



Ref: SMTA/JUL .2022/EBM Emergent/Min-05

Dated 14-07-2022

MINUTES

Pursuant to the Agenda Notice dt 14/07/2022 the 5th Executive Body Meeting of The Surgical Manufacturers & Traders Association was held on Thursday ,14 JUL 2022 at 6.00 PM sharp at Registered office of association at 60 Darya Ganj , New delhi -110002

The Following members were present

- | | |
|--|-----------------------|
| 1 : Mr Pradeep Chawla (in the chair) | |
| 2: Mr. Puneet Bhasin | 3: Mr. Harpreet Singh |
| 4: Mr. Anurag Seth | 5: Mr. Arun Sharma |
| 6: Mr.Ashu Sareen | 7: Mr. Rajesh Narula |
| 8: Mr.Rajesh Sawhney | 9: Mr. Rakesh Arora |
| 10: Mr.Rakesh Sawhney | 11: Mr. Ramesh Bhasin |

Regrets: Mr. Satish Mahajan , Mr. Ashok Sareen , Mr. Jasmeet Singh Bhatia , Mr. Prashant Narula , Mr. S.B.Sawhney , Mr. Vishal Anand

AGENDA ITEM 1 :Welcome Address by the President

President Mr. Pradeep Chawla welcomed all the members to the 4th Executive Body Meeting of the Association and requested the Secretary to start the meeting as per agenda .

AGENDA ITEM 2 :Confirmation of Minutes

The Minutes of previous Emergent executive Body held on 02/07/2022 were not yet ready and as this meeting was too an emergent meeting it was decided to take up the minutes for confirmation in the next meeting .

AGENDA ITEM 3 :To Discuss the New Draft Drug Cosmetics Medical devices Bill 2022

There is a new draft bill that proposes to replace the existing Drug and Cosmetics Act 1940 .

The draft notification dt 08/07/2022 was duly circulated among members also and it was apprised to the house about stringent criminal provisions that would now be applicable to the medical device manufacturers and importers . Some sections such as 126 for not of standard quality devices , section 127 for misbranded devices , section 128 for adulterated devices , section 129 for spurious devices shall invite fine and imprisonment of varying terms under Criminal Procedure Code .

It was also pointed out that the new bill does not mention about registration system of sales rather talks of licensing and that too with increased licence fees of rs 10000 instead of previous 3000 and also an additional amount of Rs 2000 is to be charged for inspection .

It was resolved to write our objections for removal of medical devices from the proposed act and bring a separate medical device act as these provisions are very draconian for simple devices that are non sterile / non implantable / non invasive especially those of Class A and Class B .

Further it was resolved to write for a registration system for site and product as for imported drugs and cosmetics instead of costly license currently proposed .

Further as most rules /standards / procedures for quality/ testing /sampling are yet to be informed it was resolved to write our suggestions for a simpler / cost effective procedure especially for devices mfd / imported by micro small enterprises .

Further it was resolved that a representation should also be sent to the MSME minister for taking up the grievances of the micro small enterprises with the Health Minister as it would jeopardise the existence of small units in the medical device industry .

Mr Jasmeet Singh informed the house by whatsapp that he has already spoken to the PA of Sh Narayan Rane minister of MSME for an appointment .

Mr. Ramesh Bhasin also informed the house that he will try to seek an appointment with the Health Minister to resolve the impending crisis and requested for a letter for the same .

AGENDA ITEM 4 : To Discuss non implementation of earlier proposed registration system for traders instead of licensing

The above draft Notification was issued in Feb 2022 , however the final notification has still not come and that will put the entire distribution system to halt as every retailer and distributor / wholesaler would require a drug licence to sell medical devices of Class A and Class B from 01-10-2022 .

It was resolved to immediately meet with DCGI at his office and immediately Mr Puneet Bhasin sent an request to DCGI for an appointment . It was further decided to visit his office in coming week even if no appointment is given as the road map needs to be adjourned in light of non implementation of registration system for traders .

Due to paucity of time no other matter could be taken up for discussion

The meeting came to an end with a vote of thanks to the chair.

For The Surgical Manufacturers & Traders Association,



Harpreet Singh

Secretary