MINUTES OF THE 69TH MEETING OF DRUGS TECHNICAL ADVISORY BOARD HELD ON 22nd APRIL, 2015 AT CDSCO, HQ, FDA BHAWAN, KOTLA ROAD, NEW DELHI

PRESENT

1. Dr. Jagdish Prasad, — Chairman
   Director General of Health Services,
   Nirman Bhawan, New Delhi.

2. Shri C. Hariharan — Member
   Director in-charge,
   Central Drugs Laboratory,
   Kolkata-700016

3. Dr. Sunil Gupta, — Member
   Director, Central Research Institute,
   Kasauli (HP) -173205

4. Dr. H. G. Koshia, — Member
   Commissioner, FDCA, Gujarat
   Block No. 8, Dr. J. M. Bhawan,
   Gandhi Nagar, Gujarat – 382010

5. Dr. Rao V. S. V. Vadlamudi — Member
   Flat F-6, Vora Towers,
   8-3 – 224, Yousufguda road
   Madhuranagar, Hyderabad – 500038

6. Dr. Nilima Kshirasagar, — Member
   Chair in Clinical Pharmacology, ICMR
   1501-2, Datta Tower,
   Dr. Vijay Kumar Walimbe Marg,
   Mumbai – 400012

7. Shri A. K. Tiwari, — Member
   Indian Veterinary Research Institute,
   Izatnagar

8. Prof. M. D. Karvekar, Member
   #1449, Sector, 7, 4th Main
   21st Cross, H.S.R. Lay Out
   Bangalore, 560102

9. Shri O. S. Sadhawani, Member
   Controlling authority & Joint Commissioner,
   Food & Drugs Administration, Mumbai
   Bandra Kurla Complex, Bandra (E)
   Mumbai, Maharashtra - 400051

10. Dr. Muzaffar Ahmad Member
    Rep., Medical Council of India,
    Pocket 14, Sector-8, Dwarka- Phase I
    New Delhi - 110077

CDSCO REPRESENTATIVES

1. Dr. S. Eswara Reddy,
   Joint Drugs Controller,
   CDSCO, HQ, New Delhi

2. Dr. V. G. Somani
   Joint Drugs Controller,
   CDSCO, HQ, New Delhi

3. Shri Lalit Kishore
   Consultant, DCG(I)
   CDSCO, New Delhi

4. Shri R. Chandrasekhar,
   Deputy Drugs Controller (India)
   CDSCO, New Delhi

Dr. A. Marthanda Pillai, Ananthapuri, Hospital and Res. Institute, Thiruvananthapuram, Dr. G. B. Gupta, Prof and Head, Department of Medicine, Pt. Jawahar Lal Nehru Memorial Medical College, Smt. Sushma M. Saptarshi, Government Analyst, Drugs Control Laboratory, Mumbai, Maharashtra, Shri Sheju Purushothaman, Government Analyst, RDTL, Kerala and Shri Sudhir Mehta, Chairman, M/s. Torrent Pharmaceuticals Ltd., Ahmedabad and Dr. G. N. Singh, Member Secretary could not attend the meeting because of their other commitments.

AGENDA NO. 1

CONSIDERATION OF THE PROPOSAL FOR AMENDMENT OF THE DRUGS AND COSMETICS RULES, 1945 TO MAKE MANDATORY BAR CODING ON PRIMARY, SECONDARY AND TERTIARY LEVELS OF PACKING OF DRUGS FOR TRACING THE ORIGIN AND MOVEMENT OF DRUGS FROM MANUFACTURER TO RETAIL LEVEL THROUGH A SYSTEM OF NETWORKING

Members were briefed that the proposal for bar coding of the drug formulations to enable the consumer to trace and track the source of the drug purchased was initiated on the basis of an order issued by the Allahabad High Court in the case of State Vs. Brahmaji during the hearing on 20.10.2010. The matter was considered in the 39th DCC held on 28.10.2010 and a Task Force was constituted under the Chairmanship of Shri H. G. Koshia, Commissioner, FDCA, Gujarat to examine the feasibility of networking and tracking the drug distribution system in the country from the manufacturer to retailer level. National Informatics Centre (NIC) was also a part of the Task Force for providing inputs on the requirements for the software development for drug tracking system.

Bar coding on secondary and tertiary packing has already been made mandatory by DGFT for pharmaceutical product exported from India. The Ministry of Commerce is further planning to make bar coding compulsory on primary packing also for pharmaceutical products exported from India in the year 2015. This system of bar coding was also proposed to be adopted for the drugs marketed in the domestic market also.

The system design was completed by NIC after making system requirement study at various manufacturers and State level agencies in the supply chain of the pharmaceutical industry.

Rule 96 of the Drugs and Cosmetics Rules, 1945 is required to be amended for making a provision for bar coding on primary, secondary and tertiary packings of drugs.

The chairman stated that it is very essential to have a system which should ensure that the patient is in a position to verify the authenticity of the medicines purchased by him, as it is a question of life and death for him. A system of bar coding and trace and track technology will help in tracing the origin of the drug and thereby reducing the infiltration of spurious drugs in the supply chain. He then asked NIC which has developed a software for the bar coding the system to give a presentation.

The NIC gave a presentation on their ‘Portal for Indian Drugs Authentication, Track and Trace’ named as DAVA (Drugs Authentication and Verification Application).

The objective of this application is to ensure the genuineness and authenticity of the drugs with track and trace movement in its complete supply- chain and to provide simpler means for drug authentication to the consumer through Central Portal and SMS**.** The bar coding is required to be provided on tertiary, secondary and primary packing in a parent child relationship i.e. linked bar coding in the said packing. Data will be captured / maintained on the Central Portal with Parent Child relationship for all packing levels. The GTIN + Unique Serial Number would uniquely identify a primary pack and maintain the Parent Child relationship with its Tertiary and Secondary pack. The system will provide information which can be accessed by the consumers as well as regulatory authorities. Sales premises will also be required to upload information to the portal about the movement of the drug.

The members agreed that it's a very good proposal for patient safety and as in public interest. It therefore should be implemented by the Government. The quality of drugs manufactured in the country is one of the most important criteria of healthcare system. The chemists, which sell the drugs to the patients should also be required to have authenticity of the drugs sold by them.

Shri Sudhir Mehta, Member DTAB, who could not attend the meeting because of some prior commitments, had forwarded comments on the agenda. He stated that the objective of the system is laudable to preserve the image of the country. He however, suggested that the process should be fully tested before it is made mandatory. The cost factors and technology to be used by the manufacturers should be identified and SMEs should also be taken on board for adoption of the system. A copy of his e-mail is **annexed.**

The DTAB after deliberations and taking into account the suggestions received agreed that the Drugs and Cosmetics Rules, 1945 should be amended as proposed for the adoption of the system. A suitable parent child relationship definition should also be provided for the purpose of clarity. It further, recommended that a time frame of two years after the publication of the final rules should be given for uniform implementation of the provisions by all stakeholders.

AGENDA NO. 2

CONSIDERATION OF THE PROPOSAL TO RESTRICT OR PROHIBIT THE OXYTOCIN INJECTION BECAUSE OF ITS MISUSE BY DAIRY OWNERS TO EXTRACT MILK FROM MILCH ANIMALS

The members were briefed that the issue of misuse of the oxytocin has again been raised and therefore the proposal has been placed before DTAB for its consideration and recommendations in the matter.

The members felt that as recommended earlier, the drug need not be prohibiting as it has definite use for therapeutic purposes. Shri A. K. Tiwari of IVRI stated that the drug oxytocin is an essential drug in the veterinary practice. He added that the Department of animal husbandry had also earlier given his opinion that the ban on production an use of oxytocin for veterinary used is not recommended.

The members felt that the problem of misuse of oxytocin is more related to stricter control over the manufacture and sale of the drug especially through clandestine channels. The dairy owners get the drug manufactured at dubious premises from unscrupulous suppliers. The members noted that the raid conducted at Ghazipur Dairy in Delhi by the officer of the North Zone of CDSCO have revealed that the drug was clandestinely manufactured and packed in plastic bottles and not as per provisions of the Drugs and Cosmetics Rules. Constant surveillance by the State Drug Regulatory Authorities and other such regulatory agencies can only curb the misuse of the drug. The dairy owners are needed to be educated by the Department of animal husbandry about the harmful effects of the use of oxytocin for milking the milch animals.

The members after deliberations recommended that the issue requires detailed examination with more experts from outside before we can give any decision. The matter was therefore deferred for next DTAB meeting.

AGENDA NO. 3

CONSIDERATION OF THE PROPOSAL FROM THE FDA MAHARASHTRA REGARDING DISTRIBUTION OF MEDICINES BY THE AGENCIES LIKE SNAPDEAL, AMAZON AND FLIPKART TO NATIONAL AND INTERNATIONAL CONSUMERS THROUGH INTERNET

Shri O. S. Sadhawani of Food & Drugs administration, Maharashtra raised the issue of distribution of medicines by the agencies like Snapdeal, Amazon and Flipkart to national and international consumers through internet without valid prescriptions and sale bills. He stated that these kinds of clandestinely operated distribution of medicines are developing at large scale in the country. There is every likely hood that spurious medicines may be sold online by undisclosed persons as there is no specific check in modus followed by online shopping website.

The members opined that the drugs are different from the normal merchandise and the manufacture and sale of drugs is regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. Sale of drugs is a licenced activity and the sale is required to be carried out at the licenced premises, under the supervision of a qualified pharmacist and in compliance to the provisions prescribed under the Drugs and Cosmetics Rules, 1945. Online sales in contravention to the provisions of the said Act and rules should not be permitted.

Meeting ended with the vote of thanks to the Chair.

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