डॉ. राजीव सिंह रघुवंशी
औषधि महानियंत्रक (भारत)
केंद्रीय औषधि मानक नियत्रंण संगठन
स्वास्थ्य एवम परिवार कल्याण मंत्रालय
भारत सरकार
एफ.डी.ए. भवन, कोटला रोड
नई दिल्ली–110 0 0 2

सत्यमेव जयते

Dr. Rajeev Singh Raghuvanshi
Drugs Controller General (India)
Cental 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. 22-01/2024-DC

Date: 15/02/2024

To

Members of DTAB

Subject: Minutes of the 90th meeting of the Drugs Technical Advisory Board (DTAB) held on 25.01.2024 through Hybrid mode.

Sir/ Madam,

90th meeting of Drugs Technical Advisory Board was held on 25.01.2024 through Hybrid mode.

The minutes of the 90th meeting of Drugs Technical Advisory Board duly approved by the Chairman, is annexed for your information please.

Yours faithfully,

Dr. Rajeev Singh Raghuvanshi
Drugs Controller General (India)
Member Secretary (DTAB)

Encl: Copy of the minutes of meeting

Copy to:

1. PPS to DGHS, MoHFW, Nirman Bhawan, New Delhi
2. PS to Advisor (cost), MoHFW, Nirman Bhawan, New Delhi

MINUTES OF THE 90TH MEETING OF DRUGS TECHNICAL ADVISORY BOARD HELD ON 25.01.2024 AT 10.00 A.M. AT RESOURCE CENTRE ROOM NO (445-A), DGHS, NIRMAN BHAWAN, NEW DELHI (THROUGH HYBRID MODE)

PRESENT

1. Prof. (Dr.) Atul Goel, Chairman
   Director General of Health Services,
   Nirman Bhawan, New Delhi

2. Dr. Rajeev Singh Raghuvanshi, Member
   Drugs Controller General (India),
   FDA Bhawan, New Delhi

3. Dr. Saroj Kumar Ghosh, Member
   Director (I/C),
   Central Drugs Laboratory, Kolkata (Attended Online)

4. Dr. P Dhar, Member
   Principal Scientist,
   IVRI, Bareilly, U.P. (Attended Online)

5. Dr. Radha Rangrajan, Member
   Director, Central Drug Research
   Institute, Lucknow (Attended Online)

6. Dr. Sudam P Khade, Member
   Commissioner and Controller, FDA,
   Madhya Pradesh (Attended Online)

7. Dr. Hemant G. Koshia, Member
   Commissioner, FDCA, Gujarat

8. Shri. Sudhir Mehta, Member
   Chairman, Torrent Pharmaceuticals (Attended Online)

9. Dr. Jerin Jose Cherian, Member
   Scientist D,
   Division of Basic Medical Sciences, ICMR

10. Smt. J. L. Makwana, Member
    Govt. Analyst, Food & Drugs Laboratory,
    Vadodara, Gujarat (Attended Online)

11. Dr. J.A. Jayalal, National President, Indian Medical Association (Attended Online) — Member

12. Smt. Pramila N. D., Government Analyst, Drugs Testing Laboratories, Bengaluru, Karnataka (Attended Online) — Member

CDSCO REPRESENTATIVE

1. Shri. A. K. Pradhan,
   Joint Drugs Controller (I), CDSCO (HQ), New Delhi

2. Shri Sanjeev Kumar Gupta,
   Deputy Drugs Controller (I), CDSCO (HQ), New Delhi

3. Shri Aseem Sahu,
   Deputy Drugs Controller (I), CDSCO (HQ), New Delhi

4. Shri Ashish Kumar Rai,
   Assistant Drugs Controller (I), CDSCO (HQ), New Delhi

5. Shri Bibekananda Behera,
   Drugs Inspector (I), CDSCO (HQ), New Delhi

6. Shri Ranjeet Singh Patel,
   Drugs Inspector (I), CDSCO (HQ), New Delhi

The Board meeting was conducted through hybrid mode. Dr. Rajeev Singh Raghuvanshi, DCG(I), Member-Secretary, DTAB welcomed the Chairman of the Board Prof. (Dr.) Atul Goel, DGHS and all the esteemed members participating through physical and online mode for sparing their valuable time to deliberate various listed agendas. The Chairman of the Board greeted all attendees and had a brief introduction from all the members.

Thereafter, with the permission of the Chairman, Dr. Rajeev Singh Raghuvanshi, DCG(I) initiated the agenda-wise proceedings of the meeting for its deliberations.

AGENDA NO. 1

ACTION TAKEN REPORT (ATR) FOR 89th DTAB MEETING HELD ON 10.05.2023

The Action Taken Report (ATR) on the recommendations of DTAB in 89th meeting was approved by the Board.

AGENDA NO.2

CONSIDERATION OF THE PROPOSAL TO DISCUSS THE ISSUES OF MEDICATION SAFETY UNDER PATIENT SAFETY

There was a proposal to strengthen various regulatory activities related to patient safety which include the following:

- Strict enforcement of existing regulations including Schedule H1
- Central online register of all drugs and formulations available in the country
- Central online registration of drug (brand) name
- Patient friendly medicine name, labelling and packaging regulations and guidelines for manufacturers.
- Child proof packaging
- Ensuring good quality of the medicines are available in the market.
- Regulating off-label use of medicines
- Regulation of E-pharmacy or online pharmacies

Medication safety is increasingly being considered as a fundamental patient right and not as an option. Every patient has the right to receive effective medication in the safest possible manner.

DTAB deliberated the matter and agreed with proposal. Further the Board also discussed about self-medication and it was opined that DGHS office may issue an advisory to the public that self-medication of prescription drugs is harmful as well as detrimental to health and same needs to be avoided. Further the issue of same brand name (Including look alike and sound alike) for different category of products was also discussed during the meeting and it was opined that in order to ensure patient safety, the manufacturing and marketing of different drugs with same brand name should not be allowed and it was opined that the issue also needs to be deliberated in the DCC meeting. Further Board also suggested that opinion of States may also be taken during DCC meeting for having single licensing/ approving authority in the country. The Board also recommended for writing a letter by DGHS office to the Trademark authority regarding strict implementation of brand name especially in case of medicines.

AGENDA NO.3

CONSIDERATION OF PROPOSAL OF HAVING REGULATORY OVERSIGHT ON POST-APPROVAL CHANGES TO THE LICENSED PRODUCTS TO ENSURE THEIR QUALITY, SAFETY AND EFFICACY THROUGHOUT THE PRODUCT LIFECYCLE

The Board was apprised that post-approval Change is a change to any aspect of a pharmaceutical product, including but not limited to change in the method and

site of manufacture, specifications for the finished pharmaceutical product and ingredients, container, labelling, product information etc.

These changes may be made for the purpose of maintaining routine production, improving the quality attributes or improving the efficiency of manufacture or updating product labelling information. Any change to a licensed product may impact on the quality, safety and efficacy of the product and any change to the information associated to the product may impact on the safe and effective use of the product. These changes can be categorized as major, moderate and minor changes, depending on the potential of impact on the quality, safety and efficacy of the product and different regulatory approaches should be applied to guarantee the adequate regulatory oversight and different supporting data are needed to demonstrate and confirm the comparability of the "new" product manufactured with changes to the licensed product.

Further, the proposal was deliberated in the 61st DCC meeting and recommended that the rules should be amended to incorporate appropriate provisions under the Conditions of license to make it mandatory that the manufacturers provide the details of the critical/ major Post –approval changes to the licensing authority

DTAB deliberated the matter and agreed to incorporate appropriate provisions under the Conditions of license to make it mandatory that the manufacturers provide the details of the critical/ major Post –approval changes to the licensing authority and for small changes the manufacturer needs to notify the same.

AGENDA NO.4

CONSIDERATION OF THE PROPOSAL FOR FINALIZATION OF THE DRAFT G.S.R. 393(E) DATED 25.05.2022 FOR AMENDMENT IN THE SCHEDULE K OF THE DRUGS RULES, 1945 TO INCORPORATE NECESSARY PROVISIONS FOR DRUGS TO BE SOLD OVER-THE-COUNTER

The Board was apprised that based on the recommendation of the sub-committee of DTAB and as recommended by DTAB the Department of Health & Family Welfare had published a draft Gazette notification vide GSR 393(E) dated 25.05.2022 for amendment in the Schedule K of the Drugs Rules, 1945 to incorporate necessary provisions for drugs to be sold Over-The-Counter for providing exemptions from requirements of Sale license/ prescription of RMP etc. on recommendations of the 87th DTAB held on 08.11.2021.

In addition to above, there are individual's applications from some companies, details are as under: -

a) Intermed Laboratories Private Limited- **Diclofenac DiethylamineTransdermal Patch 200 mg**

b) M/s Reckitt Benckiser Private Limited- **Acetylsalicylic Acid effervescent 500 tablets**
c) Glenmark Private Limited- **Dextromethorphan HBr Lozenges 50 mg, Mometasone Furoate Nasal Spray 50 mcg**

DTAB deliberated the matter and recommended to constitute a sub-committee to examine the matter with reference to various conditions based on which status of a drug as an OTC is decided and a detailed mechanism is to be developed for the drugs to be considered as OTC. The Board also recommended for a comprehensive revisit of the draft notification for which international guidelines may also be considered and the sub-committee should submit its report to the Board.

AGENDA NO.5

CONSIDERATION OF THE PROPOSAL TO INCORPORATE PROVISION IN RULE 96 OF DRUGS RULES 1945 TO AFFIX BAR CODE OR QUICK RESPONSE CODE ON ITS PRIMARY PACKAGING LABEL OR, IN CASE OF INADEQUATE SPACE IN PRIMARY PACKAGE LABEL, ON THE SECONDARY PACKAGE LABEL ON ALL VACCINE THAT STORE DATA OR INFORMATION LEGIBLE WITH SOFTWARE APPLICATION TO FACILITATE AUTHENTICATION

The Board was apprised that WHO Benchmarking is a process of assessment of National Regulatory Authority (NRA) based on Global Benchmarking Tools (GBT) done by team from WHO. Global Benchmarking of vaccine is the tool followed by WHO that involves the implementation of various regulatory functions at relevant institute of India including CDSCO as NRA. In India, the last NRA assessment was carried out by WHO in the year 2017. As a prerequisite of WHO prequalification programme of vaccine, WHO has communicated for benchmarking of Indian NRA. Therefore, it is required to prepare for the same by CDSCO and State Regulators.

Marketing Surveillance and Control is one of the important function amongst the nine functions of WHO Benchmarking tool audited by WHO NRA assessment team. Under the above function, there is sub-indicator MC 1.05 which is as below; - "*MC01.05: Legal provisions and/or regulations exist for placement of a product's **unique identification number** on its outer packaging"* under first indicator "*MC01: - Legal provisions, regulations and guidelines required to define regulatory framework of market surveillance and control activities"*.

In this regard, Government of India vide Gazette notification GSR 449 (E) dated 3rd June 2015 published a draft rule for tracking and tracing of product which was not finalized. Further, gazette notification vides no. GSR 20 (E) was published on 18th Jan, 2022 for bearing "Quick Response Code" on label at each level of packing for Active Pharmaceutical Ingredients.

Further, draft gazette notification vide no. GSR 448 (E) was published on 14th June, 2022 which was finalised vide no. GSR 823 (E) dated 17th November, 2022 which is reproduced as below: -

"The manufacturers of drug formulation products as specified in Schedule H2 shall print or affix Bar Code or Quick Response Code on its primary packaging label or, in case of inadequate space in primary package label, on the secondary package label that store data or information legible with software application to facilitate authentication.

This is applicable for 300 brands of different products, inserted as Schedule H2 after Schedule H1 and this includes 7 brands of vaccines as below: -

1. EASY SIX PREFILLED SYRINGE 0.5 ML
2. HEXAXIM INJECTION 0.5 ML
3. INFANRIX HEXA INJECTION 0.5 ML
4. MENACTRA INJECTION 0.5 ML
5. PREVENAR 13 INJECTION 0.5 ML
6. SYNFLORIX INJECTION 1
7. VARILRIX INJECTION 0.5 ML

This rule has become effective from 1st August 2023. However, to fulfil the requirements of sub indicator 1.05 of function "Marketing Surveillance and Control" under Global Benchmarking Tools for Maturity Level 4, it is required to make legal provision/ regulations for affixing of***unique identification number*** *on outer packaging"* of each vaccine product.

In view of the above, it has been proposed to meet the WHO expectation in the GBT and obtain Maturity Level 4 in the sub indicator 1.05 of function "Marketing Surveillance and Control" under Global Benchmarking Tools, it is required to affix ***unique identification number*** *on outer packaging"* of each vaccine product.

DTAB deliberated the matter and agreed for the proposal to affix Bar Code or Quick Response Code on all vaccine products. Further the same may be extended to all antimicrobials, narcotic & psychotropic substances in a phase wise manner. The Board also recommended that implementation of existing system of QR Code in the states for top 300 brands shall also be monitored.

AGENDA NO.6

CONSIDERATION OF THE PROPOSAL TO AMEND ENTRY NO.33 OF SCHEDULE K TO INCLUDE NICOTINE ORALLY DISINTEGRATING STRIPS ALONG WITH NICOTINE GUMS AND LOZENGES FOR EXEMPTION FROM THE PROVISION OF SALE LICENSE

The Board was apprised that DTAB in its 89th meeting held on 10.05.2023 deliberated the said agenda and recommended that ICMR should be requested to give comments/ inputs for taking further action in the matter.

Accordingly, based on the recommendation of DTAB, an OM dated 11.08.2023 was forwarded to ICMR to provide inputs/ comments in the subject matter for taking further necessary actions.

In this regard, ICMR has forwarded their inputs/ comments in the matter mentioning that though NRTs are efficacious there is a chance of abuse potential of OTC NRT among non-smokers and smokers. Accordingly, ICMR has recommended that all NRTs should used under medical supervision and to be available on prescription only.

DTAB deliberated the matter and agreed with the report of the ICMR. Further DTAB recommended to make appropriate amendments in the rules based on ICMR recommendations.

AGENDA NO.7

CONSIDERATION OF THE PROPOSAL TO BAN VETERINARY USE OF ALL FORMULATIONS OF DRUG NIMESULIDE FOR VULTURE CONSERVATION

The Board was apprised that Bombay Natural History Society (BNHS) had stated that one of the most important extant risks that the vulture populations in India are still facing is the veterinary use of Nimesulide. to treat cattle. Nimesulide - similar to diclofenac, aceclofenac and ketoprofen - have been found to be toxic to vultures, leading to mortality through visceral gout and renal failure.

Additionally, the MOEF&CC supported the safety-testing of Nimesulide on vultures carried out collaboratively by the BNHS and the Indian Veterinary Research Institute (IVRI). As mentioned in the Summary of annual report (2021-22) Project: "Assessing the Safety of Vultures (Gyps Spp.) of Non-Steriodal Anti-Inflammatory Drugs in Veterinary Use in India of The vultures treated with Nimesulide died by 24 hours post treatment (kindly refer letter no. F. No. 141/TTNM/2022-21/CWL dated01/08/2022 and annual report attached herewith.

Based on this background, alongside recommendation of ban on veterinary use of aceclofenac and ketoprofen, it was requested to consider ban on veterinary use of all formulations of Nimesulide.

Since Nimesulide, Aceclofenac and Ketoprofen are also used to treat humans, their ban must cover manufacture, distribution, sale, and use of bolus and injectable formulations in doses fit for large animals (vials > 3 ml). This would help in avoiding the possible loophole of relabeling larger vials (used for veterinary purposes) as multi-dose vials for humans, which could then be readily misused. Also, along with the ban, issuing appropriate instructions to the manufacturers of Aceclofenac, Ketoprofen and Nimesulide to destroy existing stock of drugs may kindly be considered.

Further, In the High Court of Delhi at New Delhi in the hearing vide order dated-01.09.2023 of case W.P.(C) 7493/2022&CM APPL. 22886/2022 Gaurav Kumar Bansal Vs Union of India directed to furnish the reason as to why the drug 'Nimesulide' has not been banned, and deliberations undertaken in this regard.

DTAB deliberated the matter and agreed to ban on veterinary use of all formulations of Nimesulide. Further it was decided that ICMR may also be requested to study the effect of Nimesulide on adult Human beings for further course of action in light of the fact that nimesulide drug has been prohibited in children below 12 years of age.

AGENDA NO.8

CONSIDERATION OF CERTAIN PROPOSALS FOR RE-DELIBERATIONS

The Board was apprised that there are 20 agenda which were already deliberated in various DTAB meetings and the recommendations were forwarded to the Ministry for further action including publication of draft rules etc.

Ministry has informed that after receipt of the above said proposals for the amendments, a number of major/important notifications for amendment of rules under the Drugs and Cosmetics Act, 1940 have been issued. Accordingly, while drafting the proposed amendments, the same may be required to be considered and required to be critically reviewed and revised in context of updated rules and recent notifications.

Accordingly, the proposals for re-deliberated in 90th DTAB meeting

AGENDANO. 8.1

CONSIDERATION OF THE PROPOSAL TO ADD PROVISIONS IN RESPECT OF THE WAIVER OF EVALUATION FOR IVDs, IN-LINE WITH WAIVER GIVEN FOR MEDICAL DEVICE UNDER RULE 63 OF MEDICAL DEVICES RULES, 2017

The said agenda was earlier deliberated in 79th DTAB held on 16.05.2018 (Ag. No. 10.2) wherein it was proposed to add identical provisions in rule 64 of MDR, 2017 for in-vitro Diagnostic Devices similar to that of Rule 63 of MDR, 2017 regarding permission to import or manufacture of Medical devices which does not have any predicate devices.

DTAB was apprised about the details in this regard.

DTAB deliberated the matter and did not agree to consider the proposal in present context.

AGENDA NO. 8.2

CONSIDERATION OF THE PROPOSAL TO AMEND MDR, 2017 IN A MANNER WHEN MEDICAL DEVICES WHICH ALREADY EXIST IN THE INDIAN MARKET FOR USE ARE BROUGHT IN FUTURE UNDER REGULATION, AND THEN SUCH DEVICES SHALL NOT BE A NEW MEDICAL DEVICE

The said agenda was earlier deliberated in 79th DTAB held on 16.05.2018 (Ag. No. 10.3) wherein it was proposed that when a medical device which already exists in the Indian Market for use are brought in future under regulation, then such devices shall not be a new medical device.

DTAB was apprised about the details in this regard.

DTAB deliberated the matter and recommended that the list of such old devices may be prepared which may be placed before the Board for further deliberation.

AGENDA NO. 8.3

CONSIDERATION OF THE PROPOSAL TO AMEND MEDICAL DEVICES RULES, 2017 TO AMEND THE DEFINITION AND APPLICABILITY CLAUSE FOR THE INCLUSION OF DISINFECTANTS

The said agenda was earlier deliberated in 79th DTAB held on 16.05.2018 (Ag. No. 10.11) wherein it was proposed to amend the definition and applicability clause for the inclusion of disinfectants under the MDR, 2017.

DTAB after deliberation recommended for amendment of the definition of medical devices in clause (ii) of rule 2 and clause (ii) of rule 3(zb) as under:

"For the words "substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified under sub-clause (ii); following is proposed to be substituted: "disinfectants that are used to pre-clean or decontaminate medical devices prior/after to patient use and substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), notified under sub-clause (ii).

Further, the Board also recommended for allied amendments in preamble/scope in the rules."

DTAB was apprised about the details in this regard. DTAB deliberated the matter and agreed for the proposed amendment.

AGENDA NO. 8.4

CONSIDERATION OF THE PROPOSAL TO AMEND THE MEDICAL DEVICES RULES, 2017 TO ALLOW AUDIT OF THE MANUFACTURING SITE OF CLASS B, AFTER GRANT OF THE LICENSE TO MANUFACTURE, AS IN CASE OF CLASS A MEDICAL DEVICES

The said agenda was earlier deliberated in 80th DTAB held on 25.07.2018 (Ag. No. S-1) wherein it was proposed to amend the Medical Devices Rules, 2017 to allow audit of the manufacturing site of Class B, after grant of the license to manufacture, as in case of Class A Medical Devices.

DTAB was apprised about the details in this regard.

DTAB deliberated the matter and did not agree in the present context.

AGENDANO. 8.5

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

The said agenda was earlier deliberated in 82nd DTAB held on 02.04.2019 (Ag. No. 8.1) wherein it was proposed 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.

Fifth Schedule 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. It is proposed for

amendment of Fifth Schedule of Medical Device Rules, 2017in line with ISO 134185: 2016.

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

DTAB after deliberation agreed for the proposal and recommended to amend the Fifth Schedule of the Medical Device Rules, 2017 to incorporate necessary provisions in this regard.

DTAB was apprised about the details in this regard.

DTAB deliberated the matter and agreed for the proposal.

AGENDANO. 8.6

CONSIDERATION OF THE PROPOSAL TO AMEND FORM MD-11 UNDER THE MEDICAL DEVICES RULES 2017

The said agenda was earlier deliberated in 83rd DTAB held on 11.06.2019 (Additional Ag. No. S-3) wherein it was proposed to amend Form MD-11 under the Medical Devices Rules, 2017.

DTAB was apprised about the details in this regard.

DTAB deliberated the matter and agreed for the proposal.

AGENDA NO. 8.7

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

Matter was earlier deliberated before the DTAB in its 82nd meeting (Ag No 13) held on 02.04.2019 wherein it was proposed to amend the Drugs Rules, 1945 for incorporating a provision in Form 20D for mentioning the name of competent person-in-charge as it is mentioned in Form 20C and Form 20E.

DTAB was apprised about the details in this regard.

DTAB deliberated the matter and recommended to take opinion of Ayush Ministry for further consideration.

AGENDANO. 8.8

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 RULES, 1945

Matter was earlier deliberated before the DTAB in its 82nd meeting (Ag No S-3) held on 02.04.2019 wherein it was proposed to amend the Drugs Rules, 1945 for incorporating a provision in Form 20D for mentioning the name of competent person-in-charge as it is mentioned in Form 20C and Form 20E.

DTAB after deliberation agreed to amend Drugs Rules, 1945 for incorporating a provision in Form 20D for mentioning the name of competent person-in-charge as it is mentioned in Form 20C and Form 20E.

DTAB was apprised about the details in this regard.

DTAB deliberated the matter and agreed for the proposal.

AGENDANO. 8.9

CONSIDERATION OF THE PROPOSAL TO AMEND DRUGS RULES, 1945 FOR INCLUDING MANDATORY PROVISION OF PHARMACEUTICAL COMPANIES TO SPEND AT LEAST ONE PER CENT OF THEIR NET PROFIT FOR PROVIDING FREE MEDICINES IN MEDICINE BANK TO BE USED BY THE CENTRAL GOVERNMENT DURING HEALTH EMERGENCIES, DISASTER OR ANY OTHER CIRCUMSTANCES CONSIDERED NECESSARY BY THE CENTRAL GOVERNMENT AS PART OF CORPORATE SOCIAL RESPONSIBILITY (CSR)

Matter was earlier deliberated before the DTAB in its 79th meeting (Ag No 9) held on 16.05.2018 wherein it was proposed to amend the Drugs Rules, 1945.

DTAB was apprised about the details in this regard.

DTAB deliberated the matter and opined that MoHFW may consider to write to Corporate Ministry for their opinion

AGENDANO. 8.10

CONSIDERATION OF THE PROPOSAL TO AMEND DRUGS AND COSMETICS RULES, 1945 TO INCORPORATE A PROVISION OF APPROVAL OF THE LAYOUT PLAN OF MANUFACTURING SITE BEFORE GRANT OF LICENCE FOR THE SITE TO MANUFACTURE FOR SALE OF DRUGS

Matter was earlier deliberated before the DTAB in its 79th meeting (Ag No 22) held on 16.05.2018 wherein it was proposed to amend the Drugs Rules, 1945.

DTAB was apprised about the details in this regard.

DTAB deliberated the matter and agreed for the proposal for approval of the layout plan of manufacturing site jointly by the State and CDSCO authorities before grant of licence for the site to be licensed for manufacture for sale of drugs.

AGENDA NO. 8.11

CONSIDERATION OF THE PROPOSAL FOR EXEMPTION UNDER PARA 15 OF DMR(OA), 1954 TO COMMUNICATE "FEVER" FOR CREATING PUBLIC AWARENESS ON MANAGEMENT OF FEVER ASSOCIATED WITH COMMON SELF-LIMITING CONDITIONS SUCH AS FEVER ASSOCIATED WITH COMMON COLD AND FLU, DENGUE, CHIKUNGUNYA, FEVER ASSOCIATED WITH VACCINATION ETC.

Matter was earlier deliberated before the DTAB in its 80th meeting (Ag No 11) held on 25.07.2018 wherein it was proposed for exemption under Section 15 of Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 to communicate "Fever" for creating public awareness on management of fever associated with common self-limiting conditions such as fever associated with Common Cold and Flu, Dengue, Chikungunya, fever associated with vaccination etc. The Board further clarified that the exemption under Section 15 of DMR (OA)shall be provided for generic name of Paracetamol to communicate fever and not for Brand name.

DTAB was apprised about the details in this regard.

DTAB deliberated the matter and did not agree to the proposal in the present context.

AGENDA NO. 8.12

CONSIDERATION OF THE PROPOSAL FOR ALLOWING DRUG SUBSTITUTION FOR JAN AUSHADHI STORES UNDER PMBJP FOR PROMOTION OF QUALITY GENERIC MEDICINES AT AFFORDABLE PRICES

Matter was earlier deliberated before the DTAB in its 81st meeting (Ag No 6) held on 29.11.2018 wherein it was proposed to amend rule 65(11A) of the Drugs and Cosmetic Rules 1945 for allowing substitution of drugs specified in Schedule H, Schedule H1 or Schedule X with drugs containing same substance, strength and dosage form only in Jan Aushadhi stores under Pradhan MantriBhartiya Jan AushadhiPariyojana (PMBJP) for promotion of quality generic medicines at affordable prices.

DTAB was apprised about the details in this regard.

DTAB deliberated the matter and recommended that a sub-committee may be constituted for further detailed deliberation before consideration. The Board also suggested to include one member from National Medical Commission (NMC) in the sub-committee**.**

AGENDA NO. 8.13

CONSIDERATION OF THE PROPOSAL FOR AMENDMENT OF RULE 96 UNDER DRUGS & COSMETICS RULES, 1945 FOR DISCLOSURE OF PRICES AT FIRST POINT OF SALE/PRICE TO TRADE (PTT)/ EX-FACTORY PRICE OR IMPORT PRICE ALONG WITH MRP

DTAB was apprised about the details in this regard.

DTAB deliberated the matter and suggested to refer the matter to NPPA.

AGENDANO. 8.14

CONSIDERATION OF THE PROPOSAL TO AMEND DRUGS RULES, 1945 TO PROHIBIT ADVERTISEMENTS OF DRUGS SPECIFIED IN SCHEDULE G

Matter was earlier deliberated before the DTAB in its 81st meeting (Ag No S-2) held on 29.11.2018 wherein it was proposed to prohibit the advertisements of drugs specified in Schedule G under Drugs Rules, 1945.

DTAB was apprised about the details in this regard.

DTAB deliberated the matter and agreed for the proposal.

AGENDANO. 8.15

CONSIDERATION OF THE PROPOSAL TO AMEND DRUGS RULES, 1945 FOR DECLARING THE NOT OF STANDARD QUALITY (NSQ) DRUGS UNDER DIFFERENT CATEGORIES BY REGULATORY AUTHORITIES

Matter was earlier deliberated before the DTAB in its 79thmeeting (Ag No 13) held on 16.05.2018 wherein it was proposed to amend the Drugs Rules, 1945 for categorizing the Spurious, Adulterated & Not of Standard Quality drugs for the purpose of taking action in this regard.

DTAB was apprised about the details in this regard.

DTAB deliberated the matter and opined that the Drugs, Medical Devices and Cosmetics Bill is under consideration to the Ministry. Therefore, the proposed agenda may not be considered in the present context.

AGENDA NO. 8.16

CONSIDERATION OF THE PROPOSAL FOR NOTIFICATION AND RECOGNITION OF THE INDIAN INSTITUTE OF INTEGRATIVE MEDICINE (IIIM), JAMMU AS CENTRAL DRUGS LABORATORY (CDL) FOR TESTING OF PHYTOPHARMACEUTICAL CLASS OF DRUGS

Matter was earlier deliberated before the DTAB in its 81st meeting (Ag No 14) held on 29.11.2018 wherein it was proposed for notification of Indian Institute of Integrative Medicine (IIIM), Jammu as Central Drugs Laboratory (CDL) for testing of Phytopharmaceutical drugs under the provisions of Drugs Rules, 1945 subject to the condition that the institute should provide dedicated lab facility to act as an independent laboratory as CDL separated from the research and manufacturing facilities of the institute.

DTAB after deliberation agreed for notification of Indian Institute of Integrative Medicine (IIIM), Jammu as Central Drugs Laboratory (CDL) for testing of Phytopharmaceutical drugs under the provisions of Drugs and Cosmetics Rules, 1945 subject to the condition that the institute should provide dedicated lab facility to act as an independent laboratory as CDL separated from the research and manufacturing facilities of the institute.

DTAB was apprised about the details in this regard.

DTAB deliberated the matter and recommended that the area as well as personnel working in manufacturing facility and testing laboratory of Indian Institute of Integrative Medicine (IIIM), Jammu should be separate to avoid any conflict of interest and same need to be verified for further action in the matter.

AGENDA NO. 8.17

CONSIDERATION OF THE RECOMMENDATIONS OF THE SUB-COMMITTEE OF DTAB ON HOMEOPATHY FOR AMENDMENT OF DRUGS RULES, 1945

Matter was earlier deliberated before the DTAB in its 81st meeting (Ag No 17) held on 29.11.2018 wherein it was proposed to amend the Drugs Rules, 1945 as per recommendations of the Sub-committee of DTAB on Homeopathy.

DTAB was apprised about the details in this regard.

DTAB deliberated the matter and suggested that matter may be referred to Ministry of AYUSH for examination and recommendation in the matter.

AGENDA NO. 8.18

CONSIDERATION OF PROPOSAL FOR AMENDMENT OF RULE 121 PERTAINING TO TEST FOR PYROGENS UNDER THE DRUGS AND COSMETICS RULES, 1945

Matter was earlier deliberated before the DTAB in its 84th meeting (Ag No 6) held on 27.08.2019 wherein it was proposed to amend rule 121 of the Drugs Rules, 1945 in line with IP 2018 regarding test for pyrogen.

DTAB was apprised about the details in this regard.

DTAB deliberated the matter and agreed for the proposal.

AGENDANO. 8.19

CONSIDERATION OF THE PROPOSAL TO AMEND THE DRUGS RULES, 1945 FOR MAKING A PROVISION FOR IMPORT OF DRUGS FOR TREATMENT OF PATIENTS SUFFERING FROM RARE DISEASE WHICH IS LIFE THREATENING OR CAUSING SERIOUS PERMANENT DISABILITY FOR WHICH THERE IS NO THERAPY

Matter was earlier deliberated before the DTAB in its 84th meeting (Ag No S-5) held on 27.08.2019 wherein it was proposed to amend the Drugs Rules, 1945 to include the provision for import of drugs for treatment of patients suffering from rare disease which is life threatening or causing serious permanent disability for which there is no therapy.

DTAB was apprised about the details in this regard.

DTAB deliberated the matter and recommended that the proposal may not be considered in the present context.

AGENDA NO. 8.20

CONSIDERATION OF THE PROPOSAL FOR AMENDMENT OF PARA 10.9 OF SCHEDULE M OF DRUGS RULES, 1945 FOR WAIVER OF REQUIREMENT FOR VACCINES MANUFACTURED USING LESS THAN 60% RESIDUAL SHELF-LIFE PERIOD IN THE COUNTRY

DTAB was apprised about the details in this regard.

DTAB deliberated the matter and opined that the matter has already been addressed in the revised Schedule M hence no further action required.

AGENDA NO.9

CONSIDERATION OF THE PROPOSAL REGARDING W.P(C) 10098 OF 2018, M/S EMCURE HEALTHCARE LTD. VERSUS DRUGS CONTROLLER GENERAL (INDIA) & ANR, BEFORE HON'BLE DELHI HIGH COURT AT NEW DELHI FOR FDC OF S(+) ETODOLAC+ PARACETAMOL

The Board was apprised that in light of the 78th DTAB dated 12.02.2018 and as per Supreme Court order dated 15.12.2017 pertaining to the notifications issued by GoI prohibiting the manufacture, sale and distribution of 344 FDCs + 5 FDCs vide S.O. Nos. 705(E) to 1048 (E) dated 10.03.2016 and S.O. no. 1854 (E) to 1855 (E) dated 08.06.2017, the Board constituted the subcommittee on 19.02.2018 under the Chairmanship of Dr.Nilima Kshirsagar, for evaluation of 349(344+5) FDCs. Accordingly, on 19.07.2018 the sub-committee recommended that 343 FDCs be prohibited and that 6 be restricted/regulated. 03 needed to be restricted for specific indications. 03 other FDCs were recommended to be restricted to specific quantities/strengths of ingredients and for specific indications.

Based on recommendation of DTAB, the Central Government has prohibited the subject FDC vide S.O. 4706 (E) dated 07.09.2018 with the reasons that "the FDC may involve risk to human beings. Hence, in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26A of Drugs & Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended."

M/s. Emcure Pharmaceuticals Ltd., filed W.P. (C) 10098/2018 in High Court of Delhi, challenged the Notification S.O.No 4706(E) dated 07.09.2018 for prohibiting the manufacture, sale and distribution for human use of FDC drug S(+) Etodolac + Paracetamol.

As per the Judgment dated 22.01.2020 by the Hon'ble Delhi High Court that "This court is of the view that the Impugned Notification, is so far as it is stated to be applicable to the FDC of S(+) Etodolac + Paracetamol, cannot be sustained. The

same is set aside. The matter is remanded back to DTAB/Sub-committee constituted by it to examine the issue regarding the said FDC in accordance with the directions issued by the Supreme Court in Pfizer Limited and others (Supra). The DTAB/Sub-Committee shall submit its report to the Central Government who may act thereon in accordance with law."

The Drugs Technical Advisory Board in its 88th meeting held on 26.09.2022 deliberated the issue relating to ban of FDC of S(+ Etodolac + Paracetamol vide notification S.O. 4706 (E) dated 07.09.2018 for human use in light of the judgment of Hon'ble High Court of Delhi dated 22.01.2022 and recommended for constitution of a Sub-committee under the Chairpersonship of Dr.Lalit Kumar Gupta, Director Prof., Department of Pharmacology, LHMC and Associated Hospitals, New Delhi to examine the issue regarding the said FDC.

Accordingly, a Sub-Committee was constituted under the Chairmanship of Dr.Lalit Kumar Gupta, Director Prof., Department of Pharmacology, LHMC and Associated Hospitals, New Delhi vide OM no. 14-38(56/2018-DC) dated 15.12.2022.

The Sub-Committee evaluated the replies/clarifications presented by the firms which were received by CDSCO in response to the notices issued in respect of the said FDC considered as Irrational by the Dr.Nilima Kshirsagar Sub-Committee.

DTAB deliberated the matter and agreed for prohibiting the manufacture, sale and distribution for human use of FDC drug S(+) Etodolac + Paracetamol.

AGENDA NO.10

CONSIDERATION OF THE PROPOSAL TO AMEND DRUGS RULES, 1945 TO REGULATE ALCOHOL CONTENT IN TINCTURES/ OTHER ALCOHOLIC PREPARATIONS TO CURB THEIR ILLEGAL SALE ACROSS PHARMACIES

The Board was apprised that representation was received to take necessary action to amend the provisions in the Drugs and Cosmetics Act and Rules thereunder with respect to the misuse of the drugs containing alcohol/ tincture.

The proposal was deliberated in 61st DCC meeting held on 01.06.2023 wherein the committee recommended that the rules may be amended and exemption provided for alcoholic preparations containing the alcohol content 30ml or above in Schedule K may be removed and such preparation may be included in Schedule H1. The Committee recommended for suitable amendments in Drugs Rules, 1945 to restrict pack size of these item to maximum 30ml.

DTAB deliberated the matter and agreed that the rules may be amended and exemption provided for alcoholic preparations containing the alcohol content 30ml or above in Schedule K may be removed and such preparations may be included in Schedule H1.

AGENDA NO.11

CONSIDERATION OF PROPOSAL FOR INCLUSION OF NEW FORM FOR THE ISSUANCE OF TEST REPORT BY THE REGISTERED MEDICAL DEVICE TESTING LABORATORY UNDER RULE 85 OF MEDICAL DEVICES RULES, 2017

The Board was apprised that Chapter X of Medical Devices Rules, 2017 provides provision for grant of registration of a medical device testing laboratory to carry out testing or evaluation of a medical device on behalf of a licensee for manufacture for sale. The Central Licensing Authority, after satisfying the requirements as laid down in rules, shall grant registration to the applicant.

As there is no specific proforma for issuance of the test report by the registered medical device testing laboratory in the Medical Devices Rules, 2017, therefore, in order to have uniform reporting of result of the test(s) carried out by the lab, a suitable proforma having minimum requirement shall be incorporated in the Medical Devices Rules, 2017. A new provision and draft Form is proposed as under for necessary amendment in the Rule:

DTAB deliberated the matter and agreed for the proposed inclusion of new Form for the issuance of test report by the registered medical device testing laboratory under rule 85 of medical devices rules, 2017

AGENDA NO.12

CONSIDERATION OF PROPOSAL FOR AMENDMENT IN THE FORM MD-34, FORM MD-35, FORM MD-36, FORM MD-37 AND FORM MD-38 OF MEDICAL DEVICES RULES, 2017

The Board was apprised that on review of the Forms prescribed in the Medical Devices Rules, 2017, it has been observed that Form MD-34, Form MD-35, Form MD-36, Form MD-37 and Form MD-38 require certain corrections and modifications in respect of present practices being followed and in the light of online provisions.

DTAB deliberated the matter and agreed for the proposed amendment in the Form MD-34, Form MD-35, Form MD-36, Form MD-37 and Form MD-38 of Medical Devices Rules, 2017.

AGENDA NO.13

CONSIDERATION OF PROPOSAL FOR AMENDMENT IN THE SR NO 39 (H) OF THE SECOND SCHEDULE OF MEDICAL DEVICES RULES, 2017

The Board was apprised that on review of the Fee payable for the retention of Import license for in vitro diagnostic medical device prescribed in the Medical Devices Rules, 2017, the statement “one overseas site manufacturing Class C or Class D

medical device other than in vitro diagnostic medical device" is found repeated at Sr no. 34 (c) and Sr no 39(h) of the Second Schedule of MDR-2017.

The subject statement at Sr no. 39(h) of Second Schedule of MDR-2017 is mentioned as "one overseas site manufacturing Class C or Class D medical device other than in vitro diagnostic medical device" instead of "one overseas site manufacturing Class C or Class D in vitro diagnostic medical device". This may be due to typographical error and hence require certain corrections.

The correction in the respective fee payable in Second Schedule is proposed as under for consideration.

DTAB deliberated the matter and agreed for the proposed amendment in the SR. No. 39 (h) of the second schedule of medical devices rules, 2017.

AGENDA NO.14

CONSIDERATION OF PROPOSAL FOR INCLUSION OF FORM MD-11 AS INSPECTION BOOK THAT NEEDS TO BE MAINTAINED BY THE REGISTERED MEDICAL DEVICE TEST LABORATORY UNDER RULE 85 OF MEDICAL DEVICES RULES, 2017 IN ORDER TO ENABLE THE MEDICAL DEVICE OFFICER TO RECORD NON-COMPLIANCE WITH THE PROVISIONS OF THE ACT AND RULES MADE THEREUNDER

The Board was apprised that Chapter X of Medical Devices Rules, 2017 provides provision for grant of registration of any medical device testing laboratory to carry out testing or evaluation of a medical device on behalf of a licensee for manufacture for sale. The Central Licensing Authority, after satisfying the requirements as laid down in rules, shall grant registration to the applicant.

There is no specific proforma for maintaining the record of non-compliances observed during the inspection of the registered Medical Device Testing Laboratory in the Medical Devices Rules, 2017. However, for the audit or inspection of the manufacturing premises by the Notified Body or Medical Device Officer, a Form MD-11 is prescribed in MDR-2017 as per provisions under Rule 26 of MDR-2017 for the record of observations and non-conformity (if any).

In order to have a proforma for recording of non-compliance raised by the Medical Device Officer at the premises of Medical Device Testing Laboratory, provision in the existing Form MD-11 may be incorporated and the Rule 85 (ix) may be amended accordingly.

DTAB deliberated the matter and agreed for inclusion of Form MD-11 as inspection book that needs to be maintained by the registered medical device test laboratory under Rule 85 of Medical Devices Rules, 2017 in order to enable the medical device officer to record non-compliance with the provisions of the act and rules made thereunder.

AGENDA NO.15

CONSIDERATION OF PROPOSAL FOR INCLUSION OF STATEMENT ON VALIDITY PERIOD (PERPETUAL) AND DATE OF ISSUE IN THE FORM MD-2, FORM MD-5, FORM MD-6, FORM MD-9, FORM MD-10, FORM MD-15 AND FORM MD-40 OF MEDICAL DEVICES RULES, 2017

The Board was apprised that in the Medical Devices Rules, 2017, the validity of licenses or registration certificate granted under respective rules (29, 37,13(7) and 84) shall remain in perpetuity, unless, it is suspended or cancelled or surrendered, provided that the registration certificate holder or license holder deposits a retention fee as specified in the Second Schedule every five years from the date of its issue.

However, on the review of the Forms prescribed in the Medical Devices Rules, 2017, it has been observed that though the licenses/registration certificates issued under MDR-2017 are in perpetuity, there is no mention of any statement on the period of the retention and the date of issue of the license/ registration certificate on the requisite Forms prescribed in the MDR-2017.

For not having the date of issue and the period of retention in the license/ registration certificate, it is difficult for the stakeholders to figure out the validity of the same.

In the case of Drugs and Cosmetics, where the license is issued in perpetuity, these informations are very much clearly mentioned on the licenses/registration certificates.

In order to have more clarity and transparency on the period of the retention and the date of issue of the license/registration certificate, it is appropriate to mention these informations in the respective Forms.

Therefore, to capture the period of the retention and the date of issue of license or registration certificate issued by the concerned licensing authority, the Forms MD-2, Form MD-5, Form MD-6, Form MD-9, Form MD-10, Form MD-15 and Form MD-40 may be amended in line with the Forms prescribed in the Drugs Rules, 1945 and Cosmetics Rules 2020

DTAB deliberated the matter and agreed for inclusion of statement on validity period (perpetual) and date of issue in the Form MD-2, Form MD-5, Form MD-6, Form MD-9, Form MD-10, Form MD-15 and Form MD-40 of medical devices rules, 2017.

AGENDA NO.16

CONSIDERATION OF PROPOSAL TO AMEND MEDICAL DEVICES RULES, 2017 TO INCLUDE THE REGISTRATION NUMBER OBTAINED FOR CLASS A (NON-STERILE AND NON-MEASURING) MEDICAL DEVICE IN RULE – 44 and RULE 45 UNDER MDR, 2017.

The Board was apprised that labelling requirements for Medical devices are prescribed in Chapter VI of MDR, 2017. One of the information to be mentioned on the label is Manufacturing Licence Number or import license number as per Rule 44 (m) & (n) and manufacturing license number as per Rule 45 (e).

However, after the implementations of notification vide G.S.R no. 777(E) dated 14.10.2022 in respect of Class A (Non-Sterile and Non-Measuring) Medical Devices, the requirement of Chapter IV, V, VII, VIII & XI are exempted except Chapter VI i.e., Labelling requirement of Medical Devices.

Such Class A (Non-Sterile and Non-Measuring) Medical Devices shall be registered by the applicant to obtain Registration Number & the said Registration Number is to be mentioned on the label of the product as per above said notification. However, in the Chapter VI, there is no provision for labelling requirement of Registration Number on the label of the product in respect of Class A (Non-Sterile and Non-Measuring) Medical Devices.

In view of above, in order to have provision of having Registration Number for Class A (Non-Sterile and Non-Measuring) Medical Devices, as obtained under MDR, 2017 by the applicant, it was proposed that the Rule 44 & Rule 45 may be amended by incorporating Registration number to comply the requirements for Class A (Non-Sterile and Non-Measuring) Medical Devices.

DTAB deliberated the matter and agreed to amend medical devices rules, 2017 to include the registration number obtained for class A (non-sterile and non-measuring) medical device in rule– 44 and rule 45 under MDR, 2017.

AGENDA NO.17

CONSIDERATION OF PROPOSAL FOR AMENDMENT IN RULE 17 (1) OF COSMETICS RULES, 2020 REGARDING IMPORT OF COSMETICS ALREADY REGISTERED FOR IMPORT

The Board was apprised that as per Rule 17 (1) of Cosmetic Rules, 2020 "*A cosmetic manufactured in a foreign site and already registered for import and sale in India, may be imported by any person or entity by making an application in online portal of the Central Government in Form COS-4 with an undertaking as specified in Sixth Schedule."*

The objective for provision of the said Rule was to have provision for the small

traders who were involved in the import of Cosmetics products for trading in the country and they do not have access / approach to the foreign manufacturers to fulfil the registration requirement and fees etc. required for obtaining the Registration Certificate for import of cosmetic products in the country. Under the earlier provision of the Registration Certificate for import of the cosmetics as mentioned in the Drugs Rules, 1945, these traders were unable to import the cosmetics in the country. Hence, the new provision, in the Cosmetics Rules, 2020 has been prescribed.

Under the said provisions, the small traders may submit the application in Form COS 4 along with the legalized self-undertaking as prescribed in the Sixth Schedule of the Cosmetics Rules, 2020. Based on the review of the document, the Licensing Authority may issue IRN (Import Registration Number) in Form-COS 4A for import of already registered cosmetics in the country and they can import the cosmetics registered under the said Form for a period of three years from the date of issue of IRN.

However, it has been observed that the applications are also being received from the Authorized Importer who have already obtained registration certificate from this office for import of cosmetic products from other foreign manufacturers in Form COS-2 e.g. Baccarose, Reliance etc. and the purpose of the provisions of the said Rule (i.e. Rule 17 (1)) is not achieving.

In order to have the provision restricted specifically to the small traders, it was proposed that the Rule may be amended by incorporating that the provisions may be applicable for the traders who are holding MSME certificate from the Ministry of MSME.

DTAB deliberated the matter and agreed for the proposed amendment in Rule 17 (1) of Cosmetics Rules, 2020 regarding import of cosmetics already registered for import.

AGENDA NO.18

CONSIDERATION OF PROPOSAL FOR AMENDMENT IN FORM COS-2, CONDITION NO. 3 OF COSMETICS RULES, 2020.

The Board was apprised that as per Rule 15(2) of Cosmetic Rules, 2020, in case of any change in respect of labelling or composition or testing of registered product or its specifications, the Central Licensing Authority shall be informed by manufacturer or by the authorised agent or the importer or the subsidiary in India authorised by the manufacturer **within fifteen days** along with an undertaking that products comply with standards laid down by the Bureau of Indian Standards as referred in the Ninth Schedule.

However, the Condition no. 3 of the COS-2 i.e. Registration Certificate for the import and marketing of the cosmetic products, for such changes, the importer shall notify to the Central Licensing Authority **within a period of 30 days**.

In view of above and in order to comply the requirement of Rule 15 (2) the Cosmetics Rules, 2020, the Condition no. 3 of the Registration Certificate in COS-2 shall be amended.

DTAB deliberated the matter and agreed for the proposed amendment in Form COS-2, condition No. 3 of Cosmetics Rules, 2020.

AGENDA NO.19

CONSIDERATION OF PROPOSAL REGARDING PROVISION FOR CATEGORIES OF THE COSMETICS FOR MANUFACTURE AND MARKET IN THE COUNTRY UNDER THE PROVISIONS OF COSMETICS RULES, 2020

The Board was apprised that Chapter IV of Cosmetics Rules, 2020 has provision for manufacturing of the Cosmetics for Sale and Distribution. As per Rule 23, the person who intent to manufacture cosmetic products shall make an application for grant of license or loan license to manufacture, sale or distribution to the State Licensing Authority through an online portal in Form COS-5 or COS-6 respectively along with requisite fees as prescribed in Third schedule along with the respective documents as specified in Part II of Second Schedule.

As per the Third Schedule, the applicant has to pay INR 10000 as an application (COS-5 / COS-6) fee for grant of licence (Form COS-8 / COS-9) to manufacture of cosmetics for sale or for distribution up to ten items of each category of cosmetics. Further, INR 500 is required to be paid for each additional item for the category of the cosmetics.

However, the category of the cosmetics, according to which the applicant has to pay fees to the Govt. of India, has not been prescribed in the Cosmetics Rules, 2020.

The Fourth Schedule prescribes the list of the categories of the Cosmetics for import only. Moreover, these categories of Cosmetics are also applicable for manufacture of Cosmetics in the country.

It is therefore proposed that the Fourth Schedule of the Cosmetics Rules, 2020 may be re-framed.

DTAB deliberated the matter and agreed for proposal regarding provision for including categories of the cosmetics in relevant sections for manufacture and market in the country under the provisions of Cosmetics Rules, 2020.

AGENDA NO.20

CONSIDERATION OF THE PROPOSAL REGARDING COMPETENT TECHNICAL STAFF HAVING DEGREE IN BIOTECHNOLOGY, BIOCHEMISTRY, MICROBIOLOGY, ZOOLOGY, BOTANY AND LIFE SCIENCE STUDY

The Board was apprised that representation was received for approval of Competent Technical Staff having degree in Biotechnology, Biochemistry, Microbiology, Zoology, Botany and Life Science Study with relevant experience for manufacturing & testing of Cell or Stem Cell derived product.

It was mentioned that for manufacturing the above product, they require staff that have Degree or Post Graduate Degree in Biotechnology, Biochemistry, Microbiology, Zoology, Botany and Life Science Study and / or experience in manufacturing of Biotechnology Products.

Rule 76 does not mention the educational qualification requirements of Competent Technical Staff to manufacture Cell Therapy/ Stem Cell derived product viz. Degree or Post Graduate Degree in Biotechnology, Biochemistry, Microbiology, Zoology, Botany and Life Science study and/ or experience in manufacturing of Biotechnology products.

The above rule is hurdle for the firm for complying requirement of Competent Technical Staff as per Drugs and Cosmetics Act, 1940 and Rules thereunder.

The proposal was deliberated in 61st DCC meeting held on 01.06.2023 wherein the committee recommended to amend the Drugs Rules, 1945 incorporating specific requirement of competent technical staff for cell or stem cell derived products as a separating category.

DTAB deliberated the matter and agreed for proposal regarding competent technical staff having degree in biotechnology, biochemistry, microbiology, zoology, botany and life science study for cell or stem cell derived products as a separate category.

AGENDA NO.21

CONSIDERATION OF THE PROPOSAL TO INCORPORATE PROVISION FOR INCLUSION OF DETAILS OF EXCIPIENT ON EVERY STRIP OF MEDICINES

The Board was apprised that a grievance was received that the parabens are used in pharmaceutical products as preservatives, which is one of the product used as excipients. There is no clear cut indication of composition of excipient on strips of medicines available on retails medical shops and he is unable to find paraben free antihypertensive medicines. Many other people may also be allergic to other excipient also. The applicant has requested to rectify this problem to stop suffering of many people like him and suggested to add details of excipient or INS codes of excipient on every strip of medicines.

Further, the proposal was deliberated in 61st DCC meeting where the committee deliberated the matter that details of the excipients should be in the package inserts of the medicines. However, presently there is no provision which make it mandatory for the manufacturers to provide package inserts along with the drugs manufactured/ marketed in the country. The criteria to mandate mentioning of the details of excipients on drug formulations have to be evaluated at length for its implementation.

Considering overall perspective, the committee after detailed deliberation recommended to issue an advisory for mentioning details of excipients on drug formulation by various means/ modality on voluntary basis.

DCC in its 62nd meeting held on 26.09.2023 while reviewing the Action Taken Report of 61st DCC for agenda no. 8 recommended that mentioning of all the excipients on the product label is a practical challenge and there is no mandatory requirement. DCC deliberated and suggested for capturing this information through the QR code or by capturing this information in the package insert. DCC recommended that GSR no. 823 (E) dated 17.11.2022 may be amended for capturing the requisite information in the QR code at least for Top 300 brands initially.

DTAB deliberated the matter and opined that it is difficult to include the details of all excipient on every strip of medicines. Further the Board also suggested to prepare a list of excipients causing hypersensitivity which may be considered for mentioning on the label. However, DTAB agreed for the proposed amendment w.r.t. capturing the requisite information in QR Code for top 300 brands.

AGENDA NO.22

CONSIDERATION OF THE PROPOSAL ON RECOMMENDATION OF INTER-MINISTERIAL COMMITTEE ON "DUAL USE" AND ILLICIT TRAFFICKING OF PRESCRIPTION DRUGS AND PRECURSORS

The Board was apprised that DCC in its 61st meeting held on 01.06.2023 was apprised about the recommendation of Inter-Ministerial Committee on "Dual Use" and illicit trafficking of prescription drugs and precursors and that the DCC recommended to introduce digital track and trace system through block chain technology Bar coding/QR Coding System for the identified pharmaceutical ingredients (API) / formulations (list below) on the line of recent introduction of similar mechanism for API / 300 branded formulations by MoH&FW to get information like Unique Product identification code, Name of the API, Brand name (it any), Name and address of the manufacturer, Batch no, Batch Size, Date of manufacturing, Date of expiry or retesting, Serial shipping container code, manufacturing License no. or import license no. Special storage condition required (if any) etc.

1. Codeine based Cough Syrups,
2. Fentanyl & its analogues,

3. Buprenorphine injections
4. Tramadol,
5. Alprazolam,
6. Nitrazepam,
7. Diazepam,
8. Lorazepam,
9. Clonazepam,
10. Zolpidem and
11. Ketamine

The 61st DCC committee was further informed that, for introducing bar code/QR code on all formulations containing listed 11 APIs, requires amendment to the Drugs Rules, 1945, which will be helpful in real time tracking & tracing of the same to prohibit illicit manufacturing as well as sale and purchase at supply chain level of these 11 APIs containing formulations.

After a detailed discussion, the 61st DCC committee recommended that the provisions made vide G.S.R 823(E) dated 17.11.2022 enlisting top 300 Brands of drugs may be extended to cover the drug formulations of the above listed 11 APIs.

DTAB deliberated the matter and agreed for the proposal as in case of agenda no 5.

AGENDA NO.23

CONSIDERATION OF THE PROPOSAL FOR IMPLEMENTATION OF TESTING CHARGES FOR ANALYSIS OF NEW DRUGS SUBSTANCES AT INDIAN PHARMACOPOEIA COMMISSION

The Board was apprised with reference to letter received from MoHFW regarding Minutes of 23rd governing body of the IPC and the testing charges were then proposed and approved by the 23rd meeting of Governing body of IPC. The Testing charges needs to be included in the New Drugs and Clinical Trail Rules, 2019.

DTAB deliberated the matter and agreed for amendment in NDCT Rules for implementation of testing charges for analysis of new drugs substances at Indian Pharmacopoeia Commission as approved by the Governing Body of IPC.

AGENDA NO.24

CONSIDERATION OF THE PROPOSAL TO NOTIFY COCHIN & THIRUVANANTHAPURAM UNDER RULE 43A OF DRUGS RULES 1945 IN RESPECT TO DRUGS IMPORTED BY AIR INTO INDIA

The Board was apprised that email dated 16.09.2023 received from CDSCO Sea Port office, Cochin. In the said email, it has been stated that as per Rule 43A of Drugs Rules 1945 and Rule 22 of Cosmetics Rules 2020, Cochin is a notified port for Drugs, Cosmetics and Medical devices imported by Sea into India. However, import

bills from International Airport Cochin (INCOK4) and Trivandrum (INTRV4) that are not notified places as per Rule 43A of Drugs Rules 1945, are forwarded to their office for clearance. Cochin is the nearest notified Sea port in the State of Kerala and in line with the earlier practice, import bills from other locations were cleared by them. As per the office order no. 2-51/SZ/Admn/2022-549 dated 09.05.2022 of DDC(I), CDSCO, South Zone, Chennai (copy enclosed with e-mail), their office was assigned to look after the work of Cochin and Thiruvananthapuram Air cargo.

It is further stated that during faceless assessment of import bills, the stakeholders have received query from customs stating that "Cochin Air Cargo and Thiruvananthapuram Air cargo" are not notified port of entry under Rule 43A and got delayed to get clearance and happened to pay huge demurrage. Incidentally, Dept. of Revenue, Ministry of Finance vide letter D.O. F.No. 450/25/2009-Cus.IV dated 07.01.2019 (copy enclosed with e-mail) has instructed to improve the easy of doing business and 24X7 customs clearances by making arrangements for deploying staff at sea port / air cargo where 24 X 7 customs clearance is operational. Cochin and Thiruvananthapuram Air cargo have facilities for 24 X 7 customs clearance. In this regard, they have requested to notify Cochin and Thiruvananthapuram under Rule 43A of Drugs Rules 1945 in respect to drugs imported by Air into India.

DTAB deliberated the matter and agreed to notify Cochin & Thiruvananthapuram under rule 43A of Drugs Rules 1945 in respect to drugs imported by Air into India.

AGENDA NO.25

CONSIDERATION OF THE PROPOSAL TO AMEND ENTRY NUMBER 31 OF SCHEDULE K RELATING TO HOMOEOPATHIC MEDICINES SO AS TO ALLOW ALLOPATHY DRUGS WHOLESALE DEALERS TO KEEP HOMOEOPATHIC MEDICINES FOR MAINTAINING THE SUPPLY CHAIN OF HOMOEOPATHIC MEDICINES IN ALLOPATHIC RETAIL STORES

The Board was apprised that the Drugs Rules, 1945 under rule 23 provides that drugs specified in Schedule K shall be exempted from the provisions of Chapter IV of the Act and the rules made there under to the extent and subject to conditions specified in that Schedule.

The Indian Homeopathic Drug Manufacturers Forum made a representation to the Ministry of Ayush regarding entry number 31 of Schedule K of Drugs Rules, 1945 related to Homoeopathic medicines. As per entry number 31, which was last amended in the year 2017 with the recommendation of 715 DTAB, the Retail license holders (allopathic drugs retail sale outlets) under Rule 61 can keep and sell all Homeopathic medicines in sealed packing. The objective of this exemption under Schedule K was to enhance the availability of Homoeopathic medicines to the masses as allopathic drugs retail sale outlets are presently available at far-reaching places as compared to Homoeopathic medicines retail sale outlets.

The Homeopathic Association have proposed that the wholesale distributors underRule 61 (allopathic drugs wholesale sale distributors) may also be allowed to keep Homeopathic medicines, as the supply chain of allopathy and homeopathic medicines are different, so if such a provision is not made the objective of the exemption under Schedule K is not being realized. The agenda was placed in the Ayurvedic, Siddha, Unani Drug Technical Advisory Board (ASUDTAB) meeting held on 25.5.2023 under the chairmanship of DGHS. It has been recommended by the ASUDTAB that "the matter involves changing the criteria of exemptions for dealers of medicines licensed under rule 61 in Schedule K which is for allopathy drugs, it may be referred to DTAB for their deliberations/consideration".

The proposal was related to amendment in Schedule K of the principal Rules, for entry number 31, under the column, —Extent and Conditions of Exemptions, the words "in Form 20 C" and "retail" wherever appearing shall be omitted.

DTAB opined that for wholesale license, requirements for specific area storage and other conditions have been specified in the Drugs Rules, 1945 which are applicable to allopathic drugs. In case homeopathic drugs are to be stored in the same premises, such conditions need to be revisited. Therefore, DTAB recommended that matter may be referred to ASUDTAB for consideration as above and comments in this regard.

AGENDA NO.26

CONSIDERATION OF THE PROPOSAL TO REGULATE ANTIBIOTIC AND ITS IRRATIONAL USE

The Board was apprised that a meeting of the expert group was held on 25.04.2023 at ICMR HQ, New Delhi on pathway for strategic access to new antibiotics and regulation against excessive and irrational use of antibiotics in India.

One of the recommendations of the expert group was to take steps that inappropriate combinations being sold currently should be banned immediately and steps should be taken that the inappropriate combinations do not find their way to India markets in future.

The meeting was held on 16.10.2023 under Chairmanship of Dr. Atul Goel, DGHS in resource centre, Nirman Bhawan, New Delhi to discuss how to regulate antibiotics overuse and irrational use. The committee has decided that CDSCO shall review 6 monthly fixed drug combinations of antibiotics marketed in various states and irrational and unscientific combination may be banned.

DTAB deliberated the matter and recommended to constitute a sub-committee including pharmacologist, medicine specialist and microbiologist for detailed examination and recommendation for further necessary action in the matter.

ADDITIONAL AGENDA NO. 1

CONSIDERATION OF THE PROPOSAL TO AMEND THE HEADING OF CHAPTER IX OF THE MEDICAL DEVICES RULES 2017

The Board was apprised that on review of the Chapters prescribed in the Medical Devices Rules, 2017, it has been observed that the heading of Chapter IX requires a correction in respect the Duties of Notified body.

Duties of Notified Body is already mentioned in Rule 14, under Chapter III, of Medical Devices Rules, 2017, wherein it is stated that – *"a registered Notified Body, referred to in rule 13, shall carry out its duties and functions, in respect of Class A (other than non-sterile and non-measuring) or Class B medical devices as specified in Part II of the Third Schedule."*

Further it is observed that the heading of Chapter IX also mentions Duties of Notified body, however there is no rule mentioned under Chapter IX prescribing or referring to the Duties of Notified body.

In view of the above, following amendments was proposed to be incorporated in the heading of Chapter IX of MDR-2017:

From

"DUTIES OF MEDICAL DEVICE OFFICER, MEDICAL DEVICE TESTING OFFICER AND NOTIFIED BODY"

To

"DUTIES OF MEDICAL DEVICE OFFICER AND MEDICAL DEVICE TESTING OFFICER"

DTAB deliberated the matter and agreed for the proposed amendment.

ADDITIONAL AGENDA NO. 2

CONSIDERATION OF THE PROPOSAL TO INCLUDE THE REQUIREMENTS FOR CONDUCTING INSPECTION OF MEDICAL DEVICE TESTING LABORATORY BY MEDICAL DEVICE OFFICER UNDER MEDICAL DEVICES RULES 2017

On review of the Rules on the Registration of Laboratory for Carrying out Test or Evaluation on behalf of a manufacturer under Chapter X, it is observed that the requirements/standards for conducting inspection of Medical Device Testing Laboratory by Medical Device Officer is not prescribed in MDR-2017.

As per Rule 83 (1) of MDR-2017 – it is stated that "Before grant of registration to any medical device testing laboratory by the: Central Licensing Authority, the premises shall be inspected by the Medical Device Officer appointed by the Central Government with or without an expert in the concerned field for adequacy and suitability."

However, the rule does not capture the details on the basis or standard, which needs be followed by Medical Device Officer for carrying out the inspection of such medical device testing laboratory.

In view of the above, in order to specify the requirement for carrying out the inspection of medical device testing laboratory by MDOs in the rules, it was proposed to amend the Rule 83(1) of MDR-2017 as under:

In the said rules, in rule 83(1),–

From

"Before grant of registration to any medical device testing laboratory by the: Central Licensing Authority, the premises shall be inspected by the Medical Device Officer appointed by the Central Government with or without an expert in the concerned field for adequacy and suitability.";

To

"Before grant of registration to any medical device testing laboratory by the: Central Licensing Authority, the premises shall be inspected by the Medical Device Officer appointed by the Central Government with or without an expert in the concerned field for adequacy and suitability with respect to the latest version of IS/ISO/IEC 17025 and IS/ISO 15189 standards as published by BIS from time to time"

DTAB deliberated the matter and agreed for the proposed amendment.