

**Minutes of the meeting held on 05-12-2015 in Room No. 249,
Nirman Bhawan, New Delhi to discuss pending issues concerning
medical devices**

The following were present:

MoHFW

1. Shri K.L. Sharma, Joint Secretary
2. Shri D.N. Sahoo, Deputy Secretary

CDSCO

3. Dr. G.N. Singh, DCGI
4. Dr. E.S. Reddy, JDC
5. Shri Aseem Sahu, DDCI

Medical Device Associations:

CII

6. Shri Himanshu, Polymediarre
7. Smt. Sumati Randeo, Abbott
8. Shri R. Ashok Kumar,
9. Smt. Elizabeth Jose,
10. Shri Prabaht Jain, Abbott

FICCI

11. Shri Rishi Dev Sharma
12. Shri Vineet Sharma
13. Shri Vineet Gupta, GE
14. Shri Rakesh Sharma
15. Shri Alok Kumar Soni

AIMED

16. Shri Rajiv Nath
17. Shri Anuj Dureja, Siora
18. Shri Kishore Khan, Somrous
19. Shri Bansi Dhurandhar, Microtrol India
20. Shri P.K. Sharma
21. Shri Gurmit Singh, Translumina

ASSOCHAM

22. Shri Sudarkar Mairpadi
23. Shri Karanveer Singh

IDMA

24. Shri Ashok Madan

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1. Shri K.L. Sharma, Joint Secretary, Ministry of Health and Family Welfare welcomed everyone to the meeting and briefly recapitulated the agenda for the meeting. He informed how the Government is pro-actively engaged in promotion of medical devices industry in India and make the country a hub for manufacturing medical devices to meet not only the domestic but also global requirements of medical devices. He also recapitulated the steps taken for regulation of medical devices in the country. He, thereafter, requested the members of the Associations present to briefly present the issues that the Associations would like to

discuss. The issues discussed and decisions taken in brief are as follows:

I. GMP Compliance as per IS/ISO 13485 and delinking of Schedule M from Schedule M III for Medical Devices.

Decision: it was decided to circulate the Draft Schedule M-III which had been prepared after detailed discussion to all the Medical Device Associations to enable them to give their feedbacks/comments by 14th Dec 2015. **[Hard and soft copies of the draft Schedule M III have been given on 05.12.2015 itself to all Associations] [Action: All Associations]**

II. Batch release criteria of EO Sterile Medical Devices on the basis of Biological Indicator and Process Validation.

Decision: After discussion, it was proposed that since the issue is a complex one, it might be in order to constitute an Expert Committee comprising one Microbiologist (preferably from Shri Chittra Institute), one statistician (preferably from AIIMS), one representative from Notified Body (BSI/TUV/SGS) and Sterilization expert from an appropriate agency and request them to examine the matter and make their recommendations. The CDSCO will send a formal proposal to the Ministry of Health and Family Welfare for consideration/approval. **[Action: CDSCO]**

III. (a) Validity of Free Sale Certificate from 2 years to 5 years for Notified Medical Devices.

Decision: As the Associations and CDSCO agreed, a circular may be issued to all State Licensing Authorities by Drugs Controller General (India) for extending the validity from of Free Sale Certificate from

2 years to 5 years subject to the validity of manufacturing license held by the firm. Additionally, it was also decided that a fee of Rs. 5000 per application will be chargeable from the manufacturer for obtaining the Free Sale Certificate from the State Licensing Authority. **[Action: CDSCO]**

III. (b) For Non-Notified Medical Devices:

Views of Associations:

Associations raised a concern that the country was losing a considerable amount of export opportunity due to non-availability of Free Sale Certificate for Medical Devices that have not been notified as drugs by the Ministry of Health and Family Welfare. This is so as many importing countries require Free Sale Certificate to be issued by the Ministry of Health and Family Welfare. Associations had requested that the certificate issued by DGFT could be endorsed by the Ministry of Health and Family Welfare.

Decision: The matter was discussed and everyone present felt that for issuance of such a certificate, basic information has to be available with the Regulator. It was decided that to begin with, database for this will be developed. Associations were requested to propose a pro-forma for capturing the information and data for voluntary sharing of information by the manufacturer of non-notified medical devices at the earliest. It was agreed that the DCG(I) would examine the feasibility of evolving an online voluntary registration format and for ensuring the authenticity of manufacturer. It was also suggested that the manufacturer should have minimum degree of QMS compliance (ISO 9001, etc). Associations were also

requested to give their suggestions for evolving a longer term solution.

[Action: All Associations/ DCGI]

III. (C) Waiver of Brand Approval of Notified Medical Devices for export

Decision: After presentation by Associations, it was indicated by JDCI that a way out could be, that for export purposes, a direction under Section 33(P) of Drugs and Cosmetics Act could be issued by the Ministry of Health and Family Welfare to all the States/UTs to issue a license to a manufacturer for notified medical device in generic name only. However, in certain cases, for purposes of export, if it is necessary to do so, and, if the manufacturer requests to register the brand name, the free sale certificate may include brand name also. It was decided that CDSCO will send a formal proposal with full justification after obtaining suggestions from Associations.

[Action: CDSCO]

III. (D) Waiver of No Objection Certificate (NOC) from ADC Port for export of Notified Medical Devices.

Decision: After detailed discussion, it was noted that copies of the license and other relevant documents are always made available to the Custom Authorities and can be verified by them and the reference to the ADC was not necessary as he is not in possession of any additional information. Therefore, it was decided to waive of the NOC requirement from ADC port for export of Notified Medical Devices to United States, European Union, Japan, Canada and Australia in the first phase and, the list could, thereafter, be further expanded in due course of time with the caveat that customs

authorities may, in cases of doubt consult, ADC Port office. The position can be reviewed after 3-4 months. **[Action: CDSCO]**

IV Amendments of G.S.R 690(E) date 25.09.2014, for amending Clause 3 (Rule 1A) to ensure minimal Labeling on Unit Pack in addition to Shelf Box, if Space Permits and to ensure Basic Labeling is printed before importing Devices into Countries to avoid misuse and Amend Clause 7 (Rule 1A), delete reference of International Pharmacopeia Standard for Medical Device.

Decision: It was decided that Associations will share their views with each other and preferably come up with an agreed position. The issue could, thereafter, be discussed further.

V Guidelines for manufacturers of Notified Medical Devices:

AIMED mentioned the Draft Guidelines on the following could be discussed:

- Initial Factory Audit of QMS & Infrastructure.
- Export Labeling, Additional Brand, Neutral Code, Free Sales Certificate,
- Clarification for Import and Sale of Non sterile Assembled Devices (Bulk),
- Clarification for Clinical Evaluation and Adverse Event Reporting.

Decision: It was decided that since these documents prepared by AIMED are not in the knowledge of anyone else, these may be circulated by AIMED to all Medical Device Associations for enabling comments. The Associations could also discuss these issues amongst themselves in the first instance.

2. The meeting ended with a vote of thanks to and from the Chair.

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4. The Terms of Reference (TOR) of the committee could be as under:

A. To establish the efficacy of validated sterilization process for ensuring desired sterility assurance level (SAL 10⁻⁶) consistently by alternate method of biological testing as per ISO 11135 standards (in case of ethylene oxide sterilization) and as per ISO 11137 standards (in case of gamma sterilization) by Dosimetry, ISO 17665 (in case of steam sterilization).

B. To prepare guidelines as per applicable ISO standards for the validation of the process which includes:-

- i) IQ (Installation Qualification);
- ii) OQ (Operational Qualification);
- iii) PQ (Performance Qualification)

C. To prepare the guidelines for the release of finished products as per the parameters validated for the process as well as the results of biological indicators/Dosimetry.

D. The Committee could invite comments/ have consultation with all concerned stakeholders for preparation of final report to be submitted to the Ministry.