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Ref: SMTA/SEP 2024/EBM/Min-08 Dated 18/09/2024

MINUTES

Pursuant to the Agenda notice dt. 09/09/2024, the 8th Executive Body Meeting of The Surgical Manufacturers & Traders Association was held on Saturday, 14th SEP. 2024 at 7.30 PM at The Dhupia lounge, Chelmsford Club, New Delhi.

The Following members were present.

1. Mr Rajesh Sawhney (in the chair)

2. Mr. Puneet Bhasin 11. Mr. Arun Sharma

3. Mr. Harpreet Singh 12. Mr. Karan Bir Suri

4. Mr. Anurag Seth 13. Mr. Ashu Sareen

5. Mr. Kapil Sareen 14. Mr. Pradeep Chawla

6. Dr. Bobin Saluja 15. Mr. R.C. Gupta

7. Mr. Ramesh Bhasin 16. Mr. Summit Narula

8. Mr. Rajesh Narula

9. Mr. Amit Sareen

10. Mr. Jasmeet Singh

Regrets: Mr Rakesh Arora, Mr. Vishal Anand and Mr. Rakesh Sawhney had informed their inability to attend the meeting before hand.

Absentees : Mr. Satish Mahajan

Special Invitees: Mr. Ashok Sareen

AGENDA ITEM 1: Welcome Address by the President

The President Mr. Rajesh Sawhney welcomed all the members and special invitees present.

Obituary:

The President with heavy heart informed the house about the sad demise of Shri Krishan lal Budhiraja, Father of Mr. Dimple Budhiraja of M/s Dimple Surgical & Scientific Instrument manufacturing Company, Bhagirath palace, Delhi.

The members present observed silence while standing for paying homage and prayed for the departed soul.

The President then requested the Secretary to start meeting as per the agenda.

AGENDA ITEM 2: Confirmation of Minutes of Previous Executive Body Meeting

The Minutes of the 07th Executive Body meeting held on 19th June, 2024 were circulated vide circular No. SMTA/JUN 2024/EBM/Min-07 dt. 24-06-2024. The same were read by the secretary and there being no objection raised and none on the record, the minutes were confirmed and adopted.

It was requested by members to expound on the meeting held with Invest India for possibility of setting up of a medical device park for SMTA members. It was informed to the house by Mr. Jasmeet Singh, who had steered the meeting with Invest India. He told that INVEST INDIA had requested for information regarding our requirement of no. of plots and size so that a proposal can be specially made for SMTA. To gather this info it has been decided to request the members to send their EXPRESSION OF INTEREST (EOI) to association for purchasing the industrial plot in the proposed SMTA medical device park with desired plot size so that same can be collated and submitted to the Invest India organization for further action.

A circular with a format of EOI shall be soon sent to all members.

AGENDA ITEM 3: To Discuss the recent Marketing Ethics Code for medical devices (UCPMP)

The salient points of the ethics code were read out and it was pointed out that day by day the compliance burden was increasing on the medical device entrepreneurs and further it now put additional burden on the associations also to act as complaint resolution centre for complaint arising for violations under the UCPMP. It was discussed that association shall upload the copy of this code on their website however other provisions were condemned and it was decided to send a representation to the concerned ministry to keep the code voluntary for at least micro and small enterprises' associations.

AGENDA ITEM 4: To discuss the issues of CDSCO licensing delays and difficulties

A letter was received from our member from Mumbai M/s Hemant Surgical Industries Ltd. pointing out that there are inordinate delays of 8-9 months in grant of Import and Manufacturing licences by CDSCO . A letter to DCGI was sent along with a copy of the letter requesting for quicker grant of licences and removal of bottlenecks on an immediate basis as non grant of licences is causing loss of business to our members and causing inaccessibility in arranging of high quality medical devices for the hospitals / doctors / patients.

It was further pointed out that a representation has also been sent thereafter to DCGI / MOHFW for bringing out changes in the current MDR 2017 which was duly explained to the house by Dr. Bobin Saluja. It was also informed that a PPT presentation in this regard also needs to be prepared for which Mr Amit Sareen volunteered to help along with Mr Anurag Seth.

AGENDA ITEM 5: To discuss the matters pertaining to QCO for mandatory BIS certifications

It was informed to the house that DPIIT has been issuing QCO's for various products and a number of laboratory glassware have also come under its ambit. This mandates obtaining the BIS certificate before mfg. / import which is very tough and unfeasible for most micro enterprises and is a costly time consuming exercise which mostly puts micro / small enterprises at an disadvantage. A representation was sent to the DPIIT requesting to exempt micro and small enterprises having

turnover upto 10 cr from this QCO. A meeting under the forum of CESTA was also attended by SMTA office bearers at the commerce ministry in this regard where strong objections were raised .

Thereafter DPIIT called a virtual meeting with CESTA which was attended by Mr. Jasmeet Singh - Convenor CESTA and Mr. Harpreet singh from SMTA along with other trade associations of Ambala. The BIS and NABL officials were also present. It was informed by NABL that they have no testing standards / protocols for testing such devices and hence they are unable to test them. It was deplored that on one hand govt. is gunning for quality certifications and on the other hand testing facilities are unavailable. It was also mentioned in our representation to make all testing / audit / marking charges by BIS absolutely free of charge so that it can genuinely bring in a quality culture where any organisation no matter how small can easily go and get certification.

AGENDA ITEM 6: To review the Directory Publication matters

It was informed to the house that approx 275 members have confirmed the listing details and rest members are requested to send their updated contact detail forms at the earliest possible – not later than 30-09-2024 as otherwise old contact details as per last directory shall have to be printed. It was also requested that all members who wish to advertise should send their advertisements at the earliest possible.

AGENDA ITEM 7: To discuss the issue of holding the AGM

It was discussed that AGM may be held at a suitable date after 15th NOV. and the directory publishing sub – committee would like the Directory release to coincide with it.

AGENDA ITEM 8: Any other matter with permission of the chair

SUB AGENDA ITEM 1: Issue of Illicit sale/ mfr. of unlicensed medical devices:

As informed by Mr. Pradeep Chawla, It was informed to the house that a representation in this regard had already been prepared with his inputs. It further asked to go through the same, and suggest, if it is fine or if it needs some updating of recent facts.

Some members questioned as how we can call them unlicensed devices as maybe those entities have the mfg. / import licences, for which it was pointed out that the same facts have already been cross checked with CDSCO website and these entities have not obtained any mfg. / import licence for the devices being openly sold in the market. Further there is no mandatory licence /registration No mentioned on the product packaging .

It was pointed out by some members that such complaints by association may lead to harassment of all members even of those doing legitimate business. Mr. Karan Bir Suri also informed the house that a similar complaint was also sent out by Dental association against a few entities and they had to face some defamation action too. It was suggested to instead issue an advisory that members may only buy from licensed mfr. / importer and trade with dealers having MD 42 / DL only. It was pointed out that such advisories have already been sent earlier but there has been no let down in such illicit sales and that the association cannot be a silent spectator to these activities as they are hurting the legitimate trade of our members in an unprecedented manner.

It was reminded that the same matter had been brought up before the house by Mr.Pradeep Chawla ji in the 5th EBM held on 13th Mar. 2024. At that time also, the house did not deem it proper and the matter was left un resolved.

Finally, after due deliberations, it was unanimously decided and resolved to create a special sub-committee headed by Shri Ramesh Bhasin, who may co-opt his committee members along with Shri Pradeep Chawla and take the requisite steps in such matters.

SUB AGENDA ITEM 2 : GST issues : It was pointed out by Shri Puneet Bhasin that GST officials are intercepting vehicles and checking invoice / eway bill and if the signatures on the Invoice are not of the authorized signatory then huge penalties are being levied. This being a serious issue especially in the light of E invoice where all invoice particulars can be checked just by scanning the QR code on the invoice, this insistence of signatures by authorised signatory are frivolous with a mischievous intent and need to be reported to the GST higher officials.

SUB AGENDA ITEM 3 : New Membership - It was informed to the house that four new membership applications have been received and that the same were found to be in order and can be accepted as new members. The details are as under :

- 1: M/s Plaza Industrial Corporation, 36/21, Dilshad Garden Industrial Area, New Delhi-110095.
- 2: M/s Sareen Surge Impex, (2nd Floor) F-2/14 Krishna nagar, New Delhi-110051.
- 3: M/s Macro Scientific Works Pvt. Ltd; B-35/3, G.T. Karnal Road Industrial area, Delhi-110033.
- 4: M/s Indian Surgical Udyog, GF 38/2/40 Site-IV, Sahibabad Industrial Area, Ghaziabad, UP 201010.

SUB AGENDA ITEM 4 : Renewal of FD's : It was informed by the treasurer, Mr. Kapil Sareen that the two matured FD's have got renewed at a higher interest rate than before. The house applauded the efforts of Mr. Kapil Sareen in getting the work done by his diligent persistent efforts.

SUB AGENDA ITEM 5 : Increment of Mr. Satish Srivastava : It was decided to increase the salary of Mr. Satish Srivastava – the office assistant by Rs. 1,000.00 wef 01-04-2024.

There being no other matter, the meeting came to an end with thanks to the chair and gratitude towards Mr. Kapil Sareen, Mr Jasmeet Singh, Mr. Arun Sharma and Mr. Satish Mahajan for hosting a wonderful and delectable dinner and drinks meet. A special thanks to Mr. Jasmeet Singh for making the arrangements for the meeting at the vintage venue.

For The Surgical Manufacturers & Traders Association,

(Harpreet Singh)

Secretary