MINUTES OF THE 88TH MEETING OF DRUGS TECHNICAL ADVISORY BOARD HELD ON 26.09.2022 AT 2.00 P.M. IN CONFERENCE HALL (443-A), 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. V.G. Somani Member Secretary
   Drugs Controller General (India),
   FDA Bhawan, New Delhi

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

4. Dr. Dimple Kasana Member
   Director, Central Research Institute,
   Kasauli, Himachal Pradesh

5. Dr Montu M. Patel Member
   President, PCI

6. Dr. Hemant Koshia Member
   Commissioner, FDCA, Gujarat

7. Dr. Navin Sheth, Member
   Elected Member (PCI)

8. Shri. Sudhir Mehta Member
   Chairman, Torrent Pharmaceuticals

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

10. Dr. Sudam P Khade, Member
    Commissioner and Controller, FDA,
    Madhya Pradesh

11. Shri. Gopal S. Magadum Member
    Govt. Analyst,Karnataka

12. Smt. J. L. Makwana — Member
    Govt. Analyst, Food & Drugs Laboratory,
    Vadodara, Gujarat

CDSCO REPRESENTATIVE

1. Shri. A. K. Pradhan
   JDC(I), CDSCO (HQ), New Delhi

The Board meeting was conducted through hybrid mode. Dr. V.G. Somani, 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 some important agendas. The Chairman of the Board greeted and had a brief introduction from all the members.

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

AGENDA NO. 1

ACTION TAKEN REPORT (ATR) FOR 87th DTAB MEETING HELD ON 08.11.2021

The Action Taken Report (ATR) on the recommendations of DTAB in 87th meeting was approved by the Board.

AGENDA NO.2

CONSIDERATION OF DTAB SUB-COMMITTEE REPORT DATED 28.12.2021 CHAIRED BY Dr. NILIMA KSHIRSAGAR WITH RESPECT TO THE FDCs CONSIDERED AS IRRATIONAL BY PROF. KOKATE COMMITTEE

The Board was apprised that Prof. Kokate Committee submitted its 2nd Assessment report to the Central Government on the FDCs which could not be assessed in their first lot. Based on the recommendations of the Prof. Kokate Committee, 324 applications of FDCs corresponding to 177 FDCs which were declared as irrational were referred to the sub-committee of DTAB under the Chairmanship of Dr. Nilima Kshirsagar.

The sub-committee submitted its report accordingly after holding a series of meeting as well as by providing hearing to the stakeholders.

DTAB examined and agreed to the report submitted by the sub-committee and recommended for further action in the matter with the additional suggestion that wherever generation of additional data is recommended by the sub-committee, a timeframe of one year may be provided to the applicants for generation of data on such FDCs.

AGENDA NO.3

CONSIDERATION OF THE REPORT BY EXPERT COMMITTEE CONSTITUTED FOR EVALUATION OF CERTAIN PRE-1988 FIXED DOSE COMBINATIONS (FDCs) DE NOVO, LICENSED FOR MANUFACTURING FOR SALE IN THE COUNTRY WITHOUT DUE APPROVAL FROM CENTRAL LICENSING AUTHORITY

The Board was apprised that the Hon'ble Supreme Court vide its judgment dated 15.12.2017 *inter alia* mentioned that in respect of 15 FDCs claimed to be approved prior to year 1988, Central Government may, if it so chooses, *de-novo* carry out an inquiry as to whether fixed dose combinations licensed prior to 1988 should be the subject matter of a notification under Section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940).

The Supreme Court vide its judgments dated 14.02.2019 has stated that the drugs claimed to be *manufactured pre-1988 would be at par with the list of 15 drugs that were referred to in our judgment. They may be continued to be manufactured/distributed and sold notwithstanding any notifications that may have been issued, and will be subject to the same directions as that contained for the 15 drugs that are pre-1988 in para 36 of our judgment.*

Accordingly, Ministry of Health & Family Welfare vide order No. X11035/53/2014-DFQC (Part-IV) dated 02.02.2021 constituted an Expert Committee under the Chairmanship of Dr. M. S. Bhatia, Professor & Head, D/o Psychiatry, University College of Medical Sciences, New Delhi for examining pre-1988 FDCs *de-novo* licensed for manufacturing for sale in the country without due approval from Central Licensing Authority.

The Expert Committee submitted its report accordingly on these 19 FDCs claimed to be pre-1988 after holding a series of meetings as well as by providing hearing to the stakeholders.

DTAB examined and agreed to the report submitted by the sub-committee and recommended for further action in the matter with the additional suggestion that wherever generation of additional data is recommended by the sub-committee, a timeframe of one year may be provided to the applicants for generation of data on such FDCs.

AGENDA NO.4

CONSIDERATION OF THE REPORT OF EVALUATION OF FIXED DOSE COMBINATIONS (FDCs) RELATED TO VITAMINS, MINERALS FORMULATIONS, ETC. CONSIDERED AS IRRATIONAL BY THE PROF. KOKATE COMMITTEE AND WHERE SHOWCAUSE NOTICES WERE ISSUED TO THE APPLICANTS FOR SUBMITTING THEIR REPLIES

The Board was apprised that the Ministry of Health & Family Welfare vide order No. X11035/53/2014-DQC 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 Drug Licensing Authorities without due approval of Central Licensing Authority.

The Board was also apprised that Prof. Kokate Committee has submitted its report to the Government from time to time and last such report was submitted related to Vitamins, Minerals and micronutrients formulations along with other remaining FDCs.

The Board deliberated the report of Committee and opined that Prof. Kokate Committee may be requested to apprise the Board about the report for further course of action.

AGENDA NO.5

CONSIDERATION OF THE PROPOSAL TO REMOVE THE REQUIREMENT OF A PRESCRIPTION IN RESPECT OF DRUG PRODUCT, "REFRESH TEARS" (CARBOXYMETHYLCELLULOSE SODIUM EYE DROPS IP 0.5% W/V) STERILE OPHTHALMIC SOLUTION FOR RETAIL SALE

The Board was apprised that the representation was received from M/s Allergan India Pvt Ltd, seeking approval to remove the requirement of a prescription from Registered Medical Practitioner (RMP) in respect of drug product, "Refresh Tears" (Carboxymethylcellulose Sodium eye drops IP 0.5% w/v) for its retail sale.

The firm has submitted that its product "Refresh tears" containing Carboxymethylcellulose Sodium eye drops 0.5% w/v, sterile ophthalmic solution, indicated for the temporary relief of burning, irritation, and discomfort due to dryness of the eyes or exposure to wind or sun, and may be used as a protectant against further irritation and stated that the product is being marketed since 1998. The firm has requested for change the category of this product from prescription drug to the category of non-prescription drug i.e "Rx to Over-The-Counter (non-prescription)".

Consequently, firm has sought an exemption from putting the "Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only" on the labels and package insert of “Refresh Tears” as applicable for a prescription drug.

The proposal was deliberated in SEC (Ophthalmology) meeting held on 28.01.2022, wherein the committee recommended that the said drug product may be sold by retail without the prescription of a Registered Medical Practitioner. Further, action may be taken as per the rules.

The Board after detailed deliberation agreed to remove the requirement of a prescription from Registered Medical Practitioner (RMP) in respect of drug product, “Refresh Tears” (Carboxymethylcellulose Sodium eye drops IP 0.5% w/v) for its retail sale. Accordingly, relevant provisions of the Rules may be amended.

AGENDA NO.6

CONSIDERATION OF PROPOSAL FOR CHANGE IN SCHEDULE OF THE DRUG “ZOLPIDEM TARTRATE” FROM SCHEDULE H1 TO SCHEDULE H OF THE DRUG RULES, 1945

The Board was apprised that the representation was received from M/s. Abbott India Ltd and FICCI wherein it has been requested to change schedule of Zolpidem Tartrate from Schedule H1 to Schedule H of the Drugs Rules, 1945.

The proposal was deliberated in the SEC (Neurology & Psychiatry) meeting held on 18.12.2019, wherein the committee deliberated the proposal in detail and recommended that the drug should continue to be Schedule H1 as it has potential for dependence.

The Board after detailed deliberation agreed to the recommendations made by the Subject Expert Committee and recommended that Zolpidem preparations shall continue to be in Schedule H1 of the Drugs Rules, 1945.

AGENDA NO.7

CONSIDERATION OF THE PROPOSAL OF CERTAIN AMENDMENTS MADE TO THE MEDICAL DEVICES RULES, 2017 VIDE G.S.R. 19(E) DATED 18.01.2022

The Board was apprised that the Ministry of Health and Family Welfare has amended certain provisions pertaining to registration of medical devices under Medical Devices Rules, 2017 vide G.S.R. 19(E) dated 18.01.2022.

The Board after detailed deliberation ratified the amendments to the Medical Devices Rules, 2017 made vide G.S.R. 19(E) dated 18.01.2022.

AGENDA NO.8

CONSIDERATION OF AMENDMENTS MADE TO THE MEDICAL DEVICES RULES, 2017 PERTAINING TO UNIQUE DEVICE IDENTIFICATION OF MEDICAL DEVICES, VIDE G.S.R. 918(E) DATED 31.12.2021

The Board was apprised that Ministry of Health and Family Welfare has amended Rule 46 of Medical devices rules, 2017, vide G.S.R. 918(E) dated 13.12.2021, that every medical device approved for manufacture for sale or distribution or import, shall bear a unique device identification in the manner as may be specified in such order.

The Board after detailed deliberation ratified the amendments to the Medical Devices Rules, 2017 made vide G.S.R. 918(E) dated 13.12.2021.

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 recommendations of DTAB, the Central Government has prohibited the FDC of Etodolac + Paracetamol vide S.O. 4706 (E) dated 07.09.2018 with the reasons that "the FDC may involve risk to human beings.

However, 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 Board deliberated the matter in detail and recommended that the matter should be re-examined by a sub-committee constituted under the Chairmanship of Dr. Lalit Kumar Gupta, Director, Prof., Department of Pharmacology, LCMH Hospital, New Delhi and one expert each from Clinical Pharmacology, Orthopaedics and Medicine.

The sub-committee may co-opt subject experts as and when required. Sub-Committee shall submit its interim report within four weeks and final report within twelve weeks.

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

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