**MINUTES OF THE 87TH MEETING OF DRUGS TECHNICAL ADVISORY BOARD HELD ON 08.11.2021 AT DGHS, NIRMAN BHAWAN, NEW DELHI (THROUGH VIDEO CONFERENCE)**

**PRESENT**

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| 1. Dr. Sunil Kumar,<br>Director General of Health Services,<br>Nirman Bhawan, New Delhi | Chairman |
| 2. Dr. V.G. Somani<br>Drugs Controller General (India),<br>FDA Bhawan, New Delhi | Member Secretary |
| 3. Shri C. Hariharan<br>Director (I/C),<br>Central Drugs Laboratory, Kolkata | Member |
| 4. Dr. Dimple Kasana<br>Director, Central Research Institute,<br>Kasauli, Himachal Pradesh | Member |
| 5. Dr. Pronab Dhar<br>IVRI, Izatnagar, UP | Member |
| 6. Dr. B. Suresh<br>President, PCI | Member |
| 7. Dr. Hemant Koshia<br>Commissioner, FDCA, Gujarat | Member |
| 8. Prof. Dr. Shailendra Saraf,<br>Elected Member (PCI) | Member |
| 9. Shri. Sudhir Mehta<br>Chairman, Torrent Pharmaceuticals | Member |
| 10. Dr. Jerin Jose Cherian, Scientist D,<br>Division of Basic Medical Sciences,<br>ICMR | Member |
| 11. Dr. J. A. Jayalal<br>National President, IMA | Member |
| 12. Shri. Gopal S. Magadum<br>Govt. Analyst,Karnataka | Member |

13. 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

President, National Medical Commission; Director, Central Drugs Research Institute, Lucknow; Commissioner, FDA, Madhya Pradesh; Dr. Vijay Oza, elected member by National Medical Commission; Dr. T.V. Narayana, elected member by Indian Pharmaceutical Association could not attend the meeting because of their other commitments.

Dr. V.G. Somani, DCG(I), Member-Secretary, DTAB welcomed the Board members under the supervision of Chairman Dr. Sunil Kumar, DGHS. All members were introduced to the Chairman. The Chairman then requested DCG(I) to initiate the proceedings. DCG(I) initiated the deliberation on DTAB agenda along with Action Taken Reports on previous DTAB recommendations.

## AGENDA NO. 1

## ACTION TAKEN REPORT (ATR) FOR 86th DTAB MEETING HELD ON 13.04.2021

The Action Taken Report (ATR) on the recommendations of DTAB in 86th meeting was approved by the Board.

## AGENDA NO.2

## CONSIDERATION OF THE PROPOSAL ON ISSUE OF BAR CODING/QR CODING FOR INTRODUCTION OF TRACE AND TRACK FOR MOST POPULAR OR TOP 300 PHARMACEUTICAL BRANDS AVAILABLE IN INDIAN MARKET BY THE MANUFACTURERS

The Board was apprised that earlier, draft rules were published for comments vide G.S.R. 449 (E) dated 03.06.2015. These rules could not be finalized as many of the pharmaceutical companies showed their inability to introduce this sophisticated technology in their manufacturing processes. It is however observed that some of the pharmaceutical companies have already introduced bar coding system in some of the brands.

The DTAB in its 79th meeting held on 16.05.2018 deliberated the matter and agreed for introduction of trace and track mechanism for major 300 pharmaceuticals brands on voluntary basis. The Board informed that an order may be issued by DCG (I) to all the concerned to this effect.

Subsequently, Ministry of Health and Family Welfare, has published draft notification vide G.S.R. 567 (E) on 08.08.2019 mandating QR code for APIs only based on the recommendations of 82ndDTAB. A number of objections have been received from the Industry, which are being examined.

In this regard, an Inter-Departmental Committee (IDC) was constituted by Ministry of Health and Family Welfare (MoHFW) on 13.07.2020 on the issue of implementation of Barcode/QR code on packing of drugs (including Medical Devices).

As per the recommendations of IDC, the implementation of authentication mechanism for the top 300 drug formulation brands in the first phase may be carried out.

Accordingly, a roadmap has been prepared to complete following activities in systematic manner along with constitution of a committee for the said activities is under consideration:

A. Identification of Top 300 brands, Technologies that can be used including cost, procurement of hardware, changes in packing lines/ packing material, if any etc.
B. Stakeholder consultation, obtaining their comments and rollout for Top 300 brands and all items meant for Government procurement

Accordingly, it was proposed to consider the introduction of QR code in phase wise manner, so that trace and track mechanism by QR coding system on packaging may be implemented initially for the top 300 brands through amendment in the Drugs Rules, 1945 and the earlier draft notification issued in this regard vide G.S.R. 449 (E) dated 03.06.2015 may be withdrawn.

The Board after detailed deliberation recommended for introduction of bar-code/QR code in the top 300 brands of the drug products and also to withdraw the earlier draft notification issued in this regard vide G.S.R. 449 (E) dated 03.06.2015.

## AGENDA NO.3

## CONSIDERATION OF THE PROPOSAL FOR PARALLEL SUBMISSION OF APPLICATION FOR IMPORT REGISTRATION, MARKETING AUTHORIZATION AND IMPORT LICENCE

The Board was apprised that a committee was constituted by MoHFW and one of the recommendations was relating to making provisions for parallel submission of application for import registration, Marketing Authorisation (MA) and import licence.

In case of import of new drugs, the applicant initially files an application for grant of permission for import and marketing of new drugs with CDSCO. As per the current practice, the application is disposed within a period of 90 days. However, if clinical data is required to be submitted along with the application, the applicant will conduct a clinical trial which may take from 1-3 years depending upon the phase of clinical trial and data required.

After obtaining the permission to import and market the new drug, the applicant is required to obtain import registration certificate (RC). The duration specified for processing such application is 270 days. After obtaining the RC the applicant shall submit an application for grant of import licence which will require 30 days for processing. Thus, the entire process of obtaining new drug permission, import registration and import licence is sequential, which is leading to delay in placing the product in the market.

In this regard, the committee has recommended for making provisions for parallel submission of application in such way that the application for grant of RC and import licence shall be processed simultaneously instead of present practice of sequential processing, with the application for grant of permission of new drug. This will reduce the processing duration by about 3-6 months.

Accordingly, a draft of amendment in the rules was placed before the DTAB.

The Board after detailed deliberation agreed for the necessary amendment in the Rules in this regard.

## AGENDA NO.4

## CONSIDERATION OF THE PROPOSAL FOR PARALLEL SUBMISSION OF APPLICATION FOR MARKETING AUTHORISATION AND GRANT OF MANUFACTURING LICENCE IN FORM 28-D

The Board was apprised that a committee was constituted by MoHFW and one of the recommendations of the Committee was related to making provisions for parallel submission of applications for marketing authorization and grant of manufacturing licence in Form 28-D.

In case of manufacture of new drugs, the applicant initially files an application for grant of permission for manufacture and marketing (Marketing Authorisation [MA]) of new drugs with CDSCO. As per the current practices the application is disposed with in a period of 90 days. However, if clinical data is required to be submitted along with the application, the applicant will conduct a clinical trial which may take from 1-3 years depending upon the phase of clinical trial and data required.

After obtaining the MA for the new drug, the applicant shall make an application to the state authority for grant of manufacturing licence in Form 28-D. The application is processed by State Licensing Authority in about 60 days without inspection. If inspection needs to be carried out the application is processed in 90 days. The state authority will forward the manufacturing licence in Form 28-D to the DCG(I) for approval. The application is processed at CDSCO within 30 days.

In this regard, the committee has recommended that provisions may be made such that the applications may be submitted simultaneously so that they are processed simultaneously instead of the present practice of sequential processing. This may reduce the processing duration by about 2-3 months.

Accordingly, a draft of amendment in the rules was placed before the DTAB.

The Board after detailed deliberation agreed for the necessary amendment in the Rules in this regard.

## AGENDA NO.5

## CONSIDERATION OF THE PROPOSAL FOR AMENDMENT IN THE PROVISION OF NEW DRUGS AND CLINICAL TRIALS RULES, 2019 TO MANUFACTURE AND STOCK NEW DRUG FOR SALE OR DISTRIBUTION WHICH IS UNDER CLINICAL TRIAL

The Board was apprised that a committee was constituted by MoHFW and one of the recommendations is related to making provisions for grant of license to manufacture and stock of new drug for sale and distribution which is under clinical trial.

The committee has recommended that specific provisions may be made under the New Drugs and Clinical Trial Rules, 2019 to enable manufacture of unapproved new drug while it is still under clinical development, subject to conditions.

Currently as per the Rule 83 of ND&CT Rules, 2019, a person shall make an application for grant of license to manufacture for sale or distribution to State Licensing Authority (SLA) only after obtaining permission in Form CT-23 granted by Central Licensing Authority (CLA) as per rule 81 of ND&CT Rules, 2019.

In view of the above, it is proposed to amend the ND&CT Rules, 2019 providing that in case a person intends to manufacture and stock a new drug which is under clinical trial, subject to condition that the licensee shall sell or distribute the drug only after obtaining permission for such drug (new drug) in Form CT-23 from the Central Licensing Authority (CLA) under the ND&CT, 2019, the requirement of obtaining the permission in Form CT-23 under Rule 81 shall be deferred for grant of license to manufacture for sale or for distribution under Drug rules, 1945 and such person shall obtain the said permission after successful completion of the clinical trial and submission of application along with fees, data and particulars in accordance with the provisions of the ND&CT, 2019.

Accordingly, a draft of amendment in the rules was placed before the DTAB.

DTAB after detailed deliberation recommended that the proposed provisions for (grant of license to manufacture and stock of new drug which is under clinical trial) is considered appropriate for drugs/vaccines being developed for emergency/life-saving/ COVID-19 and similar such conditions of public health importance. However, such drugs should be marketed, sold and distributed only after clearance of clinical trials results.

**AGENDA NO.6**

**CONSIDERATION OF THE PROPOSAL FOR STREAMLINING OF REGULATORY PROCESS FOR STRENGTHENING THE ECOSYSTEM TO BOOST INNOVATION BY PROVIDING FOR DEEMED APPROVALS FOR VARIOUS PERMISSIONS UNDER ND&CTRULES, 2019**

The Board was apprised that a committee was constituted by MoHFW and one of the recommendations is related to making provisions forstreamlining of regulatory process for strengthening the ecosystem to boost innovation by providing for deemed approvals for various permissions under ND&CT Rules, 2019

In order to streamline such regulatory processes, the Committee recommended that there should be provisions of deemed approval of proposals in all cases like various permissions, License approvals for 'various stages of drug development viz. manufacturing of trial batches, conduct of phase I, II, III, IV clinical trial etc. except in cases of grant of permission/ License for import/ manufacture of

drugs including new drugs and vaccines, biologicals etc., for sale and distribution for domestic purpose. Accordingly, the relevant legislation should be amended.

Accordingly, a draft of amendment in the rules was placed before the DTAB.

The Board after detailed deliberation agreed for the necessary amendment in the Rules in this regard.

## AGENDA NO.7

## CONSIDERATION OF THE PROPOSAL FOR AMENDMENT IN THE NEW DRUGS AND CLINICAL TRIALS RULES, 2019 WITH RESPECT TO THE PROVISIONS FOR REGULATION OF CLINICAL RESEARCH ORGANIZATIONS (CRO)

The Board was apprised that a committee was constituted by MoHFW and one of the recommendations of the committee was related to making provisions forsetting up of provisions for regulation of Clinical Research Organizations.

Further, in light of recommendations of NITI Aayog, the draft notification for amendment in ND&CT Rules, 2019 with respect to the registration of Clinical Research Organizations (CROs) was prepared and forwarded to the Ministry.

The draft of amendment in the rules was placed before the DTAB.

The Board after detailed deliberation agreed for the necessary amendment in the Rules in this regard.

## AGENDA NO.8

## CONSIDERATION OF THE PROPOSAL FOR THE RECOMMENDATIONS SUBMITTED BY SUB-COMMITTEE OF DRUGS CONSULTATIVE COMMITTEE (DCC) ON OVER-THE-COUNTER (OTC) DRUGS

The Board was apprised that the agenda of considering the sub-committee report on OTC drugs was deliberated in 57th meeting of DCC held on 08.08.2019 and the committee recommended that the recommendations of the Sub-committee should be considered for suitable amendment in the Schedule K of the Drugs and Cosmetics Rules, 1945 to incorporate necessary provisions for such drugs for providing exemptions from requirements of Sale license/ prescription of RMP etc. subject to appropriate conditions. Accordingly, the DCC further recommended that the sub-committee should identify such list along with conditions and frame draft for amendments in the Rules.

In this regard, sub-committee in its last meeting held on 20.10.2021 deliberated issues with respect to certain drugs along with experts in the field of Pharmacology and Medicine and recommended 16 drugs as OTC drugs.

Copy of Minutes of the sub-committee meeting along with the list of 16 drugs was placed before the DTAB.

The Board after detailed deliberation agreed for the necessary amendment in the Rules in this regard. Further, the Board recommended that a proposal for adopting best practices with respect to the dispensing of drugs by various professionals should be prepared for further consideration.

## AGENDA NO.9

## CONSIDERATION OF PROPOSAL TO AMEND THE DRUGS RULES, 1945 REGARDING PROVISIONS TO DISPLAY THE PICTURE OF THE LICENCE HOLDER IN THE SHOP

The Board was apprised that the practice of medicine is changing rapidly. With these rapidly changing ground realities, the practices of allied professionals such as the “Druggists & Chemists” also need to change synchronously. Professionals associated with this complementary profession too need to adopt “Good Practices” whole heartedly.

In view of the above, several observations were received for improving the current practices at the retail outlets or medicine shops out of which one of the observation was to display the picture of the licence holder in the shop.

In this regard a joint meeting was convened by CDSCO and PCI with various stakeholders i.e. AIOCD, AICDF and SCDA wherein the observations which required elaborate deliberations were discussed.

Further, the said proposal was deliberated in 59th DCC meeting held on 02.03.2021 and the committee recommended that the Drugs Rules may be amended to provide provision for display of the picture of the license holder in the shop.

The Board after detailed deliberation agreed for necessary amendment in the Rules to have provision for display of the picture of the license holder in the shop.

The meeting ended with a vote of thanks to Chair.

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