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Press Release

The Health ministry has already notified 4 common healthcare devices namely nebulizer, blood pressure, digital thermometer , glucometer as drugs wef 01-01-2020 and have issued a draft notification dt 18-10-2019 to regulate **all medical devices** as drugs .

We wish to submit that this would lead to disastrous consequences for the local manufacturers and traders who would be unable to produce / stock / sale under the stringent conditions of the DRUG Act . By bringing the devices as medical devices under the Drug act very onerous licensing norms would be applicable on sale, import , manufacture, stock thereby restricting the shops / outlets from where these goods can be sold to customers /patients . This in a nut shell means that to sell even a digital thermometer a retail shop has to hire a pharmacist !.

The requirement of pharmacist for wholesaling / retailing these devices is totally baseless as pharmacist has no experience or technical know how for these electro mechanical medical equipment . Moreover high cost of hiring a pharmacist by surgical goods wholesaler / retailer would sound the death knell of lakhs of standalone surgical goods shops.

Further it would also lead to increasing of product prices for final customers as cost of compliance would spiral in terms of product registration fees , annual testing and licensing fees along with regular inspections by state drug control departments . It would also lead to monopolizing of trade by few large pharmaceutical companies who have the wherewithal to comply to the provisions of drug act.

India imports 80-90% of medical devices and the CDSCO licensing fees for imported medical devices is 28 to 140 times at least of the local produced devices This would greatly enhance the healthcare costs in the country. This is obvious that this isn't just a licensing fee but a non tariff barrier for which Health ministry has no official mandate as it is the domain of the ministry of Finance /commerce to decide on tariffs or non tariff barriers for imported medical devices which are in any case being subjected to custom duty / surcharge / gst at time of import

A separate medical devices act should have been brought in first which could provide the correct ecosystem for regulating these medical equipment as most of these devices are neither invasive nor sterile nor implantable. Regulating these products in same manner as that of medicinal drugs would not be in the right spirit and would cause unnecessary burden and hardship to manufacturers and traders and also to general

In a nut shell regulating medical devices under drugs is not in the interest of small scale traders / mfrs / importers and absolutely not in the public interest whose cost for healthcare will increase dramatically once this notifications are implemented.

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