Date : 21.07.2023

To,
Shri Mansukh L. Mandaviya,
Union Minister of Health & Family Welfare India,
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AiMED
Encouraging responsible manufacturing
Association of Indian Medical Device Industry

Sub : Re : Draft of the DRUGS, Medical Devices and Cosmetics Bill, 2023

Respected Shri Mansukh L. Mandaviya ji,

Many Thanks for our Meeting on dt : 19.07.2023 and your assurance to address our concerns through your Team and the Final Draft of Bill shared with us. Please find below our initial comments on the Final Draft Bill, 2023. We will share further comments on wider consultancy with our Membership.

We have reviewed Draft of **the Drugs, Medical Devices and Cosmetics Bill, 2023** in context of AiMeD suggestions made on previous Draft of **new Drugs, Medical Devices and Cosmetics Bill, 2022 (text in black)** and included our conclusion in *Red* giving a reference of corresponding section of Draft **of the Drugs, Medical Devices and Cosmetics Bill, 2023.**

1) Strategic Key Principle Comments :
(i) While appreciating the intent of MOH&FW and Authors of the Bill to regulate all Devices appropriately and to bring in reforms but the objective is not being met. We regret to note that instead of proposing an independent Medical Device Regulations and Patient Safety Bill, a combined complex Bill for Regulating Drugs, Medical Devices and Cosmetics has been proposed which again nearly treat Devices as Drugs as in Drugs & Cosmetics Act with most punitive action of treating an errant Manufacturer as being criminal which is not the case in most Countries.

This is fundamentally incorrect and a non starter in case of Medical Devices. We will strongly recommend once again for a separate simple, implementable regulation for Medical Devices if 'Make in India' of Medical Devices is to be encouraged and if government is keen to address the ongoing 80% import dependence. The law needs to be 'civil' in nature as is case of FSSAI regulations or under International Medical Device Regulations as by Canada, EU, Brazil, Saudi Arabia, Japan etc which no more seeks imprisonment for offences and for most short coming / errors do not treat manufacturers as a criminal as making these Devices are as an engineering product and not like making pharmaceutical medicines.

The Law needs to give a sense of Direction to Policy Makers and Rule Makers and the enforcing Regulators.

Medical Devices are not Drugs and in past a few of them have been attempted to be incorrectly regulated as Drugs under Drug Rules and Drugs Act until 2017 when Medical Devices Rules were introduced that recognized the need for separate Regulatory Controls but even these Rules were put under the antiquated Drugs Act which is being replaced by proposed Bill that is not motivating but discouraging.

(ii) India is 80% Import Dependent. One major reason is shift from manufacturing to more convenient and cheaper import based trading activity leading to Pseudo Manufacturing whereby the entity instead of calling himself Marketing Company still labels Products as "Manufacture by" incorrectly and now the revised definition of Manufacturer will legally permit him to do so (?).

(iii) The MOH&FW instead of supporting and contribution to improving on the Medical Device (Safety, Effectiveness and Innovation) Bill 2019 proposed by NITI Aayog set up a Committee of Regulators to draft a New Bill to regulate Devices as Drugs as a Compulsory Regulation but is still having the old mindset approach of treating Manufacturers as Criminals rather than seeking preventive steps of enforcing Quality Management System and Quality Assurance and seeking progressive improvement in implementation and enforcement to ensure Public Safety while not being a bottleneck of access to affordable innovations. While the NITI Aayog Bill focus was on innovative Medical Devices this has hardly any mention in the proposed DMDC Bill 2022.

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The proposed Bill must ensure Public Safety but not throttle investments or kill existing SME's making Medical Devices.

The punitive and criminal judicial action may be maintained only for any Non Licensed or Non Registered manufacturing facility of Medical Devices and manufacturer who has not even applied for registration / licensing compliance.

Any person who is a regulated / licensed manufacturer / exporter / importer / reseller of Medical Device is to be considered as willing to subject himself to Conformity Assessment and abide with prescribed regulations and regulatory process and needs to be disciplined by the regulatory authority through an administrative process, to strive for improvements in quality, consistency and patient safety.

This willingness to abide and be disciplined can be part of the Licensing procedures as an undertaking. Reliance needs to be of Correction and Improvement of Processes and Controls at the manufactures / logistics / warehousing / retailing /final utilization for ensuring Patient Safety through administrative methods before using the Judiciary which is already overburdened with pending cases. The Regulatory Authority should have Administrative Powers for putting things Right in a progressive manner added to risk proportionate regulatory controls e.g. Show Cause Notice, warning. Recall of Goods, Field Corrective Action, Levying a Fine, Suspension of License etc. If it's a mislabeling issue e.g. mismatching of a letter of a Batch No. of a Unit Pack or Shelf Box it should not warrant Jail Terms for Managing Directors ! You do not need to kill a fly with a machine gun. **This will discourage Make in India and innovate in India.**

(iv) While the Bill mentions Risk Proportionate Regulations there is no clarity of exemptions or diluted regulatory and penal requirements for very Low Risk Non Sterile Surgical Instruments and other non measuring Non Sterile Medical Devices as is usually done in Regulation by EU, USA, Canada etc.

(v) Similarly the concept of having a Central Medical Device Testing Laboratory as a corresponding equivalent to a Central Drug Laboratory as an Apex all inclusive Testing Centre is questionable. There are over 6000 Medical Devices and depending upon the Material Science or stream of Scientific & Testing expertise a limited range of Devices can usually be tested at a Centre of Excellence but wishing to consider one National Laboratory at a single location to do Biocompatibility Testing, Animal Studies & Testing, Mechanical & Chemical Testing or Electronic Component & Product Testing will be overly ambitious and may not be practical.

(vi) Regulatory Controls need to split and shared between Centre, State and Conformity Assessment Notified Bodies but in Bill we notice no clear lines or directions but continuity of earlier system of duplication of State and Central Govt. Regulations and no accountability of a State Regulator to the Central Licensing Authority or a National Regulator which lead to non harmonious enforcement. While onus is on Manufacturer the onus of competency of Regulatory Officer is not defined nor of the user. Law should also clarify Role of Regulator in supervision of the Conformity Assessment Bodies. Medical Devices Regulation is a good opportunity to experiment different than Drugs and apply successful learning to Drugs later.

2) General Comments :

i) The draft bill essentially makes it a criminal offence to import, manufacture or sale medical devices **without** the required licenses and certifications.

The bill should also ensure there is an obligation on the part of the buyer/user to purchase or use only those medical devices that has the required licenses and certifications. Preferably to make it a criminal offence if anyone purchases/uses non-certified equipment. If this provision is not included, the victims will be those manufacturers who are committed to following the provisions of the bill, while its uninterrupted business as usual for the non-licensed manufacturer if they have willingly buyers.

ii) There shall be provisions to facilitate clinical investigation and user feedbacks. Our experience is that users are generally not ready or eager to participate in any clinical investigation or evaluation studies or providing formal written feedback due to legal risks involved and a tedious process.

iii) The BILL and MDR'17 does not address Imports of Spares for medical devices. There should be provision for importing Spares without registering the Main device.
For example, suppose an X-Ray machine has been sold a few years ago, and if the Importer is no longer representing the Original Manufacturer but is still obligated to provide Service Support to the end user, the importer will not be able to clear spare parts at customs.

iv) There are many Indian Companies that are only in the business of providing Service Support. Such companies are now forced to shut down because they are authorized by Original Manufacturers to Service/Repair their devices in India, but not to sell.

v) The BILL does not address SKD manufacturing in India. In these cases, the original design ownership should rest with the original overseas manufacturer and the Indian Manufacturer's obligation should be limited to quality of devices manufactured by them.

vi) We have observed that, there is no provision made on the following subjects :
(a) Responsibility for Market Access Authorization Holder
(b) Responsibility of BIS (Bureau of Indian Standards)
(c) Responsibility of Reseller – Hospital
(d) Responsibility of User
(e) Provision for Market Access Authorization Holder
(f) Provision for Grievance Handling, Tribunal etc.
(g) Provision for Advertising & Claiming Performance
(h) Provision for Restricting Reuse of Single Use Medical Devices
No provision added in the draft bill, 2023

(i) Provision to Ban / Restrict Import of Preowned / Refurbished Medical Devices and address Medical Electronics generated E-Waste.
No provision added in the draft bill, 2023

We would suggest that appropriate provisions should be made on the above subjects either in the Law Book or the Rule Book.

vii) Penal provisions: The punitive and criminal judicial action may be maintained only for any Non Licensed or Non Registered manufacturing facility of Medical Devices and which has not even applied for registration / licensing compliance. The provision of imprisonment in the following sections should be deleted and made appropriate administrative / penalty provisions.
Reference section 59 (6) of draft bill, 2023 (No change)

a) Reference Section 134 (5) of draft bill, 2022
Imprisonment up to 1 year for obstructing a Medical Device Officer may be deleted

Reference section 59 (6) of draft bill, 2023 (No change)

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b) Reference Section 146 of draft bill, 2022
Imprisonment up to 1 year for failure to provide medical management and compensation may be deleted
Reference section 78 of draft bill, 2023 (No change)

c) Reference Section 152 (a) of draft bill, 2022
Imprisonment up to 7 years for import or manufacture or adulterated or spurious may be deleted
Reference section 85 (1) of draft bill, 2023 (No change)

d) Reference Section 169 of draft bill, 2022
Imprisonment up to 2 Years for submission of misleading or wrong information's or refusal to furnish information's may be deleted
Reference section 92 of draft bill, 2023 (No change)

3) Specific Comments on some of the provisions are as follows :
i) Reference Section 3 (v) of draft bill, 2022 "investigational medical device"

As it is not practicable to consider device which is not having predicate device or a substantially equivalent approved earlier by the central licensing authority as investigational. Substantial equivalence considering safety and performance of the device can be demonstrated based on the global regulatory approvals or market clearance (like, EU, USA, Australia, Japan, Canada or others)

Therefore, it is suggested to modify as below,
'investigational medical device' means a device that is assessed in a clinical investigation, a systematic investigation involving one or more human/animal subjects, undertaken to assess the safety or performance of a device.
Reference section 2 (zb) of draft bill, 2023
Aimed suggestion not considered

ii) Reference Section 3 (zc) of draft bill, 2022 "manufacturer"
The definition of manufacturer is not appropriate in Indian context & can be misused, where by marketer claim to a manufacturer. We would suggest the following definition
"Manufacturer is a person, an enterprise, or an entity who himself makes a product through a process involving raw materials, components, or subassemblies, usually on a large mass production scale with different operations divided among different workers and fulfills the following 2 conditions:

A. Change of Tariff Sub Head (CTSH): There will be a change of the 8 digit ITC Sub Heading of assembly of inputs for enabling 'Substantial Transformation' to produce the output Product by the Manufacturer in India.

B.

Category of Medical Devices	% of Minimum Local Content*
Medical Disposables and Consumables	50%
Medical Electronics, Hospital Equipment, Surgical Instruments	25%
Implants	40%
Diagnostic Reagents / IVD	25%

*As defined in Guidelines by DOP on Make in India PPO, subject to revision.

iii) The following Definitions related to regulating Medical Devices may also be included in Section 3

- Accessories: An article intended specifically by its manufacturer to be used together with a specific medical device(s), to enable the medical device to be used in accordance with its intended use.
- Abnormal Use: Act or omission of an act by the operator or user of a medical device as a result of conduct that is beyond any reasonable means of risk control by the manufacturer.
- Clinical Evaluation: The assessment and analysis of clinical data pertaining to a medical device to verify the clinical safety and performance of the device when used as intended by the manufacturer.

Reference section 2 (zf) of draft bill, 2023
Aimed suggestion not considered

iv) Reference Section 3 (zd) (b) of draft bill, 2022
in-vitro diagnostic device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination thereof intended to be used for examination and providing information for medical or diagnostic purposes by means of examination of specimens derived from the human bodies or animals;
We would suggest to include "software or an accessory" to the definition of IVD
Reference section 2 (zg) (ii) of draft bill, 2023
Aimed suggestion not considered

v) Reference Section 6 (xiv) of draft bill, 2022
We question the need for a Pharmacologist on MDTAB where Devices are not Pharmaceuticals ? It can be a Biomedical Engineer. While DTAB permit 3 Industry Experts in DTAB but has considered only 2 Experts in MDTAB. We recommend one from large Industry, one from MSME and one from IVD Industry.
Reference section 4 (2) (q) of draft bill, 2023
Aimed suggestion not considered

vi) Reference Section 11 (1) of draft bill, 2022
In the DCC there are no Industry / User / Patient Safety NGO Representatives. These may be considered or the Rule Book will be made only with the eye of Drug (Pharma) Experts. Why should Drug Experts deicide solely what is good / appropriate for Medical Device Industry ? Can Police decide for the Army or vice versa ?
Reference section 12 of draft bill, 2023
Aimed suggestion not considered

vii) Reference Section 72 (1) of draft bill, 2022
No person shall by himself or by any other person on his behalf shall conduct any clinical trial in respect of a new drug, investigational new drug, bioavailability or bioequivalence study of any new drug, in human participants except under, and in accordance with, the permission granted by the Central Licensing Authority subject to such conditions and in such form and manner as may be prescribed.
Explanation:

For the removal of doubt, it is hereby declared that the person includes sponsor, clinical research organization, any other organization or investigator.

We would suggest to include "clinical investigations that are intended to be used only for academic or research purposes and not for seeking approval of the Central Licensing Authority or regulatory authority of any country for marketing or commercial purpose."
Reference section 34 of draft bill, 2023
Aimed suggestion not considered

viii) Reference Section 74 (2) of draft bill, 2022 .Constitution, functions and responsibilities of Ethics Committee

The Ethics Committee shall consist of not less than seven members from medical, scientific, non-medical, non-scientific, legal and social fields including an individual from general public.
We would like to clarify does "Scientific member include Academia" ?
We would suggest, to include member from Civil Society Organizations, Patient Safety Forums in ethics committee.
Reference section 36 (2) of draft bill, 2023
Individual from civil society included

ix) Reference Section 75 (2) of draft bill, 2022. Action against Ethics Committee

Where an Ethics Committee is debarred, its permission or registration shall be deemed to have been revoked.

We would suggest that whenever action is taken against ethics committee details of such cancellations, debarring e.t.c. should be uploaded in Regulators, CTRI portal too for public reference.
When permission to registration is debarred, any accreditations, certifications awarded to these committees also should be cancelled.
Reference section 37 of draft bill, 2023
Aimed suggestion not considered

x) Reference Section 127 (d) of draft bill, 2022 .Misbranded medical devices

Medical Device shall be deemed to be misbranded if it "**containing colours not expressly permitted in the license or permission issued under this Act**"
In this regard we would like to clarify that in Medical Devices colours are used not only for brand and logo but also for the identification of size / gauge of Medical Devices. The colour are as per the relevant standard (e.g. IS/ISO 6009 for colour coding of Devices)
Reference section 2 (zl) of draft bill, 2023
Aimed suggestion not considered

xi) Reference Section 128 (a) of draft bill, 2022. Adulterated Medical Device

A Medical Device shall be deemed to be adulterated, "if it consists in whole or in part, of **rusted or corroded** or filthy or putrid or decomposed substance".

In this regard we would like to submit that above definition of adulterated medical device does not fit well with the construction and nature of most of the medical devices which are engineered products made under a tolerance where the storage, usage conditions and usage skills need to be considered before putting a criminal insinuation on a manufacturer For example, a Device made of standard stainless steel (e.g. SUS 304 grade) can get rusted / corroded in case it is exposed to acidic or corrosive fumes (during transportation or storage) or with anesthesia fluids during usage / surgery which may not be in control of the manufacturer. By application of above definition the device manufacturer can be held responsible and be punished up to 7 years imprisonment for a defect which is beyond his control (!) and not done willfully. The Law needs to be fair and not punish innocent well meaning law abiding licensed manufacturers. The definition need to be deleted and expunged as impractical for engineering goods.
Reference section 2 (e) of draft bill, 2023
Aimed suggestion not considered

xii) Reference Section 130 (4) of draft bill, 2022. Prohibition of import or manufacture and sale of medical devices

No person shall himself or by any other person on his behalf sale, distribute or offer for sale the medical devices by online method, as may be prescribed, for which a license or permission is required to be obtained from the licensing authority, except under and in accordance with such license or permission subject to such exemptions and conditions and in such form and manner as may be prescribed.

We would suggest to define what is Online and Offline Mode for greater clarity and understanding of all stakeholders from a policy maker/regulatory perspective.

Both Methods of Sale are totally different and communities health and well being is compromised with sale/delivery formats which have no clarity.

xiii) Reference Section 134 (1) of draft bill, 2022
The provisions of a Medical Device Officer are needing to be linked to his competency and should not be a mirror copy of a 'Drug' Inspector under different name.
Reference section 59 (1) of draft bill, 2023
Aimed suggestion not considered

xiv) reference Section 134 (1) a of draft bill, 2022
The word 'Inspection' needs to be expunged from the regulation and replaced with the word 'Audit' for seeking Compliance and improvements and the word 'Search' needs to be replaced with 'Surprise Audit'. The word search and seizure or use of Police support should be restricted to non licensed illegal manufacturing facilities. If a Manufacturer got a license that is indicative that he was by and large Compliant and for lapses done subsequently he is ready to seek improvement in demonstrating Conformity Assessment.
Reference section 59 (1) (a) of draft bill, 2023
Aimed suggestion not considered

xv) Reference 134 (2) of draft bill, 2022
The provision of Code of Criminal Procedure need not apply for Licensed Manufacturers but only for any illegal activity as unlicensed manufacturer (beyond a stipulated transition period of onset of New Regulations).
Reference section 59 (2) of draft bill, 2023
Aimed suggestion not considered

xvi) Reference Section 134 (5) of draft bill, 2022 regarding powers of Medical Device Officer
Even though the clause uses the word **willfully**, there is no way to prove for the manufacturer that the charges are false or obstruction is not done "willfully". Also, by having a penal provision of imprisonment **and** fine up to Rs 2 Lakh rupees is way too stringent compared to penalty of Rs 30 thousand Rupees to Medical Device Officer. Practically, this will also increase corruption as the Medical Device Officer will not have any substantial fear of any false implications made by him.
Reference section 59 (6) of draft bill, 2023
Aimed suggestion not considered

xvii) Reference 134 (5) and 152 and 153 and 169 of draft bill, 2022
Threat of imprisonment of one year may be deleted for a claim of a Medical Officer of inadequate production of records to his satisfaction. The purpose of regulation should be prevention and seeking improvement by disciplining manufacturers by administrative means and civil penalties or loss of business as being done in FSSAI regulations by MOH&FW.
Reference section 59 (6), 85 & 92 of draft bill, 2023
Aimed suggestion not considered

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xviii) Reference Section 152 & 153 of draft bill, 2022 Offences and Penalties
The punitive and criminal judicial action may be maintained only for any Non Licensed or Non Registered manufacturing facility of Medical Devices and which has not even applied for registration / licensing compliance.

Explanation : Any person who is a regulated / licensed manufacturer / exporter / importer / reseller of Medical Device is to be considered as willing to subject himself to conform and abide with prescribed regulations and regulatory process and needs to be disciplined by the regulatory authority through an administrative process, to strive for improvements in quality, consistency and patient safety.
This willingness to abide and be disciplined can be part of the Licensing procedures as an undertaking. Reliance needs to be of Correction and Improvement of Processes and Controls at the manufactures / logistics / warehousing / retailing /final utilization for ensuring Patient Safety through administrative methods before using the Judiciary which is already overburdened with pending cases. The Regulatory Authority should have Administrative Powers for putting things Right in a progressive manner added to risk proportionate regulatory controls e.g. Show Cause Notice, warning. Recall of Goods, Field Corrective Action, Levying a Fine, Suspension of License etc. If it's a mislabeling issue e.g. mismatching of a letter of a Batch No. of a Unit Pack or Shelf Box it should not warrant Jail Terms for Managing Directors ! You do not need to kill a fly with a machine gun. **This will discourage Make in India and innovate in India.**
Reference section 85 of draft bill, 2023
Aimed suggestion not considered

xix) Reference Section 158 (z) of draft bill, 2022 Powers of the Central Government to make rules for Chapter VI
To prescribe the manner of regulating online sale or distribution or offer for sale of the medical device.
We would like that better clarity is provided on the following :

- Whether Online players in Medical Devices are also covered under Consumer Protection (ecommerce rules), 2020 under Consumer Protection Act 2019?
- Whether they are also subject to Medical Device Regulation?

They are also covered under IT Act.

If so, online businesses will be subject to multiple regulations and all acts have to be cross referenced for better clarity to protect consumer safety.

Communities , Consumers are often under the impression that Online businesses are strictly regulated and all regulatory , licensing aspects are already addressed. Food Safety Standards and Regulations Authority can be referred as FSSAI has brought all Online FBOs under strict regulatory mechanism with well defined Regulatory specification.

Marketing Code of Conduct (UCMDMP) should include Marketing Code of Conduct for Online players based on the Consumers Protection (ecommerce rules) 2020, released by Ministry of Consumer Affairs under the Consumer Protection Act 2019. Basic Marketing Code of Conduct is defined for Online players under the said rules.

xx) Reference Second Schedule Fee Structure of draft bill, 2022
Fee for Grant or renewal of license for medical device and fee for Import license are not in line with the Medical Devices Rules 2017 Second Schedule for e.g.
fee for manufacturing license for Class A & B Medical Devices is 5000 Rs. and for each medical devices 500 Rs. whereas as per Draft bill fee are Rs. 50000 and 1000 respectively.
The fee are for grant or **renewal** of license whereas as per Medical Device Rules 2017, there is no provision for renewal of license. The manufacturer has to pay fee for **retention** of license.

We would suggest that any provision, which are already explicitly stated in the MDR'17 should not be included in the Act, other than for giving a sense of direction to the Rule making bodies. The Govt. should have the freedom to review and revise the fees without going back to the Parliament.
Fee structure not included of draft bill, 2023

xxi) Reference Section 185 of draft bill, 2022
Transition period need to give clear direction for allowing switching of labelling whenever Rules are changed for labelling requirements changes as these can't be done overnight and both earlier and revised condition need to co-exist for 6 month to 1 year while inventory is depleted of packaging materials of unpacked Devices as well as of packed Devices, for the shelf life of Product, as relabelling may not be practically possible in most cases.
Reference section 187 of draft bill, 2023
Aimed suggestion not considered

Thanks & Regards

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