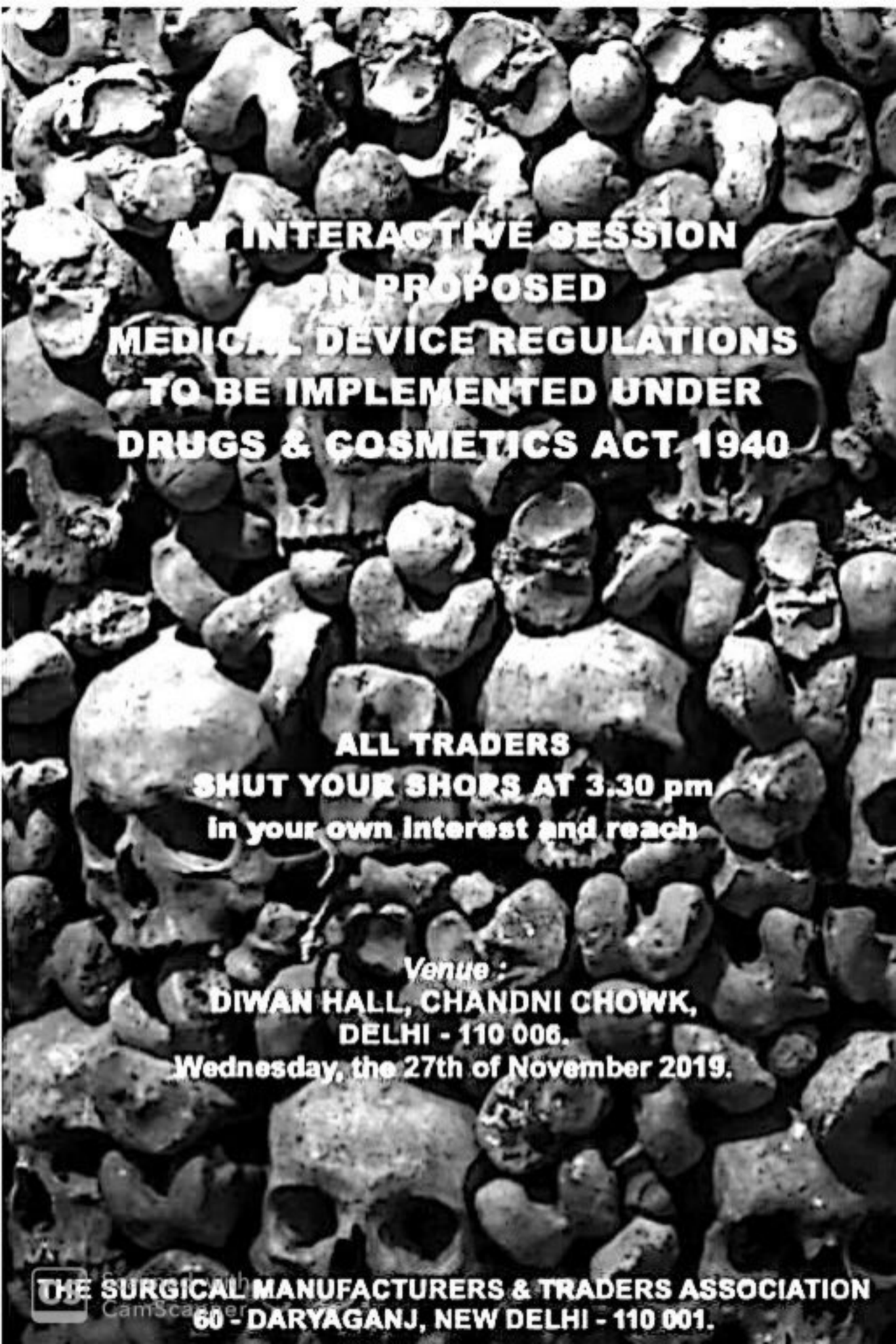
AN INTERACTIVE SESSION
ON PROPOSED
MEDICAL DEVICE REGULATIONS
TO BE IMPLEMENTED UNDER
DRUGS & COSMETICS ACT 1940
ALL TRADERS
SHUT YOUR SHOPS AT 3.30 pm
in your own interest and reach
Venue :
DIWAN HALL, CHANDNI CHOWK,
DELHI - 110 006.
Wednesday, the 27th of November 2019.
THE SURGICAL MANUFACTURERS & TRADERS ASSOCIATION
60 - DARYAGANJ, NEW DELHI - 110 001.

Dear Associates,

As we all know that as per the new Govt. notification - many every day use surgical items and health aids are already / going to be covered under the MEDICAL DEVICES and All Medical Devices are slated to be regulated by the Drugs & Cosmetics Act 1940.

Please find mentioned here under the implications of such regulations on all the stake holders.

FOR TRADERS :

1. Traders need wholesale Drug License from their respective State Licensing Authority which is hard to obtain due to the requirements for minimum size, height and commercially located premises.
2. Traders also need requisite experience certificate in selling drug items for obtaining such license.
3. Whole sale dealers need to obtain separate license for their godowns, offices, shops and that too seperately for each premises - An altogether additional strain on the already meagre resources.
4. Traders require a separate retail licence from their respective State Licensing Authority.
5. For retail Licence, the requirement of engaging a Pharmacist would not be viable for the small shops.

FOR IMPORTERS :

1. Importers too would require wholesale Drug License from respective State Licensing Authority.
2. License fee to the tune of 30 - 140 times that of the fee payable by any local manufacturer for the same item, thus increasing the financial inputs manifold.
3. Requirement of Batch testing at Ports at the time of import and ADC Clearance formalities would add to the Product cost and would block working capital for 6 - 8 weeks in addition to the hefty test charges. Moreover, the goods could be sold only after the test reports are submitted.
4. Importers have to mantain 3x quantity as control for three years, which is quite impractical and the high cost of storage is involved because the goods are costly as well as space consuming.
5. Importing new products with latest technology would not be easy as the license cost would be unbearable.
6. India imports 80 - 90% of Medical Devices. This would increase manifold, the cost of landing and selling and would thus increase the health cost for general public. Moreover, many important but less required components would be out from the market as the License fee etc. would not be practically affordable.
7. Since, it would not be easy to change over the suppliers and the models, the markets would remain flooded with obsolete equipments only and those too at higher cost.
8. Every importer would have to register and seek license for products of same brand and same supplier.

FOR MANUFACTURERS :

1. Need to upgrade manufacturing facilities as per ISO : 13485 standards with huge financial requirement which would not be possible for most of the MSMEs already on verge of closure due to the Govt. apathy.
2. Requirement of hefty fee for annual audits and compliance certificates from notified bodies would push the manufacturers into the deeper trench.
3. MSMEs would be forced to closure due to very low profitability owing to the high costs for testing etc.
4. 3x quantity of samples would have to be mantained thus blocking the cost. Please note that these are not pharma products, that require low cost and lesser space as compared to most of the medical devices.
5. Tedious licensing procedures and increased processing windows would lead to lesser innovations and lower motivation for any industry to sustain and survive.
6. As all these requirements need permanent addresses, the industries running on leased / tenanted premises would loose their viability.
7. Manufacturers currently working in / as cottage and household industries would have to be shut down as they would not be able to bear the licensing and compliance cost after every change of lease.

FOR CONSUMERS :

1. The cost of these crucial health products would increase manifold for the actual end users, thus hampering the health and maintenance of any person.
2. Most of the things would either be not available or available at a very high cost beyond general affordability.

All are requested to join this seminar in their own interest and in the interest of Surgical Trade and also our country and its people on whole.

Thank you.

THE SURGICAL MANUFACTURERS & TRADERS ASSOCIATION
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