**MINUTES OF THE 84TH MEETING OF DRUGS TECHNICAL ADVISORY BOARD HELD ON 27.08.2019 AT DGHS, NIRMAN BHAWAN, NEW DELHI**

**PRESENT**

1. Dr. A. K. Saxena — 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 C. Hariharan — Member
   Director (I/C),
   Central Drugs Laboratory, Kolkata
4. Dr. A. K. Tahlan — Member
   Director, Central Research Institute,
   Kasauli, Himachal Pradesh
5. Dr. P. Dhar — Member
   IVRI, Izatnagar
6. Dr. Pallavi Jain Govil — Member
   Principal Secretary, Health, M.P.
7. Prof. M. D. Karvekar — Member
   Bengaluru
8. Shri. Pankaj Patel — Member
   Chairman and Managing Director,
   Zydus Cadila Group, Ahmedabad
9. Dr. Nilima Kshirsagar — Member
   Chair in Clinical Pharmacology,
   ICMR, Mumbai
10. Dr. R.N. Tandon — Member
    Past Honorary Secretary General, IMA, New Delhi
11. Prof. Dr. T.V. Narayana — Member
    President , IPA, Bengaluru
12. Shri. M.S Lokesh Prasad — Member
    Scientific Officer & Govt. Analyst,
    Bengaluru, Karnataka
13. Dr. Vaishali N Patel — Member
    Govt. Analyst, Food & Drugs Laboratory,
    Vadodara, Gujarat

*undergo processing steps beyond rinsing, cleaning or sizing and these steps shall not be considered as processing."*

DTAB deliberated the matter in length and in principle, agreed to the proposal and further recommended that it is given to understand that ICMR/ DHR is making guidelines for this and therefore, while considering the issuance of such clarification on stem cell derived products, those guidelines to be published by the ICMR may be considered.

DTAB also recommended that, the routine practices/ transplantations/ surgeries/therapies undertaken by doctors involving stem cell for treatment of their own patients and not for commercialization of the same outside their own hospitals/clinics fall outside the purview of Drugs and Cosmetics Act, 1940 and the New Drugs and Clinical Trials Rules, 2019. Therefore, shall be dealt outside the said regulation.

Further, DTAB recommended that, till such time the clarification about stem cell derived product is brought out by ICMR etc., communication should be issued to the State Licensing Authorities and other stake holders that the overall issue is under process and it is inappropriate to intervene from regulatory angle on routine practices/therapies/surgeries/transplantations undertaken by Registered Medical Practitioners/ physicians / doctors in their clinics/hospitals involving such stem cells for the treatment of their patients based on their medical expertise.

## AGENDA NO. 4

## CONSIDERATION OF THE PROPOSAL FOR AMENDMENT OF THE EXEMPTIONS PROVIDED UNDER SCHEDULE K REGARDING SUPPLY OF MEDICINES BY REGISTERED MEDICAL PRACTITIONERS TO THEIR PATIENTS

DTAB was apprised that, Registered Medical Practitioners (RMP) can supply different categories of medicines including vaccines to their patients as per the exemption provided with certain conditions under Schedule K of the Drugs and Cosmetics Rules, 1945.

Currently, there is no specific category which can be supplied by RMP to their patients and therefore, it was proposed to incorporate the certain additional conditions under the conditions of exemption to prevent the misuse of the exemption.

DTAB deliberated the matter and rejected the proposal, as it is not in line with the reality and rights of RMPs for prescribing medicines as per their experience and expertise.