drugs and Cosmetics Act, 1940**.**

ADDITIONAL AGENDA NO. S-2

CONSIDERATION OF THE PROPOSAL FOR THE PREPARATION OF ROAD MAP ON THE REGULATION OF ALL MEDICAL DEVICES IN A PHASE WISE MANNER ALONG WITH THE MANPOWER REQUIREMENTS

DTAB was apprised that, currently 23 categories of medical devices are regulated under the provisions of Drugs and Cosmetics Act, 1940.

Representations have been received from various stakeholders for regulating all non-notified medical devices since concerns have been raised from time to time in different fora regarding safety, quality and performance of various Medical Devices including diagnostic kits manufactured/imported in the country. Many of the Medical Devices like equipments, analyzers, instruments etc. used in various healthcare facilities for diagnosis, treatment, mitigation are currently out of scope of regulation under Drugs and Cosmetics Act.

Keeping in view the need for such comprehensive regulation of all medical devices, Ministry of Health and Family welfare, had constituted a committee vide order No.11035/61/ 2019-DR dated 04.02.2019. The committee after deliberations with industry stakeholders and concerned departments has submitted its report.

The recommendations of the committee are as follows:

A) All medical devices should be regulated in Drugs and Cosmetics Act, 1940 in a phase wise manner as following:

In the first phase, all manufacturers and importers of all non-regulated Medical Devices should register the details of the devices manufactured/imported by them in a special SUGAM portal to be developed for this purpose and a notification should be issued under the Act in this regard as proposed in the report.

- Such registration should be initially on voluntarily basis up to 18 months from the date of notification and thereafter, it should be made mandatory for all importers and manufacturers in the country.
- During this phase, all manufacturers and importers should report the Serious Adverse Events (SAEs) to CDSCO as well as Materiovigilance Programe of India (MvPI) so that these reports could be analysed to assess the safety and performance of the devices and take appropriate regulatory interventions to ensure patients safety.
- Similarly cases of complaints on such devices regarding failure in Quality Management System, design, product quality etc., should be reported to CDSCO for appropriate investigation and regulatory actions to ensure quality, safety and performance of the Medical Devices marketed in the country.

In the second phase, registration of Class A & B devices shall be followed by mandatory licensing within 12 months after 18 months of registration period is over i.e. for manufacture, import and marketing of all low risk Medical Devices falling under Class A & Class B, notified under 1st phase, requirement of prior license under Medical Devices Rules, 2017 should be made mandatory within 12 months after implementation of provision of registration under phase one. After the 12 months period, no person, company, organization should be allowed to manufacture, import, sale or distribute Class A & Class B Medical Devices without prior license under the Medical Devices Rules, 2017.

In the third phase, registration of Class C & D devices shall be followed by mandatory licensing within 24 months after 18 months of registration period is over i.e. all high risk Medical Devices falling under Class C & D notified under 1st phase, requirement of prior license under Medical Devices Rules, 2017 should be made mandatory within 24 months after implementation of provision of registration under phase one. After the 24 months period, no person, company, organization should be allowed to manufacture, import, sale or distribute Class C & Class D Medical Devices without prior license under the Medical Devices Rules, 2017.

The committee has proposed draft notification along with exemptions in this regard which are elaborated below:

"In pursuance of sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940(23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby specifies the following devices intended for use in human beings for the purposes referred to in the said sub-clause as drugs from 18 months after the date of this notification"

"*All Medical Devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assisted in its intended function by such means for one or more of the specific purposes of,-*

a) *diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;*
b) *diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;*
c) *Investigation, replacement or modification or support of the anatomy or of a physiological process;*
d) *supporting or sustaining life;*
e) *disinfection of Medical Devices;*
f) *control of conception;"*

I. Further, since this notification will cover all the Medical Devices, the provisions in MDR, 2017 will be automatically applicable to them without individual or class notification which is not the proposed transition scheme by way of registration. Therefore, an exemption needs to be given for obtaining license for import, manufacturing, clinical investigation and performance evaluation permission, test licence of such devices which would be first registered only, as mentioned above.

II. The exemptions can be given in the Rule 90 of MDR, 2017 by making amendment (addition to the Rules) as following:

Class of Medical Devices	***Extent and Condition of Exemption***
All devices notified as per definition under section 3b (iv) of Drugs & Cosmetic Act vide S.O. no…..dated…… Except those which are already notified or regulated presently	*Provisions of Medical Devices rules* *a) To obtain license for import/manufacturing for sale or for distribution* *b) To obtain permission to conduct clinical investigation or clinical performance evaluation.*

	c) To obtain permission to import or manufacturing for sale or for distribution of medical device/ new in-vitro diagnostic medical devices which do not have predicate medical device. *d) To obtain license for import/manufacturing for the purpose of clinical investigation, test, evaluation, examination, demonstration or training.* *These exemptions are valid for medical devices of Class A & B upto 30 months and for medical devices of Class C & D upto 42 months from the date of notification of these exemptions.* *Provided such device shall be registered with CDSCO on the special SUGAM online portal and shall bear the registration number issued by CDSCO to manufacturer or importer as per the procedure laid down in the guidelines issued by the CDSCO"* *Procedure for registration of such medical device and surveillance mechanism shall be as following:* • *To import or manufacture of such devices, the applicant will upload information and data as specified in the special SUGAM portal to obtain Registration.* • *Documents to be uploaded in the portal includes:-* 1. *Details of the manufacturer or importer and his products.* 2. *Certificate of compliance with respect to ISO 13485 standard accredited by NABCB/IAF.* 3. *Legal undertaking stating that device is complying with all relevant standards as per Rule 7 of Medical Devices Rules, 2017 and all documents including ISO 13485 Certification submitted by the applicant are true and authentic.*

	• *Once applicant submits above information on special SUGAM portal, Registration will be generated which shall be printed on label by the manufacturer or importer.* • *CDSCO shall verify the documents at any point of time and investigate quality/safety related failure/complaints and suspend/cancel the registration based on the findings/outcome of verification/investigation, after giving an opportunity to show cause to the registrant.*

B) The medical device vertical with respect to manpower and infrastructure to be established in CDSCO as per details provided below:

i. Considering that bringing all Medical Devices into regulatory control will lead to increase in work load considerably, the regulatory infrastructure including manpower need to be strengthened proportionately for ensuring efficient and transparent regulatory services for licensing as well as enforcement activities in a balanced manner.

ii. Therefore, the committee recommended for creation of vertical under CDSCO as below:

a. The vertical under Drugs Controller General (India) should be lead by an Additional Drugs Controller (India).

b. There should be four Joint Drugs Controller (India) to assist the Additional Drugs Controller (India), one each for specific function like -

i. Invasive Medical Devices

ii. Non-Invasive Medical Devices

iii. In-vitro Diagnostic Medical Devices

iv. MvPI, Enforcement, Legal and Training

c. There should be twelve Deputy Drugs Controllers (India), forty eight Assistant Drugs Controllers (India), One Hundred and ninety two each of Drugs Inspectors (Medical Device) and Assistant Drugs Inspectors (Medical Device).

d. Before implementation of second phase, the vertical should have the necessary manpower in line with the roadmap for bringing all Medical Devices under regulation.

e. There should be 71 data entry operators (3 for office of Additional Drugs Controller (I), 2 each for JDC(I), 1 for each for DDC(I), ADC(I) and 71 office assistants which may be hired through outside agency.

f. There should be experts as given below on deputation/contractual basis

S. No.	Expert and Specialist (Scale)	Post proposed
1	Orthopedician (7600)	3
2	Dermatologist (7600)	2
3	Surgeon (7600)	2
4	Biomedical engineers (6600)	20
5	Biocompatibility expert (6600)	1
6	Cardiologist (7600)	3
	Total	31

g. There should be 20 Research Associates having Post Graduate Qualification in areas of Bio-Medical Engineering/Bio-Technology/Microbiology to assist in developing various guidelines and review of materiovigilance data which may be hired through outside agency.

h. Further, the list of panel experts from various clinical fields including specialists in In-Vitro Diagnostics evaluation shall be utilized on the basis of need for Medical Devices including In-Vitro Diagnostics evaluation on the lines of Subject Expert Committees.

i. In addition to the above, following cells also need to be established utilizing the above mentioned permanent staff lead by Deputy Drugs Controller (I) and some outside expert on need basis namely:

- Materiovigilance cell
- IT cell
- Field Vigilance cell and Enforcement cell
- Training cell
- Information & Public education cell

j. In order to accommodate the manpower of Medical Device Vertical, minimum of 60,000 sq. ft additional space is required at Head Quarters.

iii. The committee also recommend that five laboratories should be set up within a span of five years for testing of various Medical Devices and In-vitro Diagnostics Medical device.

iv. Considering that each laboratory should have 1 Director, 4 Deputy Directors, 8 SSO, 16 JSO and 32 SAs, the committee recommended that there should be total 5 Director, 20 Deputy Directors, 40 SSO, 80 JSO and 160 SAs with adequate supporting staff.

v. The training of regulators, laboratory personnel and stakeholders should be conducted regularly and consultative mechanism at national and international

level with stakeholders and related organisations also need to be undertaken for seamless development of proper regulatory regime for Medical Devices including In-Vitro Diagnostics Medical Devices.

Therefore, in view of huge workload being undertaken by regulator and in order to further regulate the large number of Medical Devices/ equipments/ IVD's, it has been proposed to strengthen the medical device vertical with following regulatory officials, Laboratories personnel, experts and panel of experts in CDSCO.

Proposed Vertical for Medical Device in CDSCO under DCG(I)

S. No.	Regulatory officials	Strength
1	Additional Drugs Controller (I)	1
2	Joint Drugs Controller (I)	4
3	Deputy Drugs Controllers (I)	12
4	Assistant Drugs Controllers (I)	48
5	Drugs Inspector (Medical Device)	192
6	Assistant Drugs Inspector (Medical Devices)	192
	Total	449

Laboratories Personnel		
S. No.	**Designation (Scale)**	**Post proposed**
1	Director (8700)	5
2	Dy. Director (7600)	20
3	SSO Grade-I (6600)	20
4	SSO Grade-II (5400)	20
5	JSO (4800)	80
6	SA (4200)	160
	Total	305

Total of CDSCO regulatory officers and laboratories staff = 754

In addition to above, it is also proposed to recruit some experts on deputation or contractual basis for the following category:

S. No.	Expert and Specialist (Scale)	Post proposed
1	Orthopedicians (7600)	3
2	Dermatologists (7600)	2
3	Surgeons (7600)	2
4	Biomedical engineers (6600)	20
5	Biocompatibility expert (6600)	1
6	Cardiologists (7600)	3
	Total	31

DTAB deliberated the matter and agreed to notify all medical devices as drug under the Section 3(b)(iv) of the Drugs and Cosmetics Act, 1940 and also to provide exemptions in the Rule 90 of the Medical Device Rules, 2017 during the transition period. The Board further agreed that CDSCO should be strengthened with respect to manpower and infrastructure to regulate all medical devices. The Board further recommended to include dentists and ophthalmologists in the category of experts to be recruited.

The Board also recommended that manpower and infrastructure in all States should also be strengthened and an advisory may be issued to all the States in this regard.

ADDITIONAL AGENDA NO. S-3

CONSIDERATION OF THE PROPOSAL TO INCORPORATE THE PROVISION FOR COMPETENT PERSON IN FORM 20B & FORM 21B AND FOR QUALIFIED PERSON-IN-CHARGE IN FORM 20G UNDER SCHEDULE A OF THE DRUGS AND COSMETICS RULES, 1945

The Board was apprised that licences to sell, stock or exhibit or offer for sale or distribute drugs by retail (in Form 20, Form 20F & Form 21) and wholesale (in Form 20B, Form 20G & Form 21B) are issued under the provisions of the Drugs and Cosmetics Rules,1945.

In the Drugs and Cosmetics Rules, 1945, there is a provision in Form 20, Form 20F & Form 21 to mention name of qualified person in-charge and in Form 21B to mention name of competent person. However such provision is not there in Form 20B and Form 20G.

Under the conditions of licence in Form 20, Form 20F and Form 21 there is provision for reporting of any change in the qualified staff in-charge within one month of such change to the licensing authority (Point No. 3 under the conditions of licence in Form 20 and Point No. 2 under the conditions of licence in Form 20F & Form 21). But such provision under conditions of licence is not provided in Form 20B, Form 20G & Form 21B.

Representation has been received for incorporation of the provision for mentioning the name of competent person or qualified person-in-charge and incorporating condition of licence for reporting of any change in the competent person or qualified person-in-charge within one month to the licensing authority in Form 20B, Form 20G and Form 21B under Schedule A of the Drugs and Cosmetics Rules, 1945.

DTAB deliberated the proposal and agreed to amend the Drugs and Cosmetics Rules, 1945 to incorporate necessary provisions in this regard.

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

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