



Ref: SMTA/Apr.2019/EBM/MIN -12

Date: 20.04.2019

MINUTES

Pursuant to agenda notice no.: SMTA/Apr.2019/Agenda -12 dated 4th April 2019, the **12th Executive Body meeting** of The Surgical Manufacturers and Traders Association was held on the 16th of April 2019 at the Association's registered office, 60, Daryaganj, New Delhi - 2.

Following members were present:

1. Mr Rajesh Sawhney (In the Chair)

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| 2. Mr. Puneet Bhasin | 3. Mr. R.C. Gupta |
| 4. Mr. Ashu Sareen | 5. Mr. R.S. Pasricha |
| 6. Mr. Anurag Seth | 7. Mr. Rakesh Arora |
| 8. Mr. S. B. Sawhney | 9. Mr. Harpreet Singh |
| 10. Mr. Karan Bir Suri | 11. Mr. Rajesh Narula |
| 12. Mr. Rakesh Sawhney | 13. Mr. Ramesh Bhasin |

Regrets:

Mr Naresh Grover, Mr. Arun Sharma, Mr. Ashok Sareen, Mr. Ravi Awasthi, Mr. Satish Mahajan, Mr. Pradeep Chawla and Mr. Vijay K. Aggarwal had registered their inability to attend the meeting.

Welcome Address by the President

Mr Rajesh Sawhney welcomed all the members present and thanked all who contributed for the Pulwama Martyrs' bereaved families. He informed the members that a sum of Rs 9,02,000.00 (Rupees Nine lakh & two thousand only) has been donated to the " BHARAT KE VEER" on Pulwama Martyrs' families account. The House applauded the efforts of the office bearers and sub-committee members.

Obituary:

Mr. Rajesh Sawhney reminded the house about the sad demise of Smt Arvinda Rani Khanna, m/o Sh. Kishore Narayan Khanna, Sh. Lalit Narayan Khanna & Sh. Rakesh Narayan Khanna, of M/s Romsons Scientific Industries Pvt. Ltd., Shri Hari Chand Makker, f/o Shri Ashok Makker of M/s Ramon Surgical Co., and Smt. Davinder Kaur Pasricha, m/o Shri R.S. Pasricha of M/s Kay & Company, New Delhi. The Members Present chanted the Gayatri Mantra and prayed for peace of the departed souls.

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Thereafter, the President called the house to order and requested the secretary Mr. Puneet Bhasin to conduct the meeting as per agenda.

Confirmation of Minutes:

The minutes of the previous meeting circulated vide circular no.: SMTA/Feb.2019/EBM/MIN-11 dated 22nd February, 2019 were read and there being no objection to the same and none on record, the minutes were confirmed and adopted.

Holding of 67th Annual General Body Meeting

Considering the time constraint for getting the venue for the proposed AGBM booked in time and the preoccupation and his non-availability expressed by the Chairman – Entertainment sub-committee Mr. Pradeep Chawla, The Secretary - Mr. Puneet Bhasin along with the President Mr. Rajesh Sawhney visited different properties to search for the venue for holding 67th Annual general Body Meeting.

All the options were presented before the house and after due deliberations, it was decided to finalise **The Lalit** as the venue for the 67th AGM to be held on **31st August, 2019**. The budget was projected and house unanimously approved an adhoc sum of Rs 6 lakh for the said event.

Letter to Health Minister for appointment Pertaining to inclusion of BP monitor, Nebulizer, Glucometer & Digital Thermometer under the purview of the Drug & Cosmetic act 1940 & ISI Mark being made mandatory.

The matter pertaining to inclusion of BP monitor, Nebulizer, Glucometer & Digital thermometer under the purview of the Drug & Cosmetic act 1940 was discussed in the earlier meetings and representations to the effect had been sent to the Honourable Minister of Health & Family welfare without any success. The house decided to seek an appointment from Minister of Health & Family welfare, to put our grievance in person. The tremendous burden of product registration/licensing for Manufacturers/Importers with multiple regulating bodies is most likely to wipe out Micro, Small, Medium Enterprises out of business. It was stressed that it should be taken under Medical devices, where the ecosystem of sale/stocks/manufacturing of medical devices & the rules thereof be made clear and acceptable to all stakeholders. It was decided that the request for seeking an appointment should be sent on urgent basis to put forth our concerns & suggestions.

82nd Meeting of the Drug Technical Advisory Board (DTAB)

With reference to minutes of the 82nd meeting of the Drug Technical Advisory Board(DTAB) held on 2nd April,2019, Ministry of Health & family Welfare had constituted a Committee which has given recommendation that All medical devices should be regulated in Drugs & Cosmetic Act, 1940 in a phased manner. The Committee has proposed draft notification along with the exemptions in this regard as under:

“In pursuance of sub –clause(iv)of clause (b)of section 3 of the Drug & Cosmetic Act,1940, the Central Government, after consultation with the Drug Technical Advisory Board(DTAB), hereby specifies the following devices intended for use in human beings for the purpose referred to in the said sub-clauses drugs from 18 months after the date of this notification.”

“All medical devices including an instrument, apparatus , appliance, implant, material or other articles whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specifically for human being or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assisted in its intended function by such means from one or more of the specific purposes of,-

- a) Diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder.*
- b) Diagnosis, monitoring, treatment ,alleviation or assistance for, any injury or disability.*
- c) Investigation, replacement or modification or support of the anatomy or of a physiological process.*
- d) Supporting or sustain life.*
- e) Disinfection of Medical devices.*
- f) Control of conception.*

Further, since this notification will cover all the Medical Devices, the provisions in MDR, 2017 will be automatically applicable to them without individual or class notification which is not the proposed transition scheme by way of registration. Therefore, an exemption needs to be given for obtaining license for import, manufacturing, clinical investigation and performance evaluation permission, test license of such devices which would be first registered only, as mentioned above.”

The detailed minutes of the 82nd meeting of the Drug Technical Advisory Board (DTAB) are uploaded on the SMTA websites & circulated on the SMTA Whatsapp group for your immediate reference & perusal. All members of the Association are requested to send their Feedback/ Suggestion at their earliest to the President or the Secretary at the below mentioned email ids enabling us to include them in our further representations/meetings

1) president@smta.in 2) secretary@smta.in

Mandatory ISI mark for BP Instrument & Other Equipment

Recently, Ministry of Chemical & Fertilizers, Department of Pharmaceuticals issued a public notice regarding quality control order of various medical equipment. As the above was supposed to be answered before 15th April, a letter was drafted with all our Objections & Suggestions. The reply was sent to the Ministry of Chemical & Fertilizers, and was read in front of the house.

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CHANGES IN E-Way Bill SYSTEM :

New notification of changes in the E-Way bill system, dated 25-03-2019, was received and is hereby being sent as an attachment. Further it was felt that letter should be sent to Sh. Manish Sissodia , who had declared in October last year that the limit for intra state transaction would be enhanced to Rs 2,00,000/- (Rs Two Lakhs.) which was never notified. The House suggested that the simplification in making of E Way bill should be stressed upon and practical problems like filling vehicle details & re-entering complete invoice again in the system etc. should be simplified in the larger interest of trade.

Any Other Matter :

It was suggested again to send the letter to the Honourable Minister of Finance & all the GST Council members for the reduction in the GST rates for all the medical devices. The house decides to send the letter with the illustrations showing difference in taxation from VAT to GST regime. A request should be made to revisit the strategy for taxing the healthcare sector and try to tax at minimum possible rates.

There being no other matter, the meeting came to an end with a vote of thanks to the chair.

For THE SURGICAL MANUFACTURERS &TRADERS ASSOCIATION,



(PUNEET BHASIN)
Hony. SECRETARY

**NOTE: For any query/correspondence, Members are requested to contact us at
e-mail ids 1) president@smta.in 2) secretary@smta.in**