

**MINUTES OF THE SPECIAL MEETING (62<sup>nd</sup> MEETING) OF DRUGS TECHNICAL ADVISORY BOARD HELD ON 30<sup>th</sup> January, 2013 IN THE COMMITTEE ROOM, FDA BHAVAN, KOTLA ROAD, NEW DELHI – 110002**

**PRESENT**

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| 1. Dr. Jagdish Prasad,<br>Director General of Health Services,<br>Nirman Bhawan, New Delhi.                                  | Chairman         |
| 2. Sh. C. Hariharan<br>Director I/C, Central Drugs Laboratory,<br>3, Kyd Street, Kolkata-700016                              | Member           |
| 3. Dr. Sunil Gupta,<br>Director, Central Research Institute,<br>Kasauli, (HP) -173205  | Member           |
| 4. Dr. S. D. Seth,<br>Advisor CTRI,<br>National Institute of Medical Statistics,<br>ICMR, Ansaari Nagar,<br>New Delhi-110002 | Member           |
| 5. Dr. A. K. Tiwari<br>Indian Veterinary Research Institute,<br>Izatnagar-243122 (U.P)                                       | Member           |
| 6. Dr. B. Suresh,<br>President, Pharmacy Council of India<br>New Delhi   | Member           |
| 7. Sh. Satish Gupta,<br>Controller Drugs & Food (J&K),<br>Drugs Control Organization,<br>Patoli Mangotrian, Jammu – 180002   | Member           |
| 8. Dr. Dhruvajyoti Bora,<br>26, M.G. Road, Christian Basti<br>Dispur, Guwahati - 781007                                      | Member           |
| 9. Dr. G. N. Singh,<br>Drugs Controller General (India)<br>FDA Bhawan, New Delhi-110002                                      | Member Secretary |

10. Dr. J.A.S. Giri  
815A, Road No. 41  
Jubilee Hills, Hyderabad-500033

Representative of  
Indian Pharmaceutical Association

### **CDSCO REPRESENTATIVES**

1. Shri A.K. Pradhan  
Deputy Drugs Controller (India)  
CDSCO, New Delhi
2. Shri Lalit Kishore  
Consultant, DCG(I)  
CDSCO, New Delhi
3. Dr. S.Eswara Reddy  
Assistant Drugs Controller (India)  
CDSCO, New Delhi

Dr. T.K. Chakraborty, Director, CDRI, Lucknow; Prof. K.K. Talwar, Chairman, Board of Governors, MCI, New Delhi; Dr. Dharam Prakash, Delhi; Dr. B. R. Jagashetty, Drugs Controller, Karanataka, Dr. K. Chinnaswamy, Coimbatore, Dr. B.P.S. Reddy, Hyderabad, Dr. J.K. Rajvaidya, Bhopal and Shri Yatendra Raj Mehta, Drug Testing Laboratory, Jaipur 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 and requested the Chairman to initiate the proceedings as the quorum was complete as per bye-laws.

## **AGENDA NO. 1**

### **CONSIDERATION OF THE PROPOSAL TO INTRODUCE A SEPARATE SCHEDULE H1 UNDER THE DRUGS AND COSMETICS RULES, FOR REGULATING SALE OF ANTIBIOTICS, CERTAIN ANTI-TB DRUGS AND HABIT FORMING DRUGS**

The chairman briefed the members that the meeting was convened to finalize the draft rule published by the Ministry of Health and Family Welfare vide Gazette Notification GSR 228(E) dated 20<sup>th</sup> March, 2012 for incorporation of a separate Schedule H1 under the Drugs and Cosmetics Rule, 1945 for regulating sale of antibiotics, certain anti-TB drugs and habit forming drugs. The notification was published in pursuance of the recommendations of the Task Force set up by the Government of India under the Chairmanship of Dr. R.K. Srivastava, the then Director General of Health Services, to assess, review and suggest measures to contain antimicrobial resistance. The Task Force had recommended that a separate Schedule may be incorporated under the Drugs & Cosmetics Rules to address the issue of antibiotic resistance in the country to contain indiscriminate use of antibiotics in the country. The matter was also considered in the Drugs Consultative Committee Meeting held on 28<sup>th</sup> October, 2010 and it recommended that certain Anti-TB drugs and habit forming drugs which are commonly misused should also be included the Schedule to curb their indiscriminate use.

In the context of development of resistance to the present day drugs, the chairman stressed the need of encouragement of clinical research in the country, so that newer medicines are made available to the patients to fight the disease burden of the country.

The draft rules published were considered in the 61<sup>st</sup> meeting of the DTAB and it gave it concurrence to the proposed amendment. The Schedule was proposed to have a list of 91 drugs including antibiotics and certain habit forming and anti-TB drugs and these drugs to be labeled with the following words in a box with red border:

‘Schedule H1 drug – warning:

-It is dangerous to take this preparation except in accordance with the medical advice.

-Not to be sold by retail without the prescription of a Registered Medical Practitioner.”

During the discussions on a Parliament question in the Lok Sabha on 30.11.2012, Dr. Jyoti Mirdha, MP, Lok Sabha, drew attention to the report of the Task Force where it was recommended to generate double prescription for the purpose of auditing so as to find out how these drugs are being sold and used, while the Government has proposed Schedule H1 containing all antibiotics. It would have been worthwhile to properly monitor and audit fourth generation antibiotics. Further, the anti-TB drugs included in Schedule H1 would affect the anti-TB programme. The Union Health Minister assured that the notification will be further reviewed before finalization, in the light of suggestions made by the Hon’ble MP.

The Board was also informed that the Central TB Division, DGHS in the meanwhile, had recommended that the following Anti-TB drugs are also needed to be included in the revised Schedule H1 so that these are not indiscriminately used leading to drug resistant cases.

1. Ethionamide
2. Cycloserine
3. Sodium Para –aminosalicylate
4. Rifabutin
5. Capreomycin
6. Clofazimine
7. Amoxyclav (Amoxicillin & Potassium Clavulanate)
8. Thiacetazone

DTAB after due deliberations recommended that the Schedule H1 should have only 3<sup>rd</sup>, 4<sup>th</sup> generation and carbapenem class of antibiotics. The members also agreed upon for incorporation of Anti-TB and habit forming drugs included in the draft rules. The

Anti-TB Drugs as suggested by the Central TB Division should also be included in the Schedule. The word 'warning' in the cautionary note should be in red capital letters and in more conspicuous manner than the name of the drug.

It was further recommended that in order to keep a check or monitor the sale of such drugs, a condition should be incorporated under Rule 65 that the supply of any drug covered in the Schedule shall be recorded in a separate register at the time of supply giving the name and address of the prescriber, the name of the patient and name of the drug and the quantity supplied. These records shall be maintained for three years and open for inspection.

The list of the drugs proposed to be included under Schedule H1 is annexed.

## **AGENDA NO. 2**

### **CONSIDERATION OF THE PROPOSAL FOR INCLUSION OF ZINC SULPHATE TABLETS UNDER SCHEDULE K OF THE DRUGS AND COSMETICS RULES**

The members were briefed that during 61<sup>st</sup> meeting of DTAB held on 24<sup>th</sup> July, 2012, it was recommended that Zinc Sulphate Tablets/Oral Solutions IP of 5mg and 10mg should be given exemption from the sale license under Schedule K of the Drugs & Cosmetics Rules for the purpose of controlling the childhood diarrhea. Prof.. S.D. Seth, Advisor, Clinical Trial Registry, had however, written to the Member Secretary that in his opinion Zinc Tablets of 10mg/20mg should be approved rather than 5mg/10mg.

The Indian Pharmacopoeia in the monograph of Zinc Sulphate Dispersible Tablets gives the usual strength as 10mg/20mg of elemental Zinc (as Zinc Sulphate monohydrate).

The Board after deliberation agreed that the Zinc Sulphate Tablets/Oral Solutions having 10mg and 20mg of elemental Zinc be given exemption from sale license under Schedule K of the Drugs and Cosmetics Rules in place of 5mg or 10mg as recommended earlier.

Meeting ended with the vote of thanks to the chair.

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**LIST OF DRUGS TO BE INCLUDED UNDER SCHEDULE H1**

**A. IIIrd, IVth generation antibiotics and Carbapenum groups of drugs.**

1. Meropenem
2. Imipenem
3. Ertapenem
4. Doripenem
5. Feropenem
6. Balofloxacin
7. Cefdinir
8. Cefditoren
9. Cefepime
10. Cefetamet
11. Cefixime
12. Cefoperazone
13. Cefotaxime
14. Cefpirome
15. Cefpodoxime
16. Ceftazidime
17. Ceftibuten
18. Ceftizoxime
19. Ceftriaxone
20. Gemifloxacin
21. Levofloxacin
22. Moxifloxacin
23. Prulifloxacin
24. Sparfloxacin

**B. List of the Habit forming Drugs including in Schedule H1**

1. Alprazolam
2. Buprenorphine
3. Chlordiazepoxide
4. Codeine
5. Dextroropoxyphene
6. Diazepam
7. Diphenoxylate
8. Midazolam
9. Nitrazepam
10. Pentazocine
11. Propoxyphene
12. Tramadol
13. Zolpidem

**C. List of the Anti-TB Drugs**

1. Ethambutol Hydrochloride
  2. Isoniazid
  3. Pyrazinamide
  4. Rifampicin
  5. Ethionamide
  6. Cycloserine
  7. Sodium Para-aminosalicylate
  8. Rifabutin
  9. Capreomycin
  10. Clofazimine
  11. Thiacetazone
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