MINUTES OF THE 67TH MEETING OF DRUGS TECHNICAL ADVISORY BOARD HELD ON 1ST APRIL, 2014 IN THE CHAMBER OF DGHS, NIRMAN BHAWAN, 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. S. D. Seth, — Member
   Advisor CTRI,
   National Institute of Medical Statistics,
   ICMR, Ansaari Nagar,
   New Delhi-110002

5. Dr. A. K. Tiwari — Member
   Indian Veterinary Research Institute
   Izatnagar-243122 (U.P.)

6. Dr. B.P.S. Reddy, — Member
   CMD, Hetero Drugs Pvt. Ltd.,
   Hyderabad

7. Dr. J.A.S. Giri — Member
   815A, Road No. 41,
   Jublee Hills, Hyderabad-500033
   Andhra Pradesh

8. Dr. G. N. Singh, Member Secretary
   Drugs Controller General (India)
   FDA Bhawan, New Delhi-110002

CDSCO REPRESENTATIVES

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

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

Dr. T. K. Chakraborty, Director, CDRI, Lucknow; Secretary, Medical Council of India, New Delhi; Dr. K. Chinnaswamy, Coimbatore; Prof. B. Suresh, President, Pharmacy Council of India; Shri Satish Gupta, Controller Drugs and Food, J&K; Dr. Dharam Prakash, Delhi and Dr. Dhrubajyoti Bora, Guwahati could not attend the meeting because of their pre-occupation.

Dr. G. N. Singh, Drugs Controller General (India) and Member Secretary DTAB welcomed the Chairman and members of the Board. In his introductory address he stated that this meeting of the DTAB is the last meeting of the outgoing DTAB. The process of reconstitution of DTAB has already begun. The Associations and Councils have been requested to nominate members for the new DTAB. The present DTAB had met quite frequently and has taken momentous decisions in respect of quality of drugs for patients and animals safety. Incidentally, CDSCO is celebrating the year 2014 as year of Patient and Animal Safety. He thanked the members that inspite of their hectic schedules, they have been able to spare time to attend the meetings and contribute to the deliberations. He requested the Chairman to send individual letters of appreciation to the outgoing members. He further suggested that for the purpose of continuity, the present members may be re-nominated as far as possible. This would help in better deliberations on the various agenda items with the background knowledge of earlier deliberations of DTAB.

The Chairman agreed to the suggestions of sending letter of thanks to the outgoing members.

The Chairman in his address raised the issue of wide variation in the quality of drugs manufactured in the country especially in respect of generic drugs manufactured in the small scale sector. He stated that complaints have been received from various quarters that the drug products manufactured by many of the Indian Drug Manufacturers, which might otherwise be of as standard quality, have not been found to be effective by the consumers because of low bioavailability. It is therefore, necessary that the drug manufacturers should have an R&D Laboratory in their premises or get affiliated to such a laboratory, so that the drugs manufactured by them have comparable therapeutic efficacy. The promotion of generic drugs would only be effective if their efficacies are comparable to the products manufactured with the approval of the DCG(I). He suggested that a meeting of the representatives of the drug manufacturers associations, pharmacologists and representatives of Research and Development centres may be convened by the office of DCG(I) to find out the ways and means so that the manufacturers have necessary arrangements either in house or with tie up with some R&D centre to test the efficacy and stability of the products before these are marketed. The committee may suggest changes, if any, under the Drugs and Cosmetics Rules, 1945 also to ensure that the generic drugs available to the public are of comparable quality and the patients develop confidence in the use of the generic drugs.

Dr. B.P.S. Reddy, raised the issue of import of large quantities of bulk drugs in the garb of intermediates from certain countries at very low prices. The bulk drug industry in the wake of such imports is facing stagnation. Even in the import of APIs permitted by the DCG(I), the authenticity of the documents relating to the manufacturing licences and the Good Manufacturing Practices followed for the manufacture etc. submitted for obtaining the necessary registration under the Drugs and Cosmetics Rules, 1945 are not easily verifiable.

The Chairman agreed that regulatory regimes in many countries are being tightened and barriers being raised to protect domestic industry. He, however, asked

the DCG(I) to ensure that the imports into India should be permitted only after ensuring that the documents submitted by the manufactures are authentic and duly verified and drugs have been manufactured under proper good manufacturing practices. Wherever required, the manufacturing facilities of the manufacturer may be inspected to verify the authenticity of the documents and the claims made about the quality of the drugs to ensure that only quality drugs are permitted to be imported into the country.

AGENDA No. 1

CONSIDERATION OF THE ISSUE OF MISUSE OF OXYTOCIN INJECTION BY THE DAIRY OWNERS TO EXTRACT MILK FROM MILCH ANIMALS AND ITS HARMFUL EFFECTS

The members were briefed that the issue of misuse of Oxytocin injections has been deliberated by the DTAB in its previous meetings also. The DTAB in its 65th meeting held on 25th November, 2013 considered the issue and recommended that as the drug has a definite use for therapeutic purposes and need not be prohibited. It however, recommended that the manufacturers of bulk drug should supply active pharmaceutical drug only to the manufacturers licensed for manufacture of formulations and the formulations meant for veterinary use are sold to the veterinary hospitals only.

On the basis of recommendations of the DTAB, the Ministry of Health and Family Welfare issued a notification G.S.R 29(E) dated 17.01.2014 restricting the manufacture and sale of oxytocin as under:

1. The manufacturers of bulk oxytocin drug shall supply the active pharmaceutical drug only to the manufacturers licensed under the Drugs and Cosmetics Rules, 1945 for manufacture of formulations of the said drug.
2. The formulations meant for veterinary use shall be sold to the veterinary hospitals only.

Smt. Maneka Sanjay Gandhi, M.P. has however, again written to the Secretary, Ministry of Health and Family Welfare that the misuse of Oxytocin, is leading to a

substantial loss of livestock in the country. Not only does this drug made cows barren sooner, but also lowers the life span of the animal, thus causing economic loss to the owner in the long run. It is being widely used in the dairy industry despite there being a ban on its sale, except by a prescription from a registered medical practitioner. Various states have raised concern regarding the illegal manufacture and sale of crude oxytocin. Most dairies use this hormone on milch animals twice every day, regardless of the fact that the drug might find its way into the milk obtained. Ingestion of such milk can cause serious hormonal complications in consumers. The misuse of oxytocin is critical for human health and livestock health and that there should be a complete ban on the circulation of this hormone.

Secretary, Health and Family Welfare, had therefore, desired that the matter should be expeditiously placed before the DTAB for its considerations.

After deliberations members were of the view that the drug is already a prescription drug and can be sold only under the prescription of an RMP. The drug as such has a definite role in the medical field both for humans and animals and as such the legitimate manufacture and sale of the drugs cannot be stopped. For the purpose of medical emergency in rural or remote areas, the drug could only be obtained from the sale outlets only. The misuse of the drug for milking purposes is however, a matter of serious concern and is required to be stopped for the health of the livestock.

So far as the manufacture and sale of the drug through illegal channels is concerned, it cannot be simply stopped by banning the drug as the bulk drug is liable to be smuggled from the neighboring countries for illegal use. Misuse can only be contained by enhanced surveillance by the regulatory authorities followed by strict action against the violators. The public at large is also required to be sensitized. Campaigns could be launched by the public spirited organizations in the areas prone to such misuse through print and audio visual media to educate the public about the harmful effects of misuse of Oxytocin. The help of the local police could also be enlisted to book cases under Prevention of Cruelty to Animals Act, 1960, the Drugs and

Cosmetics Act, 1940 which does not permit the sale of the drug except under proper prescription.

The committee after deliberations recommended that in order to curb the illegitimate sale by the chemists, a new clause may be added to the already issued notification stating that the supply of the oxytocin shall be recorded by the retail chemist at the time of supply giving the name and address of the prescriber, the name of the patient and the quantity supplied. Such records shall be maintained for three years and be open for inspection. This would help in not only maintaining the legitimate supply of the drug but also to curb misuse of the drug through the legitimate sale channels.

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

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(Extracts of the minutes of 67th DTAB meeting)

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